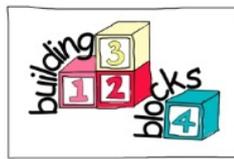




South East Wales  
Trials Unit  
Uned Ymchwil  
De-ddwyrain Cymru



# The Building Blocks Trial

Department of Health Policy Research Programme Project

Evaluating the Family Nurse Partnership Programme in England:

A Randomised Controlled Trial 006/0060

*International Standard Randomised Controlled Trial Number: ISRCTN23019866*

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## Chief Investigator

Dr Mike Robling, Reader and Co-Director,  
South East Wales Trials Unit, Cardiff University

## This report was prepared by the authors on behalf of the Building Blocks Study Team

Dr Marie-Jet Bekkers, Cardiff University

Dr Kerry Bell, University of York

Professor Christopher C Butler, Cardiff University

Dr Rebecca Cannings-John, Cardiff University

Dr Sue Channon, Cardiff University

Belen Corbacho Martin, University of York

Professor John W Gregory, Cardiff University

Professor Kerry Hood, Cardiff University

Professor Alison Kemp, Cardiff University

Professor Joyce Kenkre, University of South Wales

Professor Alan Montgomery, Nottingham University

Gwenllian Moody, Cardiff University

Dr Eleri Owen-Jones, Cardiff University

Professor Kate Pickett, University of York

Dr Gerry Richardson, University of York

Dr Zoë E S Roberts, Cardiff University

Sarah Ronaldson, University of York

Dr Julia Sanders, Cardiff University

Eugena Stamuli, University of York

Professor David Torgerson, University of York



# Abbreviations

A&E	Accident and Emergency
AIC	Akaike Information Criterion
ANCOVA	Analysis of covariance model
AT	Acute Trust
AUC	Area under the curve
BB	Building Blocks
BMI	Body mass index
BRTC	Bristol Randomised Trials Collaboration
BTEC	Business and Technician Education Council
BW	Birth weight
C	Control
CACE	Complier averaged causal effects
CAPI	Computer assisted personal interview
CAS	Composite Abuse Scale
CASIS	Centre for Advanced Software and Intelligent Systems
CATI	Computer assisted telephone interview
CC	Complete case
CCA	Complete case analysis
CCG	Clinical commissioning group(s)
CEAC	Cost effectiveness acceptability curves
CHE	Centre for Health Economics, University of York
CHPP	Child Health Promotion Programme
CI	Confidence interval(s)
CIP	Continuous patient spells
CME	Core Model Elements
CMO	Chief Medical Officer
COVER	Cover of Vaccination Evaluated Rapidly
CQ	Closed question
CR	Complex reflection
CRO	Contract research organisation
CRF	Case report form
DAAG	Data Access Advisory Group
DCE	Discrete choice experiment
DH	Department of Health
DOB	Date of birth
EDD	Expected Delivery Date
ELM	Early Language Milestone Scale
ELSA	Early Labour Support and Assessment
EMWP	Economics and modelling work package
EPDS	Edinburgh Postnatal Depression Scale
EPHPP	Effective Public Health Practice Project
EQ-5D	European Quality of Life-5 Dimensions
FCE	Finished Consultant Episode
FG	Fidelity Goals
FN	Family Nurse
FNIPS	FNP information system
FNP	Family Nurse Partnership
FNP NU	FNP National Unit
GCP	Good clinical practice
GCSE	General Certificate of Secondary Education
GI	Giving information
GP	General Practitioner
HCP	Healthy child programme
HES	Hospital Episodes Statistics
HR	Hazard ratio
HRG	Healthcare resource group
HRQoL	health related quality of life
HSCIC	Health and Social Care Information Centre

HTA	Health technology assessment
HV	Health visitor
I	Intervention
ICC	Intra-cluster correlation coefficients
ICER	Incremental cost-effectiveness ratio
IDMC	Independent data monitoring committee
IMD	Index of multiple deprivation
IPD	Individual participant data
IRR	Incidence rate ratios
ITT	Intention to treat
LEA(s)	Local education authority/ies
LMP	Last menstrual period
LR(s)	Local Researcher(s)
LOA	Limits of agreement
LR	Local Researcher
MAR	Missing at random
MCAR	Missing completely at random
MI	Motivational interviewing
MIA	Motivational interviewing adherent
MIm	Multiple imputation
MINA	Motivational interviewing non-adherent
MITI	Motivational interviewing treatment integrity
MW	Midwife
NB	Net benefit
NBM	Negative Binomial model
NEET	Not in education, employment or training
NFP	Nurse Family Partnership
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMB	Net monetary benefit
NMC	Nursing and Midwifery Council
NS	Non-significant
NSO	National Service Office
NVQ	National Vocational Qualification
OLS	Ordinary least squared
ONS	Office for National Statistics
OQ	Open question
OR(s)	Odds ratio(s)
PCT	Primary Care Trust
PE	Process evaluation
PEWP	Process evaluation work package
PI	Principal investigator
PRC	Participant Resource Centre
PSSRU	Personal Social Services research unit
QALY(s)	Quality-adjusted life year(s)
QC	Quality control
R&D	Research and development
RCT	Randomised controlled trial
RDF	Record Definition File
REC	Research Ethics Committee
REML	Restricted maximum likelihood
SAE	Serious adverse event
SAS	Statistical analysis system
SD	Standard deviation
SES	Socioeconomic status
SEWTU	South East Wales Trials Unit
SHA	Strategic health authority
SIDS	Sudden infant death syndrome
SIEWP	Stakeholder involvement and ethics work package
SMG	Stakeholder management group
SMS	Short message service
SOGS	Schedule of Growing Skills
SR	Simple reflection

SSLP(s)	Sure start local programme(s)
SQL	Structured query language
SUR	Seemingly unrelated regression
TSC	Trial steering committee
TWP	Trial work package
UK	United Kingdom
US	United States
WTP	Willingness to pay

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# Executive Summary

## Evaluating the Family Nurse Partnership programme in England: The Building Blocks randomised controlled trial

### The study aimed to:

- Compare the effectiveness of the Family Nurse Partnership (FNP) in conjunction with usual care to usual care alone in terms of three programme domains: pregnancy and birth, child health and development, parental life course and self-sufficiency
- Assess the incremental costs and consequences of FNP in conjunction with usual care compared to existing services alone
- Explore possible longer-term costs and effects of FNP
- Evaluate processes that influence FNP outcomes in order to assess applicability to other settings and to make recommendations for optimising future implementation

### Background

Teenage mothers in the UK face individual, social and economic challenges in providing a successful start for their children's lives and to ensuring their own longer-term economic and social development. There is evidence for both short and longer-term benefit from a programme of home visiting (the Family Nurse Partnership, FNP) delivered by specially trained nurses from trials undertaken in the United States (US). Although the feasibility and acceptability of the programme had been evaluated in an English setting, the clinical and cost-effectiveness of the programme was unknown.

### Methods

#### Trial design

Individually randomised controlled trial with a parallel economic modelling study and an integrated process evaluation.

#### Participants

Nulliparous women aged 19 or under with a confirmed pregnancy were eligible if they lived within the catchment area of a local Family Nurse Partnership team. Women expecting multiple births and women with a previous pregnancy ending in miscarriage, stillbirth or termination were eligible. Women could not be recruited after 24 weeks gestation and were required to be Gillick competent to provide informed consent, including competence in English at conversational level or higher. Women who at study entry planned to have their child adopted, who planned to leave the FNP catchment area during the trial for more than three months or who would have required an interpreter to receive the intervention were ineligible.

## Setting

Eighteen sites across England where local partnerships, including primary and secondary National Health Service (NHS) organisations and local authorities were established to provide FNP.

## Interventions

*Experimental intervention:* FNP is an intensive programme of home visits developed in the US for women expecting their first baby and which has now been adapted for delivery in England by specially trained Family Nurses from early pregnancy until the first child is two years old. A scheduled maximum of 64 visits: 14 during pregnancy, 28 during infancy (0 to 12 months postpartum) and 22 during toddlerhood (13 to 24 months postpartum) cover content domains of personal and environmental health, life course development, maternal role, family and friends and access to health and Social Services. Actual number of visits is determined by individual need, maternal engagement and gestational age at enrolment. Nurse visits are supported by manuals, which provide a structure and recommended content for each visit. FNP is informed by theories of Human Ecology, Self-efficacy and Attachment and aims to affect risks and protective factors within each of three domains: prenatal health-related behaviours, sensitive and competent care of the child, and early parental life course. In England, core model elements specified under licensing terms aim to replicate the original research conditions and additional fidelity goals are intended to evidence a high standard of programme delivery. Family Nurses also take responsibility for delivering the Healthy Child Programme (HCP) of universally offered screening, education, immunisation and support during the antenatal period and after birth until the child's second birthday.

*Control:* While participants in both study arms received usually provided health and social care services for pregnant and new mothers, participants in the Control arm received these services alone. Usual services included maternity care appropriate to the woman's clinical needs (e.g. community-based antenatal care or hospital-based obstetric care, and postnatal midwifery care up to 28 days postpartum) and the HCP delivered by Midwives and Specialist Community Public Health Nurses (Health Visitors).

## Outcomes

**Primary:** (i) self-reported prenatal tobacco use at late pregnancy calibrated using urinary cotinine, (ii) birth weight, (iii) proportion of women with a second pregnancy by two years postpartum, (iv) emergency attendances and hospital admissions for the child within two years of birth.

**Secondary maternal outcomes:** pregnancy and birth (smoking cessation method, gestation at delivery, planned and actual place of birth, use of antenatal care), child health and development (social support, family resources, relationship support), parental life course (education, employment, receipt of benefits / financial support, homelessness, self-efficacy, adaptive functioning, contraceptive use, use of: dental care, primary care, secondary care, non-health services and foster care), other maternal health-related outcomes (general health

status, weight, psychological distress, postnatal / depression, domestic abuse, smoking at home, alcohol / drug use) from late pregnancy up to two years postpartum.

**Secondary parenting and child outcomes:** pregnancy and birth (prenatal attachment, birth outcome, Apgar score at one and five minutes, head circumference, neonatal unit admission) from late pregnancy to birth, child health and development (anticipatory parenting attitudes, breastfeeding: intentions, initiation and duration, parental role strain, maternal child interaction, mother and child living apart, toddler diet, cognitive and language development, home safety, use of childcare, use of Children's Centres, immunisations, primary and secondary care consultations for injury and ingestions, referrals to Social Services, safeguarding events) from birth to two years postpartum

**Economic:** a within-trial cost-utility analysis using incremental costs and incremental health benefits expressed in QALYs to assess value for money. A secondary cost-consequences analysis providing a descriptive summary of all relevant health and non-health related resource use and costs for both trial arms, as well as primary trial outcomes (consequences).

**Process evaluation:** fidelity of intervention delivery to FNP core model elements and fidelity goals and consistency with Motivational Interviewing, mapping of usually provided care, participant reported engagement and satisfaction with FNP, professional reported impact of FNP implementation.

## Randomisation

Allocation was in a ratio of one-to-one, stratified by site, and minimised by gestation (<16 weeks / 16+ weeks), smoking status at recruitment (smoker / non-smoker) and first or preferred language (English / non-English). The allocation algorithm minimised imbalance with respect to minimisation variables with a probability of 0.8.

## Outcome assessment

Outcome data were obtained via abstraction from routine healthcare records or through maternal self-report. Data for some outcomes could be obtained from both routine records and self-report. To enable the use of a calibrated measure of self-reported smoking, urine samples for cotinine assay were collected during face-to-face interviews at baseline and by post at late pregnancy.

**Routine data:** Antenatal, birth and neonatal data (including birth weight) were collected from maternity records. Secondary care data (including emergency attendances and admissions, attendances related to second pregnancies) were collected via the NHS Health and Social Care Information Centre (HSCIC). Primary care data were collected directly from GP records. Linked anonymised abortions data were provided by the Department of Health. Immunisation data were provided by Primary Care Trusts / Local Clinical Commissioning Groups. FNP consultation data were sourced via the national FNP Information System.

**Self-report data:** Baseline and 24 months postpartum computer-assisted personal interviews (CAPIs) were conducted by field-based researchers. Computer-assisted telephone interviews (CATIs) were conducted at late pregnancy (approximately 34-36 weeks gestation), six, 12, and 18 months postpartum by office-based researchers. A minimum dataset for the 24 months postpartum assessment was collected either by telephone interview or postal questionnaire if a face-to-face interview was not possible.

## Blinding

Participants were not blinded to the intervention. However, baseline assessment was undertaken by field-based researchers prior to intervention allocation and primary outcomes were measured using routinely collected data (birth weight, emergency attendances and admissions, second pregnancies) or at late pregnancy using maternal self-report to telephone interviewers who were blind to arm allocation (prenatal tobacco use). Self-reported secondary outcomes at late pregnancy, six, 12 and 18 months were measured using telephone interview by researchers blind to arm allocation. Secondary self-reported outcomes at 24 months were measured by face-to-face interviews using a structured CAPI by field-based researchers not blinded to arm allocation but independent of service delivery (intervention or control).

## Sample size

We estimated that a sample of 1,418 for analysis would provide at least 90% power at the two-sided 2.5% alpha level to detect differences between trial arms of 10% (40% to 30%) in the proportion having any emergency attendance or hospital admission, and of 7.5% (20% to 12.5%) in the proportion with a second pregnancy by 24 months postpartum. For each outcome, the expected improvement for the Intervention arm equates to a small standardised difference (about 0.2 or odds ratio 0.6). We allowed for a pregnancy loss of 1.5%. We expected to obtain follow-up data for three of the four primary outcomes (birth weight, emergency attendances and admissions, second pregnancy) on at least 90% of participants by accessing medical records. Therefore, we aimed to recruit 1,600 pregnant women. We chose a 2.5% alpha level to allow for multiple primary outcomes within each individual population in the trial (i.e. two primary outcomes for the mother: prenatal tobacco use and second pregnancy; two for the baby: birth weight and emergency attendances and admissions). This gave a 5% type 1 error rate for each population.

## Details of patient and public involvement in the research

Both trial governance committees (Trial Steering Committee, Data Monitoring Committee) included independent lay and professional members. A Stakeholder Management Group took responsibility for coordinating the trial team's approach to user involvement and considering service user perspectives. A key strategic element of this involved coordinating on going advice from two teenage mothers' groups based in Wales where FNP is not delivered and with no connection to the intervention. The mothers contributed tailored input at key developmental phases of the study, including review of participant materials and advice on a range of participant recruitment and retention strategies.

## How the work addressed equality and diversity issues

FNP was developed for mothers expecting their first child and introduced in England as part of the Government's action plan on social exclusion. Young maternal age was identified as a risk factor for poor child outcomes that is easily measurable in pregnancy. Therefore, the trial was open to all women expecting their first child, under 20 in recruiting sites. In the US the intervention has been formally tested in randomised controlled trials in samples consisting of ethnically white, African American and Hispanic women. As the intervention has not been validated for delivery via a translator women required a minimum of conversational English to participate. This reduces the generalisability of findings to women confident to speak in English. However, participants were able to provide research data through an interpreter if they preferred. A task & finish group ensured that study procedures were sensitive to diversity issues and minimised the risk of discrimination occurring in terms of trial participation.

## Results

**Recruitment and randomisation:** 3,251 women were screened for eligibility by community-based professionals at trial sites and details passed to field-based Local Researchers. 1,606 were excluded due to not meeting full eligibility criteria (n=638), declining to participate (n=727), inability to be contacted by researcher within recruitment period (n=205), and for no recorded reason (n=36). 1,645 participants were recruited to the trial between June 2009 and July 2010, five of whom were subsequently assessed as ineligible with no further data collection. Following withdrawals of consent from a further 22 participants, a total of 1,618 participants were included at baseline with 808 allocated to the Intervention arm and 810 allocated to the Control arm. The number of participants recruited at each site ranged from 35 to 150. Trial arms were balanced at baseline on balancing variables of reported gestational age and smoking status. For the third variable, language only six participants did not report a preference for data collection to be conducted in English.

**Participants:** Participants were mostly ethnically white (88.1%) with a median age at study entry of 17.9 years. A large minority (n=599, 37%) no longer lived with a parent and 22.7% (n=368) reported living with the father of their baby. 571 (41.3%) of those aged 16 or older at the end of the previous academic year, were not in education, employment or training. 232 (14.4%) reported that they had planned their pregnancy and most (n=1,222, 75.5%) described themselves as either closely involved with, or the girlfriend of their baby's father. 744 participants (46%) reported currently smoking at baseline, and 16.6% reported having quit smoking earlier in their pregnancy.

When compared using FNP enrolment data rather than trial baseline data, trial participants allocated to the Intervention arm were similar to 3,311 women subsequently enrolled to FNP at the same sites but outside of the trial (up to December 2013) in terms of mean age at enrolment (17.4 years and 17.2 years respectively) and mean gestation (17.9 weeks and 18.2 weeks respectively). The proportion of women enrolled by 16 weeks gestation was similar in both trial (39.7%) and non-trial (41.6%) clients. The proportion of ethnically white women was higher amongst trial clients than in non-trial clients (85.5% and 77.5% respectively). The

proportion of women not in education, employment or training was higher amongst trial clients (68.1%) than non-trial clients (60.5%). Rates of recent smoking recorded at intake were also higher for trial clients (40.8%) compared to non-trial clients (32.9%).

**Follow-up:** There were 83 mandatory withdrawals (e.g. due to miscarriage) and 110 elective withdrawals (for whom data collected to point of withdrawal were retained unless consent was also removed). The four primary outcomes were measured at different time points and from varying sources. Smoking data were collected at the late pregnancy interview for 1,237 participants (83% of 1,497 non-withdrawn participants). Calibrated smoking data for 1,092 participants were included in the primary comparison (Intervention arm: 547, Control arm: 545). Birth weight data were collected as part of the antenatal and birth experience dataset for all participants not withdrawn by the time of the child's birth (782 and 796 records for intervention and Control arms respectively). Birth weight data for 1,509 babies were included in the primary comparison (Intervention arm: 741, Control arm: 768). Data on emergency attendances and secondary care admissions were retrieved from the HSCIC for 1,496 out of 1,502 children including for 12 sets of twins. Attendance and admission data for 1,478 children were included in the primary comparison (Intervention arm: 725, Control arm: 753). Data on subsequent pregnancies were primarily identified in secondary care records and retrieved for 1611 out of 1618 participants. Pregnancy data for 1,289 participants were included in the primary comparison (Intervention arm: 643, Control arm: 646). Combined maternal / child case report forms were retrieved from primary medical care records for 476 (57.8%) participants in the Intervention arm and 486 (59.1%) in the Control arm. At 24 months postpartum, 1,154 participants provided self-reported secondary outcome data (77.8% of all non-withdrawn participants).

## Primary outcomes

**Smoking:** We found no difference in rate of smoking in late pregnancy between intervention (55.6%) and control (56.1%) arms for the 1,092 participants for whom a calibrated smoking score was available (adjusted OR: 0.90, 97.5% CI: 0.64 to 1.28). The finding was robust to sensitivity analyses that examined the sample with complete self-report and cotinine data at both baseline and follow-up (n=870). There was no difference in reported number of cigarettes smoked at late pregnancy for participants (n=610) classified at baseline as smokers (adjusted difference in means, Intervention-Control: 0.119 cigarettes, 97.5% CI: -0.73 to 0.97).

**Birth weight:** Mean (SD) birth weights were 3,217.4 grams (618.0) and 3,197.5 grams (581.5) for intervention and Control arms respectively. There was an adjusted difference in mean birth weight between trials arms of 20.75 grams (97.5% CI: -47.73 to 89.23) but no evidence of a difference.

**Second pregnancy within two years postpartum:** For the 1,289 participants included in the primary comparison there was no difference in the proportion with a second pregnancy within two years of their first child's birth between Intervention arm (66.3%) and Control arm (66.1%), an adjusted odds ratio of 1.01 (97.5% CI: 0.77 to 1.33).

**Emergency attendances and hospital admissions within 2 years of birth:** For the 1,478 children included in the primary comparison, rates of emergency attendance and admission for any reason in secondary care by their second birthday were high at 81.0% and 76.6% for the Intervention and Control arms respectively. This represented an adjusted odds ratio of 1.32 (97.5% CI: 0.99 to 1.76).

**Planned sub-group analyses for primary outcomes:** There were no differential effects due to age, deprivation, participation in employment, education or training, or basic life skills for any of the primary comparisons.

## Secondary outcomes

**Pregnancy and birth:** There was no evidence for differences between trial arms for either maternal or parenting and child outcomes.

### **Child health and development:**

Developmental concern there was no difference between arms at 12 and at 18 months in terms of maternally reported developmental concerns. However, at 24 months the proportions of children with a concern were 8.1% and 12.6% in the Intervention and Control arms respectively (adjusted odds ratio: 0.61, 95% CI: 0.40 to 0.90).

Language Maternally reported rate of developmental delay in language was lower for children in the Intervention arm (11.0%) compared to the Control arm (19.9%) at 12 months with an adjusted odds ratio of 0.50 (0.35 to 0.72). At 18 months the pattern was similar with 17.1% in the Intervention arm compared to 24.2% in the Control arm (adjusted odds ratio of 0.66 (0.48 to 0.90)). At the end of the trial period, maternally reported language development was better in the Intervention arm compared to the Control arm with mean (SD) Early Language Milestone percentiles of 60.8 (31.4) and 55.7 (31.4) respectively (adjusted difference in means of 4.49, 95% CI: 0.52 to 8.45).

Breastfeeding More pregnant participants in the Intervention arm expressed an intention to breast feed (58.4%) than in the Control arm (50.4%), an adjusted odds ratio of 1.32 (95% CI: 1.02 to 1.70). However, there was no difference in the proportion of participants in the Intervention arm initiating breastfeeding (57.6%) compared to the control group (54.9%), or in the median duration of breastfeeding reported at six months by participants in the Intervention arm (7 days) and Control arm (14 days) where initiated and subsequently ceased.

Injuries / ingestions A greater proportion of children in the Intervention arm than the Control arm attended an Emergency Department (ED) for an injury or ingestion by six months (4.1% and 2.8% respectively; adjusted OR: 1.52, 95% CI: 0.86 to 2.70) and by 24 months of age (30.8% and 27.8% respectively; adjusted OR: 1.16, 95% CI: 0.92 to 1.46). However, a smaller proportion of children in the Intervention arm were admitted to hospital with an injury or ingestion compared to the Control arm by six months of age (1.9% and 2.4% respectively;

adjusted odds ratio 0.79, 95% CI: 0.39 to 1.60) and by 24 months (4.8% and 6.6% respectively; adjusted odds ratio: 0.72, 95% CI: 0.46 to 1.12). However, there was no statistical evidence of differences between trial arms for children with injuries and ingestions presenting to an ED or being admitted.

Visiting Children's Centre Although a larger proportion of participants in the Intervention arm (35.3%) reported at 24 months visiting a Children's Centre than in the Control arm (27.7%), there was no overall difference across the full follow-up period.

Social Services referral At two years postpartum a greater proportion of participants in the Intervention arm reported that their child had ever been referred to Social Services (n=119, 20.5%) compared to the Control arm (n=91, 16.8%), an adjusted odds ratio of 1.27 (95% CI: 0.93 to 1.73).

Safeguarding Over the same time period, for the 945 children for whom data were available, a greater proportion of children in the Intervention arm had a safeguarding event recorded in their GP record (n=64, 13.6%) compared to the control group (n=38, 8.0%) an adjusted odds ratio of 1.85 (95% CI: 1.02 to 2.85).

Other outcomes There was no statistical evidence for differences between trial arms for any other maternal or parenting and child outcomes.

***Parental life course:***

NEET / employment / education For the period from birth to two years postpartum, there was no overall difference between trial arms in reported rates of either employment or education. However, at two years postpartum participants in the Intervention arm reported lower rates of not being in employment, education or training (62.1%) than in the Control arm (69.7%). At the same point in time, participants in the Intervention arm reported higher rates of being in paid employment (18.7%) than in the Control arm (15.7%), but there was no statistical evidence for a difference. However, for both outcomes there was no overall difference between arms across the full follow-up period.

Connexions At six months postpartum participants in the Intervention arm reported higher rates of access to the Connexions (employment) advisory service (32.9%) than in the Control arm (27.9%), but there was no statistical evidence for a difference across the reporting period.

Contraception Reported contraceptive use at 24 months postpartum was 72.6% in the Intervention arm and 67.9% in the Control arm. However, across the whole period up to two years the odds of contraceptive use by participants in the Intervention arm compared to the Control arm was 1.25 (95% CI: 0.98 to 1.60).

Social support A larger proportion of participants in the Intervention arm reported a maximum level of social support at 18 months postpartum (25.7%) compared to those in the Control arm (20.3%) with a similar

difference at 24 months (27.9% v 23.1%). Across the whole follow-up period there was a small difference between arms with an odds ratio of 1.50 (95% CI: 1.06 to 2.12). Similarly with relationship quality, a small difference was observed between arms in relationship quality score with an adjusted difference in means of 0.17 (95% CI: 0.28 to 1.20).

Homelessness 30.4% of participants in the Intervention arm reported ever being homeless in the period from study entry to 24 months postpartum compared to 36.3% in the Control arm (adjusted odds ratio of 0.76, 95% CI: 0.55 to 1.05).

Self-efficacy Across the full follow-up period there was a small difference between arms for self-efficacy score of 0.44 (95% CI: 0.10 to 0.78) with higher reported levels in the Intervention arm.

Other outcomes There was no statistical evidence for differences between trial arms for any other maternal outcome.

**Economic analysis:** The intervention was associated with minimal gains in Quality-Adjusted Life Years (QALYs). The base case analysis showed that there was no statistically significant difference between trial arms either when adjusting for baseline utility (mean difference 0.0036, 95% CI: -0.017 to 0.025) or after adjusting for balancing covariates (mean difference 0.0030, 95% CI: -0.017 to 0.027). There was no difference in total costs between the groups. FNP cost on average £1,992.89 more per participant over the duration of the programme when compared to usual care alone (95% CI: -2,700.3 to 5,744.4). The incremental costs decreased slightly (mean difference £1,811.57, 95% CI: -2,814.7 to 5,744.4) when adjusting for the remaining covariates. The probability of being cost-effective remained low even when adopting a higher willingness to pay threshold (below 20%). A cost-consequence analysis found that overall health resource costs were lower and non-health resource costs higher in the Intervention arm, resulting in an overall reduction in cost before FNP costs were considered. A top-down analysis applied these costs to estimated costs of delivering FNP to provide an indication of the funding set aside for delivering the intervention, and the potential for alternate investment.

**Process evaluation:** We assessed intervention implementation against FNP Core Model Elements and Fidelity goals using programme monitoring data and trial recruitment records. FNP clients met programme eligibility criteria and a high proportion of women (75%) offered FNP enrolled. The proportion of participants enrolled onto the programme by 16 weeks gestation (39.7%) was lower than targeted (60%) but similar to that observed at the same trial sites in the two-and-a-half-year period subsequent to the end of trial recruitment (41.6%). The mean number of valid visits received by phase (9.71, 18.63 and 13.22) was lower than targeted (14, 28 and 22) but greater than observed in the English implementation evaluation, and the first two US NFP trials. The proportion of participants who completed the programme meeting or exceeding target rates of expected visits (Pregnancy: 80%, Infancy: 65% and Toddlerhood: 60%) were 57.7%, 53.0% and 43.6% respectively. Rates of programme attrition by phase were 3.6%, 10.1% and 7.9% respectively with a cumulative

attrition rate of 21.2%, well within the maximum acceptable rates (by phase 10%, 20%, 10%, overall: 40%). On average, visits were 79.14 minutes in duration, approximately 30% longer than the target minimum of 60 minutes. Nurse-reported programme content was broadly in line with prescribed targets although with a greater emphasis upon Environmental health in each phase and with less variability in overall domain coverage than indicated by independent rating of consultation recordings. Family Nurses demonstrated programme delivery consistent with principles of Motivational Interviewing although for some specific behaviours observed levels of practice were more modest.

**Harms:** We found no harms attributable to FNP. Although a large number of adverse events in both arms were reported to the trial team, this was expected given such a large group of young women mostly pregnant for the first time, many of whom would have experienced additional challenging personal circumstances. Many adverse events related to social as well as medical events.

**Relevance to policy:** FNP is a maternal and early years programme for young mothers which aims to improve pregnancy outcomes to provide the best start in life for their baby, to improve child health and development by developing parenting knowledge and skills and to improve parents' economic self-sufficiency by helping them achieve their aspirations, including for education and employment. FNP is intended to improve the life chances of the most disadvantaged families in society by intervening in the early years of a child's life to have a lasting impact upon their future health, happiness, relationships and achievements. The primary and secondary outcomes assessed directly address key programme goals.

## Conclusions and further research

FNP is an intensive programme of antenatal and postnatal visiting by specially trained nurses to support young pregnant women. The Building Blocks trial found that FNP is no more effective than routinely available healthcare alone in reducing smoking in pregnancy, improving birth weight, reducing rates of second pregnancies by two years postpartum or reducing rates of emergency attendance or hospital admission for the child for any reason by the child's second birthday when delivered in an English healthcare setting.

Given only small observed differences related specifically to healthcare sought for child injuries and ingestions we conclude that there is evidence that the programme is no more effective at preventing physical harm to children than normally provided care up to two years postpartum. The strong statistical evidence for differences in child safeguarding reports in primary care records is consistent with maternal reports of Social Services referral. Safeguarding is a positive intervention to protect children at risk of, or actually experiencing harm and is a function of underlying level of risk / harm, detection and thresholds for intervention. There is no obvious rationale for considering that FNP would increase underlying levels of risk or harm. It is more likely that the greater level of health professional contact (with Family Nurse) would lead to more children being identified with concerns. The personal relationship with the Family Nurse may also facilitate disclosure by the mother of concerns and further referral or help seeking behaviour. For either trial arm, undetected risk or

harms for the long-term emotional, behavioural and developmental effects of early childhood maltreatment may arise subsequently, after the current follow-up period. Additional data for safeguarding events documented in primary care records were limited. Further work would be required to establish their nature and determine the pattern of safeguarding interventions over a longer time period.

The trial provides evidence that the intervention may promote cognitive and language development more effectively than normally provided care alone up to a child's second birthday. Like attendance and admission to secondary care, this outcome lies within the programme's Child health and development domain. This is consistent with the greater proportion of time Family Nurses report spending on Environmental health than allocated in the programme. The trial demonstrates small programme benefits for the mother within two years postpartum in terms of maximum social support, generalised self-efficacy and relationship quality, which may provide some longer-term benefit for the child.

Allocating women to FNP costs £1993 more per participant when compared to usual care alone, therefore the programme is not cost-effective when assessed against the minimal gains in maternal health. As non-health resource costs were greater for Family Nurse-visited families it is possible that a small collective impact on accessing services resulted from FNP.

Analysis of the three primary outcomes based on routine data had at least 90% power to detect small intervention effects (0.2 or less). For the fourth primary outcome, differences in smoking rates and numbers of cigarettes smoked were of negligible clinical importance. The lack of differences found for smoking, birth weight and second pregnancies were not the result of inadequate sample size (Type II error).

Data on birth weight were abstracted from maternity records and is not likely to have been subject to bias. Our measurement of smoking calibrated for self-report using urine cotinine and is likely to have resulted in a more valid assessment than using self-report alone. Sensitivity analyses including complete case analysis (self-report and cotinine at both baseline and later pregnancy) did not alter our conclusions. Measurement of second pregnancy used multiple sources of data to identify a pregnancy rather than relying solely on self-report. Sensitivity analyses explored use of data sources separately (NHS secondary care records, primary care records, maternal self-report) and did not alter our conclusions.

We are unable to comment on how the recruited sample compared to all eligible women in trial sites but not recruited to the trial. However, the sample of participants studied were broadly representative of the population to whom the intervention is currently being delivered in England with only minor differences evident. Ethnically white women and baseline smokers were slightly over-represented in the study sample. Both of these observations may be attributable to differences between sites included in the trial and other sites delivering FNP. The requirement for conversational English reduced generalisability but overall we consider the trial sample to be a good basis for extrapolating to the intended service population. We have

reported the impact of loss to follow-up on the samples available for analysis for different outcomes. Overall those lost to follow-up had marginally higher rates of characteristics indicative of disadvantage such as Not being in Education, Employment or Training (NEET). However, sub-group analyses of primary outcomes consistently found no differential programme effect by age, NEET status, difficulty with basic life skills or area-based deprivation level.

Delivery of the intervention in the trial met some but not all of the programme fidelity targets. For several components it exceeded performance reported in both the English implementation evaluation and in the first two US trials of FNP. The impact of varying exposure to the intervention (number of expected visits) was assessed in sensitivity analyses and did not alter our conclusions about effectiveness for the three primary outcomes where no intervention effect was shown. It is likely that delivery in the trial has benefited from learning accrued from FNP teams who participated in the implementation evaluation, either directly or indirectly. Such learning may have continued as the intervention continues to be delivered in England although has still to be determined. Delivery and management of the intervention was independent from the trial team, and we consider that the trial represents a good test of the intervention as currently deliverable in an English setting.

In England, health and other supportive services for young first-time mothers are numerous, mostly provided free at the point of delivery and likely to be more comprehensive than in the settings for the three original US trials. This may reduce the potential for additional programme effects, although for the primary outcomes of smoking and second pregnancies rates in both trial arms remained high. Our trial was more pragmatic in nature than previous trials of the FNP in that it was led independently of service delivery, covered more sites and had a greater number of nurses delivering the programme. FNP enrolment criteria underpinning trial participant eligibility may have resulted in a more heterogeneous and relatively less disadvantaged sample compared to study sample sub groups where the most evident intervention effects have been previously reported. We have not assessed all programme-defined outcomes and some important benefits may remain undetected. However, we have assessed against most key FNP goals and our analysis has included a large number of comparisons and sensitivity analyses with the detection of a small number of positive programme effects. The Building Blocks trial could only assess short-term impact for a programme that has existing evidence of longer-term benefits. Some effects detected in our trial suggest the potential for such longer-term benefits, and also the need to evaluate further the impact upon maltreatment.

In conclusion, our trial found there was little advantage to adding FNP to existing health service provision in England and was not cost-effective from the perspective of maternal outcomes. There was some benefit for the child by their second birthday, although evidence for child health and development outcomes would mainly arise in children after the age of two and longer-term follow-up is therefore required for this outcome.

**Recommendations for research:** As the effectiveness and cost-effectiveness of the intervention have been most strongly established in previous evaluations in the US with a longer follow-up, we consider a similar longer-term perspective should be adopted for this cohort. We are planning to do so for mainly maltreatment outcomes using routinely available data. We recommend that this focus be expanded to accommodate emotional, behavioural and developmental outcomes for the child and life course outcomes for the mother.

## **Dissemination plans**

Dissemination will be directed towards stakeholders comprised of funders, policy partners and leads, lay and professional study participants, the research and professional community. Mechanisms for dissemination include formal reporting of the trial to the funders via this report, written and other forms of feedback to study participants, submission for publication in scientific journals, presentation at scientific meetings and invited stakeholder meetings.

**Trial registration:** This trial is registered as ISCRCTN23019866.

**Funding:** The trial was funded by the Department of Health Policy Research Programme (006/0060).

# 1 Introduction

## 1.1 What are the challenges for first-time teenage mothers and their children?

The individual, social and economic circumstances faced by teenage mothers in the UK present challenges to securing a successful start for their children's lives and to their own longer-term economic and social stability. Short-term indicators of being at such disadvantage include adverse health behaviours such as smoking in pregnancy and sub-optimal levels of support from health and social care services, and in the longer-term a lack of engagement with education and employment. Intervening early in the lives of young families may help to modify the life chances for both mother<sup>1</sup> and child and counteract the disadvantage of social circumstances that may otherwise be transmitted through the generations. By enabling new mothers-to-better understand the needs of their new child, to provide more appropriate and safer care and to establish a more secure future, the potential exists to make a significant impact on those in society who have most to gain. In this section we consider some of the particular challenges for teenage mothers and their children before turning to the potential to successfully intervene.

Previous studies have demonstrated that infants<sup>2</sup> born into socioeconomic deprivation are more likely to have teenage mothers, to have been exposed to cigarette smoke during pregnancy, to have poor prenatal health profiles, and are at greater risk of adverse short-term and long-term outcomes.<sup>2-7</sup> In 2008 there were 44,691 live births to women under the age of 20 in England and Wales.<sup>8</sup> Children born to teenage mothers have lower birth weights, are less likely to be breast fed, exhibit higher mortality rates, and are more likely to suffer accidents. They do worse educationally, experience more emotional and behavioural problems, and are more likely to become teenage parents themselves. This report presents the main results of the Building Blocks trial which evaluated the effectiveness of a home visiting intervention, the Family Nurse Partnership (FNP), which aims to support young first-time mothers and their children in an English setting. Some of the particular challenges faced by young socially deprived mothers: smoking, low birth weight, emergency admission and attendance of infant to hospital and subsequent pregnancies, were selected to be the primary outcomes for the trial and are described in more detail below.

### 1.1.1 Smoking

**Smoking in Pregnancy in the UK:** In the UK in 2010, 26% of women smoked cigarettes in the year before they become pregnant, and although most would like to quit,<sup>9</sup> only around half of these women manage to do so before or during pregnancy, which means that 12% of women are persistent smokers throughout.<sup>10</sup> These statistics mask large variations by age, socioeconomic status, and region. Data from the NHS Information Centre for the prevalence of smoking at birth in 2011, show a 20% prevalence in the North East of England,

compared to 6% for London,<sup>11</sup> and data from the 2010 Infant Feeding Survey reveal that the highest levels of smoking before or during pregnancy were among mothers in routine and manual occupations (40%) and among those aged under 20 (57%).<sup>10</sup> Mothers under 20 years of age were also the least likely to have given up smoking before or during pregnancy (38%), and by socio-economic group, mothers who had never worked were the least likely to have quit (29%).<sup>10</sup>

Women who smoke in pregnancy are more likely to be depressed,<sup>12,13</sup> stressed,<sup>14</sup> single or co-habiting,<sup>15,16</sup> to have a partner who smokes<sup>17,18</sup> or who abuses them.<sup>19</sup> They have less social support,<sup>20</sup> and are more likely to be living in a working-class neighbourhood.<sup>21,22</sup> Women who quit smoking and women who continue to smoke in pregnancy also differ in the ways they relate to other people, in how well they cope with day-to-day life and in their likelihood of engaging in other risky health behaviours.<sup>23-26</sup> Thus, smoking in pregnancy is embedded in a very complex psychological and social context, with important implications for smoking cessation and harm reduction efforts.

***Consequences of Smoking in Pregnancy:*** Smoking during pregnancy is associated with economic costs and a large number of potential short and longer-term consequences for both the mother and the exposed fetus.<sup>9,27-29</sup> These consequences include an increased risk of congenital anomalies, low birth weight, fetal growth restriction, preterm birth, infant mortality and Sudden Infant Death Syndrome. In childhood and beyond, those whose mothers smoked during pregnancy are at greater risk of reduced lung function and respiratory illness (including asthma), obesity, type II diabetes, brain tumours, leukaemia and lymphoma. A robust, although not as yet conclusive, literature links smoking in pregnancy to poorer cognitive development and behavioural problems in offspring.

### **1.1.2 Low birth weight**

Children born to young and economically disadvantaged mothers who have been exposed to family poverty and social disadvantage are at increased risk of low birth weight.<sup>30,31</sup> Multiple mechanisms are thought to account for this risk, including maternal exposure to environmental hazards,<sup>32</sup> stress and adversity caused by maltreatment in adolescence,<sup>33</sup> reduced size of the mother<sup>34</sup> and the presence of infections predisposing to premature delivery.<sup>35</sup> Maternal smoking represents a major risk factor for low birth weight given that evidence in the UK Millennium Cohort Study found 36% of infants were exposed in utero to maternal smoking.<sup>36</sup> Maternal smoking may predispose to low birth weight, particularly when associated with maternal respiratory conditions.<sup>37</sup> Furthermore, passive exposure of the mother to environmental smoke produced by others<sup>38</sup> has been shown to be associated with a 22% increased risk of birth weight below 2,500 grams.<sup>39</sup> The Millennium Cohort Study suggests that compared to newborns of mothers not exposed to smoke, offspring of smoking mothers are 146 grams lighter and those of mothers passively exposed to environmental smoke produced by others in the home are 36 grams lighter.<sup>36</sup> Other health-threatening behaviours such as heavy alcohol consumption<sup>40</sup> during pregnancy may predispose to low birth weight. In a UK context, there is no evidence

over the last 40 years that the adverse consequences on birth weight of socioeconomic deprivation are diminishing.<sup>32</sup>

Low birth weight due to in utero growth restriction or prematurity has been shown to have significant adverse consequences on health in later life.<sup>41</sup> It seems that growth restriction in utero leads to permanent changes in the body's structure, function and metabolism that predispose in particular to coronary heart disease and the related conditions of stroke, hypertension and type 2 diabetes as well as a range of other disorders, including neurological impairment and cognitive difficulties.<sup>42</sup>

### **1.1.3 Maltreatment**

Maltreatment involves acts of omission (neglect) or commission (abuse) often by caregivers that either threaten to risk, risk or actually cause harm to a child.<sup>43</sup> Neglect represents persistent failure to meet a child's basic physical or psychological needs, often resulting in serious impairment of the child's health or development.<sup>44</sup> Neglect may involve failing to protect a child from physical and emotional harm or danger, ensure adequate supervision or ensure access to appropriate medical care. In the year ending 31<sup>st</sup> March 2010 in England there were 603,700 referrals to children's social care services, 375,900 children in need (an overall rate of 341.3 per 10,000) and 44,300 children became subject of a child protection plan.<sup>45</sup> Of children who became subject of a child protection plan, the most common initial category of abuse was neglect (43.5%), followed by emotional abuse (27.9%) and physical abuse (14.1%). Child maltreatment is associated with adverse physical, social, emotional and cognitive long-term outcomes which may arise throughout the child's lifetime.<sup>46</sup> Young maternal age, and factors associated with teenage motherhood, such as lower levels of education and income, are indicators of the risk of maltreatment.<sup>47,48</sup>

Maltreatment may be partially evidenced through attendance in hospital emergency departments. Infants attending UK Accident and Emergency departments represent a significant proportion of overall child attendances. The main clinical diagnoses include local infections (estimated 8% of all admissions), gastrointestinal (10%), respiratory problems (15%), whilst some 10-30% appear to have no discernible underlying abnormality. The commonest injuries in this age group are head injuries (9.4%); fractures, burns and scalds, lacerations, contusions, abrasions are each responsible for < 1% of attendances.<sup>49,50</sup> Whilst some attendances at emergency departments may reflect local arrangements whereby primary care or 'out of hours' facilities are provided within emergency units, evaluating the specific reason for attendance and hospital admission has the potential to offer a reasonably standardised measure of health or injury status.

### **1.1.4 Subsequent pregnancy**

Delaying repeat pregnancies may allow mothers to more successfully care for their first child.<sup>51</sup> In one sample of teenage mothers, fertility control across the maternal life-time was associated with better long-term economic outcome (employment & education)<sup>52</sup> Seitz showed that a delay in subsequent childbearing of at least two years had significant benefits in terms of improved contemporary (i.e. by two years) educational

outcomes and in the longer term (six years postpartum) for teenage mothers.<sup>53</sup> In the UK it is difficult to determine national rates of rapid repeat pregnancies (i.e. within 12-24 months of previous pregnancy) for teenagers due to the way that official data on pregnancies and births are collated. A review by Rigsby and colleagues cites rates of between 30% and 50% in the absence of postpartum intervention from a series of US studies.<sup>54</sup> For example, in one large US study of 3412 first-time teenage mothers enrolled in the Teenage Parent Demonstration Project, 64% had a second pregnancy within the follow-up period which averaged 29 months (75% of these pregnancies occurred within first 24 months).<sup>55</sup>

Predictors of rapid repeat pregnancy amongst adolescents include younger age, low socioeconomic status, low education of teen's mother or head of household, marriage, intended or desired first pregnancy, and choice of contraceptive method.<sup>54</sup> Factors found to be predictive of repeat pregnancy amongst teenagers attending a parenting programme in Utah include younger age, ethnicity, being in a stable relationship with baby's father and significant psychiatric history.<sup>56</sup> Another factor associated with rapid repeat pregnancy among low-income adolescents was found to include experience of interpersonal violence.<sup>57</sup> A social ecological theoretical perspective on repeat adolescent pregnancy presented by Rowlands<sup>58</sup> identified different levels of influence on behavioural outcomes (e.g. individual, family, peer, social).

## **1.2 UK policy response**

### **1.2.1 UK policy context**

In England, the Healthy Child Programme (HCP)<sup>31</sup> forms the universal offer of clinical and public health for children and families during pregnancy to when the child is 19 years of age.<sup>59</sup> It provides a schedule of evidence-based care, including additional support as required, and is led by health visiting teams. This universal service is intended to ensure a healthy start for children and their families to support parents and promote access to relevant community services and resources. Public health improvement outcomes specific to children include breastfeeding initiation and prevalence at 6-8 weeks after birth, child development at 2-2.5 years, hospital admissions for all injuries and public health protection including vaccination coverage. Furthermore, effective implementation of the HCP is intended to promote strong parent-child attachment, positive parenting, healthy eating and increased activity levels, readiness for school and improved learning and early detection of growth disorders and risk factors for obesity.

In the UK, preventing maltreatment is an important focus of government concern. The Children Act 1989 specifies agencies' responsibilities to cooperate in the interests of vulnerable children, for Children in Need and children suffering or likely to suffer from significant harm. How individuals and organisations should work together to safeguard and promote the welfare of children is set out in the statutory guidance document Working Together to Safeguard Children.<sup>44</sup> Every Child Matters, the Green Paper around the Children's Act 2004 (which made structural and organisational changes to children's services and inter-agency working),

emphasised support for parents (including targeted services) and carers and early intervention as two of four areas of focus. There has been an increasing emphasis upon the primary prevention of child maltreatment, including interventions directed at general populations and those targeting high-risk groups.

### **1.2.2 Usually provided care**

In England, hospital and community based maternity care is provided by the National Health Service, it is universally available and free at the point of delivery. Minimum standards for maternity care are recommended by the National Institute for Health and Care Excellence and include a minimum of 10 antenatal check-ups for women expecting their first baby.<sup>60,61</sup> Specific additional care is recommended for pregnant women under 20 and includes allocating a named midwife to provide the majority of the teenager's care, supported by direct telephone access to midwifery advice.<sup>62</sup> Health Visitors (specialist community public health nurses) provide support to new mothers and their children up to the child's fifth birthday with the level and nature of engagement depending on local resources and individual need.

### **Specific programmes**

Specific programmes to support the life chances of children growing up in disadvantaged circumstances have also been introduced in the United Kingdom. Sure Start Local Programmes (SSLPs) were area-based interventions for all children under the age of five years, and involved local areas improving and creating services to support young families. Although initial evaluations of SSLPs found some evidence of effectiveness, children in more disadvantaged circumstances, including those with teenage mothers appeared to fare less well (e.g. lower verbal ability, social competence and higher behaviour problems).<sup>63</sup> Although SSLPs changed to come under the control of local authorities and were run from Children's Centres, considerable variation in delivery remained. Nevertheless, the benefits of the programmes now appeared to be more equitably experienced by sections within Sure Start areas, an effect attributed to maturation of programmes with time and experience gained from earlier phases of implementation.<sup>63,64</sup> Broadly experienced positive effects of SSLPs at age seven included mothers engaging in less harsh parenting and providing a more stimulating home learning environment for their children.<sup>65</sup>

Furthermore, a more targeted programme, Sure Start Plus was piloted with the aim of reducing the social exclusion associated with teenage pregnancy by providing additional community-based support programmes and facilities. Whilst models of provision varied across sites, a central feature of the programme was an advisor to provide individual support to young women. The pilot study of Sure Start Plus suggested benefits including crisis support for women, increased support for emotional issues and increased educational participation for those aged under 16 years. However, it appeared less successful in changing health damaging behaviours such as smoking and in the promotion of breastfeeding.<sup>66</sup>

## **1.3 Home visiting and the Potential of the Nurse Family Partnership programme**

### **1.3.1 The home visiting model**

As a delivery model, home visiting programs typically address a range of maternal and child outcomes and evidenced benefits include cognitive and socioeconomic development, and reducing potential abuse (e.g. injuries and ingestions, emergency room attendances) when delivered by professionals or paraprofessionals.<sup>67-</sup>  
<sup>69</sup> Home visiting programmes can improve birth outcomes, increase use of preventative healthcare (e.g. immunisations) and reduce maltreatment.<sup>70</sup> For maltreatment outcomes, theory-based programmes are more likely to be effective and those delivered by professionals most cost-effective.<sup>71,72</sup> In Dalziel and Segal's review of trials reporting child maltreatment outcomes seven of 22 programmes of at least adequate quality were cost saving when lifetime cost offsets.<sup>72</sup>

The current evidence base is dominated by US-based studies. In Mikton and Butchart's review of universal and selective child maltreatment prevention which assessed seven types of interventions, including home visiting, 82.9% of 298 publications were from the US and nearly all were from high-income countries.<sup>73</sup> In the US, the Maternal Infant and Early Childhood Home Visiting Program provides \$1.5 billion of federal investment over five years for evidence-based home visiting programs.<sup>74</sup> The US Department of Health and Human services undertake annually updated reviews of evidence of effectiveness for home visiting programmes and identifies the Nurse Family Partnership (NFP) as one of 12 programmes meeting criteria for evidence-based models.<sup>75</sup> NFP is one of six programmes under this review reporting positive effects in some aspect of maltreatment reduction, and one of five programmes reported favourable effects on healthcare usage (e.g. increased use of preventative healthcare).<sup>70</sup> The HomVEE review includes not only RCTs and most programmes report a large number of outcomes without corrections for chance findings.<sup>70,75</sup>

### **1.3.2 Description and theoretical framework of the Nurse Family Partnership**

The Nurse Family Partnership programme was developed in the US by Professor David Olds in an attempt to improve outcomes for socially disadvantaged younger first-time mothers and their children. The programme aims to reduce known associations between younger mothers and poor birth outcomes, social exclusion, child abuse and neglect, and diminished economic self-sufficiency. The programme also aims to promote sensitive and competent caregiving and to reduce maltreatment through activities such as education about child development, modelling sensitive parent-child interaction, and guidance on accessing appropriate childcare.

NFP is a structured, intensive programme of home visits delivered by specially trained Family Nurses. A scheduled maximum of 64 visits (14 during pregnancy, 28 during infancy and 22 during toddlerhood) cover core content areas of personal and environmental health, life course development, maternal role, family and friends and access to health and Social Services. The programme commences, ideally, early in the second trimester of pregnancy and visits decrease in frequency over the first two years of the child's life. The exact

number of visits will be determined by individual need and engagement and by gestational age at enrolment. Visits are supported by manuals, which provide a structure and recommended content for each visit.

The programme draws upon three guiding theoretical perspectives. First, from Human Ecology, a child's development is seen as critically influenced by the care received from their parent, who in turn is influenced by their own social and environmental context.<sup>76</sup> This perspective is represented in the programme by the nurse facilitating involvement of key family members such as the father and promoting access to supportive services (e.g. health and social care). Second, Bandura's Self-efficacy theory informed how individuals make important decisions about their own behaviour.<sup>77</sup> Decision-making is guided by one's belief that a given behaviour will result in certain outcomes (outcome expectations) and the individual's confidence in successfully changing that behaviour (efficacy expectations). The programme provides educational resources to show how maternal behaviour can influence both mother and her child. Mothers are supported to set and achieve realistic personal goals with the intention that accumulated success raises expectation and further increases confidence. The importance of self-efficacy was raised following observation from a first trial of NFP in which the most important treatment effects, such as reduction in maltreatment, were most commonly found for women who at baseline had little sense of control over their own lives. Similarly maternal expectations of the programme are enhanced by sharing with mothers the outcomes of the previous US trials. Third, attachment theory describes the survival instinct for infants to form affectionate bonds with a primary caregiver for purposes of safety and security.<sup>78</sup> How an individual subsequently views himself or herself and forms relationships with others is determined by the quality of attachment they achieved as an infant with a responsive caring adult. This has informed programme design with the promotion of sensitive, responsive and engaged care-giving by nurses who encourage mothers to consider both their own childhood experiences and also how they wish to care for their own child. Whilst the NFP programme originally drew most heavily on the theory of human ecology, the emphasis on attachment and self-efficacy has increased in line with an interventional focus promoting adaptive behavioural change.<sup>51</sup> Olds aligns this to Bronfenbrenner's person-process-context model of human development, with attachment and self-efficacy integrated within the person and process elements.

Olds summarised the NFP conceptual model to clearly represent how programme elements act together to influence maternal and child health development.<sup>79</sup> The programme aims to affect proximal risks and protective factors within each of three domains; prenatal health-related behaviours; sensitive and competent care of the child; early parental life course. Corresponding short-term outcomes influenced by programme activities are then birth outcomes; child maltreatment (including unintentional injuries); child neurodevelopment; and later parental life course. Longer-term outcomes arising after the end of the programme include antisocial behaviour and substance abuse in the child/adolescent. The theory of change logic model for NFP has more recently been summarised by Ruth O'Brien.<sup>80</sup>

A central concept in the programme drawn from Attachment Theory is the therapeutic relationship that forms between the nurse and her client.<sup>51</sup> The relationship provides a model of care and support. Mothers develop experience of being the recipient of a positive and caring relationship, and this positive relationship can, in turn, be extended to their child.

The programme focus upon first-time mothers is based upon the concept of ecological transition, such that nurses support mothers in learning about their new maternal role and develop resources that are also supportive for subsequent children. Helping the mother plan more effectively for the future includes planning for subsequent pregnancies and reducing unintended pregnancies, thereby allowing the mother to care more successfully for her first child.<sup>51</sup>

### **1.3.3 Current evidence of NFP programme effectiveness**

Existing evidence of NFP programme effectiveness is available from three randomised trials conducted in the US. Collectively these have shown the NFP programme to improve prenatal health behaviours, birth outcomes, sensitive childcare, child and adolescent functioning and maternal life course (e.g. greater workforce participation, fewer subsequent pregnancies, reduction in welfare requirements), and reduce child injuries, abuse and neglect.<sup>79,81-90</sup> The NFP had greatest impact amongst those with low psychological resources. The cost of the programme for low-income and unmarried mothers was recovered by the child's fourth birthday, whilst amongst married women or those of higher socio-economic status a net financial saving has been demonstrated over a longer period.<sup>91</sup> A summary of each of the three US trials, and their outcomes by the time the child's second birthday is provided below.

### **1.3.4 Elmira trial**

An efficacy trial of NFP in Elmira, a semi-rural county of New York state, recruited 400 pregnant women between April 1978 and September 1980.<sup>83,85</sup> Reported as well served by health and human services, the community consistently had the highest rates of confirmed maltreatment in the state, and whilst the trial was underway, was rated the worst economic Standard Metropolitan Statistical Area in the US. Pregnant women were recruited if they were nulliparous, less than 26 weeks gestation and had at least one risk factor for infant health and developmental problems (aged < 19 years, single status, low socio-economic status), although the latter criterion was overridden for women who requested to take part with ages ranged from 14 to 34 years. In two control groups, families received sensory and developmental screening for the child at 12 and 24 months, and in one of these groups, additional free transport to prenatal and well-childcare until the child's second birthday. With no difference in actual use of care services, the groups were combined as the control condition in analysis. In the two intervention groups the same screening and transportation services were provided, with the addition of nurse visits during pregnancy. Nurse visits were also continued until the child's second birthday in one of these two intervention groups. For prenatal outcomes the two intervention groups were combined for comparative analysis.

Significant findings by the 2 year follow-up are summarised in Table 1.1. Across the full study sample, in the pregnancy and birth phase, nurse-visited women had fewer kidney infections, greater dietary improvements, greater paternal involvement and greater awareness and uptake of community services compared to women in the control group. Amongst smokers at baseline, there was a greater reduction in number of cigarettes smoked for nurse-visited women compared to women in the control groups (a difference of four cigarettes). Whilst there were no overall differences in birth weight or gestational age, for baseline smokers nurse-visited women had fewer preterm deliveries. For older (17+ years) non-smoking women, nurse-visiting was associated with a higher rate of low birth weight babies, shorter length of gestation and a greater rate of pre-term delivery (an unexpected difference apparently related to lower levels of social support within this older non-smoking sub-group of nurse-visited women). For participants aged 14-16 years, nurse-visited women had heavier babies (by an average of 395 grams), an effect concentrated in those who enrolled in the programme before mid-gestation.

There were fewer emergency department visits for the child in their first year of life, and in their second year of life within the nurse-visited group compared to the control group. Visits specifically for accidents and poisonings were also reduced in the second 12 months of the child's life for nurse-visited women compared to the control group (a 56% relative reduction). For the most disadvantaged group of poor unmarried teenagers, 19% of the women in the control group and 4% of nurse-visited women had maltreated their child ( $p=0.07$ ). At six months of age, babies of nurse-visited women were reported to have a more positive mood than that reported by women in the control group but more frequent episodes of resistant eating. Nurse-visited women reported greater concerns regarding problems they reported about their infants' behaviour at six months. Amongst poor unmarried teenagers, nurse-visited mothers punished and restricted their children less frequently, and provided a larger number of appropriate play materials compared to control group mothers at both 10 and 22 months.

### **1.3.5 Memphis trial**

The second NFP trial sought to determine the effectiveness of the programme within a large sample of low income African-American women living in a major urban setting when delivered through an existing health department.<sup>92</sup> 1139 low-income nulliparous women, less than 29 weeks gestation were recruited from the obstetric clinic in a regional medical centre. Eligible women had at least two socio-demographic risk factors (unmarried, less than 12 years of education, unemployed), whilst women with chronic conditions considered to increase the risk of fetal growth retardation or preterm delivery were excluded. Ninety-two per cent of participants were African American and 98% were unmarried. Sample size calculations allowed for the detection of effects in the higher risk group of mothers with few psychological resources (intellectual functioning, mental health, sense of control). Different expected treatment effects during prenatal (smaller) and postnatal (larger) phases led to a disproportionate allocation to the four study groups. The treatment conditions accumulatively provided (i) free transport to planned prenatal care appointments, (ii) developmental screening and referral services for the child at six, 12 and 24 months of age (iii) nurse-visiting in

pregnancy plus a postpartum visit at both hospital and at home and (iv) continued nurse-visiting until the child's second birthday. Modelling pregnancy outcomes primarily compared women in groups 1 and 2 with women in groups 3 and 4, whereas for postnatal outcomes the principal comparison was between groups 2 and 4.

There were no treatment main effects for tested birth outcomes (birth weight, length of gestation, low birth weight, spontaneous or indicated preterm delivery or Apgar score). Nurse-visited women were more likely to use community services during pregnancy, although there was no difference in use of standard prenatal care or obstetrical emergency services. The rate of pregnancy induced hypertension (PIH) was lower in the nurse-visited group. By age two, nurse-visited children had received fewer healthcare encounters in which injuries and ingestions were detected compared to the control group, mostly attributable to differences in outpatient visits. This may have been reduced through parents being encouraged to communicate with office staff prior to seeking care. Nurse-visited children were also hospitalised for fewer days due to injuries and ingestions. Both effects were stronger amongst families where the mother had fewer baseline psychological resources. Nurse visited mothers reported more breastfeeding initiation, but with no difference in duration, held fewer child-rearing beliefs associated with maltreatment and lived in homes more supportive for children's development compared to mothers in the control group. Finally, nurse-visited mothers had fewer pregnancies and births, and a greater sense of mastery by 24 months postpartum compared to mothers in the Control arm, although there were no differences in reported educational achievement or length of employment. There were no differences in children's use of well-childcare, rates of immunisations, mental development or behavioural problems.

### **1.3.6 Denver trial**

The Denver trial aimed to determine whether limited observed effects for home visiting programmes delivered by paraprofessionals were due to insufficient training or the use of underdeveloped programme models.<sup>89</sup> Across both private and public care settings, 735 nulliparous pregnant women who were either eligible for Medicaid or had no private health insurance were randomised to control, paraprofessional or nurse conditions. Women could enrol at any time before delivery. Similar to the Memphis trial, sample size considerations allowed for assessment of treatment effects amongst higher-risk women (for example, low psychological resources). Developmental screening and referral services for the child were provided to the control group and also to the other two study groups who additionally received home visiting during pregnancy and infancy (first two years of life) from either a paraprofessional or a nurse. Modelling outcomes involved comparison across each study group, with planned contrasts testing nurse versus control and paraprofessional versus control.

Overall, there was only one significant effect related to paraprofessional-visitation (mother-child pairs interacting more responsively) and only amongst mothers with low psychological resources at baseline. Nurse visiting was associated with greater reductions in cotinine during pregnancy for baseline smokers, reduced

rates of a second pregnancy (29% vs 41%) and birth (12% vs 19%) by 24 months postpartum. Nurse-visited women were employed for longer in the second year after their first child was born. For caregiving and child outcomes, nurse-visited mother-infant dyads interacted more responsively than control dyads. Nurse-visited infants were less likely to demonstrate emotional vulnerability in response to fear (at six months) compared to those in the Control group. Infants of women with low psychological resources who were nurse-visited were less likely to exhibit low emotional vitality following joy and anger stimuli. Language delays at 21 months were less prevalent in children of nurse-visited women compared to the control group. For women with low psychological resources, nurse-visited children had superior language and mental development at 21 months postpartum compared to children in the control group.

Table 1.1. NFP trial results from pregnancy to 2 years: reported treatment main effects and sub-group findings

NFP compared to usual care <sup>‡</sup>			
	Elmira n=400	Memphis n=1139	Denver n=735
<b>Study Description</b>	Randomisation groups: 1 Control (n=90) 2 Free transport to antenatal & child clinics (n=94) 3 As 2 + antenatal NFP (n=100) 4 As 3 + NFP to aged 2 (n=116) Note: Groups 1&2 and 3&4 combined for analysis. Non-white women and those with medical conditions excluded from analysis, (n=66)	Randomisation groups: 1 Free transport to antenatal care (n=166) 2 As 1 + child screening at 6, 12, & 24 months (n=515) 3 As 2 + NFP in pregnancy + 2 postnatal visits (n=230) 4 As 3 + NFP to aged 2 (n=228) Note: Pregnancy related outcomes compared Groups 1 and 2 v 3 and 4). Postnatal outcomes compared Groups 2 and 4	Randomisation groups: 1 Control (n=255) 2 NFP (Paraprofessional) to aged 2 (n=245) 3 As 2 NFP (nurse) (n=235) Note: Listed findings relate to Group 3 v Group 1.
<b>Pregnancy and birth</b>			
Birth weight	↑% Low birth weight ( ≥17 year olds, non-smokers) <sup>1,**</sup> ↑Birth weight (14-16 year olds) <sup>3,*</sup> ↑Birth weight (14-16 year olds enrolled < 20 weeks gestation) <sup>3,***</sup> Birth weight(14-16 year olds enrolled ≥ 20 weeks gestation) <sup>3,NS</sup>		
Gestation at birth	↓Gestation at birth (Age 17+, non-smokers) <sup>1,**</sup> ↑%Preterm birth (Age 17+, non-smokers) <sup>1,*</sup> ; ↓%Preterm birth (smokers ≥5 cigarettes/day) <sup>1,*</sup>		
Smoking and tobacco dependency	↓Cigarettes per day between intake and 32 weeks gestation (smokers at baseline) <sup>***</sup>		↓Cotinine reduction between intake and 36 weeks gestation (smokers at baseline) <sup>*,8</sup>
Antenatal Complications	↓Kidney infection in pregnancy <sup>**</sup>	↓Pregnancy Induced Hypertension <sup>5,**</sup>	
Improved maternal diet	↑Use of nutritional vouchers, at 32 weeks gestation* ↑Adequacy of diet at 32 weeks gestation*		
Social Support and networks	↑Fathers' interest in pregnancy at 32 weeks gestation* ↑Accompanied in labour <sup>**</sup>		
Awareness and uptake of services	↑Awareness of available services at 32 weeks <sup>**</sup> ↑Attendance at antenatal education <sup>**</sup> ↑Talked more frequently about problems*	↑Use of community services <sup>7,**</sup>	

<b>Child Health and Development</b>			
Infant feeding	↑Resist eating at 6 months <sup>2,*</sup>	↑Breastfeeding initiation <sup>6,**</sup>	
Temperament / Emotional development	↑Positive mood of babies at 6 months <sup>2,*</sup>		↓Child fear stimuli at 6 months <sup>8,*</sup> ↓Low child vitality at 6 months (low resource group) <sup>8,9,*</sup>
Language development			↑ Language Development Index at 21 months, (low resource group) <sup>8,9,*</sup>
Home Environment	↑Provision of appropriate play materials at 10 and 22 months (poor, unmarried, teenagers) <sup>2,**</sup>	↑HOME scores at 24 months <sup>6,**</sup>	
Parent-child interaction	↓Restriction and punishment (poor, unmarried, teenagers) <sup>2</sup> (10 months)**, (22 months)*		↑ Mother / child interaction* (Note: assessed at 6,12,15,21 and 24 months, reported as single outcome )
Safeguarding	Confirmed reports of abuse or neglect <sup>NS</sup>	↓Beliefs associated with child abuse at 24 months <sup>6,**</sup>	
Emergency room visits / admissions	↓Number of total emergency room visits [during 1st year] <sup>4,*</sup> [during 2nd year] <sup>4,**</sup>		
Infant healthcare encounters	↓Emergency visits for accidents and poisonings 12-24 months <sup>4,*</sup>	↓Total health care encounters for injuries / ingestions 0-24 months <sup>6,*</sup> ↓Outpatient visits for injuries / ingestions 0-24 months <sup>6,*</sup> ↓Days hospitalised for injuries / ingestions 0-24 months <sup>*6</sup>	
<b>Maternal Life course and economic self-sufficiency</b>			
Subsequent pregnancies & births	↓Subsequent pregnancies 0-22 months (Poor, unmarried women) <sup>2,*</sup>	↓Subsequent pregnancies and fewer subsequent births by 24 months <sup>6,**</sup>	↓Subsequent pregnancy or birth by 24 months <sup>8,*</sup>

Employment, childcare	<p>↑Months employed 0-22months postpartum (Poor, unmarried, older women)<sup>2,*</sup></p> <p>↑Concern about eventually finding employment (Poor, unmarried, teenagers) [at 10months]<sup>2,*</sup> and [at 22months]<sup>2,*</sup> postpartum</p> <p>↓Concern about eventually finding employment (Poor, unmarried, older mothers) at 22months<sup>2,*</sup> postpartum</p> <p>↑Help with childcare (Poor, unmarried, older women) at 10 months postpartum<sup>2,*</sup></p>		<p>↑ Proportion employed 13-24 months<sup>8,*</sup></p>
Sense of mastery		<p>↑Mastery at 24 months<sup>6,**</sup></p>	

<sup>†</sup>Excludes reported outcomes at significance level P≥0.05. Note: \* P≤0.05, \*\* P≤0.01, \*\*\* P≤0.001, NS P≥0.05. All results are either treatment main effects for whole sample or where indicated by indented text, by sub-group. Adjusted for<sup>1</sup> pre-pregnancy weight, pre-pregnancy height and intake smoking habit; <sup>2</sup>husband /boyfriend support and maternal sense of control; <sup>3</sup> pre-pregnancy weight, pre-pregnancy height, intake smoking habit and gestation at birth; <sup>4</sup> husband/boyfriend support; <sup>5</sup> mean arterial BP at booking; <sup>6</sup> maternal psychological resources, household income and poverty level; <sup>7</sup> whether women were in school at registration; <sup>8</sup> maternal age, housing density, gestation <sup>±28</sup> weeks at recruitment, maternal conflict with partner and maternal conflict with mother. <sup>9</sup> Low resource group: 40% of sample (variable created from average baseline scores of mental health, sense of mastery and intelligence).

### 1.3.7 Governance and international replication

NFP is currently offered in 43 US states, and is available in more than 440 counties serving in excess of 26,000 families.<sup>80,93</sup> The University of Colorado owns NFP intellectual property and retains authority for approving all alterations to the model and Visit-to-Visit Guidelines.<sup>93</sup> In the US, a National Service Office (NSO) supports quality replication of the programme through contracts with individual sites in the US. Revenue generated through the NSO services is used to support NFP core functions, and support research developing the programme directed by the Prevention Research Center for Family and Child Health at the University of Colorado. A model of international replication for the US follows four stages: (i) adaptation to local context, (ii) pilot testing of feasibility and acceptability, (iii) randomised controlled trial and (iv) replication and expansion.

In addition to the original trials and programme implementation in the US, and the present Building Blocks trial, a trial of NFP has been conducted in the Netherlands.<sup>94</sup> This sought to culturally adapt NFP and assess its effectiveness in preventing child abuse and other maternal and child outcomes. The study was comprised of three phases: (i) translation and cultural adaptation, (ii) piloting to examine implementation conditions and (iii) a trial of NFP (named VoorZorg) compared to usual care. To date, the trial team has reported lower rates of domestic abuse in the intervention group during pregnancy and in the first two years since birth compared to the control group<sup>95</sup>. The proportion of smokers was lower in the Intervention arm compared to the Control group during pregnancy (40% vs 48%), and in the first two months following birth (49% vs 62%) and mothers in the Intervention arm were less likely to smoke near their baby. The study groups did not differ in birth weight or gestational age. Reported rates of breastfeeding at six months were greater in the Intervention arm (13%) compared to the Control group (6%).

A pilot study in Canada asked whether the programme can be implemented with fidelity and what adaptations may be required to be acceptable to service providers and families.<sup>96</sup> The pilot demonstrated that 16 of 18 fidelity targets were attainable, with a principal change being a reduction in nurse caseload from 25 to 20 clients. This was the precursor to an effectiveness trial of NFP currently being run in British Columbia (BC Healthy Connections Project) which began recruiting 1000 pregnant women from October 2013. In Australia, NFP has undergone a formative evaluation to consider the establishment and early implementation process amongst selected indigenous communities at four sites.<sup>97</sup> The mainly qualitative evaluation positively evaluated NFP despite an existing culture of locally derived or adapted initiatives. Given the high cost of programme delivery to a small number of sites and clients it was recognised that without economies of scale being achieved it is not possible to adequately test the programme in this Australian setting.

## **1.4 Evaluating the Family Nurse Partnership in England**

### **1.4.1 Adaptation and setup**

In 2006, HM Government published 'Reaching Out: an Action Plan on Social Exclusion', announcing the intention to introduce initial testing of the Family Nurse Partnership in 10 sites in England,<sup>98</sup> one in each region/SHA. Eligibility criteria for FNP clients were informed by Hall and Hall's review of maternal characteristics evident in pregnancy that predicted poor child outcome.<sup>99</sup> Young maternal age was considered to be one criterion that was likely to be easily available in clinical records, was a good proxy for low income (a key inclusion criterion in the US trials) and associated with long-term child outcomes.

There are now over 11,000 places on the programme in over 90 local areas throughout England. The Government is intending to increase the number of places on the programme to 16,000 by 2015. In 2013, the leadership of FNP in England was contracted from the Department of Health to a newly formed partnership of three organisations: the Tavistock and Portman NHS Foundation Trust, the Impetus Trust and the Social Research Unit at Dartington. The partnership assumed responsibility for national leadership, strategic development & governance, education and coaching of nurses and supervisors. FNP is now included in the operating framework for the NHS in England<sup>100</sup> and in the joint Department of Health, Department for Education policy statement, Supporting Families in the Foundation Years.<sup>101</sup> The latter in particular reflects the policy perspective of a strong evidence base, and the role of FNP as an intensive preventative home-visiting service complementing the work of midwives and health visitors.

### **1.4.2 FNP Core model elements and fidelity goals**

Specified within the UK FNP management manual are core model elements (CMEs) and fidelity goals which collectively represent the mechanism used to ensure fidelity to the programme model. CMEs are licensing requirements intended to ensure replication of the original US research conditions. They relate to both programme delivery and infrastructure requirements and specifically address client enrolment and engagement; nurse recruitment, training and working practices; supervisor recruitment, training and working practices; administrative support; implementing agencies. Additional UK specific requirements have been included which relate to regular psychological support provided to each Family Nurse, the provision of safeguarding supervision and systems and the incorporation of FNP into local clinical governance arrangements.

Fidelity goals are intended to provide evidence that the programme is being delivered to a high standard. They address matters related to client recruitment, retention, visit dosage and content coverage. As some of these goals are viewed as potentially challenging for nurses, particularly in

newly established sites where recruitment pathways would take time to develop, they have been regarded as stretch goals. CMEs and fidelity goals are summarised in Chapter 8.

### 1.4.3 Implementation evaluation of FNP in England

An implementation evaluation of the programme was led by Professor Jacqueline Barnes to determine whether it was possible to deliver the FNP in the context of the NHS in England. Specific domains of focus for the evaluation (reported separately by delivery phase: pregnancy,<sup>102</sup> infancy,<sup>103</sup> toddlerhood<sup>104</sup>) were: (i) feasibility of recruiting, training and retaining staff to deliver the programme, (ii) client group clarification, enrolment and retention including acceptability of the programme to mothers and their families, (iii) indicators of programme impact and (iv) interest in commissioners to continue to deliver FNP. The origin and nature of the US programme shaped the evaluation objectives, namely a highly structured and manualised programme to be delivered comprehensively over up to 64 visits and 30 months to set core model elements and fidelity goals by a newly recruited workforce with no existing organisational structure and to a vulnerable and potentially hard to engage client group.

From the ten pilot sites 1,217 women were enrolled (1054 aged under 20 years old) in the reporting period (April 2007 to 8<sup>th</sup> February, 2008)<sup>i</sup>. All women were first-time mothers and 88% of those aged under 20 who were referred and eligible were enrolled (exceeding the 75% fidelity target). However, the average gestational age at enrolment was 17.5 weeks, and only 51% were enrolled by 16 weeks (less than the target rate of 60%). There was considerable variability in how early sites were able to enrol clients. Performance against fidelity targets was sourced from the clinical information system based on Family Nurse reporting and provided a detailed analysis of how the programme was delivered in this relatively early stage of inception<sup>i</sup>. Potential impacts of the programme upon client and child outcomes (e.g., smoking, breastfeeding) are reported but these are appropriately contextualised to recognise the uncontrolled nature of the evaluation.

Of the 1,177 women who should have reached 24 months follow-up (based upon actual completion or expected due date at intake) 58.6% (n=690) remained enrolled during the programme. Overall, the evaluation provided support for the feasibility of delivering FNP according to required visit frequency, content and client involvement in the English NHS context. As a formative process, the learning from the implementation has already informed the continued organisation and delivery of FNP as its availability in England has expanded.

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<sup>i</sup> *The same information management system was in operation during the trial and provides the opportunity to compare achievement against fidelity targets between trial clients, pilot clients and clients in current non-trial sites.*

#### **1.4.4 Establishing an effectiveness trial in England**

The effectiveness trial of FNP was part of the cross-government R&D programme commissioned by the DH and Department for Children, Schools and Families to support implementation as part of the Child Health Promotion Programme (CHPP). The commissioning call targeted only women under 20 years old and required a focus upon outcome assessment in each of the three domains of pregnancy and birth, child health and development, and parental life course and economic self-sufficiency. In commissioning the trial, the funder required three primary outcomes: changes in prenatal tobacco use, emergency department attendance or hospital admission by child as a result of injury, and the proportion of participants with a second pregnancy within two years. Trial participation was one optional selection criterion applied by the DH for sites established in March 2007 and for those selected in March 2008. The former sites applying to take part in the trial received additional funding over non-trial FNP sites to employ extra Family Nurses for the trial. All trial sites received funding to initially support setup and staff costs from 08/09 to 10/11.<sup>ii</sup>

### **1.5 Summary**

#### **1.5.1 Rationale for the Building Blocks trial**

The social and economic circumstances for young first-time mothers place both themselves and their children at increased risk of both short and long-term disadvantage. The Nurse Family Partnership programme was developed in the US as a supportive intervention for first-time mothers to improve pregnancy outcomes, child health and development, reduce child maltreatment, and improve maternal self-sufficiency. Evidence of beneficial effects has been observed into the early adulthood amongst children exiting the programme. Now adapted for use in England, where it is known as the Family Nurse Partnership, it has been shown to be both feasible and acceptable to deliver in a manner consistent with programme fidelity standards. Given the differences that could be expected to exist between the original US trial context and present-day England, the effectiveness and cost-effectiveness of FNP compared to normally provided care alone needed to be established before recommendations can be made regarding widespread implementation. Economic evaluation supports decision making in prioritising the allocation of limited health care resources.<sup>105</sup> The economic analysis aims to assist decision making by determining whether the Family Nurse Partnership represents a cost-effective alternative compared to existing usually provided care.

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<sup>ii</sup> *Implementation evaluation sites (Also known as FNP 'Wave 1' sites) and new 'Wave 2b' sites participated in the trial. Wave 2a sites started enrolling clients from September 2008 and were not involved in the Building Blocks trial.*

### 1.5.2 Research aims

The aims of the Building Blocks trial were to:

- Evaluate the effectiveness of the FNP programme within three outcome domains: pregnancy and birth, child health and development, and parental life course and self-sufficiency. Four primary outcomes were identified: birth weight, changes in prenatal tobacco use, emergency attendances and hospital admissions for the child within two years, and proportion of women with a second pregnancy by two years postpartum.
- Assess the incremental costs and consequences of the FNP programme compared to existing services.
- Model possible longer-term costs and effects of the FNP programme.
- Evaluate what processes influence FNP outcomes in order to explore applicability to other settings and to optimise its future implementation.

The primary outcomes capture key short-term outcomes indicated by the programme theory of change logic model, which form the foundation for longer-term outcomes. These potential effects would be achieved in the following way:

- *Smoking*: Women encouraged to make proactive choices in how they will care for their children. Nurse delivered education aligns women's expectations with best evidence on influence of smoking on the mother and child. Realistic goal-setting and encouragement to try out desired behaviours and taught problem-solving skills. Family and friends encouraged to support the mother's attempts to change behaviour.
- *Birth weight*: Achieved by targeting a reduction in the maternal use of potentially fetal harming substances combined with improved exercise and nutrition, which in turn extends gestation and improves intrauterine fetal environment.
- *Emergency attendances / admissions*: Competent caregiving promoted whereby parents understand the infant's cues, understand and empathise with their children, including access to relevant supportive health services. Reduced number of Emergency department attendances and hospital admissions for illness as their children enjoy an improved health status.
- *Second pregnancy*: Nurse facilitates positive decision-making about family planning, including birth control.

### **1.5.3 Presentation of the trial report**

Following this introductory chapter, a second describes the overarching methods framework for the trial. Trial results are presented in Chapters 3 to 6 and include the study sample achieved at recruitment and retained at follow-up, the primary analyses for the primary and secondary outcomes respectively and planned sub group and sensitivity analyses. The work of the trial's stakeholder work package is presented in Chapter 7. The process evaluation is described in Chapters 8 to 13 and incorporates the assessment of intervention delivery against the stated FNP Core Model Elements and Fidelity Goals, findings from process evaluation sub-studies and presents participant reported use of usual care services. The economic evaluation is presented in Chapters 14 to 16 and includes the main within-trial cost-effectiveness analysis (Chapter 14) and additional economic sub-studies (Chapters 15 and 16). Finally, overall discussion and conclusions are provided in Chapter 17. All relevant data are provided within the body of each relevant chapter and the appendices therefore present cited references, acknowledgements, and key study documentation, including governance information.

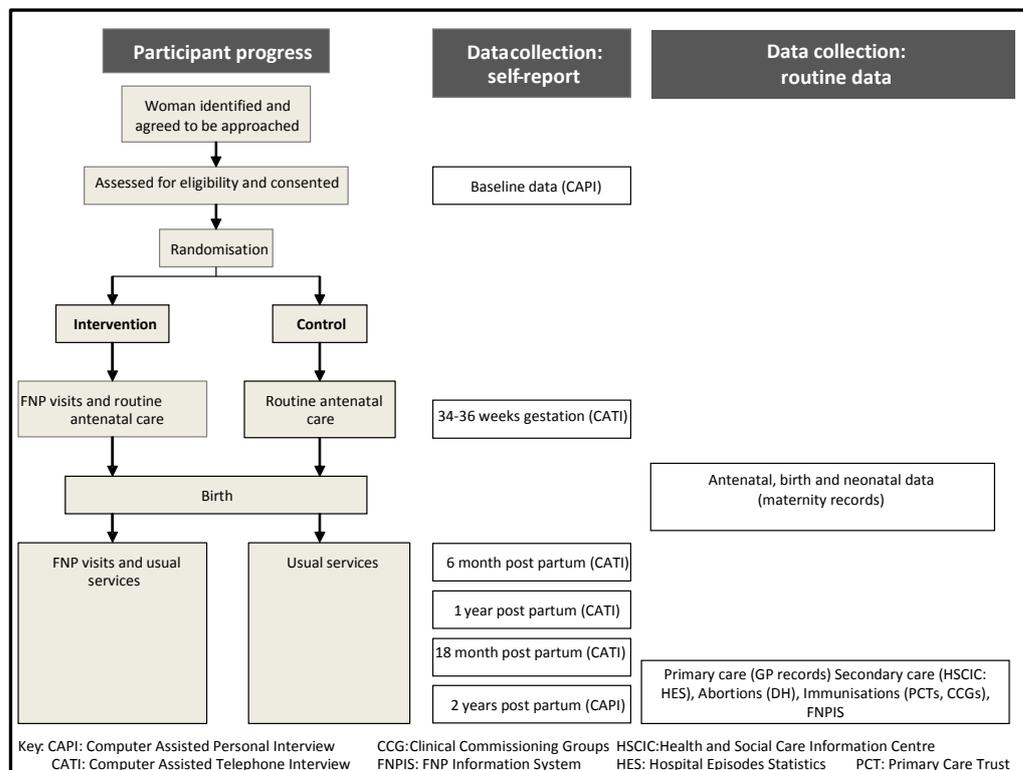
## 2 Methods

### 2.1 Trial design

Building Blocks was an individually randomised controlled trial (RCT) with a parallel economic modelling study and an integrated process evaluation. Trial participants received *either* universal services (control) *or* universal services with health visiting being replaced by regular visits from trained Family Nurses (FN) from early pregnancy (of their first child) until their child was two years old (intervention).<sup>106</sup>

Throughout the trial, various methods of data collection were utilised e.g. self-report and routine data collection. Routine data collection avoided a dependency upon self-report for key outcomes and the associated loss to follow-up that could otherwise arise. Figure 2.1 shows timing and methods of data collection.

Figure 2.1: Timings and methods of data collection in the Building Blocks trial



## 2.2 Trial site selection and application process to the Department of Health

The first wave of Family Nurse Partnership (FNP) sites in England were asked to demonstrate strong partnership working and a high degree of NHS / Local Authority service integration, community engagement, commitment to progressive universalism, workforce capacity and capability, effective local leadership, a relevant demographic profile and capacity to identify families, IT capacity, a record of successful innovation, and a plan that demonstrated the capacity to deliver according to the proposed timetable. Successful sites were offered funding to deliver the FNP programme for one year provided the Primary Care Trusts (PCTs) / Local Authorities were committed to supporting the service until the clients' children were 24 months old.

To become a provider for FNP, potential sites formally applied to the Department of Health with a case summarising local clinical need, and the commitment to sustain FNP delivery by local consortia made up of local stakeholders, including Primary Care Trust (PCT), Acute Trust (AT) and Local Authority staff. Following 63 applications, ten were selected; two sites were established in London and one in each of the remaining Government Office regions. The first ten sites to offer FNP also undertook the implementation evaluation.

<sup>102,103,107</sup> The detail covered in the FNP bids are shown in Appendix 1.

During the second commissioning process to expand the number of FNP sites, sites were encouraged to express willingness to participate in the trial. Eight implementation evaluation sites took part in the trial and a further ten new sites were selected to participate in the RCT evaluation of the FNP programme. The 18 selected trial sites are listed in Table 2.1. In most cases FNP was delivered across the whole area covered by each PCT, but for some sites availability of the programme was restricted to particular areas within the PCT.

*Table 2.1: FNP sites participating in trial*

<b>Implementation evaluation / original FNP sites</b>	<b>New FNP sites / second commissioning process</b>
Barnsley	Cornwall
Berkshire East	Coventry
Derby	Cumbria
Manchester	Hull
South East Essex	Lambeth
Southwark	Leeds
Tower Hamlets	Liverpool
Walsall	Northamptonshire
	South Birmingham
	Sunderland

NHS Trusts providing maternity services at each trial site were identified. 14 sites had one corresponding NHS Trust, three sites had two NHS Trusts, and one site had three NHS Trusts. The 18 RCT sites started to recruit women into the trial from June 2009.

## **2.3 Usual care services for teenage parents within England**

FNP in England is provided in addition to existing services. Existing health, education, social and financial services and support continued to be available to all trial participants regardless of trial allocation. The exception to this was the Health Visiting service, usually provided to all new parents in England which, for the intervention group, was replaced by FNP during pregnancy and during the child's first two years. The range of usual care services provided by trial sites to teenage mothers is more fully described in Chapter 11.

## **2.4 Family Nurse Partnership**

FNP teams throughout the UK are supported by a central FNP team. The roles undertaken by the central team include: training of the local FNP teams and supervisor, acting as holder of the license to deliver the programme, providing funding for setting up the programme locally and on-going support for the research sites, facilitating sites to embed the FNP in wider universal services and the Child Health Promotion Programme, providing partnership and joint learning between the central team and the sites and providing materials and guidelines from the US model for use in England.<sup>108</sup>

### **2.4.1 FNP teams**

FNP team members were employed by each PCT with each team being comprised of a supervisor, up to eight Family Nurses and an administrator. Family Nurses were recruited from existing Nursing and Midwifery Council (NMC) registrants. Family Nurses are encouraged to work at least half time and discouraged from working in any other clinical capacity. Each nurse is expected to have a caseload of approximately 25 mothers. Family Nurses are provided with training specifically to deliver the FNP intervention, which combines residential weeks and ongoing learning. Training is provided in the structure of the programme, areas such as the building of therapeutic relationships, motivational interviewing, attachment, behaviour change and the use of FNP materials. Supervisors provide individual and team supervision, manage the team and also have a caseload of 2-3 women. The supervisor is expected to meet one-on-one with each Family Nurse at least weekly to provide clinical supervision, conduct at least four team meetings per month, make a minimum of one home visit every four months with each nurse and ensure timely reporting of team activity. The administrator maintains the database and provides general administrative support including preparation of materials for visits. FNP Programme Core Model Elements and Fidelity Targets are provided to FNP sites and individual Family Nurses, these are presented in Chapter 8.

## **2.5 Eligibility criteria**

Trial eligibility criteria matched the FNP programme enrolment criteria as closely as possible (Table 2.2). Trial participants were recruited to the trial ideally within the first 15 weeks gestation, and no later than 24<sup>+6</sup> weeks

gestation - this was to enable enrolment to FNP (for those randomised to the Intervention arm) in line with the programme fidelity requirements (60% of clients to be enrolled by 16 weeks gestation, and all by 28<sup>+6</sup> weeks).

102-104

Table 2.2: Trial eligibility criteria

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**Inclusion criteria**

- Aged 19 or under (at recruitment / consent).
- Lived within the catchment area covered by the local FNP team.
- First pregnancy confirmed by health services (including those expecting multiple births) unless previous pregnancy ended in miscarriage, stillbirth or termination.
- Recruited no later than 24<sup>+6</sup> weeks gestation.
- Gillick competent to provide informed consent to research participation.
- Competence in English at conversational level or higher<sup>1</sup>.

**Exclusion criteria**

- Planned to have child adopted.
- At study entry, planned to leave the FNP area during the time of the trial either for an extended period of time (3 months or longer) or permanently.
- Required a third person (translator, sign interpreter) to receive the FNP programme<sup>1</sup>.

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<sup>1</sup>Notes about eligibility criteria: Trial participants needed to be able to speak and understand English as FNP had only been validated to be used in the original English language, and also not using a third person (e.g. an interpreter). However, self-reported data collection was offered via an interpreter if requested (although but this was only required in one case).

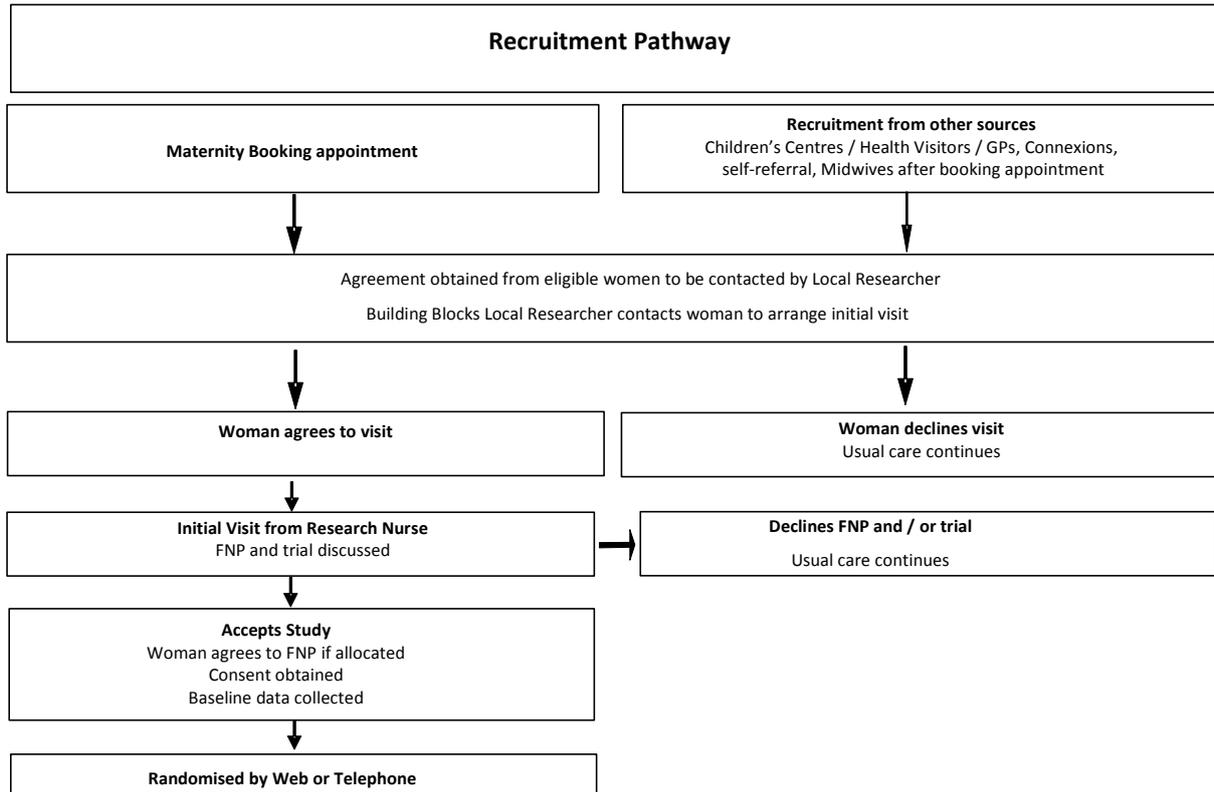
## 2.6 Recruitment methods: identification, approach and consent

**Establishing referral pathways:** In preparation for the trial, a brief questionnaire was sent to each maternity unit involved in the trial to determine standard local management pathways for pregnant women. For the implementation evaluation sites, information about existing referral routes was also obtained from the local FNP team. A generic route for the identification, approach and consent of women to the trial was established (Figure 2.2). Women were identified opportunistically by community midwives in local antenatal clinics. Some tailoring of recruitment approaches was also possible, for example, where maternity services information systems and staff had capacity to do so, or where specialist teenage pregnancy midwives were employed. In one site, a viable identification and approach route via a local Connexions service was also utilised. It was possible for women to self-refer, or be approached through other community-based services such as GP surgeries.

To improve recruitment at a local level, a referral pathways questionnaire was sent to all Local Researchers in November and December 2009. The questionnaire examined how community midwives were organised, who else the Local Researcher had visited / contacted with regards to giving information about the trial, determined sources of existing referrals, asked how long the researchers were taking to follow-up the referrals, and reasons that potential trial recruits gave for not wanting to join the trial.

**Approach and consent process:** Initial contact with potential trial participants was via a current caregiver. The woman was asked to complete a referral slip if she agreed for her details to be passed to the Local Researcher. The Local Researcher then contacted the woman to arrange a recruitment visit. The visit was usually at the trial participant's home, where they were provided with an information sheet explaining the trial. Women were encouraged to discuss the trial with friends and family, if needed, before deciding about participation. Informed, written consent was obtained by the Local Researcher before any trial procedures were carried out. A copy of the Participant Information Sheet and Consent Form are shown in Appendices 2 and 3 respectively.

**Figure 2.2: Recruitment pathway for identifying eligible women and entry into the trial**



At all trial sites, enrolment into FNP during the recruitment period was only available to women participating in the trial. Any direct referrals made to the FNP team during the recruitment period were passed back to the Local Researcher to discuss trial participation. At the point of approaching women, Local Researchers were also required to verify that the local FNP team had current capacity to take on new clients. Women allocated to FNP but who withdrew from the trial were also required to discontinue receipt of FNP.

**Supporting recruitment:** Trial promotional and recruitment materials were made available at local clinics (antenatal clinics, GP surgeries, Children’s Centres, local Connexions offices) and included posters<sup>iii</sup> and recruitment packs for community midwives. The latter were distributed to all community-based midwives at all trial sites. The packs contained trial information with referral slips, contact details of the Local Researchers, and promotional Building Blocks materials e.g. gestation wheels, pen torches and tape measures. To encourage completion of referral slips and remind them of the trial, each maternity unit was also provided with promotional packs, including items such as trial branded mugs, and labour flipcharts (for individual and group antenatal education). Monthly Building Blocks trial newsletters were also emailed to the Local Researchers (see example in Appendix 4).

<sup>iii</sup> This included material designed by the lay stakeholder group working with the trial as part of the Stakeholder Work Package.

## 2.7 Local Researchers

Each NHS trial site employed a Local Researcher. Local Researchers were usually midwives or nurses and one had a clinical background in physiotherapy. To enable the opening of some trial sites where an NHS appointment was delayed due to internal procedures, agency staff from a Contract Research Organisation were utilised until an NHS appointment was made. All Local Researchers received trial-specific induction training from the trial team at the outset and annually or more frequently thereafter. Induction training included an overview of the trial, the FNP programme, consent and recruitment procedures. Emphasis was placed on the assessment of the competence of potential trial participants to provide consent, explaining both arms of the trial without bias, trial outcomes, Serious Adverse Event (SAE) monitoring and reporting, and withdrawal from the trial. Subsequent training addressed retention strategies, birth-related data collection, organising and conducting the two-year home based interview, including language development assessment, data collection from primary care records and conducting qualitative research interviews. Throughout the trial the Local Researchers were tasked with maintaining current contact details for participants.

## 2.8 Trial Outcomes

Table 2.3 details the maternal and Table 2.4 the neonatal and infant outcomes and assessment points throughout the trial. Data for some outcomes were available from more than one source, enabling missing data from an indicated primary source to be supplemented from elsewhere (for example, in sensitivity analyses). Appendix 5 details all measure modifications and scored variables.

Table 2.3: Maternal outcomes and assessment points

Outcome (name / source of measure <sup>1</sup> )	Baseline	Late Pregnancy	Birth record	6 m	12 m	18 m	24 m	HES	GP	Abortion
<b>Socioeconomic</b>										
Not in education, employment or training (NEET status) <sup>109,110</sup>	X			X	X	X	X			
Hours in formal education <sup>109,110</sup>				X	X	X	X			
In paid employment <sup>109,110</sup>	X			X	X	X	X			
Type of employment <sup>109,110</sup>	X			X	X	X	X			
In receipt of benefits <sup>109,110</sup>	X						X			
Other financial support <sup>109,110</sup>	X						X			
Ever been homeless <sup>109,110</sup>	X			X	X	X	X			
<b>Maternal health &amp; well-being</b>										
General health status (EQ-5D) <sup>111</sup>	X	X		X	X	X	X			
Weight / BMI (Millennium Cohort Study) <sup>109,110</sup>	X						X			
Psychological distress (Kessler scale) <sup>112</sup>	X						X			
Depression (Whooley scale) <sup>113</sup>				X	X	X	X			

Outcome (name / source of measure <sup>1</sup> )	Baseline	Late Pregnancy	Birth record	6 m	12 m	18 m	24 m	HES	GP	Abortion
Postnatal depression (Edinburgh PDS) <sup>114</sup>				X						
Self-efficacy (General Self-efficacy Scale) <sup>115,2</sup>	X			X	X	X	X			
Adaptive functioning <sup>116,117,2</sup>	X						X			
Intimate partner violence (Composite Abuse Scale) <sup>118,2</sup>							X			
<b>Health behaviour</b>										
<b>Tobacco use<sup>3</sup></b>	X	X		X						
Smoking cessation method (if applicable) <sup>24,119,2</sup>		X		X						
Smoke in home					X	X	X			
Problem alcohol and drug use (CRAFFT) <sup>120,2</sup>	X						X			
Contraceptive use and method (Millennium Cohort Study) <sup>109,110</sup>	X			X	X	X	X			
<b>Pregnancy and birth</b>										
Gestation at birth			X							
Place of birth (planned, actual)			X							
Antenatal pre-eclampsia / hypertension <sup>4</sup>			X							
<b>Subsequent pregnancies<sup>3</sup></b>				X	X	X	X	X	X	X
<b>Social support</b>										
Social support and networks (MOS Survey) <sup>121,2</sup>	X			X	X	X	X			
Family resources <sup>122,2</sup>	X			X	X	X	X			
Relationship quality (Golombok Rust Inventory of Marital State) <sup>123</sup>	X	X		X	X	X	X			
<b>Use of services</b>										
Dental care							X			
Antenatal care (check-ups, planned / unplanned attendances)			X					X		
Primary care or secondary care attendance / admission		X		X	X	X		X	X	
Additional non-health (education, social, childrens', Connexions) services				X	X	X	X			
Foster care (mother)				X	X	X	X			

<sup>1</sup> Name of validated measure (items amended or partially sourced from existing measures indicated by citation only)

<sup>2</sup> Measure modified

<sup>3</sup> Primary outcome <sup>4</sup> Exploratory analysis only

Table 2.4 Parenting and child outcomes and assessment points

Outcome (name / source of measure <sup>1</sup> )	Baseline	Late Pregnancy	Birth record	6 m	12 m	18 m	24 m	HES	GP	PCT
<b>Parenting beliefs, behaviour and experience</b>										
Infant feeding intentions		X								
Anticipatory parenting (Millennium Cohort Study) <sup>109,110</sup>		X								
Prenatal attachment <sup>124,2</sup>		X								
Parental role strain (Millennium Cohort Study) <sup>109,110,2</sup>				X	X	X	X			
Maternal-child interaction <sup>125</sup>							X			
Mother and child living apart				X	X	X	X			
<b>Neonatal outcomes</b>										
Live birth			X							
Birth weight <sup>5</sup>			X							
Apgar score (1 and 5 mins) <sup>3</sup>			X							
Head circumference (at birth)			X						X	
Neonatal unit admission			X							
<b>Feeding &amp; development</b>										
Breastfeeding initiation, duration			X	X	X	X	X			
Infant diet <sup>2</sup>						X	X			
Cognitive development <sup>126</sup>					X	X	X			
Language development (inc. at 24 months Early Language Milestone Scale) <sup>126,127,2</sup>					X	X	X			
Child safety <sup>128,2</sup>					X	X	X			
<b>Health and use of services</b>										
Childcare				X	X	X	X			
Immunisations				X	X	X			X	X
Emergency attendances & admissions (all cause) <sup>5</sup>		X		X	X	X	X	X		
Primary care consultation (injuries & ingestions)		X		X	X	X			X	
Medically attended injuries & ingestions <sup>4</sup>		X		X	X	X	X	X	X	
Referral from primary care (social care, other, safeguarding)							X		X	

<sup>1</sup> Name of validated measure (items amended or partially sourced from existing measures indicated by citation only)

<sup>2</sup> Measure modified

<sup>3</sup> Apgar scores were not collected at one site

<sup>4</sup> ICD10 and A&E diagnostic codes for injuries & ingestions listed in Appendix 6

<sup>5</sup> Primary outcome

## 2.9 Baseline and demographic variables

### 2.9.1 Measure modification for baseline and demographic variables

Existing measures were used where available and these are indicated by the cited references. If an existing measure required modification, this is described in Appendix 5. Table 2.5 shows the baseline and demographic variables.

Table 2.5: Baseline and demographic variables

Baseline and demographic variable (source)	Baseline	Late	6 m	12 m	18 m	24 m
		Pregnancy				
Maternal and paternal age	X					
Household structure	X	X	X	X	X	X
Relationship status (Millennium Cohort Study) <sup>109,110*</sup>	X	X	X	X	X	X
Ethnicity and religion <sup>129</sup>	X					
Language (Millennium Cohort Study) <sup>109,110</sup>	X					
Family background / social class (Millennium Cohort Study) <sup>109,110*</sup>	X					
Home (postcode, tenure, no. bedrooms) (Millennium Cohort Study) <sup>109,110*</sup>	X		X	X	X	X
Subjective social status <sup>129</sup>	X					
Limiting long-term illness <sup>129</sup>	X					
Self-rated health <sup>129</sup>	X					
Antisocial behaviour <sup>130,131*</sup>	X					

\*Measure modified

## 2.10 Self-reported data collection

Data collection started at the baseline interview and continued until the Building Blocks child's second birthday. Following the baseline home assessment conducted by the Local Researcher, women were followed up by qualified and specially trained telephone interviewers at late pregnancy (about 34-36 weeks gestation), then at six, 12, and 18 months after birth. A final home-based face-to-face interview was conducted at twenty-four months after birth, by the Local Researcher. Staff conducting telephone interviews were based at the Participant Resource Centre (PRC) within Cardiff University. The timings and method of data collection for these interviews are represented in Figure 2.1.

Self-reported data at baseline and 24 month follow-up interviews were captured using portable computers (computer-assisted personal interviews). Computers had password-protected encrypted hard drives, and data were transmitted wirelessly using BlackBerry® modems to secure university servers, also in an encrypted mode. Once data had been transmitted from the portable computers and verified, all records relevant to that specific interview were automatically deleted from the local machine. Telephone interviews were also

delivered via a computer-driven system (computer-assisted telephone interview) which allowed data to be captured directly onto the study's clinical database through a web portal.

The protocol represented in Table 2.6 was used for telephone follow-up at the six, 12 and 18 month interviews.

*Table 2.6: Attempts to contact a trial participant for telephone interview at 6, 12 and 18 month*

<b>Unsuccessful contacts with an original phone number</b>	<b>Unsuccessful contact with a new number</b>	<b>Times contacted daily</b>	<b>Answerphone messages</b>	<b>Message left with family / friends</b>
5 working days maximum. The data manager was notified by the 'review' function on the PRC system when attempts had been made to contact a participant for 5 days. The data manager then contacted the Local Researcher to obtain a new contact number for the participant. In the interim, participant contact was attempted once or twice daily. If there was no new number then an additional 30 working days was allocated to repeat this procedure once more.	35 working days maximum.	Once or twice, but the PRC was free to increase this number if they felt they had capacity.	One message every three working days up to a total of five messages	In addition to messages left on the participant's phone, one message was left every three working days up to a total of three messages.

**The following procedure was used for the 24 month interview:**

If a Local Researcher was unable to contact the trial participant for the 24 month face-to-face interview (with a window of 1 month prior to, and 2 months after the child's second birthday), a reduced telephone interview was conducted and the protocol in Table 2.7 was used.

*Table 2.7: Attempts to contact a trial participant for telephone interview at 24 month*

<b>Unsuccessful contacts with an original phone number</b>	<b>Times contacted daily</b>	<b>Answerphone messages</b>	<b>Message left with family / friends</b>
14 working days maximum.	At least once, but the PRC were free to increase this number if they felt they had capacity.	One message every three working days up to a total of five messages.	In addition to messages left on the participant's phone, one message left every three working days up to a total of three messages.

To maximise response rates, prior to each wave of data collection, the Local Researcher was tasked with checking the current contact details of trial participants and confirming this with the trial team. Each Local Researcher was provided with monthly summary information specific to their site to help them arrange the 24 month interviews at the correct time.

The Data Manager produced an update for the 24 month interview follow-up rates once every fortnight (approximately), this query showed which participants had Building Blocks children that had reached 26 months of age (who had not completed the 24 month interview<sup>iv</sup>).

If the 24 month face-to-face and telephone interview attempts were unsuccessful in the timelines described in Table 2.7, then a reduced minimal dataset postal questionnaire was sent to the trial participant for completion.

A £10 telephone giftcard was given at the end of the Baseline interview, and after completion of the late pregnancy telephone interview. High street vouchers to the value of £25, £25 and £40 were given after completion of the 12, 18 and 24-month interviews respectively to acknowledge the trial participants' time commitment to data collection. A £10 voucher was sent to participants for any completed 24 month postal questionnaires.

## **2.11 Data collection**

### **2.11.1 Maternity records**

Following birth, medical and obstetric history items, antenatal attendances, and maternal and neonatal birth outcomes were extracted from maternity records onto an electronic Case Report Form (CRF) (either directly or indirectly via paper form) prior to upload to a SQL database. Data were collected either by the Local Researcher, or occasionally by another member of the clinical staff if the woman had given birth at a hospital outside the original trial area.

### **2.11.2 Hospital episodes statistics data**

Data on hospital attendances and admissions (including emergency attendances, and out-patient and in-patient activity) were obtained from the Health and Social Care Information Centre (HSCIC, Hospital Episodes Statistics (HES)).

### **2.11.3 Obtaining the data**

The Data Linkage and Extract Service in the Health and Social Care Information Centre (HSCIC) hold identifiable records on Hospital Episode Statistics (HES). HES is a data warehouse that contains around 1 billion records on patients attending Accident and Emergency (A&E) units, being admitted for treatment (inpatients) or

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<sup>iv</sup> Some sites were advised by the Trial Team to continue attempting to contact a participant after this 2 month window had closed if either a) the participant had received a postal questionnaire and requested an interview, or b) if there were clear operational issues that had interfered with the interview progress - specifically, the Local Researcher being on extended leave of absence or due to an acknowledged period of time during which the Local Researcher was unable to cover their responsibilities.

attending outpatient clinics at NHS hospitals in England. These data are collected during a patient's time at hospital and is submitted to allow hospitals to be paid for the care they deliver. HES data are designed to enable secondary use, that is use for non-clinical purposes. HES can also be linked to ONS (Office for National Statistics) mortality data so as to capture all deaths and not just those occurring in hospital. An application to link and access HES and ONS data was made to the Data Access Advisory Group (DAAG), an independent group hosted by the HSCIC.

#### 2.11.4 Linkage method

A pilot linkage and data extraction exercise checked how well the cohort could be matched and prepared scripts to run the analysis. Table 2.8 was provided by the HSCIC after the first linkage exercise, it provides detail on the number of records matched per step of the algorithm. The quality of the matching decreases as you move from step 1 to 8. 99.4% of records were fully or partially matched. The data fields requested from HES are shown in Appendix 6.

*Table 2.8: Matching detail of pilot linkage exercise as provided by HES*

Step	Records	Linking fields for each mother or baby			
		NHS Number	DoB	Sex	Postcode
1	2,079	Exact	Exact	Exact	Exact
2	899	Exact	Exact	Exact	No match
3	12	Exact	Partial	Exact	Exact
4	15	Exact	Partial	Exact	No match
5	27	Exact	No match	No match	Exact
6	57	No match	Exact	Exact	Exact
7	0	No match	Exact	Exact	Exact
8	14	Exact	No match	No match	No match
Unmatched	19				
Records supplied	3,120				
Match rate	99.4%				

#### **Second linkage results:**

The second linkage exercise following all births and further confirmation of linking fields at trial sites provided the final dataset for the analysis with 99.6% of records fully or partially matched.

**Table 2.9: Matching detail of second linkage exercise as provided by HES <sup>v</sup>**

Step	Records	Linking fields for each mother or baby			
		NHS	DoB	Sex	Postcode
1	2234	Exact	Exact	Exact	Exact
2	853	Exact	Exact	Exact	No match
3	2	Exact	Partial	Exact	Exact
4	0	Exact	Partial	Exact	No match
5	12	Exact	No match	No match	Exact
6	5	No match	Exact	Exact	Exact
7	0	No match	Exact	Exact	Exact
8	1	Exact	No match	No match	No match
Unmatched	13				
Records supplied	3,120				
Match rate	99.6%				

There were 1,502 live births to participants remaining in the trial at the time of birth. It was expected that, as a minimum, a birth record would be returned from HES for each of these babies. Data for 1,473 babies were returned. Five babies had NHS numbers that were unmatched, and 24 babies did not appear in the HES inpatients dataset. The cleaning process removed records that were invalid or incomplete, for example, if was no episode duration, this meant that an additional 15 babies were removed from the inpatients dataset. Analyses were performed on 1,458 babies for the inpatients data.

For the A&E and outpatients data, there is no minimum number of records that should be present in the dataset; therefore the same breakdown as for inpatients data could not be performed. The five unmatched babies were not present in these datasets.

### 2.11.5 Abortions data

Abortions data were obtained from the Department of Health, Abortion Statistics Team. Registered medical practitioners are legally required under the Abortion Act 1967 to notify the Chief Medical Officer (CMO) of every abortion performed. The Department of Health (DH) receives these notifications on form HSA4 and undertakes statistical processing and analysis. The Data Protection Act 1998 places a statutory obligation on the Department of Health to ensure that the statistics released on abortion do not relate to a living individual who can be identified from those data alone or in conjunction with other available information, unless the conditions laid out in the Act are met. Under regulation 5(e) of the Abortion Regulations 1991, patient level

<sup>v</sup> Table provided by HES contained 11 unmatched participants, 2 additional participants (twin babies) were found to have the same NHS numbers in the dataset returned, as it cannot be confirmed which twin this NHS number belonged to, both twins were added to the unmatched list to give 13 unmatched.

data may be released in a controlled manner "for the purposes of bona fide scientific research", subject to the Chief Medical Officer's (CMO) agreement and the receipt of a completed and signed confidentiality agreement.

### ***Obtaining the abortions data***

Approval was sought and granted by the CMO to access abortions data under the Abortions Act 1967. Due to the sensitive nature of the abortions data, records were obtained in a pseudonymised manner to lessen the risk of identifying individuals. This involved providing the Department of Health's Abortions Statistics Manager with the women's identifiable personal data (NHS number, date of birth and postcode) – this was sent alongside other Building Blocks datasets to be used in the analysis of second pregnancies (self-report, HSCIC and GP data). The abortions data was attached to this dataset, de-identified and returned for analysis. Datasets were password-protected and sent via fast-file, a secure transfer mechanism provided by Cardiff University.

Linkage was undertaken via a two-stage process. The first was to test the ability to link the individually identifiable data to Abortions records and the second was for the final pseudonymised linkage. This pilot linkage exercise resulted in a returned dataset which showed that 267 of the 1,618 women could be matched exactly to the women's date of birth and post code and had a record indicating that she had undergone at least one abortion. A further 34 women could be partly matched (a part match is a pair of records where postcodes differ only in the last two letters and where dates of birth matches exactly or where postcodes match exactly and dates of birth differ by only one digit). The second, linkage exercise, covering a later period, resulted in a returned dataset which showed that 150 from 1,618 women could be matched exactly, and that nine could be partially matched. This second linking exercise resulted in a smaller number of exact and partial matches than the first linking exercise. A smaller number of exact matches were found as the identifiers sent from the Trial team to the Abortions Statistics Manager were more accurate (i.e. changes had been made to some of the identifiers since the first matching exercise). There was a smaller number of partial matches during the second matching exercise because partial postcodes were more likely to result in false matches, therefore these partial matches were manually checked using NHS number (where available), this did not come to light until the second matching exercise. Finally, a smaller number of exact and partial matches were found during the second exercise due to further data cleaning whereby all abortions that pre-dated the first birth in Building Blocks Trial were removed from the dataset.

### **2.11.6 Immunisations**

Data collected on immunisations routinely offered in the UK and received by babies in the Building Blocks trial were collected via COVER (Cover of Vaccination Evaluated Rapidly) contacts at each PCT trial site. The COVER programme evaluates childhood immunisations uptake in England. An email request for data and a password-protected spreadsheet was emailed from Cardiff University to COVER contacts. The spreadsheet contained Participant ID, NHS number, gender, date of birth, and the dates between which the immunisation records

were requested i.e. from birth to two years of age for each baby born into the trial. A total of 1104 children's immunisation records were returned from 14 PCTs.

### **2.11.7 Primary care (GP) data**

Immunisation, second pregnancy, safeguarding and consultation data relating to both mothers and babies, were collected from GP practices. These data were extracted either by the Local Researchers, or by GP practice staff. Data were either collected on a paper CRF or a computerised printout of the Primary Care record was received by the trial team.

The GP CRF included data on outcomes for the mother as well as her first baby. GP records are held either electronically or manually. A month before data collection started at each GP Practice, a letter was sent to remind them about the trial and that that their Practice contained consented Building Blocks participants and that the trial team would like to collect data on these participants. Two options were given to collect the data, detailed below. The Local Researcher or trial team in Cardiff University followed this up with a phone call to the Practice to discuss which option regarding data collection would be best for the Practice. The records relating to 962 mother / infant dyads were received.

#### ***Data collected by Local Researcher***

The Local Researcher visited practices by prior arrangement and following provision of relevant consent and approvals, abstracted data directly onto portable computer (or in some cases first via a paper CRF). Encrypted data were then sent on USB by courier to the trial team in Cardiff University.

#### ***Data collected by Practice Manager***

This involved the GP Practice being paid to collect the data on a paper CRF. The Local Researcher or trial team in Cardiff co-ordinated this by assisting the GP Practices with any information they needed to identify participants and providing the Practice Manager with the relevant documentation. The request and negotiation for this work was done centrally from Cardiff University. The Practice returned the CRF by secure post or fax to Cardiff University. As an alternative to completing the CRF, the GP Practice could also send a print out of the participant's record. Once the CRFs were received the data were coded for data entry.

## **2.12 FNP Information System (FNPIS)**

The FNP Information System was a bespoke database run by 'Connecting for Health' based in Exeter, based on FNP data forms and accessible to FN teams via a portal. The system recorded clinical details of client contacts and automatically generates FN visiting schedules. This became operational in April 2009. Data could be entered directly onto the system, or FNs could download Excel-based forms, complete these, and then upload

them at a later date. Alternatively, they could use hard copies of the data forms to collect data from the client, which they would later enter manually onto the system.

At each visit a Home Encounter Visit Form (UK001) was completed. There were also additional forms that were completed on particular visits and dates; these dates were based firstly on expected delivery date (EDD), and then the baby's date of birth. Initially, a client's pregnancy schedule was generated by the system, the database calculated how many visits would be expected in pregnancy based on the FNP visit schedule. This could be updated if an EDD was amended. The schedule was re-calculated once the baby's date of birth (DOB) was entered, this would generate a schedule of visits until the baby reached two years of age. If the baby was born prematurely, the system updated the number of expected visits in pregnancy. If the client was inactive (no contact with the programme for 6 months or more) at the time of birth and there was no baby DOB available, the system would assume that the baby was born 4 weeks after the EDD and generated a schedule to reflect this.

Some additional forms were expected to be completed at certain stages of the programme's delivery, e.g. at the first postpartum visit the 'Infant birth form' (UK012) was completed in addition to the UK001 form. If they were not completed during those visits, they were marked as 'overdue' in the system. The system also comprised a number of ad-hoc forms for example, the 'Changes to client/child status form' (UK004A).

The data collection forms provided documentation of services received by clients enrolled in FNP, including number of completed visits, percentage of completed/attempted visits undertaken, visit length, and proportion of time spent on content domains. This information was used to assess fidelity against the programme model and inform programme improvement strategies both at local sites and nationally.

The Building Blocks trial team accessed some of these forms, including the UK001 form, the 'Referral made form' (UK002), the 'Telephone/TEXT encounter with family form' (UK003), the 'Client leaving/returning/inactive form' (UK004B), the 'Changes to client/child status form' (UK004A) form, and the 'Profile of Programme Staff form' (UK053).

## **2.13 Data collection technology**

The clinical database, a remote and telephone data capture system, was developed in collaboration with the Centre for Advanced Software and Intelligent Systems (CASIS, Cardiff and Aberystwyth Universities), the Participant Resource Centre (PRC) and Information Services (Cardiff University). After pilot testing with academic and research professional staff, and a member of the local young mothers group, a formal training programme was developed for both field and office-based researchers. The training took about two hours of face-to-face guidance and was conducted in trial sites as well as in Cardiff. The training was delivered by the

data manager and another member of the trial team. For the maternal sensitivity recordings, camcorders with encrypted memory sticks were used.

## **2.14 Assessments for urinary cotinine**

A urine sample for cotinine assessment was collected at the baseline visit and also in late pregnancy, the latter through visiting the participant's home, or at an antenatal clinic appointment. Samples were assayed by The Diabetes Research Network Wales Laboratory, Cardiff University who also provided materials for sample collection. These materials were delivered to each trial site prior to the start of the trial. Samples could be shipped on any day of the week.

The DRI® Cotinine Assay, manufactured by Microgenics, was used to analyse the urine samples. It is an in vitro diagnostic medical device intended for the qualitative and semi-quantitative determination of cotinine in human urine at a cut-off level of 500ng/mL. This assay was intended as an aid in the detection of cotinine after use or exposure to tobacco products. Those samples which were at the cut-off level of 500ng/mL were re-analysed to enable greater accuracy with a new lower level of 100ng/mL. The upper end was 2,000ng/mL. QC (quality control) samples for cotinine were run at the start and end of each analysis day. The coefficient of variance (CV) for the mid-level QC was 14.5% and for the high level QC was 12.5%. A negative / low-level QC was also run, and this was always <100ng/ml.

## **2.15 Sample size estimation**

It was estimated that a total sample of 1,418 mother / infant dyads for analysis would provide adequate power to detect a small effect (standardised difference of approximately 0.2 or odds ratio 0.6) in each of the four primary outcomes. This small standardised difference enabled us to detect effect towards the lower end of what we expect. For example, it would equate to at least 90% power at the two-sided 2.5% alpha level to detect differences between the two arms of 10% (40% to 30%) in the proportion having any emergency attendance or emergency admission to hospital within two years, and of 7.5% (20% to 12.5%) in the proportion with a second pregnancy within twenty-four months. We chose to use a 2.5% alpha level to allow for multiple primary outcomes within each individual population in the trial i.e. there were two primary outcomes for the mother (smoking and second pregnancy) and two for the baby (birth weight and emergency attendances / admissions). This gave a 5% type 1 error rate for each population.

We allowed a pregnancy loss of 1.5%. We expected to obtain follow-up data for three of the four primary outcomes on at least 90% of participants by accessing the medical records in hospital and primary care for both the mother and child. Follow-up smoking rates were collected through the late pregnancy telephone

interviews. We therefore aimed to recruit a total of 1,600 pregnant women to achieve our target number for analysis, as this took into account the small anticipated pregnancy loss and loss to follow-up.

## **2.16 Randomisation**

The Local Researchers used a remote randomisation service (automated telephone or web) provided by Bristol Randomised Trials Collaboration (BRTC) to allocate each woman to the Intervention or Control arm. The Local Researcher then informed the FNP team of participants allocated to receive the FNP programme. The FNP team took responsibility to enrol the woman into the programme and provided the intervention. All participants' General Practitioners were notified of their recruitment to the trial, and maternity records were flagged.

### **2.16.1 Randomisation method**

The allocation ratio was one-to-one and stratified by site, and minimised by gestation (<16 weeks / 16+weeks), smoking status at recruitment (smoker / non-smoker) and first / preferred language (English / Non-English). The algorithm allocated new participants to the study arm that minimised imbalance with respect to gestation, smoking status and language with probability of 0.8.<sup>132</sup> Therefore a random element was retained, further reducing predictability of allocation.

## **2.17 Statistical Methods**

All comparative main analyses were based on an intention-to-treat (ITT) basis (without imputation) and compared the outcome between the two arms using a three-level regression model, to allow for clustering of outcome within a site and Family Nurse (participant nested within Family Nurse nested within site). In cases where more than one nurse had delivered FNP, the nurse that delivered the most FNP was allocated. Where the clustering in the Intervention arm at level of Family Nurse was negligible, the simpler two-level model was used, which included site as a random effect since this was a stratification variable.<sup>133</sup> In addition all models were adjusted for minimisation variables (gestation, smoking status at recruitment, and first / preferred language). One participant did not have minimisation variables first or preferred language and gestational age recorded and was excluded from all analyses.

For continuous outcome variables a linear regression model was fitted and results presented as a difference in adjusted means (Intervention minus Control arm). Linearity assumptions were checked by plotting the residuals at each level against the predicted values, and examining normal probability plots where the residuals were plotted against corresponding points on a Normal distribution curve. Estimates were obtained using restricted maximum likelihood (REML). For binary outcomes a logistic model was used and the result

presented as adjusted odds ratios (ORs) - compared the odds of an event in the Intervention compared with the Control arm.

Count data were analysed using a Poisson multilevel model. If the distribution of events displayed signs of over dispersion (greater variance than might be expected in a Poisson distribution), then a Negative Binomial model (NBM) was used. Results were presented as the (adjusted) incidence rate ratio in the Intervention arm compared to the Control arm. Categorical or ordinal outcomes were analysed using multinomial regression and results presented as ORs. For all primary outcomes a 97.5% confidence interval (CI) and p-value was presented; for all secondary outcomes a 95% CI and p-value was presented.

Where baseline measurements were taken into consideration, an analysis of covariance model (ANCOVA) was used with baseline measurement as a covariate. Where data were collected over several time points, a repeated measures model (using a generalised linear mixed model) was used with time points (6, 12, 18, 24 months) nested within participants (nested within FNP nurse and site) and included an interaction term for time and trial arm to investigate any divergent / convergent pattern in outcomes.<sup>134</sup> The global interaction effect was tested and where non-significant, the interaction and time term were both dropped from the model. Both the intercepts and slopes of participants' measures were allowed to vary randomly where possible. The Akaike Information Criterion (AIC) was used to determine the best fitting model.

With validated scales, the outcome was used as directed in the manuals either as a categorical variable (using validated cut-offs) or used as a continuous score. Where no guidance was given, the continuous data were used in the primary analysis and, if necessary, the categorical outcome was examined as a secondary analysis. Un-validated measures (newly derived or modified) were validated by using Cronbach's  $\alpha$  to assess the scale reliability and a factor analysis determined factor loadings.

## 2.18 Primary Outcomes

Four primary outcomes were reported for the trial:

- Prenatal tobacco use at late pregnancy interview:
  - Proportion of smokers
  - Mean number of calibrated cigarettes smoked per day (for smokers only)
- Birth weight (grams)
- Child emergency attendances and/or admissions within twenty four months of birth:
  - Proportion of participants' children attending Accident and Emergency (A&E) and/or having an emergency admission to hospital within twenty four months of birth
- Subsequent pregnancy within twenty four months of first birth:
  - Proportion of women with a subsequent pregnancy within twenty four months of first birth

### **2.18.1 Prenatal tobacco use**

A calibrated measure of number of cigarettes smoked per day at baseline and late pregnancy was calculated using a combination of urinary cotinine results and self-reported number of cigarettes smoked per day. The calibration method was developed by Dukic and colleagues<sup>135</sup> and used self-reported smoking data (number of cigarettes smoked on the three days prior to interview, time of last cigarette, hours since last cigarette) and urine cotinine levels collected at baseline and the late pregnancy interview, and also variables such as time of interview. A modified version of the Dukic method was developed in discussion with the author (see Appendix 7). The primary analysis of prenatal tobacco use comprised two parts:

#### **Part 1**

The first part of the analysis used a binary variable (smoker or not) and compared the odds of being a smoker at late pregnancy follow-up in the Intervention arm versus the Control arm. The definition of a non-smoker was as follows:

- For those with self-report and cotinine data at both baseline and follow-up:
  - a participant with self-reported zero cigarettes in the three days prior to interview and a follow-up cotinine level of <100 ng/ml.
- For those with self-report at baseline and follow-up but cotinine only at baseline:
  - a participant with self-reported zero cigarettes in the three days prior to interview and baseline reporting behaviour classified as either accurate or over-reporter.

All other participants in the primary analysis dataset were classified as smokers.

#### **Part 2**

The second part of the analysis assessed smoking as a continuous variable among those who were classified as a smoker in part 1. It compared the mean number of calibrated cigarettes smoked at late pregnancy follow-up between the trial arms. This analysis was based on a subset of randomised participants. Baseline characteristics of smokers were examined at follow-up by trial arm, and in a secondary analysis further adjusted for variables that exhibited marked differences between the arms. Further details of the calibration method are shown in Appendix 7.

### **2.18.2 Birth weight (grams)**

The primary data source for birth weight was the maternity record and any missing data were supplemented by HES records. The main analysis compared the mean birth weight (grams) between Intervention and Control arm.

### **2.18.3 Child emergency attendances / admissions within 24 months of birth**

The primary data source for this outcome was data arising from the Health and Social Care Information Centre (HSCIC) (Inpatients and A&E data).

**Inpatients:** Emergency admissions to hospital were identified from Inpatient records where the basic counting unit for calculation is the Finished Consultant Episode (FCE), which is the total time a patient spends under the care of an individual consultant. Any one hospital admission might have associated with it a number of different episodes as a patient might pass between different hospital consultants and for this analysis. Hospital admissions occurring in the two years since the child's birth were included. All elective admissions and any FCEs relating to the child's birth were excluded to ensure that only episodes subject to external factors were included. Transfers between providers (e.g. birth transfers between hospitals, transfers between hospitals for any non-birth associated events) were also excluded to avoid double counting.

**Accidents and emergency:** Attendances to A&E for the children were examined and linked to the inpatients data using a common identifier (HESID) and arrival date in A&E attendance data and episode start date in inpatient data. To enable linkage to the inpatients data (to identify attendances that subsequently result in an admission), ID and arrival date / episode start date needed to be unique in both datasets. True duplicates (same ID, arrival date and arrival time) were deleted but a number of attendances occurred on the same day but with different times of arrival and departure. In the majority of cases these attendances are related and are thus restricted to 'first attendances' to avoid duplicates.

After linkage of these two data sources, the resulting dataset identified children with either an attendance at A&E and/or a hospital admission within 24 months of first birth. The main analysis compared the proportion of children with at least one event of an A&E attendance or emergency admissions (as a hospital inpatient) within two years of birth between the intervention and Control arm.

#### **2.18.4 Subsequent pregnancies within 24 months of first birth**

The primary data sources for this primary outcome were data arising from the Health and Social Care Information Centre (HSCIC) (providing information on hospital antenatal clinic attendances, registered births and miscarriages involving hospital attendance – see Appendix 8 for further detail on the ICD10 codes used). Data relating to abortions was provided by the Department of Health, to whom medical practitioners have a statutory requirement to report all abortions. GP and maternal self-report data provided secondary supplementary data on women (especially in the cases of miscarriages) for whom the HSCIC and abortion data report no subsequent pregnancies. A flag was created to indicate whether a second pregnancy had occurred within twenty four months of first birth. It was recognised that the outcome would be an underestimate among non-responders at two years due to pregnancies as yet unconfirmed at the time of data collection, and unrecognised early pregnancy losses and early pregnancies, confirmed by the participant but not yet recorded in GP or hospital records. It was not considered that variability in the reporting of this outcome between arms would be significant. It was recognised that any estimate of subsequent pregnancies would be an underestimate due to the woman not knowing they were pregnant at the time of self-report, missing data for

some women or the woman had not presented to the GP or hospital antenatal clinic by the time of data extraction.

The main analysis compared the proportion of women with a second pregnancy within 24 months of the first birth between the intervention and Control arms.

## **2.19 Secondary analyses of primary outcomes**

### **2.19.1 Categorisation of birth weight**

Birth weight was stratified into birth weight categories: <1,500g (very low birth weight), 1,500-2,499g (low), 2,500-3,999g (normal) and ≥4,000g (macrosomia).

### **2.19.2 Emergency attendances / admissions within 24 months of birth**

The number of A&E attendances and / or emergency admissions (as a hospital inpatient) within two years of birth (in the first and second year) was compared between arms. The number of attendances was based on the number of attendances at A&E (whether subsequently admitted or not) and admissions without preceding A&E. The match of the A&E to inpatient data was carried out where the arrival date at A&E was the same as the admission to hospital. It was possible that more attendances could be related, for example due to admittance on the subsequent day to A&E attendance. However, relaxing the rule and including these would increase the number of improper matches and the total number of attendances / episodes per child would be overestimated. Timings of attendances were also examined using a time to first event analysis.

### **2.19.3 Sensitivity analyses specific to primary outcomes**

- Further adjusting for any variables exhibiting marked imbalance at baseline to check that this does not influence the findings.
- The efficacy of FNP visits on primary outcomes were estimated in a way that preserves randomisation using complier averaged causal effects (CACE) modelling by fitting a structural mean model.<sup>136,137</sup> Adherence was defined as the number of FNP visits that a woman received during the trial.
- Changes in smoking during pregnancy was examined as a possible mediating variable in the primary outcome of birth weight using mediation analysis.
- The impact of the data source (routinely collected e.g. HES, record retrieval (GP, Birth CRF), or self-reported) on certain outcomes such as subsequent pregnancies was explored.

The impact of non-adherence (women randomised to the Control arm but received intervention) was not explored since in practice measurable cross-over was negligible (ten participants were randomised to the Control arm but received the Intervention).

#### **2.19.4 Sensitivity analyses specific to prenatal tobacco exposure**

- Calibrated number of cigarettes were categorised (0, 1-5, 6-9, 10+ cigarettes per day) and analysed using ordinal logistic regression – this was not part of pre-specified analysis but performed due to lack of model fit for calibrated number of cigarettes among smokers using linear regression.
- Adjusted ORs have been calculated to allow for variables showing imbalance between arms at baseline.
- Analyses have been performed for complete case only.
- Between arm differences in consistency of reporting behaviour between baseline and late pregnancy have been explored.

### **2.20 Sub group analyses**

Appropriate interaction terms were entered into the primary regression analyses for all four primary outcomes in order to conduct prespecified sub groups analyses: deprivation (derived as quintiles obtained from IMD score), adaptive functioning (difficulty in at least one basic skills, see appendix 5), NEET status, age (with particular interest in those <16 years old). An additional planned subgroup analysis of birth weight was undertaken for mothers who smoked at baseline to ascertain the impact on this group specifically. An adjusted smoking status at baseline was used for this subgroup analysis and derived using calibrated number of cigarettes smoked (see above). Participants were categorised as non-smokers at baseline if they self-reported zero cigarettes in the three days prior to the interview and their cotinine level indicated that they were an accurate reporter. As the trial was powered to detect overall differences between the arms rather than interactions of this kind, these analyses were essentially exploratory and would need to be interpreted with caution. Effect sizes alongside 95% confidence intervals and p-values were reported.

### **2.21 Secondary outcomes**

Analyses of the secondary outcomes were using similar approaches as described for the primary outcomes.

### **2.22 Data cleaning**

Data from participants who had either formally withdrawn consent or were ineligible were removed from the datasets. Range checks were completed on items related to scales, other non-scale items were also checked for nonsensical or obviously invalid answers. Outliers were cross-checked with other data sources and agreement on how to deal with these was done on a variable-by-variable basis. Finally, the scales in the self-report interviews were scored according to scale instructions.

## 2.23 Retention strategies

There was a planned proactive approach to retention in this trial. An initial retention strategy was iterated as the trial progressed. Three key areas were identified to promote retention. These were 1) project team management of participant information, 2) project team management of field-based research staff, and 3) enhancing the motivation of trial participants. These are summarised in Table 2.10 and detailed in Appendix 9.

Table 2.10: Summary of retention strategies

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<b>1) Project team management of participant information</b>
<ul style="list-style-type: none"><li>• Collation of data</li><li>• Use of collated data</li></ul>
<b>2) Management of field-based research nurse staff</b>
<ul style="list-style-type: none"><li>• Site support visits</li><li>• Proactive notification management</li><li>• Local problem-solving</li><li>• Engagement of local professionals</li><li>• Engaging participants</li></ul>
<b>3) Enhancing participant motivation</b>
<ul style="list-style-type: none"><li>• Use of incentives</li><li>• Providing feedback to participants</li><li>• Interview notification</li></ul>

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## 2.24 Research Governance

### 2.24.1 Ethical approval

Multi-centre approval was granted by the Research Ethics Committee (REC) for Wales (reference number 09/MRE09/8). Ethical approval was granted on the 16<sup>th</sup> March 2009. Twenty-one substantial amendments were submitted throughout the trial – these are summarised in Appendix 10.

### 2.24.2 NHS research and development (R&D) approval

A Principal Investigator (PI) was identified at each Primary Care Trust (PCT) and NHS Trust, and site-specific approval was granted at all 18 participating Primary Care Trusts and 23 Acute Trusts. The NHS research and development (R&D) approvals were gained from the first site on the 29<sup>th</sup> April 2009 and the last site on the 30<sup>th</sup> July 2009. Sites could only open following approval from both the PCT and Acute Trust at that location.

### **2.24.3 Additional R&D approval**

During the course of the trial, a subsequent 52 additional R&D site approvals were required due to participants either moving or having given birth at a location not covered by the original set of NHS sites. Of these, 22 were for PCTs and 30 were for Acute Trusts.

## **2.25 Trial management and set-up**

The Building Blocks trial comprised four work packages (WP): Trial (TWP); Economics and Modelling (EMWP); Process Evaluation (PEWP); and Stakeholder Involvement and Ethics (SIEWP). An independently chaired trial steering committee (TSC) provided trial oversight and met prior to recruitment and another six times thereafter. The independent TSC membership comprised a clinician (Chair), youth health care physician, health economist and lay member, plus the Chief Investigator and the trial statistician. The stakeholder work package (SIEWP) helped to convene the IDMC, which thereafter reported directly to the TSC. The trial's independent data monitoring committee (IDMC) consisted of an ethicist, a statistician, a clinician and a lay member. The IDMC met prior to trial start and then another nine times thereafter.

## **2.26 Site management**

Prior to each trial site opening, a site visit was undertaken attended by at least two trial team members. Additional attendees to the site visit included some or all of the following: Local Researcher; members of the local FNP team, including the FNP lead; R&D representatives; local Principal Investigators (PIs); and midwifery staff. The local PIs for the PCTs were usually the FNP lead, who were either Consultants in Public Health or Heads of Children's Services, and for the Acute Trusts Heads of Midwifery, Consultant Obstetricians or senior midwives. Local PIs were provided with site files for which they were responsible for maintaining. These contained essential trial documentation and consent forms. At the end of the trial the PI was asked to return all equipment to the trial team, and to archive their site file locally.

## **2.27 Safety and abuse monitoring**

The Composite Abuse Scale (CAS)<sup>118</sup> is a self-report questionnaire that explores partner abusive experienced by women during the previous 12 month period. The CAS was only completed when the 24 month interview was conducted face-to-face, and others, apart from children, were not present. The CAS was self-completed on a portable computer and was developed so that the Local Researcher could not see the participant's responses. Should a participant answer positively to any one of eight questions relating to serious physical abuse, a built-in flag indicated this to the Local Researcher, who passed this information onto the participant's HV or FN.

This process was detailed in a Standard Operating Procedure and participants were informed of this prior to completion.

## **2.28 Withdrawals**

Building Blocks participants were free to withdraw their participation at any point after initial recruitment. A participant could choose not to complete one or more of the self-reported assessments whilst remaining in the trial, an option which still enabled data to be collected from routine sources for the participant. At withdrawal, it was possible for a participant to remove consent to use any of their data. Withdrawals from the trial were either mandatory or elective. Reasons for mandatory withdrawal included miscarriage, death or adoption of the.

Following withdrawal the Local Researcher or the Data Manager would ensure that no further contacts were made to collect self-report data, by indicating the withdrawal on the electronic database. The Local Researcher would inform the FNP team if a participant in the Intervention arm withdrew and the FNP supervisor would arrange for the participant to be allocated a Health Visitor from that point onwards.

## **2.29 Patient and public involvement in the research**

Recognising that pregnant teenagers are potentially vulnerable, a Stakeholder Involvement and Ethics Group were responsible for working across the trial, economic and process evaluation work packages. Various sensitive and practical issues needed consideration prior to study commencement, for example, consent for those aged under 16 and procedures to be followed in the event of child safeguarding concerns. The Stakeholder Group worked to identify potential issues that may arise during the course of the trial and advised on their appropriate management. This entailed the development of a range of Stakeholder Groups to support the conduct of the trial through the various stages of development to completion.

The collaborative involvement of lay and professional people in the Stakeholder Groups provided added value to the trial teams. Public contributors were part of core trial management groups: Trial Steering Committee, the Stakeholder Management Group and the Independent Data Monitoring Committee. Reference groups, including young mothers, advised on trial information materials, provide advice at the different stages of the trial, and contributed towards the design of the trial participant website. An example of the work carried out by the young mothers group is shown in Appendix 11. Stakeholder involvement in the Building Blocks trial is presented in detail in chapter 7.

## 2.30 Process Evaluation

Increasingly, nested process evaluations are seen as essential in trials of complex interventions which are characterised by interacting and interconnecting components, such as the variety of behaviours required by those delivering and receiving the intervention, the variability of outcomes, and the degree to which it can be tailored to suit the target population.<sup>138</sup> Process evaluations are deemed especially valuable for multisite trials where contextual differences may influence how the trial is implemented and received.<sup>139</sup>

For the Building Blocks trial a comprehensive process evaluation framework was prospectively developed, using a mixed methods approach to monitor and document programme and trial fidelity, participant engagement and satisfaction, recruitment and retention to the trial, contamination between trial arms, and the way that environmental factors can impact on implementation and outcomes.<sup>138,140,141</sup>

Table 2.11 presents the Building Blocks process evaluation framework, setting out the scope and the data sources relied upon to address them. Detailed descriptions of methods for individual components of the Process Evaluation can be found in chapters 8-13.

Table 2.11: Building Blocks Process Evaluation framework

Process evaluation	Data sources	Chapter
<b>1. Recruitment &amp; retention (<i>External validity</i>)</b>		
A comparison of the characteristics of Building Blocks participants and other FNP clients	Building Blocks trial data / FNPIS	Chapter 3
Attrition rates	Building Blocks baseline characteristics / trial administrative database	Chapter 3
<b>2. Fidelity (<i>Internal validity</i>)</b>		
Compliance with the FNP model within the trial	FNPIS	Chapter 8
The structure of FNP visits within the trial	FNP IS / FNP form UK001 data. Audio-recorded home visits (4 FNP clients x 18 sites x 3 time points)	Chapter 9
FNs use of MI principles within the trial	Sample of audio-recorded home visits (4 FNP clients x 18 sites x 3 time points)	Chapter 10
<b>3. Context (<i>Generalisability</i>)</b>		
The content of universal services across sites during the trial	Mapping and assessment of usual care	Chapter 11
What factors (including barriers & facilitators) influenced implementation in RCT and may affect roll-out?	Local stakeholder focus groups (FN, HV, MW x 4 sample sites at 2 time points)	Chapter 12
Site and Family Nurse differences in outcomes	Comparative analysis for each primary outcome	Chapter 4
<b>4. Exposure (<i>Moderation of effect</i>)</b>		
Participants' experience of FNP	Face-to-face semi-structured interviews (2 FNP clients x 18 sites x 2 time points)	Chapter 13

Process evaluation	Data sources	Chapter
5. Contamination ( <i>Internal validity</i> )	Focus groups / self-report	Chapters 12, 13

### 2.31 Health Economics

The health economics work comprised a within-trial economic analysis, systematic review, extrapolation exercise and preference elicitation study, using a discrete choice experiment. The within-trial economic analysis evaluated the cost-effectiveness of the FNP intervention versus Usual care, using a cost-utility analysis and a cost-consequence analysis based on the outcomes of the trial. Intervention effects were extended beyond the health sector, both within the timeframe of the trial and in the future. Hence, the extrapolation work explored the impact of the FNP intervention for a longer-term time horizon, with a systematic review presented to inform this. The preference elicitation study measured the relative values that members of the general public placed on the different outcomes of the Building Blocks trial, which span across different sectors (i.e. health, social care, education, criminal justice). Full details of the methods that were used for the health economics components of the trial are provided in Chapters 14-16.

## 3 Descriptive Results

This chapter describes success with recruiting and following up participants for both self-reported and routine data.

### 3.1 Recruitment and follow-up rates

Participant approach and recruitment to the trial, and subsequent follow-up for self-reported outcomes is shown in Figure 3.1. Trial recruitment started in June 2009 and finished in July 2010. 3,251 women were identified as potentially eligible by local professionals at the 18 trial sites and details passed to Local Researchers. 1,606 women were not recruited for the following reasons; subsequently assessed as ineligible (n=638), declined to participate following further discussion with the Local Researcher (n=727), no further contact possible (n= 205). For 36 women no reason was recorded by the Local Researcher for non-recruitment into the study.

A total of 1,645 participants were randomised. Subsequently, three women in the Intervention arm and two in the Control arm were assessed to be ineligible by the trial team. Of these, one woman was deemed not to be Gillick competent, one woman was identified as not pregnant at the first scan, and three women were registered with a GP outside the study area. Between the baseline and the late pregnancy interview there were a total of 121 withdrawals (7.4% of all eligible women recruited). A further 72 women withdrew (4.4% of all eligible women recruited) in the period following the late pregnancy interview. Across the whole study period, there was some imbalance in the overall withdrawal rates (elective and mandatory withdrawals combined), 49.2% withdrawals were from the Intervention arm and 36.8% were from the Control arm. This overall imbalance was accounted for by withdrawals between the baseline and late pregnancy interviews, with 73 withdrawals from the Intervention arm and 48 withdrawals from the Control arm. Specifically, this may be attributable to a difference in elective withdrawals in that phase (49 vs 26 elective withdrawals for intervention and control groups respectively). Of those participants who elected to withdraw from the study, 12 in the Intervention arm and 10 in the Control arm also withdrew their consent for their data to be used. The reasons provided for mandatory and elective withdrawals are shown in full in Tables 3.1 and 3.2 respectively.

Table 3.1 Mandatory withdrawals by treatment allocation for mothers

Reason for withdrawal	Intervention	Control	Total
Ineligible	3	2	5
Miscarriage	15	16 (*3)	31
Adoption	7	7	14
Social termination of pregnancy	4 (*1)	8	12
Termination for fetal anomaly	4	3 (*1)	7
Stillbirth	3	2 (*1)	5
Neonatal death	2	2	4
Infant death	0	3	3
Molar pregnancy	1	0	1
Death of mother infant pair	1(2)	0	1
<b>Total</b>	<b>40</b>	<b>43</b>	<b>83</b>
*these participants also withdrew consent to use any of their data			

The deaths of one mother infant pair, and another three infants were reported to the trial team. One infant death was attributed to Sudden Infant Death Syndrome. The other two infants (both in the Control arm of the trial), and the mother infant pair (in the Intervention arm but declined enrolment in FNP following trial recruitment), died as a result of homicide, for which the participants' partner or ex-partner were subsequently convicted.

Table 3.2 Elective withdrawals by treatment allocation

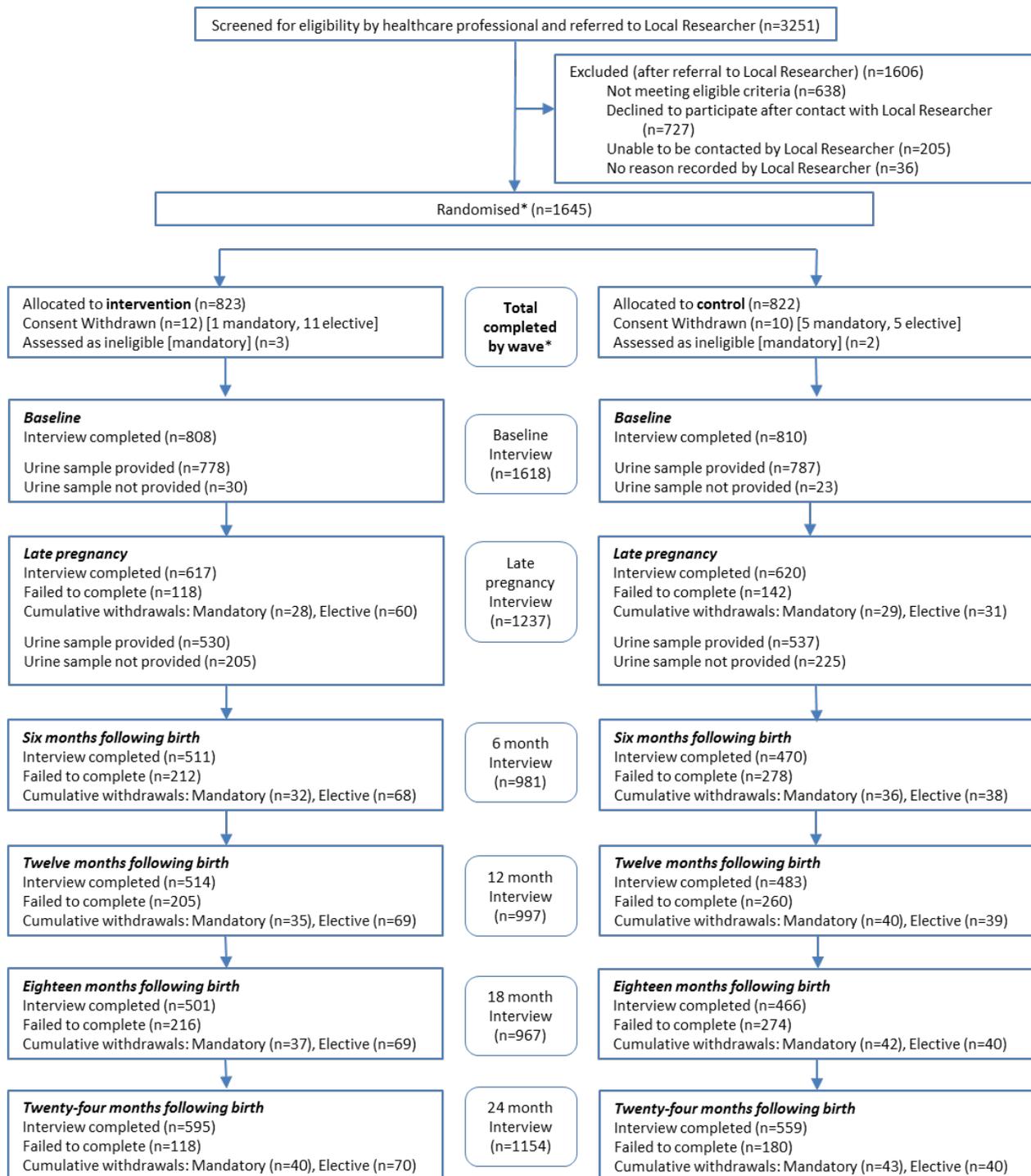
Woman's reason for withdrawal	Intervention	Control	Total
No longer wished to take part in the trial	46 (*6)	35 (*4)	81
Did not want to commit to the FNP programme	15 (*4)	0	15
Did not want to take part in the trial as not allocated to FNP	0	1	1
Participant moved from the area	0	1	1
Considering placing baby for adoption following birth	0	*1	1
No reason given	9 (*1)	2	11
<b>Total</b>	<b>70</b>	<b>40</b>	<b>110</b>
*these participants also withdrew consent to use any of their data			

Whilst trial withdrawal should have meant cessation of intervention delivery for women allocated to the intervention, it was still delivered to 26 withdrawn participants. There were also 10 participants randomised to the Control arm of the study but enrolled into the FNP. Seven of these women were referred to the FNP team, usually by a midwife, after they had been randomised to the Control arm. One woman moved away from the study site in which she was recruited to a non-trial site where she was subsequently enrolled onto the FNP. One woman was recruited at the very end of the trial recruitment phase, after this phase ended she was enrolled onto the FNP (the FNP team were unaware that she has already been recruited to the trial). One woman, randomised to the Control group received FNP, as her twin sister, with whom she shared a home, had previously been randomised to the Intervention arm. As they lived together it was considered both impractical and undesirable to attempt to exclude the second twin from programme delivery.

Non-completion of interview assessments (either due to failure to contact or failure to respond to request) in itself would not bar data abstraction from routine records (the method by which three of the four primary outcomes were mainly sourced). Therefore, participants were able to remain part of the trial even though they may have missed one

or more wave of self-reported data collection. The numbers of women remaining active and successfully followed-up are presented in the participant flowchart in Figure 3.1.

Figure 3.1 Building Blocks Self-Report Data Collection Flowchart



\*Randomisation was completed after the Baseline interview

Rates of follow-up for both study groups combined (as proportion of non-withdrawn women) were similar for the three post-birth telephone interviews (66.7%, 68.2%, and 66.4% respectively) and highest for late pregnancy telephone interview (82.6%). The follow-up rate for participants at the final assessment point was 79.5%. By the time

of the final assessment at 24 months, 83.5% of non-withdrawn participants in the Intervention arm completed follow-up (595/713), whilst 75.6% of non-withdrawn participants in the Control arm completed follow-up (559/739). Of the 1,154 interviews completed at 24 months, 76 were completed by telephone by the Participant Resource Centre, and 1,046 were completed face-to-face by Local Researchers. There were an additional 32 postal questionnaires completed by participants, these contained a core subset of questions from the 24 month interview.

Table 3.3 shows collection of routine data. Antenatal and birth experience data were collected from 1,578 maternity records. Data were successfully retrieved for all live and stillbirths and excluding babies of those who withdrew before birth and did not already have data collected for them before data collection was halted. For maternity and for primary care data the trial team obtained a single set of records for mother and child combined. For the secondary care data, the trial team obtained separate records for mother and for child. The figures for primary care, secondary care, abortions, and immunisations data are based on the 1,618 participants recruited to the trial who were not assessed as ineligible or later withdrew their consent to use their data. Data for participants who withdrew throughout the trial were collected up to the date that they withdrew. Some maternity records were not available due to participant withdrawal, even for the period that preceded their actual withdrawal. Following further consideration by the REC the collection of such antenatal and birth experience data from withdrawn participants was halted, however, data that had already been collected from withdrawn participants were not removed from the dataset. 962 Primary care records were collected, the Intervention and Control arms being fairly balanced, 476/808 (58.9%) of records collected for participants in the Intervention arm, and 486/810 (60.0%) collected for participants in the Control arm. Outcome data from secondary care were collected for 1,611 participants (mothers), 1,485 Building Blocks singleton and first twins, and 11 Building Blocks second twins<sup>6</sup>. Of these participants, 148 had one abortion, 10 had two abortions, and one had three abortions. Immunisation data was collected from PCT records. Immunisations data were collected for 1,098 (73.7%) of Building Blocks singleton and first twins and 6 (50.0%) of Building Blocks second twins.

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<sup>6</sup> Note that records would only be available for children who actually attended secondary care in the two year period following birth. Similarly abortion data would only be available if a participant underwent a termination.

Table 3.3 Routine data available for analysis: potential records and reasons for loss to follow-up

	Maternity		Primary care		Secondary care		Secondary care		Immunisation		Abortion	
	Mother and baby		Mother and baby		Mother		Baby		Baby		FNP	Control
	FNP	Control	FNP	Control	FNP	Control	FNP	Control	FNP	Control		
<b>Potentially available</b>	<b>823</b>	<b>822</b>	<b>823</b>	<b>822</b>	<b>823</b>	<b>822</b>	<b>732*</b>	<b>761*</b>	<b>732*</b>	<b>761*</b>	<b>823</b>	<b>822</b>
Ineligible	3	2	3	2	3	2	-	-	-	-	3	2
Consent withdrawn	12	10	12	10	12	10	2	1	2	1	12	10
Ethics restriction	26	14	-	-	-	-	-	-	-	-	-	-
Matching failure	-	-	-	-	3	4	4 <sup>#</sup>	1	10	10	-	-
Not provided on request	-	-	332	324	-	-	-	-	181	191	-	-
<b>Available for analysis</b>	<b>782</b>	<b>796</b>	<b>476</b>	<b>486</b>	<b>805</b>	<b>806</b>	<b>726<sup>#</sup></b>	<b>759<sup>#</sup></b>	<b>539<sup>**</sup></b>	<b>559<sup>**</sup></b>	<b>808</b>	<b>810</b>

\* Numbers exclude 5 stillborn babies, 3 in the intervention group, 2 in the control group.

<sup>#</sup> HES data were also collected on 11 second twins, 6 in the intervention group and 5 in the control group. There was one failure to match on a second twin in the intervention group.

<sup>\*\*</sup> Immunisation data were also collected on 6 second twins, 4 in the intervention group and 2 in the control group. Data were not provided on 6 second twins, 3 in the intervention group and 3 in the control group.

## 3.2 Safety Data

In line with Good Clinical Practice (GCP) we used a Standard Operating Procedure to report, assess and process of Serious Adverse Events (SAEs) within the trial including a trial-specific reporting form. Hospitalisation of the participant for a planned hospital birth was determined, a priori, not to require reporting as an SAE. It was appreciated that due to the nature of antenatal and infancy care, with anticipated frequent hospitalisations, many trial participants or their child may fulfil the criteria for SAE reporting during the trial. Whilst appreciating that a liberal approach to SAE reporting may result in a high volume of reports, it was considered justified to avoid the risk of potentially important SAEs going unreported. Local Researchers were therefore encouraged from the outset to update the trial team on participants in very difficult social circumstances so that telephone interviewers to approach them with additional sensitivity. In addition, regular updates were required from trial sites for babies born with multiple or complex congenital anomalies.

A total of 1,315 Serious Adverse Events (SAEs) were reported with 667 (41.2%) of participants (mother or child) having at least one event, 310 in the Control arm, and 357 in the Intervention arm. All SAEs were categorised (Table 3.4 and 3.5), reviewed by a clinician and details reported regularly to the Trial Management Group. Throughout the trial period none of the SAEs were considered to have been intervention related. Ongoing monitoring of SAE reporting rates identified variation in reporting rates across trial sites. This primarily reflected variation in the reporting of SAEs when identified retrospectively through the extraction of data from the maternity notes. The retrospective reporting of SAEs by this mechanism commonly identified anticipated admissions during the antenatal period, which although meeting the GCP criteria for an SAE, were not intervention related. Such reporting was subsequently discouraged through the additional training.

Table 3.4 *Categories of Serious Adverse Events reported for mothers*

SAE category	Number of SAEs reported related to mothers
<b>Pregnancy related</b>	
Abdominal pain	88
Cervical suture	1
Gestational Diabetes	2
High risk serum screening result	1
Intrapartum emergency	8
Intrauterine growth restriction(IUGR)	11
Miscarriage	29
Molar pregnancy	1
Multiple antenatal admissions	2
Pre-eclampsia (PET)	13
Pregnancy induced hypertension (PIH)	19
Premature labour (threatened)	11
PV bleed	56
Reduced fetal movements	25
Suspected/unconfirmed SROM	16

SAE category	Number of SAEs reported related to mothers
SROM confirmed	8
Termination for fetal anomaly	8
Termination of pregnancy social	8
<b>Postnatal Related</b>	
Postnatal bleeding	13
Postnatal complication	22
Postnatal infection	2
<b>Other</b>	
Asthma	2
Gastrointestinal	1
Maternal death	1
Medical / surgical follow-up	9
Medical review - mother	51
Mental illness including depression	38
Rash	1
Reassurance	2
Road traffic accident (RTA)	3
Self-harm	6
Sepsis	2
Sickle cell crisis	1
Social worker / mental health team review	4
Suspected venous thromboembolism (VTE)	4
Trauma - mother	15
UTI confirmed - mother	28
UTI unconfirmed - mother	14
Viral illness - mother	6
<b>Total</b>	<b>532</b>

Table 3.5 Categories of Serious Adverse Events reported for babies

SAE category	Number of SAEs reported related to babies
Abdominal pain	1
Accident - baby	40
Congenital anomaly	45
Conjunctivitis	3
Feeding	8
Fever	8
Failure to thrive (FTT)	5
Gastrointestinal	31
Infant death	3*
Ingestions	1
Jaundice	7
Medical / surgical follow-up	6
Medical review - baby	156
Neonatal death	4
Neonatal unit (NNU) admission	34
Premature birth	31
Prematurity	7
Rash - baby	17
Respiratory	47
Sepsis	8
Stillbirth	5

SAE category	Number of SAEs reported related to babies
Suspected non-accidental injury (NAI)	1
Urinary tract infection (UTI) - Baby	10
Viral illness - baby	17
<b>Total</b>	<b>495</b>

\* There was one other infant death; this has been counted in the Table reporting SAEs related to mothers

Table 3.6 Categories of Serious Adverse Events reported related to non-medical events relating to both mother and baby.

SAE category	Number of SAEs reported related to non-medical events of both mother and baby
Adoption/long term fostering	19
CAS flagged at Two Year Interview	33
Domestic abuse	43
Safeguarding both mother & child	43
Safeguarding child	133
Safeguarding mother	1
Social conditions	16
<b>Total</b>	<b>288</b>

Table 3.7 Number of Serious Adverse Events reported for women-child dyads (or woman only if no live birth) by trial site.

Trial Site	Participants (woman and baby dyad) with no SAE reports	Participants (woman and baby) with 1 SAE report	Participants (woman and baby) with >1 SAE report	Total number of participants recruited to site	Median no. of events reported per dyad (or woman only if no live birth)
1	4	15	24	43	1
2	21	17	11	49	0
4	101	35	7	143	0
5	16	14	9	39	0
7	40	12	2	54	0
8	29	7	3	39	0
9	23	18	6	47	0
10	55	34	24	113	0
21	89	24	2	115	0
22	6	10	52	68	1
23	70	14	15	99	0
24	66	17	10	93	0
25	92	38	20	150	0
26	31	4	0	35	0
27	93	22	27	142	0

28	63	40	36	139	0
29	79	28	10	117	0
30	73	36	24	133	0
<b>Total</b>	<b>951</b>	<b>385</b>	<b>282</b>	<b>1618</b>	<b>0</b>

Of the reported SAEs 36.7% related to mothers, 42.7% to children, and 20.6% related jointly to mother and child. Over 90% of events were reported by Local Researchers and telephone interviewers (Table 3.8).

Table 3.8 Source of SAE notification

<b>Notifier</b>	<b>Total number of events reported (%)</b>
Local Researcher	1125 (85.5%)
Telephone interviewer	75 (5.7%)
Family Nurse	68 (5.1%)
Health visitor	14 (1.1%)
Midwife	5 (0.4%)
GP	1 (0.1%)
Other medical professional	1 (0.1%)
Unknown job role	1 (0.1%)
No name on form	25 (1.9%)
<b>Total</b>	<b>1315</b>

### 3.3 Randomisation

The trial arms were well matched on the variables on which they were balanced at randomisation: self-reported gestational age and smoking status (Table 3.9). For language, with few participants in the 'Other' group balance was difficult to achieve. A greater proportion of women recruited to the study reported that they were less than 16 weeks gestation age (59.3%) and 53.2% reported being a non-smoker.

Table 3.10 shows the proportion in each strata of gestational age (<16, ≥ 16 weeks) and smoking status (smoker non-smokers) across sites. The proportion of women reporting being <16 weeks gestation age at recruitment varies by site from 33.3% to 79.1%. Similarly, the proportion of women reporting being smokers at recruitment varies widely from 3.6% to 56%. Tables 3.10 and 3.11 demonstrate that balance of allocation to arm is achieved within each level across most sites. One participant had missing balance factors as the remote randomisation service did not record the randomisation correctly.

Table 3.9 Balance factors from randomisation data by Trial arm

	<b>Intervention N=808</b>	<b>Control N=810</b>	<b>Overall N=1618</b>
	<b>N (%)</b>	<b>N (%)</b>	<b>N (%)</b>
Gestational age at baseline			
16 weeks or more	330 (50.2)	328 (49.8)	658 (40.7)
Less than 16 weeks	477 (49.7)	482 (50.3)	959 (59.3)
Missing	1 (0.1)		
Smoking status			
No	428 (49.8)	432 (50.2)	860 (53.2)
Yes	380 (50.1)	378 (49.9)	758 (46.8)
Language			
English	805 (50.0)	806 (50.0)	1611 (99.6)
Other	2 (33.3)	4 (66.7)	6 (0.4)
Missing	1 (0.1)		

Table 3.10 Balancing factors from randomisation data by site\*

Site <sup>†</sup>	Participants recruited N (%)	Gestational age at baseline <sup>‡</sup>		Smoking status
		Less than 16 weeks		No
		N (%)	N (%)	N (%)
25	150 (9.3)	107 (71.3)		68 (45.3)
4	143 (8.8)	79 (55.2)		63 (44.1)
27	142 (8.8)	100 (70.4)		71 (50.0)
28	139 (8.6)	75 (54.0)		65 (46.8)
30	133 (8.2)	87 (65.4)		77 (57.9)
29	117 (7.2)	70 (59.8)		62 (53.0)
21	115 (7.1)	73 (63.5)		55 (47.8)
10	113 (7.0)	78 (69.0)		58 (51.3)
23	99 (6.1)	45 (45.5)		57 (57.6)
24	93 (5.7)	31 (33.3)		48 (51.6)
22	68 (4.2)	34 (50.0)		44 (64.7)
7	54 (3.3)	28 (51.9)		35 (64.8)
2	49 <sup>c</sup> (3.0)	20 (40.8)		27 (55.1)
9	47 (2.9)	29 (61.7)		30 (63.8)
1	43 (2.7)	34 (79.1)		19 (44.2)
5	39 (2.4)	24 (61.5)		20 (51.3)
8	39 (2.4)	25 (64.1)		29 (74.4)
26	35 (2.2)	20 (57.1)		32 (91.4)
<b>Total</b>	<b>1618</b>	<b>959 (59.3)</b>		<b>860 (53.2)</b>

\*Language is not reported by site due to small number of participants in cells

† Sorted by percentage of participants recruited by site

‡ One participant missing gestational age and language

Table 3.11 Balance factors from randomisation data by site by Intervention arm N (%)

Site *	Gestational age at baseline				Smoking status			
	Less than 16 weeks		16 weeks or more		Yes		No	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
<b>25</b>	54 (50.5)	53 (49.5)	21 (48.8)	22 (51.2)	41 (50.0)	41 (50.0)	34 (50.0)	34 (50.0)
<b>4</b>	40 (50.6)	39 (49.4)	32 (50.0)	32 (50.0)	41 (51.2)	39 (48.8)	31 (49.2)	32 (50.8)
<b>27</b>	49 (49.0)	51 (51.0)	20 (47.6)	22 (52.4)	35 (49.3)	36 (50.7)	34 (47.9)	37 (52.1)
<b>28</b>	38 (50.7)	37 (49.3)	31 (48.4)	33 (51.6)	38 (51.4)	36 (48.6)	31 (47.7)	34 (52.3)
<b>30</b>	43 (49.4)	44 (50.6)	23 (50.0)	23 (50.0)	27 (48.2)	29 (51.8)	39 (50.6)	38 (49.4)
<b>29</b>	37 (52.9)	33 (47.1)	21 (44.7)	26 (55.3)	28 (50.9)	27 (49.1)	30 (48.4)	32 (51.6)
<b>21</b>	37 (50.7)	36 (49.3)	18 (42.9)	24 (57.1)	28 (46.7)	32 (53.3)	27 (49.1)	28 (50.9)
<b>10</b>	39 (50.0)	39 (50.0)	18 (51.4)	17 (48.6)	28 (50.9)	27 (49.1)	29 (50.0)	29 (50.0)
<b>23</b>	22(48.9)	23 (51.1)	27 (50.0)	27 (50.0)	22 (52.4)	20 (47.6)	27 (47.4)	30 (52.6)
<b>24</b>	14 (45.2)	17 (54.8)	32 (51.6)	30 (48.4)	23 (51.1)	22 (48.9)	23 (47.9)	25 (52.1)
<b>22</b>	16 (47.1)	18 (52.9)	19 (55.9)	15 (44.1)	13 (54.2)	11 (45.8)	22 (50.0)	22 (50.0)
<b>7</b>	13 (46.4)	15 (53.6)	13 (50.0)	13 (50.0)	10 (52.6)	9 (47.4)	16 (45.7)	19 (54.3)
<b>2</b>	9 (45.0)	11 (55.0)	16 (57.1)	12 (42.9)	10 (45.5)	12 (54.5)	16 (59.3)	11 (40.7)
<b>9</b>	15 (51.7)	14 (48.3)	10 (55.6)	8 (44.4)	9 (52.9)	8 (47.1)	16 (53.3)	14 (46.7)
<b>1</b>	18 (52.9)	16 (47.1)	5 (55.6)	4 (44.4)	12 (50.0)	12 (50.0)	11 (57.9)	8 (42.1)
<b>5</b>	11 (45.8)	13 (54.2)	8 (53.3)	7 (46.7)	9 (47.4)	10 (52.6)	10 (50.0)	10 (50.0)
<b>8</b>	13 (52.0)	12 (48.0)	7 (50.0)	7 (50.0)	5 (50.0)	5 (50.0)	15 (51.7)	14 (48.3)
<b>26</b>	9 (45.0)	11 (55.0)	9 (60.0)	6 (40.0)	1 (33.3)	2 (66.7)	17 (53.1)	15 (46.9)
<b>Total</b>	<b>477 (49.7)</b>	<b>482 (50.3)</b>	<b>330 (50.2)</b>	<b>328 (49.8)</b>	<b>380 (50.1)</b>	<b>378 (49.9)</b>	<b>428 (49.8)</b>	<b>432 (50.2)</b>

\*Sorted by percentage of participants recruited to the trial

### 3.3.1 Demographic characteristics of sample at baseline

A summary of baseline demographics by trial arm is presented in Table 3.12. Participants were mostly from a white background (88.1%), with a median age of 17.9 years and the majority of babies fathers were aged 16-24 (84.5%). The majority were living with either one or both parents, whilst 60% of parents were permanently separated or divorced. The results show a reasonable balance in characteristics between the two arms. Table 3.13 shows that the median age of participants varies only marginally between sites. There was variation in the ethnic mix with participants at one site being 100% white and three sites with a substantial proportion of Black or Asian participants (i.e. over 40%). The proportion of participants speaking 'English only usually spoken at home' was over 95% at all sites with the exception of three sites where the proportion ranged from 51% to 71% which reflects the local ethnic mix. A greater proportion of women (19%) were married in one London site compared with other sites.

Table 3.12 Participant demographics by trial arm. Values are N (%) unless otherwise stated.

	Intervention N=808	Control N=810	Overall N=1618
<b>Demographic</b>			
Median age at recruitment in years (25th to 75th centile)	17.9 (17.0 to 18.8)	17.9 (16.9 to 18.8)	17.9 (16.9 to 18.8)
Age of baby's father in years			
<16	28 (3.5)	17 (2.1)	45 (2.8)
16-24	698 (86.4)	669 (82.6)	1367 (84.5)
25-34	74 (9.2)	102 (12.6)	176 (10.9)
>34	1 (0.1)	12 (1.5)	13 (0.8)
missing	7 (0.9)	10 (1.2)	17 (1.1)
Ethnicity			
White background	711 (88.0)	714 (88.1)	1425 (88.1)
Mixed background	47 (5.8)	42 (5.2)	89 (5.5)
Asian background	16 (2.0)	11 (1.4)	27 (1.7)
Black background	31 (3.8)	40 (4.9)	71 (4.4)
Other background	3 (0.4)	3 (0.4)	6 (0.4)
Religion			
None	430 (53.2)	433 (53.5)	863 (53.3)
Christian	350 (43.3)	356 (44.0)	706 (43.6)
Muslim	22 (2.7)	18 (2.2)	40 (2.5)
Sikh	2 (0.2)	0 (0.0)	2 (0.1)
Any other religion	3 (0.4)	3 (0.4)	6 (0.4)
Not answered	1 (0.1)	0 (0.0)	1 (0.1)
Language usually spoken at home by participants			
English only	768 (95.0)	775 (95.7)	1543 (95.4)
English and other language	39 (4.8)	33 (4.1)	72 (4.4)
Other language(s) only	1 (0.1)	2 (0.2)	3 (0.2)
Country of birth			
England, Wales, Scotland, Northern Ireland	775 (95.9)	777 (95.9)	1552 (95.9)
Elsewhere	33 (4.1)	33 (4.1)	66 (4.1)
Relationship status with baby's father			
Married	9 (1.1)	11 (1.4)	20 (1.2)
Separated	79 (9.8)	86 (10.6)	165 (10.2)
Closely involved/boyfriend	613 (75.9)	609 (75.2)	1222 (75.5)
Just friends	107 (13.2)	104 (12.8)	211 (13.0)
Living with parents			
Both	181 (22.4)	171 (21.1)	352 (21.8)
One	318 (39.4)	349 (43.1)	667 (41.2)
Neither	309 (38.2)	290 (35.8)	599 (37.0)
Live with father of baby			
Yes	184 (22.8)	184 (22.7)	368 (22.7)
No	552 (68.3)	560 (69.1)	1112 (68.7)
Not answered	72 (8.9)	66 (8.1)	138 (8.5)
Number living in house with participant			
None	60 (7.4)	52 (6.4)	112 (6.9)
1 to 4	637 (78.8)	643 (79.4)	1280 (79.1)

	<b>Intervention N=808</b>	<b>Control N=810</b>	<b>Overall N=1618</b>
5 or more	99 (12.3)	101 (12.5)	200 (12.4)
Not answered	12 (1.5)	14 (1.7)	26 (1.6)
	<i>N=804</i>	<i>N=803</i>	
Family subjective social status	6.0	6.0	6.0
<i>Median (25th to 75th centile)</i>	(5.0 to 7.0)	(5.0 to 7.0)	(5.0 to 7.0)
	<i>N=804</i>	<i>N=807</i>	
Personal subjective social status*	7.0	7.0	7.0
<i>Median (25th to 75th centile)</i>	(6.0 to 8.0)	(6.0 to 8.0)	(6.0 to 8.0)
Parents ever permanently separated or divorced			
Yes	487 (60.3)	493 (60.9)	980 (60.6)
No	275 (34.0)	256 (31.6)	531 (32.8)
Parents never lived together	41 (5.1)	57 (7.0)	98 (6.1)
Never lived with parents/don't know	3 (0.4)	3 (0.4)	6 (0.4)
missing	2 (0.2)	1 (0.1)	3 (0.2)

\*1611 participants answered this question, seven chose not to answer

Table 3.13 Demographic balance at baseline by site: Age and ethnicity

Site	Participants recruited N (%)	Age (years) Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	Ethnicity N (%)				
			White	Mixed	Asian	Black	Other
25	150 (9.3)	17.7 (16.8 to 18.6)	145 (96.7)	4 (2.7)	0 (0.0)	1 (0.7)	0 (0.0)
4	143 (8.8)	18.2 (17.2 to 19.0)	117 (81.8)	14 (9.8)	2 (1.4)	8 (5.6)	2 (1.4)
27	142 (8.8)	17.9 (17.2 to 18.9)	134 (94.4)	4 (2.8)	1 (0.7)	3 (2.1)	0 (0.0)
28	139 (8.6)	17.7 (16.5 to 18.6)	125 (89.9)	11 (7.9)	0 (0.0)	3 (2.2)	0 (0.0)
30	133 (8.2)	18.4 (17.3 to 19.3)	131 (98.5)	1 (0.8)	0 (0.0)	0 (0.0)	1 (0.8)
29	117 (7.2)	17.8 (16.9 to 18.6)	96 (82.1)	14 (12.0)	2 (1.7)	5 (4.3)	0 (0.0)
10	113 (7.0)	17.7 (16.9 to 18.5)	103 (91.2)	8 (7.1)	0 (0.0)	2 (1.8)	0 (0.0)
21	115 (7.1)	18.1 (17.0 to 18.8)	108 (93.9)	3 (2.6)	0 (0.0)	4 (3.5)	0 (0.0)
23	99 (6.1)	18.1 (17.3 to 19.0)	99 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
24	93 (5.7)	17.7 (16.8 to 18.5)	91 (97.8)	1 (1.1)	1 (1.1)	0 (0.0)	0 (0.0)
22	68 (4.2)	18.1 (17.2 to 19.2)	67 (98.5)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
7	54 (3.3)	17.7 (16.9 to 18.7)	53 (96.3)	2 (3.7)	0 (0.0)	0 (0.0)	0 (0.0)
2	49 (3.0)	17.8 (16.9 to 18.5)	42 (85.7)	6 (12.2)	1 (2.0)	0 (0.0)	0 (0.0)
9	47 (2.9)	17.9 (17.1 to 18.4)	20 (42.6)	5 (10.6)	18 (38.3)	4 (8.5)	0 (0.0)
1	43 (2.7)	17.7 (16.7 to 18.9)	41 (95.3)	2 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)
5	39 (2.4)	18.3 (17.5 to 19.1)	35 (89.7)	2 (5.1)	2 (5.1)	0 (0.0)	0 (0.0)
8	39 (2.4)	17.5 (16.6 to 18.5)	14 (35.9)	6 (15.4)	0 (0.0)	17 (43.6)	2 (5.1)
26	35 (2.2)	17.6 (16.9 to 18.5)	5 (14.3)	5 (14.3)	0 (0.0)	24 (68.6)	1 (2.9)
<b>Total</b>	<b>1618</b>	<b>17.9 (16.9 to 18.9)</b>	<b>1425 (88.1)</b>	<b>89 (5.5)</b>	<b>27 (1.7)</b>	<b>71 (4.4)</b>	<b>6 (0.4)</b>

\*Sorted by percentage of participants recruited to the trial

### 3.3.2 Socio-economic characteristics at baseline

Of those women aged 16 years or older at the end of the previous academic year, most were either in education, employment or training (Table 3.14). For women reporting being in work, the majority were employed in regular part-time jobs. 314 women reported that they had been homeless at some time, 19.4% of all eligible women recruited to trial. There appears to be a balance in the socio-economic characteristics between trial arms, with only small differences observed. Table 3.15 shows the variation in NEET status by site with the lowest rates being 19.1% and the highest 48.6%.

Table 3.14 *Socio-economic characteristics at baseline by trial arm. Values are N (%) unless otherwise stated.*

	Intervention N=808	Control N=810	Overall N=1618
NEET status*	N=397	N=387	N=1384
Yes	333 (47.8)	330 (48.0)	663 (47.9)
No	362 (51.9)	355 (51.7)	717 (51.8)
missing	2 (0.3)	2 (0.3)	4 (0.3)
Has a paid job:			
Yes	174 (21.5)	164 (20.2)	338 (20.9)
No	634 (78.5)	646 (79.8)	1280 (79.1)
Nature of paid jobs†			
Regular and full-time	72 (41.4)	60 (36.6)	132 (39.1)
Regular and part-time	86 (49.4)	92 (56.1)	178 (52.7)
Occasional / casual work	16 (9.2)	12 (7.3)	28 (8.3)
In receipt of benefits			
Yes	301 (37.3)	283 (34.9)	584 (36.1)
No	507 (62.7)	525 (64.9)	1032 (63.8)
missing	0 (0.0)	2 (0.2)	2 (0.1)
Other financial support apart from benefits or paid work			
Yes	399 (49.4)	360 (44.4)	759 (46.9)
No	409 (50.6)	450 (55.6)	859 (53.1)
Ever been homeless			
Yes	144 (17.8)	170 (21.0)	314 (19.4)
No	664 (82.2)	640 (79.0)	1304 (80.6)
Socio-economic status: Index of Multiple Deprivation Score‡	N=802	N=804	
<i>Median (25th to 75th centile)</i>			
Overall IMD score§	38.3 (24.9 to 52.3)	38.2 (25.5 to 51.6)	38.2 (25.2 to 52.0)
IMD quintile			
1= least deprived	168 (20.8)	154 (19.0)	322 (19.9)
2	162 (20.0)	160 (19.8)	322 (19.9)
3	157 (19.4)	163 (20.1)	320 (19.8)
4	147 (18.2)	175 (21.6)	322 (19.9)
5=most deprived	168 (20.8)	152 (18.8)	320 (19.8)
Missing	6 (0.7)	6 (0.7)	12 (0.7)
Highest parental qualification			
Up to Post-graduate	108 (13.4)	111 (13.7)	219 (13.5)
Up to A-level	172 (21.3)	176 (21.7)	348 (21.5)
Overseas or other qualifications	79 (9.8)	80 (9.9)	159 (9.8)
None of these	130 (16.1)	129 (15.9)	259 (16.0)
Don't know	316 (39.1)	314 (38.8)	630 (38.9)
Not answered	3 (0.4)	0 (0.0)	3 (0.2)

\* Definition of NEET status: Not in education employment or training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)

† Question only asked to participants who had a paid job (N=338)

‡ Higher IMD score indicated more deprivation

§ Mean IMD Score for England in 2010 is 21.67<sup>142</sup>

|| IMD quintiles are based on equal participants in each group

Table 3.15 *Baseline NEET status by site\**

Site †	NEET status: Yes N (%)
25	65 (51.2)
27	72 (57.6)
4	67 (54.5)
28	44 (40.4)
30	52 (43.7)
29	46 (48.4)
21	51 (51.5)
10	47 (51.1)
23	41 (46.1)
24	39 (52.7)
22	14 (22.2)
7	24 (50.0)
2	19 (43.2)
9	27 (61.4)
1	20 (55.6)
8	14 (43.8)
5	11 (30.6)
26	10 (34.5)
Total	<b>663 (47.9)</b>

\* applicable only to those whose age at end of previous academic year at time of baseline interview was >16

† Sorted by percentage of participants recruited to the trial

### 3.3.3 Maternal health and well-being

Participants were asked to self-report at baseline about their maternal health and well-being. There was good balance on most reported variables (Table 3.16). Overall the majority of women were in full health (63.7%). Nevertheless, 17% of women reported they had a limiting long-term illness and over half of these women stated that the illness limited their activities. Around 14% of women stated that their pregnancy was planned and these women were on average older than those stating that their pregnancy was a surprise. BMI was balanced between arms as were the psychological variables. The proportion of women in less than full health varied across sites from 13.5% to 68.6%.

Table 3.16 *Maternal health and well-being reported at baseline by trial arms.*

Values are N (%) unless otherwise stated.

	<b>Intervention N=808</b>	<b>Control N=810</b>	<b>Overall N=1618</b>
General health status (EQ5D)	1.00	1.00	1.00
<i>Median (25th to 75th centile)</i>	(0.80 to 1.00)	(0.85 to 1.00)	(0.81 to 1.00)
EQ5D-Binary			
Full health*	518 (64.1)	512 (63.2)	1030 (63.7)
Not in full health	290 (35.9)	295 (36.4)	585 (36.2)
missing	0 (0.0)	3 (0.4)	3 (0.2)
Self-rated health			
Excellent	159 (16.0)	134 (16.5)	263 (16.3)
Good	530 (65.6)	555 (68.5)	1085 (67.1)
Fair	142 (17.6)	110 (13.6)	252 (15.6)
Poor	7 (0.9)	11 (1.4)	18 (1.1)
Limiting long-term illness:			
Yes	138 (17.1)	141 (17.4)	279 (17.2)
No	670 (82.9)	669 (82.6)	1339 (82.8)
Limits activities <sup>†</sup>			
Yes	79 (57.2)	78 (55.3)	157 (56.3)
No	59 (42.8)	63 (44.7)	122 (43.7)
Planned pregnancy:			
Yes	125 (15.5)	107 (13.2)	232 (14.3)
No	681 (84.3)	702 (86.7)	1384 (85.5)
missing	2 (0.2)	1 (0.1)	3 (0.2)
Body Mass Index (BMI)	22.6	22.3	22.5
<i>Median (25th to 75th centile)</i>	(20.2 to 25.6)	(20.2 to 25.8)	(20.2 to 25.7)
<b>BMI<sup>‡</sup></b>			
Underweight	27 (3.3)	26 (3.2)	53 (3.3)
Healthy	542 (67.1)	534 (65.9)	1076 (66.5)
Overweight	213 (26.4)	222 (27.4)	435 (26.9)
Missing	26 (3.2)	28 (3.5)	54 (3.3)
Psychological distress (score 10 to 50) <sup>§</sup>	20.0	20.0	20.0
<i>Median (25th to 75th centile)</i>	(16.0 to 26.0)	(16.0 to 26.0)	(16.0 to 26.0)
Generalized self-efficacy scale (score 10 to 40) <sup>  </sup>	30.0	30.0	30.0
<i>Median (25th to 75th centile)</i>	(28.0 to 33.0)	(27.0 to 32.0)	(28.0 to 33.0)
<b>Adaptive functioning</b>			
Difficulty in at least one basic skill			
Yes	230 (28.5)	200 (24.7)	430 (26.6)
No	577 (71.4)	608 (75.1)	1185 (73.2)
Missing	1 (0.1)	2 (0.2)	3 (0.2)
Had 3 or less life skills (out of 5)			
Yes	205 (25.4)	229 (28.3)	434 (26.8)

	<b>Intervention N=808</b>	<b>Control N=810</b>	<b>Overall N=1618</b>
No	599 (74.1)	579 (71.5)	1178 (72.8)
Missing	4 (0.5)	2 (0.2)	6 (0.4)
At least one burden			
Yes	228 (28.2)	248 (30.6)	476 (29.4)
No	573 (70.9)	558 (68.9)	1131 (69.9)
Missing	7 (0.9)	4 (0.5)	11 (0.7)

\* Full health is defined as a score 1 in EQ5D

† Question only asked to participants who had limiting long-term illness (N=279)

‡ Definition of BMI: Obese BMI >95th centile; Overweight BMI 85-95th centile; Underweight BMI <5th centile.

§ Higher score indicates higher level of distress

|| Higher score indicates higher level of self-efficacy

### 3.3.4 Health behaviour

Reported health behaviour at baseline is shown in Table 3.17. A high proportion of women reported that they had ever smoked (80%) with a median age of 13 years of first smoking. Of those who had ever smoked a high proportion had smoked at least 100 (84%). Current smoking status (yes or no) was used as a balancing factor in the randomisation and is reported in section 1.3. A high proportion of women reported that they had ever drunk alcohol (n=1,533, 95%), and of these women 339 reported drinking since they knew they were pregnant. Of the women who drank after learning of their pregnancy, 17% had drunk more than two alcoholic drinks in a day. A total of 29% had ever used illegal / street drugs with 11% of these still using drugs during their current pregnancy. A high proportion of women had used contraception before their current pregnancy (75%) with condoms and the contraceptive pill being the most widely used method (about 60% or more).

Table 3.17 Health behaviour at baseline by trial arm

	Intervention N=808	Control N=810	Overall N=1618
	N (%)	N (%)	N (%)
<b>Cigarette smoking</b>			
<b>Participant self-reported</b>			
Ever smoked			
Yes	648 (80.2)	643 (79.4)	1291 (79.8)
No	160 (19.8)	167 (20.6)	327 (20.2)
Age when first smoked*	N = 648	N = 643	
Median (25th to 75th centile)	13.0 (11.0 to 14.0)	13.0 (12.0 to 14.0)	13.0 (12.0 to 14.0)
Smoked at least 100*			
Yes	548 (84.4)	529 (82.4)	1077 (83.2)
No	99 (15.3)	113 (17.5)	212 (16.4)
Missing	2 (0.3)	4 (0.6)	6 (0.4)
<b>Cotinine adjusted smoking status</b>	N=759	N=766	N=1525
Yes	428 (56.4)	442 (57.7)	870 (57.1)
No	331 (43.6)	324 (42.3)	655 (42.9)
<b>CRAFFT†</b>	N = 770	N = 778	
Median (25th to 75th centile)	1 (0 to 2)	1 (0 to 2)	1 (0 to 2)
<b>Alcohol</b>			
Ever drunk alcohol			
yes	768 (95.0)	765 (94.4)	1533 (94.7)
no	40 (5.0)	45 (5.6)	85 (5.3)
During this pregnancy before you knew‡			
yes	513 (66.8)	484 (63.3)	997 (65.0)
no	254 (33.1)	281 (36.7)	535 (34.9)
missing	1 (0.1)	0 (0.0)	1 (0.1)
>2 alcoholic drinks in 1 day§			
Yes	377 (73.5)	352 (72.7)	729 (73.1)
no	134 (26.1)	130 (26.9)	264 (26.5)
missing	2 (0.4)	2 (0.4)	4 (0.4)
During this pregnancy since you found out‡			
yes	178 (23.2)	161 (21.0)	339 (22.1)
no	590 (76.8)	604 (79.0)	1194 (77.9)
missing	0 (0.0)	0 (0.0)	0 (0.0)
>2 alcoholic drinks in 1 day			
yes	30 (16.9)	28 (17.4)	58 (17.1)
no	148 (83.1)	133 (82.6)	281 (82.9)
missing	0 (0.0)	0 (0.0)	0 (0.0)
<b>Illegal/street drugs</b>			
Ever used: yes	232 (28.7)	233 (28.8)	465 (28.7)
During this pregnancy before you knew¶			
Yes	80 (34.5)	81 (34.8)	161 (34.6)
No	152 (65.5)	151 (64.8)	303 (65.2)
missing	0 (0.0)	1 (0.4)	1 (0.2)
During this pregnancy since you found out¶			
Yes	28 (12.1)	24 (10.3)	52 (11.2)
No	204 (87.9)	208 (89.3)	412 (88.6)
missing	0 (0.0)	1 (0.4)	1 (0.2)
<b>Antisocial behaviour Score (score 0-6)</b>	N = 805	N = 804	N=1609
Median (25th to 75th centile)	2.0 (1.0 to 4.0)	2.0 (1.0 to 4.0)	2.0 (1.0 to 4.0)
<b>Antisocial behaviour</b>			
Stolen			
Yes	222 (27.5)	215 (26.7)	437 (27.1)
No	582 (72.3)	587 (73.0)	1169 (72.7)
missing	1 (0.1)	2 (0.3)	3 (0.2)
Fights			
Yes	256 (31.8)	224 (27.8)	480 (29.8)
No	584 (68.1)	577 (71.8)	1125 (70.0)
missing	1 (0.1)	3 (0.4)	4 (0.2)
Police/arrested:			

	Intervention	Control	Overall
	N=808	N=810	N=1618
	N (%)	N (%)	N (%)
Yes	285 (35.4)	281 (34.9)	566 (35.2)
No	518 (64.4)	519 (64.6)	1037 (64.4)
missing	2 (0.2)	4 (0.5)	6 (0.4)
Truancy			
Yes	574 (71.3)	574 (71.4)	1148 (71.3)
No	230 (28.6)	228 (28.4)	458 (28.5)
missing	1 (0.1)	2 (0.2)	3 (0.2)
Run away over night			
Yes	250 (31.1)	225 (28.0)	475 (29.5)
No	553 (68.7)	577 (71.8)	1130 (70.3)
missing	2 (0.2)	2 (0.2)	4 (0.2)
Suspended/expelled/ excluded			
Yes	375 (46.6)	362 (45.0)	737 (45.8)
no	429 (53.3)	439 (54.6)	868 (54.0)
missing	1 (0.1)	3 (0.4)	4 (0.2)
<b>Contraception</b>			
Use before current pregnancy: yes	593 (73.4)	619 (76.4)	1212 (74.9)
Contraception type			
Condoms**	383 (64.6)	418 (67.5)	801 (66.1)
Contraceptive pill**	355 (59.9)	370 (59.8)	725 (59.8)
Emergency contraception**	115 (19.4)	129 (20.8)	244 (20.1)

\* Question only asked to participants who had ever smoked (N=1291, FNP=648, Usual care=643)

† Questions relating to drug and alcohol use. Only answered by women who have ever drunk alcohol and/or used drugs (N=1541, FNP=771, Usual care =770)

‡ Question only asked to participants who had ever drunk alcohol (N=1533)

§ Question only asked to participants who had drunk alcohol before found out they were pregnant (N=994)

|| Question only asked to participants who had drunk alcohol after found out they were pregnant (N=339)

¶ Question only asked to participants who had ever used illegal drugs (N=465)

\*\* Question only asked to participants who had used contraception before current pregnancy (N=1212)

### 3.3.5 Social support

Scores on social support variables appeared well balanced at baseline (Table 3.18). Participants reported high levels of social support, high levels of family resources and for those in a relationship, high levels of relationship quality.

Table 3.18 *Social support at baseline by trial arm*

	Intervention N=808	Control N=810	Overall N=1618
	Median (IQR)	Median (IQR)	Median (IQR)
Social support (score 0-100)*	N = 799 90.8 (77.6 to 98.7)	N = 804 90.8 (77.6 to 98.7)	90.8 (77.6 to 98.7)
Relationship quality ( <i>Golombok Rust Inventory of Marital State</i> ) (average score 1-5-) †	N = 637 4.0 (3.6 to 4.4)	N = 640 4.1 (3.6 to 4.6)	4.1 (3.6 to 4.6)
Family resources (average score 1-5) ‡	N = 775 3.5 (2.8 to 4.3)	N = 776 3.5 (2.8 to 4.3)	3.5 (2.8 to 4.3)

\* a higher score indicates higher social support

† a higher score indicating better relationship quality

‡ a higher score indicating more family resources

### 3.4 Completers at 24 month vs non completers

The characteristics of women completing the final interview assessment at 24 months and those not completing this assessment are compared in Table 3.19. Completers and non-completers (the latter including all withdrawn and non-responding women) were compared for a subset of variables that may potentially influence longer-term engagement (certain socio-demographic characteristics, self-efficacy and social competence, and health-related behaviour, specifically smoking). Although not tested statistically, some small differences seemed apparent. Those who completed included a higher proportion of women reporting that they were closely involved or the girlfriend of their baby's father (77.4% vs 71.4%), not living with the baby's father (70.3% vs 65.1%) and in education, employment or training (54.6% vs 45.3%). There were no other apparent differences for the other variables reported.

Table 3.19 Participants demographics by 24 month completion Values are N (%) unless otherwise stated

	24 month completed N=1122	24 month not completed N=496	Overall N=1618
<b>Demographic</b>			
Age at recruitment (years)	N=1122 17.9	N=496 17.8	17.8
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(16.9 to 18.8)	(16.9 to 18.7)	(16.9 to 18.8)
<b>Ethnicity</b>			
White background	1000 (89.1)	425 (85.7)	1425 (88.1)
Mixed background	61 (5.4)	28 (5.6)	89 (5.5)
Asian background	19 (1.7)	8 (1.6)	27 (1.7)
Black background	39 (3.5)	32 (6.5)	71 (4.4)
Chinese or Other background	3 (0.3)	3 (0.6)	6 (0.4)
<b>Relationship status with baby's father</b>			
Married	11 (1.0)	9 (1.8)	20 (1.2)
Separated	100 (8.9)	65 (13.1)	165 (10.2)
Closely involved/boyfriend	868 (77.4)	354 (71.4)	1222 (75.5)
Just friends	143 (12.7)	68 (13.7)	211 (13.0)
<b>Live with father of baby</b>			
Yes	253 (22.5)	115 (23.2)	368 (22.7)
No	789 (70.3)	323 (65.1)	1112 (68.7)
missing	80 (7.1)	58 (11.7)	138 (8.5)
<b>Socio-economic</b>			
<b>NEET status*</b>			
Yes	N=973 440 (45.2)	N=411 223 (54.3)	N=1384 663 (47.9)
No	531 (54.6)	186 (45.3)	717 (51.8)
missing	2 (0.2)	2 (0.5)	4 (0.3)
<b>Socio-economic status: Index of Multiple Deprivation Score<sup>†</sup></b>			
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)			
Overall IMD score <sup>‡</sup>	N=1111 38.8	N=495 40.0	39.1
	(24.4 to 52.0)	(27.8 to 52.0)	(25.1 to 52.0)
<b>Maternal health and well-being</b>			
<b>Generalized self-efficacy scale</b>			
(score 10 to 40) <sup>§</sup>	N=1104 30.1	N=488 29.7	30.0
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(28.0 to 33.0)	(27.0 to 32.0)	(28.0 to 33.0)
<b>Adaptive functioning</b>			
<b>Difficulty in at least one basic skill</b>			
Yes	274 (24.4)	156 (31.5)	430 (26.6)
No	847 (75.5)	338 (68.1)	1185 (73.2)
missing	1 (0.1)	2 (0.4)	3 (0.2)
<b>Had 3 or less life skills (out of 5)</b>			
Yes	276 (24.6)	158 (31.9)	434 (26.8)
no	843 (75.1)	335 (67.5)	1178 (72.8)
missing	3 (0.3)	3 (0.6)	6 (0.4)
<b>At least one burden</b>			
Yes	336 (29.9)	140 (28.2)	476 (29.4)
No	777 (69.3)	354 (71.4)	1131 (69.9)
missing	9 (0.8)	2 (0.4)	11 (0.7)
<b>Health behaviour</b>			
<b>Smoking (Participant self-reported)</b>			
Ever smoked: yes	896 (79.9)	398 (80.2)	1294 (80.0)
no	226 (20.1)	98 (19.8)	324 (20.0)

	<b>24 month completed N=1122</b>	<b>24 month not completed N=496</b>	<b>Overall N=1618</b>
missing	0	0	0

\* Definition of NEET status: Not in education employment or training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)  
† Higher IMD score indicated more deprivation  
‡ Mean IMD Score for England in 2010 is 21.67 Wilkinson, Dawn Louise, Falko F. Sniehotta, and Susan Michie. "Targeting those in need: Baseline data from the first English National Health Service (NHS) Health Trainer Service." *Psychology, health & medicine* 16.6 (2011): 736-748.  
§ Higher score indicates higher level of self-efficacy

### 3.5 Representativeness of the participants randomised to trial Intervention arm

To assess whether women allocated to the intervention were similar to women who are currently being enrolled into FNP across sites in England we have compared baseline demographic characteristics using summary data sourced from the FNP IS. Aggregate data for non-trial FNP clients enrolled to the programme from the 1st January 2010 to the 31st of December 2013 were obtained for both non-trial sites (n=8,755) and trial sites outside of the trial recruitment phase (n=3,311). Note that the data reported are FNP management data, which is why we are only comparing Intervention arm trial participants to non-trial participants. These data are also therefore not directly comparable to data presented elsewhere in this chapter (for example, smoking data at baseline). The three groups are similar in terms of mean maternal age at enrolment. Mean weeks gestation at enrolment was slightly higher for trial clients than for women enrolled at non-trial sites, but slightly lower than the mean gestation for non-trial clients enrolled at trial sites. The proportion of women enrolled by 16 weeks gestation was similar in both trial (39.7%) and non-trial (41.6%) clients at trial sites and in both cases lower than that achieved at non-trial sites (48.9%). Whilst the proportion of ethnically white women was slightly higher amongst trial clients than in non-trial site clients (85.5% and 82.9% respectively), it was lower amongst non-trial clients enrolled at trial sites (77.5%). The proportion of women not in education, employment or training was higher amongst trial clients (68.1%) than non-trial clients at the same sites (60.5%), and also higher than that found for non-trial site clients (63.3%). Note that for trial clients these rates are higher than those reported earlier when using trial data possibly reflecting a difference in methods of data collection. Rates of recent smoking recorded at intake were also highest for trial clients (40.8%) compared to non-trial clients at the same sites (32.9%) and at non-trial sites (34.0%). Finally, there were also small differences in rates of data recording (relationship status, living arrangements and recent smoking) between trial clients and non-trial clients (at both trial and non-trial sites) with slightly higher rates for trial clients.

Table 3.20 FNP client characteristics at enrolment: Comparison of Building Blocks clients, non-trial clients (from trial sites) and non-trial clients (from non-trial sites)

	FNP Clients RCT N=718*	FNP Programme non-RCT (RCT sites only) N=3311	FNP Programme non-RCT (non RCT sites only) N=8755
Mean age	17.4	17.2	17.3
Mean gestation at enrolment	17.9	18.2	17.4
Mean gestation at birth (weeks)	39.4	39.2	39.1
Premature infants (%)	7.5	7.8	7.4
Enrolled by 16 weeks gestation (%)	39.7	41.6	48.9
Ethnicity (%)			
White background	85.5	77.5	82.9
Mixed background	5.7	5.0	5.0
Asian background	2.1	3.4	1.4
Black background	3.6	7.1	4.9
Other background	0.4	1.7	1.2
missing	2.7	5.3	4.6
NEET (16+ only) (%)	68.1	60.5	63.3
Relationship status (%)			
With a current partner	79.5	76.6	76.4
With biological father of child	100	95.0	95.9
Relationship status recorded	97.4	94.8	95.5
Living (%)			
Living with own mother not including husband/partner	45.0	43.8	45.1
Living with own mother including husband/partner	10.2	8.5	8.7
Living with other adults	9.5	9.3	9.6
Living with foster parents	1.4	1.5	1.2
Living with husband/partner only	11.0	10.4	10.5
Living with husband/partner and others (not own mother)	7.8	6.7	7.4
Living alone	6.8	7.3	6.5
Living in a group home/shelter	4.3	5.1	4.7
Homeless	1.8	2.1	1.7
Living arrangements recorded	97.8	94.8	95.4
Smoking at intake			
Smoked in last 48 hours (%)	40.8	32.9	34.0
Smoked in last 48 hours recorded (%)	96.1	93.3	92.8
Mean number of cigarettes/smoked in last 48 hours	4.5	4.2	4.2

\*718 clients included, 3 could not be included in the dataset from the FNP IS as they did not have any recorded data.

## 3.6 FNP dosage

### 3.6.1 Defining valid FNP visits from dosage data

A Core Model Element of FNP is that the Family Nurse should follow the FNP home visit guidelines, including the frequency and timing of visits. Information on each visit was recorded by a Family Nurse on a home visit encounter (UK001) form which detailed the date of the visit, length of the visit, whether it was a scheduled or ad hoc visit, the percentage of time spent on each content domain covered, and a client involvement score. The criteria for identifying only valid visits were established in consultation with the FNP National Unit (Table 3.21). The same criteria were then used to compare valid visits for trial enrolled clients and non-trial enrolled clients.

Table 3.21 *Criteria for valid FNP visits*

Criteria for valid visits	Details	Record field
UK001 visit form is completed	Any forms that are overdue, incomplete, returned, corrected or no longer required are not valid	Record_status 3 = 'complete'
Visit is completed	Any visits recorded on the FNP IS as either attempted or cancelled are not valid.	Visits_Status_Id 0 = 'completed'
Longer than 15 minutes	Visits shorter than 15 minutes duration are not valid.	DATE_TO - DATE_FROM)/60
Client is present	Visits without a client present are not valid, unless the father is present and is listed as main carer.	Client_Involvement 1-5 = 'client was present'.
First scheduled visit of the day	Only the first scheduled visit of the day is valid. Any subsequent scheduled visits are not included.	ADHOC_OR_SCHEDULED Scheduled

### 3.6.2 Valid visits in the Building Blocks cohort

The dataset provided by the FNP national unit contained 37,850 visits for all the women recruited to the Building Blocks study (irrespective to what arm they were randomised to). A total of 9,504 records (25.1%) were excluded using the criteria given (Table 3.22). A further 493 visits were excluded from participants randomised to the Control arm, participants assessed as ineligible after recruitment into the Intervention arm, and visits that occurred after the participant withdrew from BB (but not from FNP). The 27,853 valid visits were provided by 106 Family Nurses and 25 supervisors.

Table 3.22 *Reasons for non-valid visits*

Reason for a non-valid visit	Excluded visits: n (%)
UK001 form was not completed	12 (0.1)
Visits were not completed	8,887 (93.5)
Visits were < 15 minutes duration	62 (0.7)
Visits were without a client present	284 (3.0)
Visits were scheduled and subsequent to another scheduled visit	259 (2.7)
Total	9,504 (100)

*Note: Visits were excluded using the above hierarchy and visits may have qualified to be excluded under more than one reason*

### 3.6.3 Schedule of expected and actual visits by phase

The planned schedule of FNP visits is shown in Table 3.23. For example, in the pregnancy phase, based on the assumption that clients are enrolled by 16 weeks gestation the programme should be delivered weekly for the first four weeks and then fortnightly until the baby's birth. For each participant the actual and expected number of visits are calculated for each phase. The number of visits expected in each phase is based on the time between two events and the schedule. For example, in the infancy phase, 28 visits are expected if the client stays in the programme between when the child was born and their first birthday. The number of expected visits will only vary if the client leaves the programme (withdrawal) before the end date for that phase. The expected visits in the pregnancy phase will also vary depending on when the participant was recruited and when their child was born.

The number of actual visits a client received was calculated by counting the number of valid visits as recorded on the visit encounter form. The fidelity goals for the amount of programme that should be delivered during each phase is that 80% of expected visits should be made in the pregnancy phase, 65% in the infancy phase and 60% in the toddlerhood phase.

Table 3.23 Schedule of FNP visits

Phase	Schedule	Number of visits	Maximum expected visits in phase	Start and end point / date for each phase
Pregnancy Manual visits 1-14	1 visit per week during the first month following recruitment, 16-19 weeks gestation	4	14	Date of enrolment into FNP and infant's date of birth (DoB).
	Every other week during pregnancy	10		
Infancy Manual visits 1-28	1 visit per week for the first 6 weeks after birth	6	28	Infant's DoB and the day before 1st birthday
	Every other week to 1st birthday	22		
Toddler Manual visits 29-50	Every other week to 21 months	18	22	Infants 1st and 2nd birthday
	Once a month to 2nd birthday	4		
<b>Total</b>		<b>64</b>	<b>64</b>	

### 3.6.4 Number of valid visits received

Of the 808 women randomised to start the FNP programme (and hence who should have received at least one visit), 89 (11%) did not subsequently enrol for FNP and are excluded from the analysis. For the remaining 719 (89%) who were randomised to FNP and enrolled, 716 had received at least one valid visit (with a total of 27,853 valid visits) and three women had received no valid visits (but had at least one non-valid visit)(Table 3.24). The following analysis will be based on these 719 participants. Three women had no valid visits during the pregnancy phase. For the infancy and toddler phase, a greater number of participants had zero visits (28 (3.9%) and 81 (11.3%)) respectively.

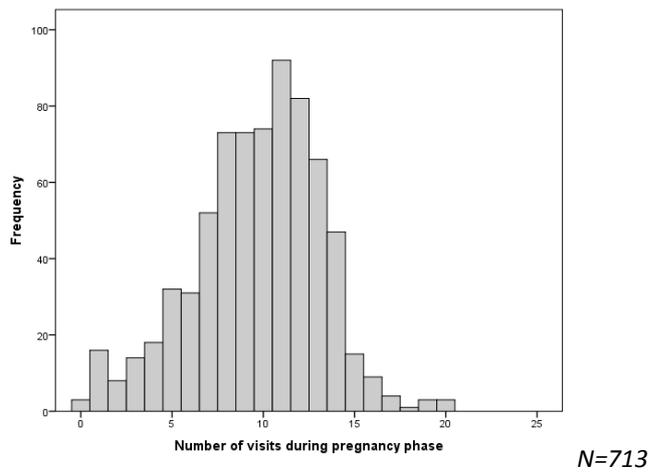
Table 3.24 Valid visits per phase

	Pregnancy phase	Infancy phase	Toddlerhood phase
N women	719	719	719
N (%) women receiving at least one valid visit	713 (99.2%)	669 (93.0%)	606 (84.3%)
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile) valid visits received	10 (8 to 12)	19 (14.5 to 22)	13 (8 to 16)
Mean (sd) valid visits received	9.71 (3.45)	18.63 (6.04)	13.22 (1.49)
Range valid visits received	0 to 20	0 to 44	0 to 37
N (%) women not receiving a single valid visit N (%)	6* (0.8%)	28 (3.9%)	81 (11.3%)
N (%) withdrew in previous phase	NA	22 (3.1%)	32 (4.5%)

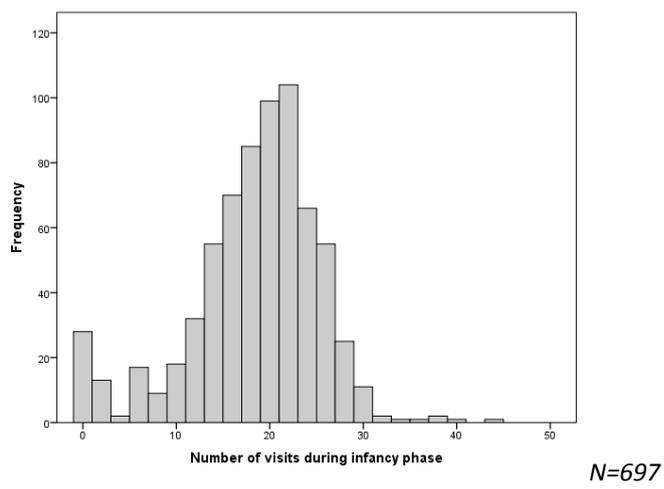
\* n=3 that had no valid visits in any of the phases; n=3 had no valid visits in the pregnancy phase only

FIGURE 3.5 HISTOGRAMS OF VALID VISITS RECEIVED PER PHASE

(a) *Pregnancy phase*



(b) *Infancy phase*



(c) *Toddler phase*

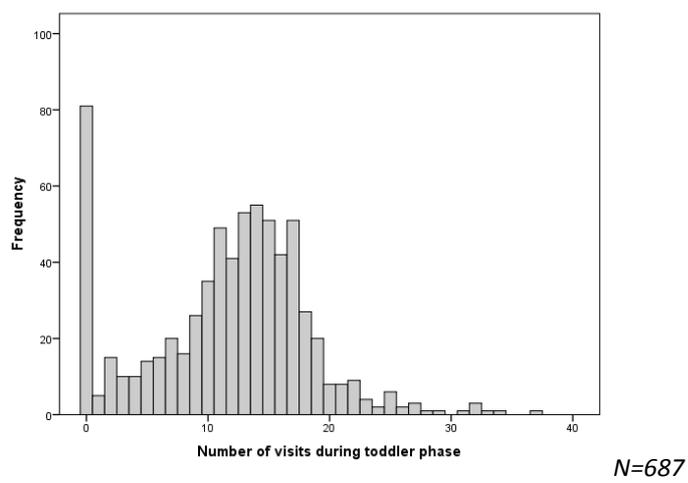


Table 3.25 Number of visits received by phase and site – median visits, % zero visits

Site ID	Number of visits received						Total N women
	Pregnancy phase		Infancy phase		Toddlerhood phase		
	Median number of visits*	N (% zero visits)	Median number of visits*	N (% zero visits)	Median number of visits*	N (% zero visits)	
1	9	0 (0)	16	0 (0)	15	4 (4.9)	21
2	9	0 (0)	19	2 (7.1)	13	5 (6.2)	25
4	10	0 (0)	19	3 (10.7)	15	7 (8.6)	63
5	12	0 (0)	22	1 (3.6)	15	2 (2.5)	19
7	12	0 (0)	23	0 (0)	11	5 (6.2)	26
8	9	0 (0)	16	1 (3.6)	11	3 (3.7)	16
9	11	1 (16.7)	20	0 (0)	13	6 (7.4)	21
10	10	4 (66.7)	18	3 (10.7)	14	3 (3.7)	48
21	10	0 (0)	20	1 (3.6)	12	3 (3.7)	44
22	10	0 (0)	21	1 (3.6)	14	6 (7.4)	32
23	10	0 (0)	20	1 (3.6)	14	6 (7.4)	49
24	8	1 (16.7)	17	1 (3.6)	13	6 (7.4)	41
25	8	0 (0)	18	4 (14.3)	12	12 (14.8)	67
26	11	0 (0)	22	1 (3.6)	14	3 (3.7)	16
27	10	0 (0)	18	4 (14.3)	13	5 (6.2)	59
28	11	0 (0)	20	0 (0)	14	5 (6.2)	62
29	10	0 (0)	20	1 (3.6)	13	4 (4.9)	55
30	11	0 (0)	21	4 (14.3)	15	5 (6.2)	55
<b>Total</b>	<b>10</b>	<b>6</b>	<b>19</b>	<b>28</b>	<b>13</b>	<b>81</b>	<b>719</b>

\*For those who had a visit

### 3.6.5 Support delivered (expected visits received)

The expected number of visits was calculated for all women who, at the start of each phase, had enrolled on to (for the pregnancy phase) or were still in the trial (had not withdrawn from the trial before the baby's date of birth (infancy phase) or the baby's first birthday (toddler phase)). There are three cohorts of women described with regards to their visit dosage. The first contains all women who started the pregnancy phase, the second excludes those who withdrew from the trial within the pregnancy phase (before the child was born), and the third cohort is based on women who withdrew from the trial within the pregnancy or the infancy phase. This is to give an optimal picture based on possibly the more engaged clients. Of the 716 clients who started the pregnancy phase, 413 (57.7%) received 80% or more of their expected visits during the pregnancy phase. For those who completed the pregnancy phase (n=694), 411 (59.2%) received 80% or more of their expected visits during that phase.

Table 3.26 Distribution of the percentage of expected visits received (max 14 visits\*) for the pregnancy phase

Percentage of all expected visits	All enrolled clients who started the pregnancy phase		All enrolled clients completing the pregnancy phase <sup>†</sup>	
	N (%)	Cumulative %	N (%)	Cumulative %
<10%	9 (1.3)	1.3	8 (1.2)	1.2
10-19%	12 (1.7)	2.9	9 (1.3)	2.4
20-29%	13 (1.8)	4.7	10 (1.4)	3.9
30-39%	13 (1.8)	6.6	8 (1.2)	5.0
40-49%	30 (4.2)	10.8	30 (4.3)	9.4
50-59%	44 (6.1)	16.9	43 (6.2)	15.6
60-69%	77 (10.8)	27.7	72 (10.4)	25.9
70-79%	105 (14.7)	42.3	103 (14.8)	40.8
80-89%	146 (20.4)	62.7	144 (20.7)	61.5
90-100%	175 (24.4)	87.2	175 (25.2)	86.7
101-120%	67 (9.4)	96.5	67 (9.7)	96.4
121+%	25 (3.5)	100.0	25 (3.6)	100.0
<b>Total</b>	<b>716 (100.0)</b>		<b>694 (100.0)</b>	
<b>N (%) reaching fidelity goal of 80% +</b>	<b>413 (57.7)</b>		<b>411 (59.2)</b>	

\* Expected visits take into account gestation at intake and leaving the programme

† Excludes women who withdrew before the baby was born (N=22)

A total of 370 (53.1%) of the 697 participants commencing the infancy phase received 65% or more of expected visits for that period. For the 687 women completing the phase, 368 (53.6%) received 65% or more of expected visits.

Table 3.27 Distribution of the percentage of expected visits received for the infancy phase

N (%) of all expected visits	All clients starting the infancy phase		All clients completing the infancy phase*	
	N (%)	Cumulative %	N (%)	Cumulative %
<10%	40 (5.7)	5.7	35 (5.1)	5.1
10-19%	11 (1.6)	7.3	11 (1.6)	6.7
20-29%	16 (2.3)	9.6	16 (2.3)	9.0
30-39%	28 (4.0)	13.6	28 (4.1)	13.1
40-49%	47 (6.7)	20.4	46 (6.7)	19.8
50-59%	101 (14.5)	34.9	99 (14.4)	34.2
60-69%	134 (19.2)	54.1	134 (19.5)	53.7
70-79%	155 (22.2)	76.3	153 (22.3)	76.0
80-89%	100 (14.3)	90.7	100 (14.6)	90.5
90-100%	46 (6.6)	97.3	46 (6.7)	97.2
101-120%	13 (1.9)	99.1	13 (1.9)	99.1
121+%	6 (0.9)	100.0	6 (0.9)	100.0
<b>Total</b>	<b>697 (100.0)</b>		<b>687 (100.0)</b>	
<b>N (%) reaching fidelity goal of 65% +</b>	<b>370 (53.1)</b>		<b>368 (53.6)</b>	

\* Excludes participants who withdrew in the infancy phase (N=10)

A total of 299 (43.5%) of the 684 participants commencing the toddlerhood phase received 60% or more of expected visits for that period. For the 681 participants completing the phase, 298 (43.8%) received 60% or more of expected visits.

Table 3.28 *Distribution of the percentage of expected visits received for the toddler phase*

N (%) of all expected visits	All clients starting the toddler phase		All enrolled clients completing the toddler phase*	
	N (%)	Cumulative %	N (%)	Cumulative %
<10%	100 (14.6)	14.6	97 (14.2)	14.3
10-19%	21 (3.1)	17.6	19 (2.8)	16.8
20-29%	29 (4.2)	21.8	29 (4.3)	21.1
30-39%	36 (5.2)	27.1	36 (5.3)	26.4
40-49%	60 (8.7)	35.8	60 (8.8)	35.3
50-59%	142 (20.7)	56.5	142 (20.9)	56.2
60-69%	100 (14.6)	71.0	99 (14.5)	70.8
70-79%	96 (14.0)	85.0	96 (14.1)	85.0
80-89%	50 (7.3)	92.3	50 (7.3)	92.2
90-100%	27 (3.9)	96.2	27 (4.0)	96.2
101-120%	14 (2.0)	98.3	14 (2.1)	98.2
121+%	12 (1.7)	100.0	12 (1.8)	100.0
<b>Total</b>	<b>684 (100.0)</b>		<b>681 (100.0)</b>	
N (%) reaching fidelity goal of 60% +	<b>299 (43.5)</b>		<b>298 (43.8)</b>	

\* Excludes participants who withdrew in the toddler phase (N=3)

### 3.6.6 Content and duration of visits

The proportion of visit time attributed by the Family Nurses to each of the five content domains is shown by trial site for each phase in Tables 3.29 to 3.31. Each Table describes the target range of coverage for each domain and the mean duration reported. For the pregnancy phase, Personal Health and Life Course were within their target range, Maternal role, Family and Friends and Environmental health were all somewhat higher than the indicated range. For the Infancy phase, Life course and Family and Friends were within the target ranges, whereas Personal Health and Environmental Health were in excess of the target ranges and Maternal Role was below the indicated range. In the Toddlerhood phase, the mean proportion of time spent on Maternal health was within target, there were small deviations from target for Personal Health, Life Course and Family and friends, and Environmental health. For each phase of delivery, mean reported visit duration was substantially longer than the 60 minutes target (79.14, 73.18 and 74.77 mins) for the three phases respectively. Mean visit durations also varied considerably by sites, for example, from 68.4 mins in one site (55 clients) and 90.0 mins in another site (32 clients) during the pregnancy phase.

Table 3.29 Nature of visits completed during pregnancy for all clients enrolled in the study (N=716)

Site	N	Personal health		Maternal role		Life course		Family and friends		Environmental health		Visit length	
Target		35-40%		23-25%		10-15%		10-15%		5-7%		60 minutes	
		Mean	sd	Mean	sd	Mean	sd	Mean	sd	Mean	sd	Mean	sd
1	22	28.42	9.3	24.13	3.51	15.82	5.14	17.13	3.39	15.47	5.31	74.14	17.92
2	24	31.29	10.67	29.33	9.54	10.88	2.97	16.28	11.93	12.22	3.75	76.82	21.16
4	63	39.7	6.29	23.17	5.79	11.23	4	13.99	3.32	12.9	3.97	79.52	11.6
5	19	36.91	3.48	28.04	2.46	10.9	1.31	14.42	2.13	9.73	2.66	77.83	10.71
7	26	24.2	5.46	23.76	4.45	17.69	4.56	20.11	2.53	17.43	4.34	85.44	8.36
8	16	33.77	4.12	30.31	4.28	11.87	2.23	13.85	2.09	10.47	2.26	74.87	6.34
9	20	25.23	4.14	32.15	6.66	14.7	3.78	13.58	2.41	14.33	4.13	76.03	16.66
10	47	36.92	4.4	26.59	3.25	13.13	2.79	13.65	2.67	9.77	4.35	72.78	5.66
21	44	36.07	9.16	23.26	4.85	12.04	4.52	16.6	4.03	12.86	4.51	84	13.91
22	32	34.96	3.85	26.05	3.36	13.67	2.35	13.72	3.43	12.02	3.54	90.03	11.55
23	49	36.47	5.02	26.42	3.97	10.32	2.48	16.23	3.68	11.24	3.84	86.1	16.71
24	40	34.87	4.08	27.51	6.47	11.83	2.96	14.21	3.51	12.28	4.73	87.2	12.14
25	67	30.48	8.3	26.91	6.4	13.01	5.09	17.44	4.55	13.54	4.96	81.34	12.18
26	16	28.45	5.74	22.66	4.47	15.47	2.98	18.41	3.8	15.26	4.27	78.16	9.89
27	59	34.64	7.91	25.36	4.4	11.9	3.85	15.36	3.62	13.53	4.32	77.86	13.42
28	62	36.07	6.73	27.66	4.57	12.77	3.24	14.09	2.73	11.25	4.11	76.46	12.07
29	55	28.49	8.34	24.81	6.79	17.42	6.15	19.63	4.12	17.72	4.6	68.4	10.84
30	55	35.37	5.93	25.58	3.44	12.72	1.51	15.1	2.57	11.63	3.37	77.13	12.87
<b>Total</b>	<b>716</b>	<b>33.74</b>	<b>7.83</b>	<b>26.01</b>	<b>5.55</b>	<b>12.99</b>	<b>4.29</b>	<b>15.74</b>	<b>4.42</b>	<b>12.93</b>	<b>4.68</b>	<b>79.14</b>	<b>13.78</b>

Table 3.30 Nature of visits completed during infancy for all clients enrolled in the study (N=697)

Site	N	Personal health		Maternal role		Life course		Family and friends		Environmental health		Visit length	
Target		14-20%		45-50%		10-15%		10-15%		7-10%		60 minutes	
		Mean	sd	Mean	sd	Mean	sd	Mean	sd	Mean	sd	Mean	sd
1	20	22.85	4.10	34.01	7.00	13.83	3.38	15.65	3.51	14.51	3.33	68.15	9.65
2	24	20.81	3.95	41.14	7.83	12.18	3.50	13.12	2.71	12.74	3.44	71.34	15.28
4	59	23.46	6.37	40.91	5.68	11.14	3.17	13.35	3.31	12.14	3.64	79.60	9.42
5	19	18.35	2.26	44.13	1.81	11.86	1.86	14.17	2.19	11.71	1.64	77.23	9.76
7	26	19.52	2.56	27.35	5.15	17.94	2.83	19.33	3.17	18.59	2.15	81.08	6.73
8	16	21.81	2.39	45.26	3.09	10.68	1.56	12.07	2.29	10.19	.74	69.28	7.85
9	20	21.90	3.93	35.64	2.87	14.84	1.96	14.43	3.07	14.18	2.32	74.10	11.94
10	46	21.21	4.66	40.87	3.18	12.98	2.97	12.24	2.11	12.96	2.77	67.69	6.22
21	44	22.92	7.53	42.27	7.95	10.42	3.19	15.02	4.01	11.69	4.17	71.88	9.97
22	32	21.37	3.80	39.85	8.16	13.20	2.32	13.00	1.86	13.43	3.42	78.82	6.90
23	48	22.41	5.05	42.91	5.13	9.30	3.31	16.02	3.34	10.47	3.83	79.47	9.85
24	40	20.74	6.57	40.10	12.53	12.19	3.77	14.22	4.81	12.87	4.11	82.82	13.91
25	65	20.21	4.47	39.83	9.83	12.34	4.14	16.98	4.75	12.93	4.23	71.63	12.31
26	13	21.20	2.38	31.93	4.78	16.70	1.81	15.13	1.69	15.29	2.63	72.90	10.66
27	57	21.75	3.81	39.96	6.65	12.22	3.03	13.77	3.20	12.95	3.90	69.46	11.16
28	62	22.86	4.70	42.60	4.82	12.52	3.12	12.35	2.63	12.97	4.59	70.13	11.49
29	54	23.07	7.41	38.39	11.56	14.81	4.47	16.92	3.67	17.34	3.62	63.44	10.05
30	52	21.51	2.96	45.02	5.53	10.92	1.65	12.67	2.69	10.60	1.38	72.83	8.81
<b>Total</b>	<b>697</b>	<b>21.77</b>	<b>5.14</b>	<b>40.26</b>	<b>8.17</b>	<b>12.43</b>	<b>3.69</b>	<b>14.47</b>	<b>3.82</b>	<b>13.07</b>	<b>4.05</b>	<b>73.17</b>	<b>11.61</b>

Table 3.31 Nature of visits completed during toddlerhood for all clients enrolled in the study (N=687)

Site	N	Personal health		Maternal role		Life course		Family and friends		Environmental health		Visit length	
Target		10-15%		40-45%		18-20%		10-15%		7-10%		60 minutes	
		Mean	sd	Mean	sd	Mean	sd	Mean	sd	Mean	sd	Mean	sd
1	20	17.29	4.82	38.85	6.40	16.02	3.22	14.80	3.65	14.19	3.76	69.12	12.91
2	24	18.76	2.28	37.95	7.59	16.40	4.34	14.34	4.50	12.55	3.03	73.67	11.04
4	59	19.71	7.12	38.91	5.14	15.15	4.26	15.44	3.44	12.63	3.59	78.57	13.11
5	19	13.73	2.38	43.48	1.11	16.04	2.70	14.66	1.99	12.46	2.44	76.97	5.08
7	26	15.81	5.41	34.58	7.37	15.51	4.55	17.54	3.22	17.02	3.02	85.06	12.05
8	16	24.37	3.56	41.08	3.81	11.30	2.42	11.51	2.63	11.73	1.79	67.14	9.09
9	20	18.93	3.50	32.99	5.80	18.87	11.01	16.00	3.36	17.93	3.93	77.64	9.61
10	44	16.77	3.76	40.28	4.17	15.24	2.79	14.15	2.48	13.93	3.32	69.27	9.34
21	43	19.13	6.89	45.64	9.95	11.72	5.35	14.67	4.86	12.44	4.92	70.54	7.96
22	32	18.24	5.30	35.86	10.69	17.50	3.07	14.43	2.22	15.72	5.13	85.71	12.33
23	47	17.16	4.81	39.34	4.36	15.30	4.12	16.04	3.04	12.31	4.72	86.11	14.82
24	39	16.42	6.20	40.49	13.92	15.59	4.28	14.76	3.94	12.74	4.34	86.02	17.20
25	64	14.88	4.94	42.25	9.23	13.55	5.19	17.56	4.41	13.24	5.12	71.97	12.09
26	12	19.58	3.72	31.73	9.00	17.40	2.13	15.14	2.04	16.15	4.07	71.98	10.97
27	57	17.48	3.60	40.61	4.78	14.84	3.10	14.05	2.41	13.46	3.00	67.27	12.98
28	60	17.65	6.10	40.85	5.89	16.40	3.90	14.22	3.21	14.07	4.32	71.47	10.49
29	54	20.77	8.32	39.46	8.22	13.82	5.80	17.41	5.25	15.99	11.40	63.26	7.15
30	51	17.56	5.10	44.90	4.69	14.07	3.41	13.45	1.87	11.58	2.91	77.88	11.71
<b>Total</b>	<b>687</b>	<b>17.80</b>	<b>5.81</b>	<b>40.18</b>	<b>8.00</b>	<b>15.01</b>	<b>4.72</b>	<b>15.21</b>	<b>3.77</b>	<b>13.70</b>	<b>5.23</b>	<b>74.75</b>	<b>13.50</b>

## 4 Results: Primary Outcomes

### 4.1 Prenatal tobacco use

The primary analysis of prenatal tobacco use is restricted to those participants who provided data on self-reported number of cigarettes for the three days prior to interview at both time points (baseline and late pregnancy) and submitted a urine sample at baseline to obtain a cotinine value (Table 4.1).

Table 4.1 Number of participants with data for smoking analysis

	<b>Baseline</b> <b>Total interviewed=1618</b>	<b>Follow-up (late pregnancy)</b> <b>Total interviewed=1197*</b>
Self-reported number of cigarettes for three days prior to interview <sup>†</sup>		
Complete	1593	1148
Partial <sup>‡</sup>	20	18
None	5	31
Urine sample submitted	1547	936

\* This includes 40 participants who did not complete smoking data due to baby being born prior to interview

<sup>†</sup> Assumed to be zero for those participants classified as non-smokers by the research nurse (see appendix 12 for methodology used)

<sup>‡</sup> Participants with partial data (i.e. missing data for at least one of the two smoking questions) are not included in the main analysis

A total of 870 participants had complete self-reported number of cigarettes and urine samples at both time points. A further 222 participants had complete self-reported number of cigarettes but a urine sample at baseline only. The total number of participants for part 1 of the primary smoking analysis was therefore 1,092. Part 1 of the primary analysis compared the percentage of smokers (cotinine adjusted) at late pregnancy between trial arms using a logistic regression multilevel model. Part 2 of the primary analysis compared calibrated number of cigarettes smoked for those classified as a smoker in part 1 between trial arms using a linear regression multilevel model.

### 4.1.1 Part 1: Main analysis

There was no evidence of any difference in percentage of smokers at late pregnancy between trial arms (Table 4.2).

Table 4.2 Number (%) of smokers by trial arm and Odds Ratio (OR) for being a smoker in late pregnancy

	N	Smokers N (%)	Adjusted* OR	97.5% CI for adjusted OR	p-value
<b>Intervention</b>	547	304 (55.6)	0.90	0.64 to 1.28	0.51
<b>Control</b>	545	306 (56.1)			
<b>Total</b>	1092	610 (55.9)			

\* Intervention compared to Control. Adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

### 4.1.2 Part 1: Sensitivity analyses

#### 4.1.2.1 Effect of missing primary outcome data

Baseline characteristics of those included in the analysis (n=1,092) were compared to those excluded (n=526) (Table 4.3). Differences have not been analysed statistically, but it is possible to see that for most variables the percentages and medians are very similar. There were a higher percentage of participants categorised as NEET in those excluded from the analysis. There also appeared to be some differences related to basic and life skills, with a greater proportion reporting problems at baseline excluded from the analysis.

Table 4.3 Between arm comparison of baseline characteristics for those participants in primary smoking analysis and those not

	In primary smoking analysis N=1092		Not in primary smoking analysis N=526	
	Intervention	Control	Intervention	Control
<b>Demographic</b>				
Age at recruitment (years)				
<i>Median</i>	17.9	17.8	17.9	17.9
<i>(25<sup>th</sup> to 75<sup>th</sup> centile)</i>	(17.0 to 18.8)	(16.9 to 18.8)	(17.0 to 18.6)	(17.0 to 18.7)
Ethnicity N (%)				
White background	475 (86.8)	485 (89.0)	236 (90.4)	229 (86.4)
Mixed background	34 (6.2)	28 (5.1)	13 (5.0)	14 (5.3)
Asian background	15 (2.7)	3 (0.6)	1 (0.4)	8 (3.0)
Black background	21 (3.8)	26 (4.8)	10 (3.8)	14 (5.3)
Chinese or Other background	2 (0.4)	3 (0.6)	1 (0.4)	0 (0.0)
Relationship status N (%)				

	In primary smoking analysis		Not in primary smoking analysis	
	N=1092		N=526	
	Intervention	Control	Intervention	Control
Married	7 (1.3)	5 (0.9)	2 (0.8)	6 (2.3)
Separated	45 (8.2)	55 (10.1)	34 (13.0)	31 (11.7)
Closely involved/boyfriend	413 (75.5)	430 (78.9)	200 (76.6)	179 (67.5)
Just friends	82 (15.0)	55 (10.1)	25 (9.6)	49 (18.5)
Lives with baby's father N (%)				
Yes	115 (21.0)	124 (22.8)	69 (26.4)	60 (22.6)
No	384 (70.2)	386 (70.8)	168 (64.4)	174 (65.7)
Not answered	48 (8.8)	35 (6.4)	24 (9.2)	31 (11.7)
<b>Socio-economic</b>				
NEET status* N(%)				
Yes	207 (43.3)	211 (45.6)	126 (57.5)	119 (53.1)
No	270 (56.5)	252 (54.4)	92 (42.0)	103 (46.0)
Not answered	1 (0.2)	0 (0.0)	1 (0.5)	2 (0.9)
Overall Index of Multiple Deprivation score <sup>†</sup>				
<i>Median</i>	37.0	37.6	39.8	41.3
<i>(25<sup>th</sup> to 75<sup>th</sup> centile)</i>	(23.5 to 51.8)	(25.3 to 51.3)	(27.6 to 53.7)	(26.4 to 52.6)
Quintile 1 = least deprived	124 (22.9)	103 (19.0)	44 (16.9)	51 (19.4)
2	111 (20.5)	117 (21.6)	51 (19.6)	43 (16.3)
3	102 (18.8)	115 (21.3)	55 (21.2)	48 (18.3)
4	97 (17.9)	106 (19.6)	50 (19.2)	69 (26.2)
5 = most deprived	108 (19.9)	100 (18.5)	60 (23.1)	52 (19.8)
Generalized self-efficacy scale (score 10 to 40) <sup>‡</sup>				
<i>Median</i>	30	30	30	30
<i>(25<sup>th</sup> to 75<sup>th</sup> centile)</i>	(28 to 33)	(27 to 32)	(28 to 33)	(28 to 33)
<b>Adaptive functioning</b>				
Difficulty in at least 1 basic skill N (%)				
Yes	136 (24.9)	126 (23.1)	94 (36.0)	74 (27.9)
No	411 (75.1)	418 (76.7)	166 (63.6)	190 (71.7)
Missing	0 (0)	1 (0.2)	1 (0.4)	1 (0.4)
3 or less life skills N (%)				
Yes	119 (21.8)	142 (26.1)	86 (33.0)	87 (32.8)
No	428 (78.2)	402 (73.8)	171 (65.5)	177 (66.8)

	In primary smoking analysis N=1092		Not in primary smoking analysis N=526	
	Intervention	Control	Intervention	Control
Missing	0 (0)	1 (0.2)	4 (1.5)	1 (0.4)
At least one life burden N (%)				
Yes	151 (27.6)	165 (30.3)	77 (29.5)	83 (31.3)
No	391 (71.5)	378 (69.4)	182 (69.7)	180 (67.9)
Missing	5 (0.9)	2 (0.4)	2 (0.8)	2 (0.8)
<b>Health behaviour</b>				
Ever smoked N (%)				
Yes	433 (79.2)	424 (77.8)	215 (82.4)	220 (82.6)
No	114 (20.8)	121 (22.2)	46 (17.6)	46 (17.4)

\* Definition of NEET: Not in education employment or training (applicable only to those whose academic age is >16 at baseline interview: N=1384, Intervention=697, Control=687)

† Higher IMD score indicated more deprivation

‡ Higher score indicates higher level of self-efficacy

#### 4.1.2.2 Adjusting for additional baseline variables

Baseline characteristics are reported for each trial arm for those in part 1 of the analysis in Table 4.3 and these were assessed to determine whether we needed to adjust the main analysis. Overall, there was good balance between the arms hence no further adjustments were considered necessary in the model. In addition, we looked at baseline levels of urinary cotinine, mean self-reported number of cigarettes smoked in 3 days prior to interview and calibrated number of cigarettes smoked and these were almost identical in both trial arms.

#### 4.1.2.3 Complete case analysis

Analyses were repeated for those participants who had complete self-report data and urinary cotinine data at both baseline and late pregnancy (n=870) and the trial arm remained non-significant with very little change in the coefficient in the model.

#### 4.1.2.4 Between arm comparison of consistency of reporting behaviour

A comparison of reporting behaviour (Over reporter, Accurate reporter, Under reporter or Extreme under reporter) between baseline and late pregnancy was carried out. This showed that out of 870 participants, 535 (61.5%) were consistent, 153 (17.6%) improved reporting behaviour and 182 (20.9%) had worse reporting behaviour. Between arm comparison of these figures showed very little variation.

#### 4.1.2.5 Treatment efficacy

The primary analysis was re-run to investigate the effect of FNP dosage using complier averaged causal effects (CACE) modelling by fitting a structural mean model. For this outcome, FNP dosage was defined as the number of valid FNP visits that a participant received between recruitment and their late pregnancy (34-36 week)

interview. The results showed that there was no change to the overall conclusions compared to the primary analysis.

### 4.1.3 Part 1: Subgroup Analyses

A pre-planned subgroup analysis was conducted employing appropriate interaction terms in the regression models to ascertain any differential effects of the Intervention and Control arms across the following baseline categories: age (less than 16 years), NEET status, difficulty in at least 1 basic skill and deprivation. Table 4.4 shows the OR for the interaction term alongside 95% CIs and p-values from the interaction effect. This shows, for example, that the OR comparing Intervention vs Control among those who are NEET is 39% lower than the OR comparing Intervention vs Control among those who are not NEET; however, the 95% CI shows uncertainty regarding the size and direction of this subgroup effect. There was no evidence to suggest that any of the factors presented in Table 4.4 had any influence on the difference between Intervention and Control arm.

Table 4.4 Subgroup analyses – smokers or not in late pregnancy

Subgroup	Adjusted OR <sup>†</sup>	95% CI for adjusted OR	p-value
Age (years) at recruitment	1.21	0.38 to 3.91	0.74
Less than 16 years			
NEET status	0.61	0.31 to 1.20	0.15
Yes NEET			
Difficulty in at least 1 basic skill	0.92	0.44 to 1.90	0.82
Yes			
Index of Multiple Deprivation			
Quintile 1 = least deprived	Reference category		0.24
2	0.90	0.35 to 2.28	
3	0.63	0.25 to 1.58	
4	0.36	0.13 to 0.96	
5 = most deprived	0.50	0.19 to 1.31	

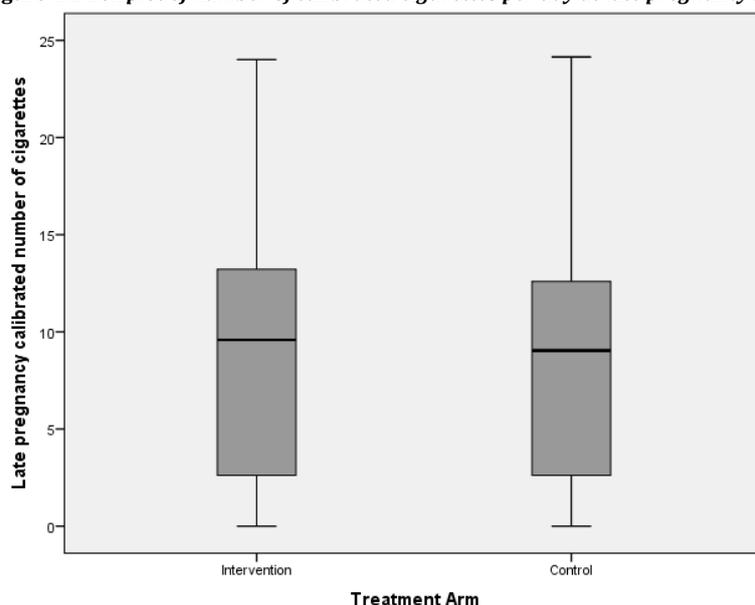
\* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age (weeks), smoking status at recruitment, and first or preferred language).

† Odds ratio for the interaction between subgroup and Intervention arm – compares the Intervention effect in the presented subgroup (e.g. Age < 16 years) and the subgroup arm or reference category (Age ≥16 years)

#### 4.1.4 Part 2: Main Analysis

A total of 610 participants in part 1 were classified as smokers. These participants are used to compare the mean number of calibrated cigarettes per day between trial arms at late pregnancy. Figure 4.1 shows that there is little variation in distribution of calibrated number of cigarettes between arms.

Figure 4.1 Box plot of number of calibrated cigarettes per day at late pregnancy by trial arm



Intra-cluster correlation coefficients (ICC) at the level of site and Family Nurse were 0.006 and 0.057 respectively. Thus, the two-level linear regression model was retained adjusting for the stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). The results of the multilevel model are in Table 4.5 and show that there is no statistical evidence for a difference in calibrated number of cigarettes smoked between arms.

Table 4.5 Mean number of calibrated cigarettes per day by trial arm and adjusted mean difference (for smokers only)

	N	Mean (SE)	Adjusted* difference in means	97.5% CI for adjusted difference in means	p-value
<b>Intervention</b>	304	8.79 (0.32)	0.12	-0.73 to 0.97	0.754
<b>Control</b>	306	8.40 (0.34)			
<b>Total</b>	610				

\* Intervention minus Control. Adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

### 4.1.5 Part 2: Sensitivity Analyses

Explorations of residuals from the multilevel model of calibrated number of cigarettes in late pregnancy showed that they do not follow a standard normal distribution (see Figure 4.2). If the chosen model was suitable we would expect all the residuals to sit on the line of equity between the inverse normal score and the standardised residuals and this is clearly not the case. This is not surprising given the unusual distribution shown in Figure 4.3. The peak in the distribution occurs where all individuals who self-report zero cigarettes and have a cotinine value indicative of low levels of smoking are assigned the same calibrated number of cigarettes smoked per day. A sensitivity analysis was undertaken to determine whether alternative methods of analysis would change our conclusion of no association between trial arm and calibrated number of cigarettes smoked in late pregnancy. Calibrated number of cigarettes were grouped into three categories and a comparison of number and percentage of participants falling within these categories by arm is shown in Table 4.6. The distribution of participants across these categories by trial arm is very similar. A single level ordinal regression was performed due to the small numbers in the middle category. The results showed that participants in the Intervention group were more likely to be in a higher smoking category than those in the Control group but the confidence interval shows that uncertainty in size and direction of this effect after adjusting for balancing factors ( $p=0.662$ ).

Figure 4.2 Standardised residuals from multilevel linear model of calibrated number of cigarettes

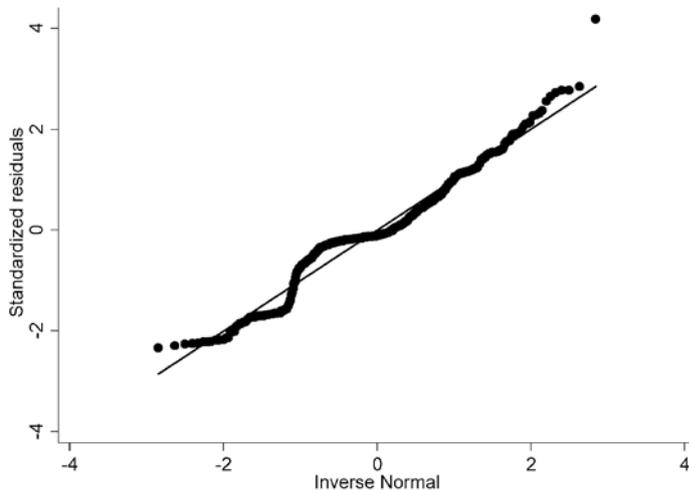


Figure 4.3 The distribution of calibrated number of cigarettes by trial arm

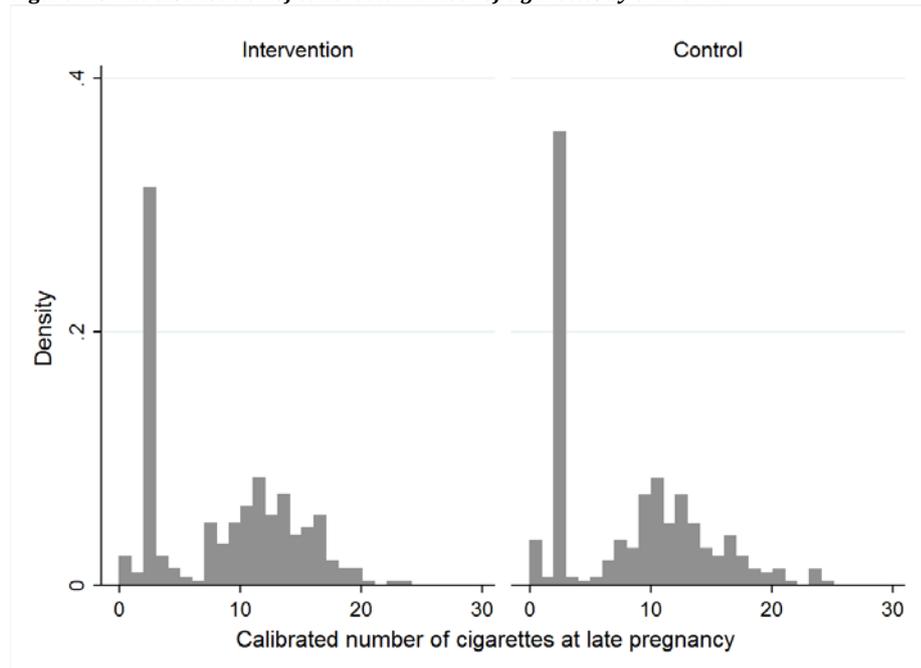


Table 4.6 Number (%) participants in each cigarette category by arm (analysis limited to smokers only)

Number of cigarettes per day	Intervention	Control	Total	Adjusted OR* (97.5% CI)	p-value
0-4.999 (cat1)	117 (38.5)	125 (40.8)	242 (39.7)	1.08 (0.72 to 1.62)	0.66
5-9.999 (cat2)	42 (13.8)	49 (16.0)	91 (14.9)		
10+ (cat3)	145 (47.7)	132 (43.1)	277 (45.4)		
<b>Total</b>	<b>304 (100.0)</b>	<b>306 (100.0)</b>	<b>610 (100.0)</b>		

\*Intervention compared to Control, OR shows effect in higher levels compared to lower levels (cat2 and cat3 compared to cat1 and cat3 compared to cat1 and cat2). Single level model adjusted for minimisation variables (gestational age (weeks), smoking status at recruitment, and first or preferred language).

#### 4.1.5.1 Adjusting for additional baseline imbalances

Baseline characteristics are reported for each arm for those in part 2 of the analysis; these are presented in Table 4.7. It was considered necessary to adjust the ordinal regression model for the NEET status variable as there was imbalance between the arms with a higher percentage in the Control arm compared to Intervention. The numbers are slightly reduced for this adjusted analysis as it is restricted to those aged 16 and over, but there remained no evidence of any difference between groups with an adjusted OR of 1.19 (97.5% CI: 0.77 to 1.84) and p-value of 0.38.

Table 4.7 Between arm comparisons of selected baseline descriptive variables for smokers only in primary analysis

	<b>Intervention N=304</b>	<b>Control N=306</b>	<b>Total Smokers in Primary Analysis N=610</b>
<b>Demographic</b>			
Age at recruitment (years)			
<i>Median (25<sup>th</sup> to 75<sup>th</sup> centile)</i>	18.0 (17.0 to 18.8)	17.7 (16.8 to 18.8)	17.9 (16.9 to 18.8)
Ethnicity N (%)			
White background	273 (89.8)	277 (90.5)	550 (90.2)
Mixed background	17 (5.6)	17 (5.6)	34 (5.6)
Asian background	4 (1.3)	1 (0.3)	5 (0.8)
Black background	10 (3.3)	9 (2.9)	19 (3.1)
Chinese or Other background	0 (0)	2 (0.7)	2 (0.3)
Relationship status N (%)			
Married	2 (0.7)	1 (0.3)	3 (0.5)
Separated	29 (9.5)	28 (9.2)	57 (9.3)
Closely involved/boyfriend	222 (73.0)	244 (79.7)	466 (76.4)
Just friends	51 (16.8)	33 (10.8)	84 (13.8)
Lives with baby's father N (%)			
Yes	69 (22.7)	70 (22.9)	139 (22.8)
No	206 (67.8)	215 (70.3)	421 (69.0)
Not answered	29 (9.5)	21 (6.9)	50 (8.2)
<b>Socio-economic</b>			
NEET status* N(%)			
Yes	120 (44.9)	135 (52.9)	255 (48.9)
No	147 (55.1)	120 (47.1)	267 (51.1)
Overall Index of Multiple			
Deprivation score <sup>†</sup>	<i>N=303</i>	<i>N=303</i>	<i>N=606</i>
<i>Median (25<sup>th</sup> to 75<sup>th</sup> centile)</i>	37.0 (23.1 to 53.4)	40.9 (26.3 to 53.3)	38.6 (25.1 to 53.3)
Quintile 1 (least deprived) N (%)			
2	68 (22.4)	47 (15.5)	115 (19.0)
3	65 (21.5)	63 (20.8)	128 (21.1)
4	58 (19.1)	61 (20.1)	119 (19.6)
5 (most deprived)	45 (14.9)	70 (23.1)	115 (19.0)
6	67 (22.1)	62 (20.5)	129 (21.3)
Generalized self-efficacy scale (score 10			
to 40) <sup>‡</sup>	<i>N=302</i>	<i>N=301</i>	<i>N=603</i>
<i>Median (25<sup>th</sup> to 75<sup>th</sup> centile)</i>	30 (27 to 32)	30 (27, 32)	30 (27, 32)

	<b>Intervention N=304</b>	<b>Control N=306</b>	<b>Total Smokers in Primary Analysis N=610</b>
<b>Adaptive functioning</b>			
Difficulty in at least 1 basic skill N (%)			
Yes	87 (28.6)	80 (26.1)	167 (27.4)
No	217 (71.4)	225 (73.5)	442 (72.5)
Missing	0 (0)	1 (0.3)	1 (0.2)
3 or less life skills N (%)			
Yes	78 (25.7)	85 (27.8)	163 (26.7)
No	226 (74.3)	220 (71.9)	446 (73.1)
Missing	0 (0)	1 (0.3)	1 (0.2)
At least one life burden N (%)			
Yes	83 (27.3)	104 (34.0)	187 (30.7)
No	220 (72.4)	200 (65.3)	420 (68.8)
Missing	1 (0.3)	2 (0.7)	3 (0.5)
<b>Health behaviour</b>			
Ever smoked (self-reported)			
Yes	280 (92.1)	273 (89.2)	553 (90.7)
No	24 (7.9)	33 (10.8)	57 (9.3)
Missing			

\* Definition of NEET: Not in education employment or training (applicable only to those whose academic age is >16 at baseline interview)  
N=522, Intervention=267, Control=255)

† Higher IMD score indicated more deprivation

‡ Higher score indicates higher level of self-efficacy

#### **4.1.5.2 Complete case analysis**

Ordinal regression analyses were repeated for those participants classed as smokers who had complete self-report data and urinary cotinine data at both baseline and late pregnancy (n=497) as the main analysis included participants who did not provide a urine sample at follow-up. The baseline smoking reporting behaviour was used to calibrate the number of cigarettes smoked at follow-up for these participants. This carries the assumption that baseline reporting behaviour does not alter between baseline and follow-up and hence we needed to check that this assumption did not bias the results. The OR was reduced to 1.01 (97.5% CI: 0.64 to 1.61).

#### **4.1.5.3 Treatment efficacy**

The primary analysis was re-run to investigate the effect of FNP dosage using complier averaged causal effects (CACE) modelling and the results showed that there was no change to the overall conclusions compared to the primary analysis.

#### 4.1.6 Part 2: Subgroup Analyses

A pre-planned subgroup analysis was conducted employing appropriate interaction terms in the ordinal regression models to ascertain any differential effects of the Intervention and Control groups across the following baseline categories: age (less than 16 years), NEET status, difficulty in at least one basic skill and deprivation. Table 4.8 shows, for example, that the OR (for higher amount of cigarettes smoked) comparing Intervention to Control among those who are NEET is 55% lower than the OR comparing Intervention vs Control among those who are not NEET; however, the 95% CI shows uncertainty regarding the size and direction of this subgroup effect. There was no evidence to suggest that any of these factors measured at baseline had any influence on the difference between Intervention and Control arms.

*Table 4.8 Subgroup analyses – categorised number of calibrated cigarettes in late pregnancy*

<b>Subgroup</b>	<b>Adjusted OR<sup>*†</sup> (95% CI)</b>	<b>p-value</b>
Age (years) at recruitment	1.11 (0.28 to 4.45)	0.88
Less than 16 years		
NEET status	0.55 (0.26 to 1.19)	0.13
Yes NEET		
Difficulty in at least one basic skill	0.74 (0.33 to 1.66)	0.47
Yes		
Index of Multiple Deprivation		
Quintile 1 = least deprived	Reference category	0.15
2	1.36 (0.43 to 4.32)	
3	0.46 (0.13 to 1.55)	
4	0.55 (0.17 to 1.74)	
5 = most deprived	1.01 (0.31 to 3.34)	

\*Intervention compared to Control. Single level model adjusted for stratification (site) and minimisation variables (gestational age (weeks), smoking status at recruitment, and first or preferred language).

† Odds ratio for the interaction between subgroup and Intervention arm – compares the Intervention effect in the presented subgroup (e.g. Age < 16 years) and the subgroup arm or reference category (Age ≥16 years)

## 4.2 Birth weight

The primary source for the birth weight (grams) data was the baby section of the maternal records. Of the 1,498 women who gave permission to collect data at birth (93% of the original 1,618), there were a total of 1,510 registered births (live or stillborn) of which 1,486 were singletons and 24 were twins. Twins and stillbirths were balanced by trial arm (Table 4.9).

Table 4.9 Birth outcomes by trial arm

	Intervention	Control	Total
Singletons	728 (98.1)	758 (98.7)	1486 (98.4)
Twins	14 (1.9)	10 (1.3)	24 (1.6)
<b>Total</b>	<b>742 (100)</b>	<b>768 (100)</b>	<b>1510 (100)</b>
Live births	739 (99.6)	766 (99.7)	1505 (99.7)
Stillbirths	3 (0.4)	2 (0.3)	5 (0.3)
<b>Total</b>	<b>742 (100)</b>	<b>768 (100)</b>	<b>1510 (100)</b>

### 4.2.1 Main analysis

Birth weight (grams) was obtained for all 1,510 registered births. The overall mean (SD) weight was 3,207.3g (599.6g) with a similar distribution in each trial arm (Figure 4.4). There was a small amount of clustering of birth weight by site, with 7.6% of the total variability in birth weights attributable to differences between sites (Figure 4.5). There was no evidence of any difference in mean birth weight between the Intervention and Control groups (Table 4.10).

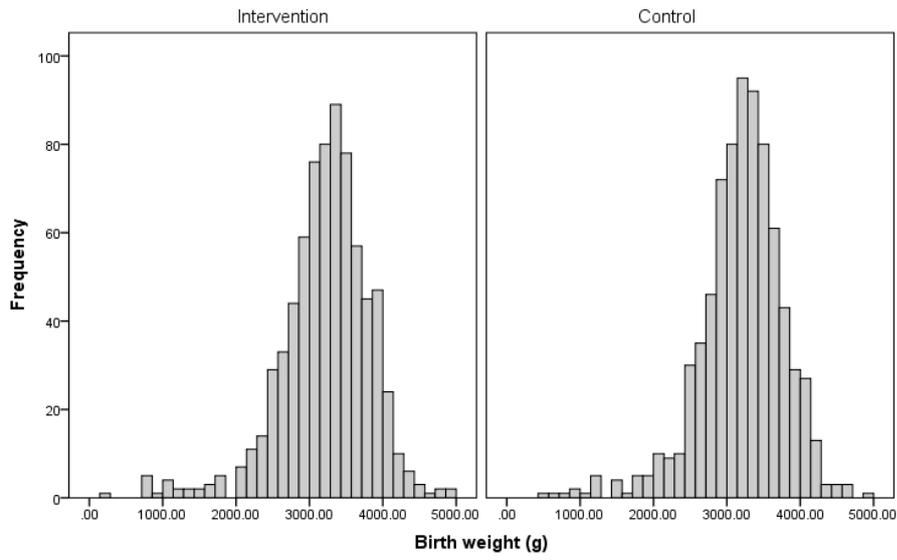
Table 4.10 Mean birth weight (grams) by trial arm and adjusted difference in means

	N	Unadjusted mean (SD)	Adjusted* difference in means† (97.5% CI)	p-value
<b>Intervention</b>	742	3217.4 (618.0)	20.75 (-47.73 to 89.23)	0.497
<b>Control</b>	768	3197.5 (581.5)		
<b>Total</b>	1510	3207.3 (599.6)		

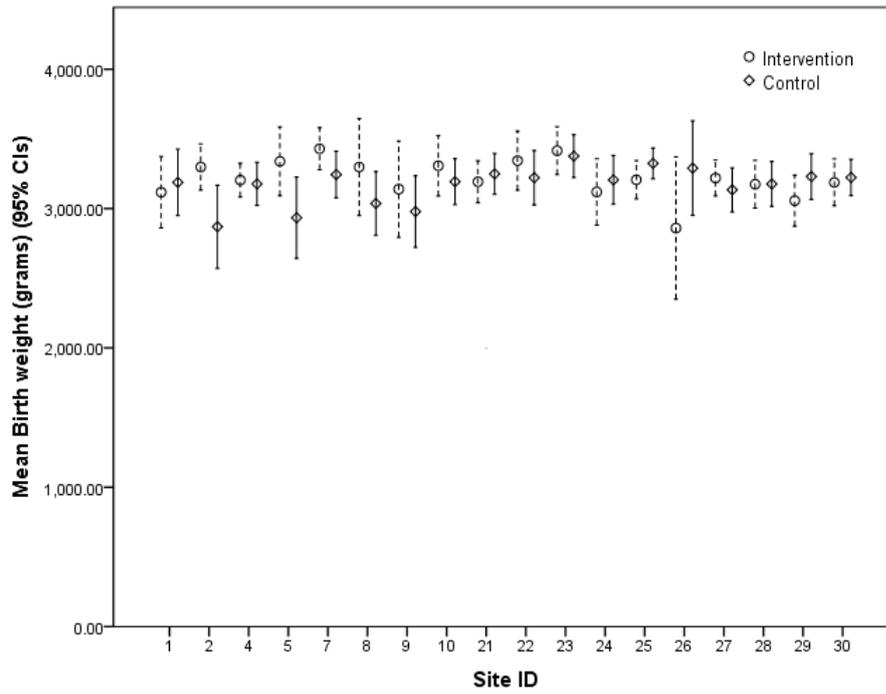
\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). One missing response for the minimisation variables first or preferred language and gestational age.

† Intervention minus Control.

**Figure 4.4 Histogram of birth weight (grams) by trial arm (N=1510)**



**Figure 4.5 Mean (95% CIs) birth weight (grams) by site and trial arm**



## 4.2.2 Sensitivity analyses

### 4.2.2.1 Adjusting for additional baseline imbalances

In light of no differences in baseline variables likely to be associated with birth weight, further adjusting for any variables exhibiting marked imbalance at baseline was not necessary.

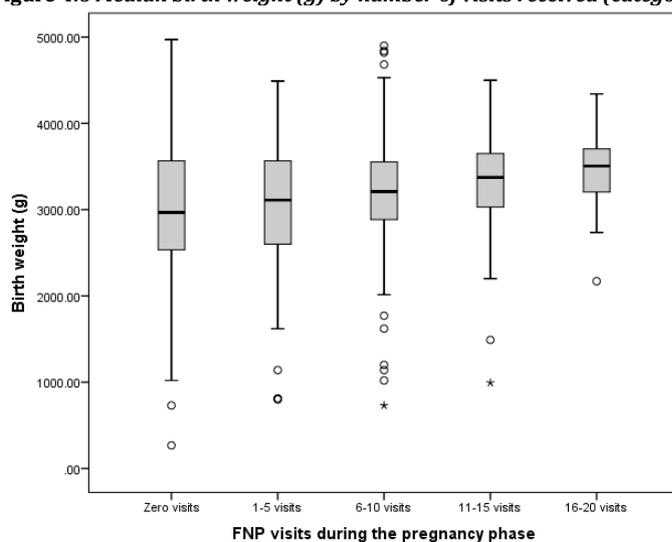
### 4.2.2.2 Treatment efficacy

The primary analysis was re-run to investigate the effect of FNP dosage using complier averaged causal effects (CACE) modelling. For this outcome, FNP dosage was defined as the number of valid FNP visits that a participant received during the pregnancy phase (from recruitment date to date of birth of first baby). The number of FNP visits received during the pregnancy phase was re-categorised in order to obtain sufficient numbers in each arm. Based on observed data in the Intervention arm, there is some evidence of an increase in mean birth weight as the number of visits received increases (Table 4.11 and Figures 4.6 and 4.7), although this could be confounded by gestation at delivery.

Table 4.11 Birth weight (grams) by number of visits received

Number of visits received (categorised)	No. participants (births)	Birth weight (grams)				
		Mean	SD	Median	Minimum	Maximum
Zero visits	48	2857.21	990.32	2967.50	268	4970
1-5 visits	72	3011.92	790.90	3110.00	800	4490
6-10 visits	300	3198.27	587.32	3210.00	730	4900
11-15 visits	302	3330.13	484.90	3372.50	993	4500
16-20 visits	20	3407.25	493.28	3505.00	2170	4340
<b>Total</b>	<b>742</b>	<b>3217.42</b>	<b>617.97</b>	<b>3280.00</b>	<b>268.00</b>	<b>4970.00</b>

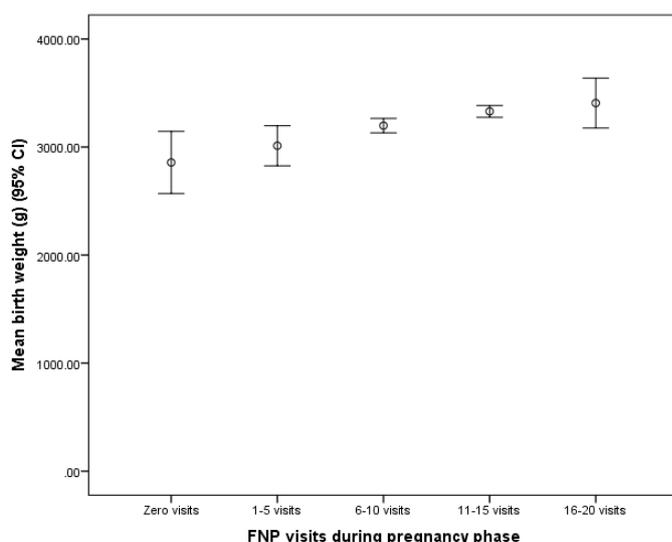
Figure 4.6 Median birth weight (g) by number of visits received (categorised)



o = Outliers. Between 1.5 and 3 times the height of the boxes (25<sup>th</sup> to 75<sup>th</sup> centiles)

\* = Extreme outliers. Values more than three times the height of the boxes (25<sup>th</sup> to 75<sup>th</sup> centiles)

**Figure 4.7 Mean birth weight (g) by number of visits received (categorised)**



Adjusting the analysis of birth weight for Intervention receipt, a 2.24 gram increase in the between-arm mean difference of birth weight is observed as the number of sessions received increases (i.e. an increase in the number of visits received is associated with an increase in birth weight) (Table 4.12). However, confidence intervals around this estimate are wide and contain zero. Based on participants entering the study at 16 weeks and giving birth on their due date, the ideal number of visits is calculated as 14 (one visit per week during the first month, one visit per fortnight thereafter until birth). The estimated treatment efficacy for participants receiving 14 visits was 31.39 (birth weight was 31.39 grams higher on average in the Intervention arm than the Control arm). However, there is substantial uncertainty around this estimate. After taking account of amount of Intervention received, either per visit or having received a minimum of 14 visits, there was no evidence of any difference between the arms.

*Table 4.12 Effect of FNP visit on the between arm difference in mean birthweight (g)*

Type of analysis	Adjusted difference* in means (97.5% CI)	p-value
Primary analysis	20.75 (-47.73 to 89.23)	0.497
Efficacy per visit	2.24 (-5.20 to 9.68)	0.500
Efficacy per 14 visits†	31.39 (-72.81 to 135.59)	0.500

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Difference= Intervention minus Control.

† The expected number of visits during the pregnancy phase (based on participants entering the study at 16 weeks, giving birth on their due date, and receiving every scheduled visit)

### 4.2.3 Subgroup analysis

A pre-planned subgroup analysis was conducted employing appropriate interaction terms in the regression model to ascertain any differential effects of the Intervention and Control groups across the following baseline categories: adjusted baseline smoking status, age at recruitment (less than 16 years), NEET status, difficulty in at least 1 basic skill and deprivation. Table 4.13 shows the Intervention effect for the interaction term alongside 95% CIs and p-values. For age subgroup, the Intervention effect was 73.35 grams higher in participants aged less than 16 years at recruitment than participants greater than or equal to 16 years of age at recruitment. However, the 95% CI shows no evidence for this subgroup effect. Likewise, there was no evidence to suggest that any of the baseline factors examined here had any influence on the treatment effect.

Table 4.13 Subgroup analyses - birth weight (grams)

Subgroup	Adjusted* difference in means† (95% CI)	p-value
Adjusted baseline smoking status		
Smoker	2.96 (-121.68 to 127.60)	0.963
Age (years) at recruitment		
Less than 16 years	73.35 (-165.85 to 312.56)	0.548
NEET status		
Yes NEET	7.672 (-122.93 to 138.27)	0.908
Difficulty in at least 1 basic skill		
Yes	-35.13 (-171.96 to 101.70)	0.615
Index of Multiple Deprivation		
Quintile 1 = least deprived	Reference	0.672
2	-128.19 (-317.26 to 60.89)	
3	-78.15 (-268.54 to 112.23)	
4	-56.03 (-246.31 to 134.24)	
5 = most deprived	-9.82 (-198.91 to 179.27)	

\*Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language).

† Treatment effect (Intervention minus Control) for the interaction between subgroup and Intervention arm – compares the between arm difference in the presented subgroup (e.g. Age < 16 years) and the subgroup arm or reference category (Age ≥16 years)

After categorisation of birth weight there was no evidence of any Intervention effect (Table 4.14). The majority of birth weights were in the normal range (2,500-3,999 g) with just under 7% of babies being classified as high birth weight.

Table 4.14 Number (%) of children in categorised birth weight (grams) by trial arm

	<b>Intervention</b> <b>N=742</b>	<b>Control</b> <b>N=768</b>	<b>Total</b> <b>N=1510</b>
<b>Very low BW (&lt;1500 g)</b>	17 (2.3)	13 (1.7)	30 (2.0)
<b>Low BW (1500-2499 g)</b>	54 (7.3)	57 (7.4)	111 (7.4)
<b>Normal BW (2500-3999 g)</b>	623 (84.0)	650 (84.4)	1271 (84.2)
<b>High BW (≥4000g)</b>	48 (6.5)	50 (6.5)	98 (6.5)

### 4.3 Child emergency attendances and / or admissions

The main analysis for this primary outcome compared the proportion of children with at least one emergency attendance and / or admission within 24 months of birth (hereafter referred to as an event) between the Intervention and Control arm. An event is defined as a child presenting at A&E (whether subsequently admitted to hospital or not) or admission directly to hospital without a preceding A&E attendance (via a GP or outpatient referral). Of the 1,505 live births, five children could not be matched to A&E or admissions data (from HSCIC). Thus a total of 1,500 children remained for the primary analysis. Overall, 1,164 (77.6%) of children had experienced an event (total of 4001 attendances and/or admissions) (Table 4.15). Complete outcome data were obtained from 1,462 children and were included in the main analysis. A total of 38 withdrew before the 2 year follow-up with 16 (42.1%) of the 38 withdrawals experiencing an event. These children were also included. We cannot ascertain that the remaining 22 would not have had an event if they had continued in the study and were excluded. Thus the population for the main analysis was based on 1,478 children.

Table 4.15 Emergency attendances and/or admission (event) in trial completers and withdrawals

	<b>Withdrew before 24</b> <b>months follow-up</b>	<b>Completers of 2 years</b> <b>follow-up</b>	<b>Total</b>
No event	22 (57.9)	314 (21.5)	336 (22.4)
At least one event	16 (42.1)	1148 (78.5)	1164 (77.6)
<b>Total</b>	<b>38 (100.0)</b>	<b>1462 (100.0)</b>	<b>1500 (100.0)</b>

#### 4.3.1 Main analysis

A greater proportion of children in the Intervention arm had at least one event when compared to the Control arm (81.0% vs 76.6%) (Table 4.16). There was no indication of clustering of outcome at site level. There was evidence to suggest a difference in event rates between the arms with 4.3% difference between groups and a 32% higher odds of an event in the Intervention arm compared to Control. There was no indication that the intervention effect varied by site.

Table 4.16 Number (%) of children with at least one event within 24 months by trial arm

	n	%	Adjusted* odds ratio† (97.5% CI)	p-value
<b>Intervention (N=725)</b>	587	81.0	1.32 (0.99 to 1.76)	0.033
<b>Control (N=753)</b>	577	76.6		
<b>Total (N=1478)</b>	1164	78.8		

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

† Intervention compared to Control

## 4.3.2 Sensitivity analyses

### 4.3.2.1 Effect of missing primary outcome data

To test the impact of excluding the 22 withdrawals (with partial follow-up) due to not experiencing an event, extreme assumptions were made where:

1. children in the Intervention arm (n=11) experienced at least one event and children in the Control (n=11) did not
2. children in the Control arm experienced at least one event and children in the Intervention arm did not

The results are shown in Table 4.17. Assuming that all formerly excluded children in the Intervention arm had experienced at least one event and those in the Control arm had not increases the OR from 1.32 (97.5% CI: 0.99 to 1.76) to 1.43 (1.07 to 1.91). Assuming the other extremity, where the Control arm all experience an event (and the Intervention do not), there is no evidence suggesting a difference between groups.

Table 4.17 Effect of FNP visit on events over 24 months (N=1500)

		n	%	Adjusted* OR† (97.5% CI)
Primary analysis	Intervention (N=725)	587	81.0	1.32 (0.99 to 1.76)
	Control (N=753)	577	76.6	
Intervention arm experienced an event	Intervention (N=736)	598	81.3	1.43 (1.07 to 1.91)
	Control (N=764)	577	75.5	
Control arm experienced an event	Intervention (N=736)	587	79.8	1.19 (0.90 to 1.58)
	Control (N=764)	588	77.0	

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

† Intervention compared to Control.

#### 4.3.2.2 Adjusting for additional baseline imbalances

In light of no differences in participants' baseline variables (from Table 3.11 in chapter 3) that were to be associated with attendances / admissions further adjusting for any variables exhibiting marked imbalance at baseline was not necessary.

#### 4.3.2.3 Impact of data source

The gold standard data source for A&E attendances and hospital admissions data was HSCIC data and no exploration or comparison was made with maternally-reported data.

#### 4.3.2.4 Treatment efficacy

The number of visits received during the total study period was re-categorised in order to obtain sufficient numbers in each group. Based on the observed data in the Intervention arm, the percentage of children experiencing an event generally increased as the number of visits received increased (Table 4.18). Adjusting the analysis for Intervention receipt we observe a 1% increased odds of an event occurring in the Intervention arm compared to Control for every unit increase in FNP visit received (Table 4.19). The expected number of visits of FNP over the whole period is 64 (14 in the pregnancy phase, 28 in the infancy phase, 22 in the toddler phase). The estimated treatment efficacy for participants receiving all 64 visits was 1.51, indicating that the odds of an event occurring was 51% higher in the Intervention than in the Control arm (97.5% CI: 1.05 to 2.18).

Table 4.18 Event by number of FNP visits over the entire program

Number of visits received (categorised)	Number of children	Emergency attendances and / or admissions	
		Event	No event
Zero visits	34	27 (79)	7 (21)
1-10 visits	32	27 (84)	5 (16)
11-20 visits	42	35 (83)	7 (17)
21-30 visits	80	57 (71)	23 (29)
31-40 visits	171	134 (78)	37 (22)
41-50 visits	234	192 (82)	42 (18)
51-60 visits	102	87 (85)	15 (15)
More than 60 visits	30	28 (93)	2 (7)
<b>Total</b>	<b>725</b>	<b>587 (81)</b>	<b>138 (19)</b>

Table 4.19 Effect of FNP visit on events

Type of analysis	Adjusted OR (97.5% CI)	p-value
Primary analysis	1.32* (0.99 to 1.76)	0.033
Efficacy per visit	1.007 <sup>†</sup> (1.001 to 1.012)	0.011
Efficacy per 64 visits <sup>‡</sup>	1.514 <sup>†</sup> (1.051 to 2.182)	0.011

\* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

<sup>†</sup> Clustering at site level could not be adjusted for in CACE model. Since there no evidence of clustering at site level, the standard errors will not be overly underestimated.

<sup>‡</sup> The expected number of FNP visits received over the entire programme (from enrolment)

### 4.3.3 Subgroup analysis

A pre-planned subgroup analysis was conducted employing appropriate interaction terms in the regression model to ascertain any differential effects of the Intervention and Control groups across the following baseline categories: age (less than 16 years), NEET status, difficulty in at least 1 basic skill and deprivation.

Table 4.20 shows the odds ratios (OR) for the interaction term alongside 95% CIs and p-values from the interaction effect. For age subgroup, an OR of 1.33 shows that the Intervention effect was 33% higher in participants aged less than 16 years at recruitment than participants greater than or equal to 16 years of age at recruitment. However, the 95% CI shows no evidence for this subgroup effect. Likewise, there was no evidence to suggest that any of the baseline factors examined had any influence on the Intervention effect.

Table 4.20 Subgroup analyses for emergency attendances and/or admissions

Subgroup	Adjusted* OR <sup>†</sup> (95% CI)	p-value
Age (years) at recruitment		
Less than 16 years	1.33 (0.45 to 3.87)	0.607
NEET status		
Yes NEET	1.56 (0.89 to 2.71)	0.118
Difficulty in at least 1 basic skill		
Yes	0.80 (0.44 to 1.45)	0.456
Index of Multiple Deprivation		
Quintile 1 = least deprived	Reference category	0.873
2	1.13 (0.54 to 2.39)	
3	0.89 (0.40 to 1.99)	
4	0.80 (0.35 to 1.79)	
5 = most deprived	0.77 (0.33 to 1.76)	

\* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

<sup>†</sup> Odds ratio for the interaction between subgroup and Intervention arm – compares the Intervention effect in the presented subgroup (e.g. Age < 16 years) and the subgroup arm or reference category (Age ≥16 years)

### 4.3.4 Secondary analyses

#### 4.3.4.1 Count of emergency attendances and / or admission

This analysis is based on children completing the 24 month follow-up (N=1,462) and therefore excluded children that withdrew (N=38). A total of 176 (23.7%) children in the Control arm had zero events over the 24 month follow-up period compared to 138 (19.2%) in the Intervention arm (Table 4.21). Both Figures 4.8 and 4.9 show the distribution of events by trial arm. An outlier of 48 attendances (five A&E attendances not resulting in admission, 34 admissions only, nine A&E attendances resulting in an admission) in the Control arm appears plausible with primary diagnoses for respiratory infections and gastro-intestinal problems.

Table 4.21 Summary statistics of the count of events by trial arm

	<b>Intervention</b> <b>N=719</b>	<b>Control</b> <b>N=743</b>	<b>Total</b> <b>N=1462</b>
Mean (sd) of events	2.87 (3.55)	2.55 (3.16)	2.71 (3.36)
N (%) with zero events	138 (19.2)	176 (23.7)	311 (21.3)
N (%) at least one event	584 (81.2)	567 (76.3)	1151 (78.7)
Median count of events	2	2	2
(25 <sup>th</sup> to 75 <sup>th</sup> centiles)	(1-4)	(1-4)	(1-4)

Figure 4.8 Boxplot of total events by trial arm

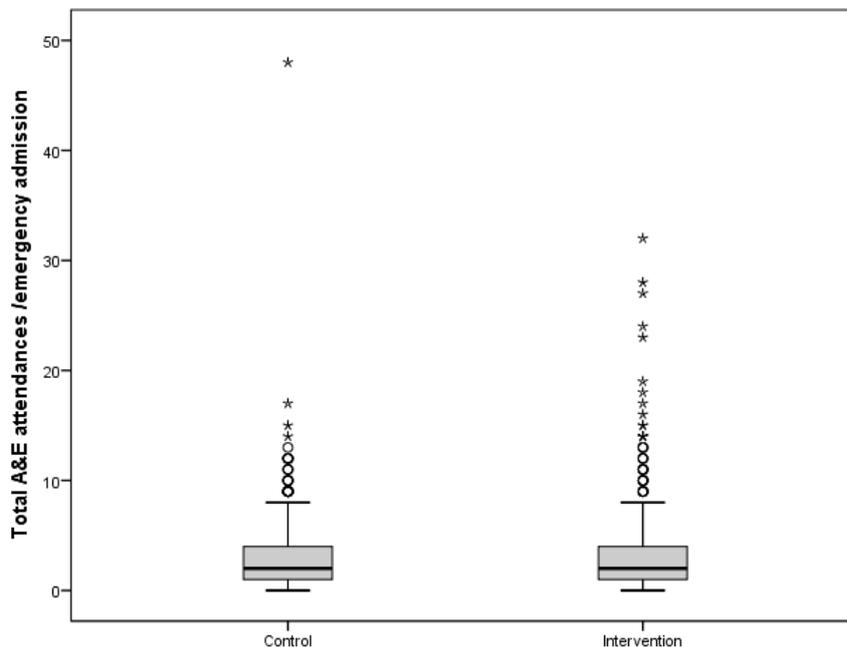
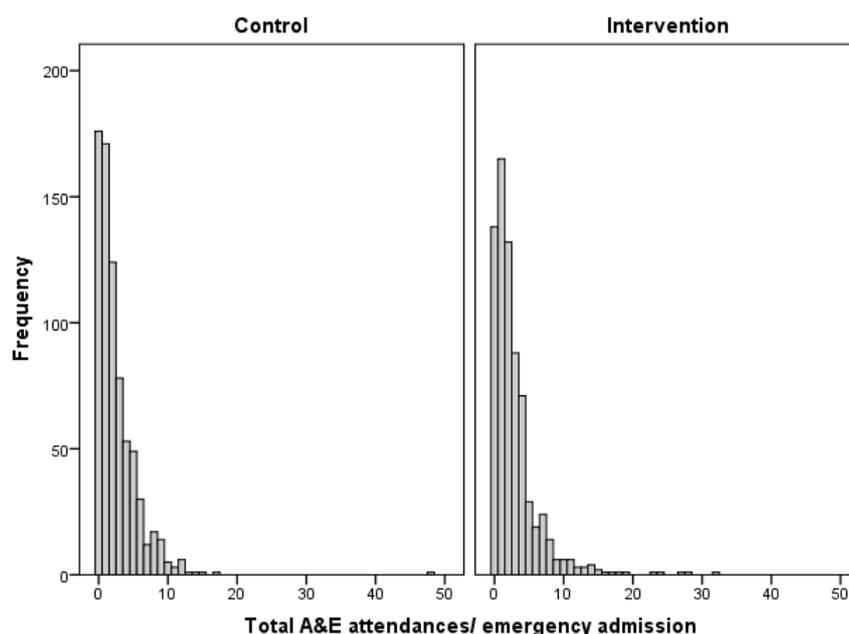


Figure 4.9 Histograms of total emergency attendances and/or admissions by trial arm



Since the distribution of the number of events displayed signs of overdispersion (greater variance than might be expected in a Poisson distribution), a Negative Binomial model (NBM) was used. The results were presented as incidence rate ratios (IRRs) with associated 97.5% confidence intervals and p-values (Table 4.22). There was no evidence to suggest a difference between arms in the number of events.

Table 4.22 Incidence rate ratio (IRR) of children's events

	Adjusted* IRR† (97.5% CI)	p-value
Intervention	1.12 (0.98 to 1.28)	0.064
Control		

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

† Intervention compared to Control

#### 4.3.4.2 Time to first A&E attendance or emergency hospital admission

All children were included in the analysis (N=1500). Time to first event (attendance or admission) in days was the outcome with 1,164 children (77.6%) experiencing an event and the remaining 336 (22.4%) were censored (either not experiencing an event at 2 years or at time of withdrawal). A two-level Cox regression model (frailty model) was fitted with days until first event (attendance at A&E or emergency admission) as the outcome. The median time to first event was 253 days in the Control arm compared to 226 days in the Intervention arm (Table 4.23). The results from the Cox regression model are presented as a hazard ratio (HR), with a HR>1 indicating that the Intervention arm presented sooner than the Control arm. Although the children in the Intervention arm presented to A&E or were admitted to hospital sooner than the Control arm (HR=1.12), there is some evidence to suggest a difference between trial arms (Figure 4.10).

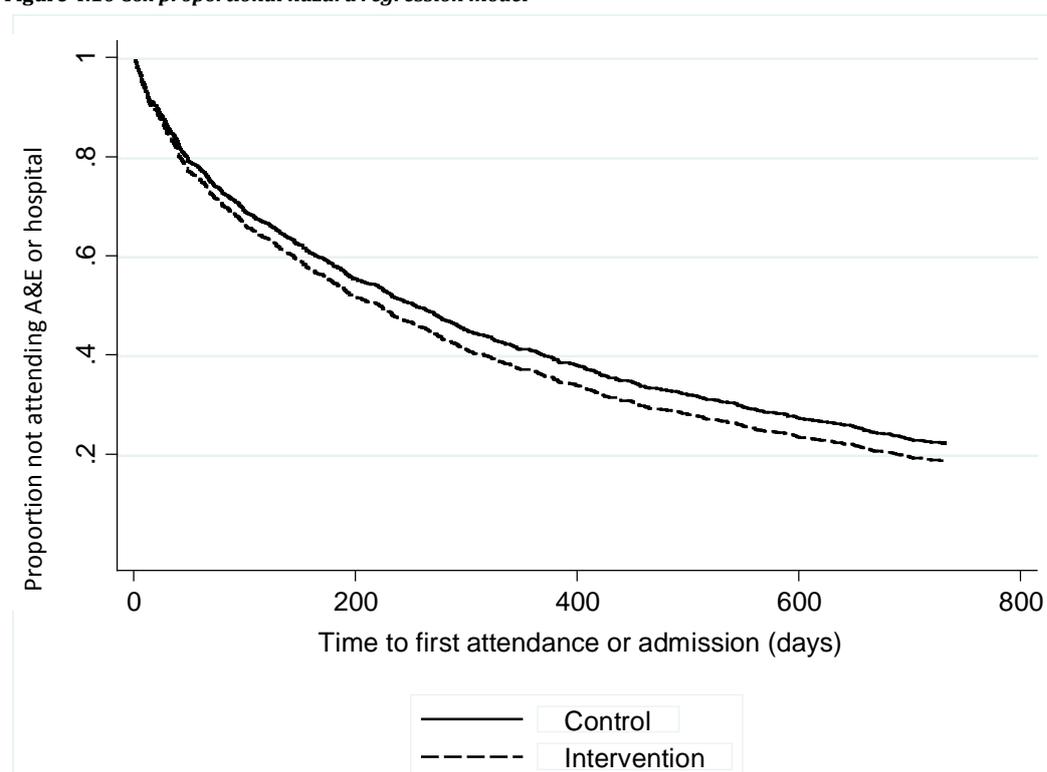
Table 4.23 Median days to 1st attendance or admission by trial arm and hazard ratio of an attendance or hospital admission

	Median days to 1st attendance or admission (95%CI)	Adjusted* Hazard Ratio† (97.5% CI)	p-value
Intervention	226 days (195.12 to 256.88)	1.12 (0.98 to 1.28)	0.053
Control	253 days (212.96 to 293.04)		

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

†Intervention compared to Control

Figure 4.10 Cox proportional hazard regression model



#### 4.4 Subsequent pregnancy

The primary source for this primary outcome was data arising from the Health and Social Care Information Centre (HSCIC) (providing information on any pregnancy-related outpatient appointments, registered births, terminations, miscarriages and any pregnancy-related hospital admission). Data relating to abortions were provided by the Department of Health, to whom medical practitioners have a statutory requirement to report all abortions. GP and maternal self-report data provided supplementary data on women (especially in the cases of miscarriages) for whom the HSCIC and abortion data report no subsequent pregnancies. If any of these data sources reported a subsequent pregnancy then it could be certain that a second pregnancy had occurred and by using a composite outcome it would reflect a truer rate of events.

From these data sources, a flag was created to indicate whether a second pregnancy had occurred within 24 months of first birth. If all of the data sources indicated that no pregnancy occurred then we could be certain as we could be that no second pregnancy had occurred. For the remainder of participants where there was missing data for at least one source and no pregnancy flagged, if the GP record or maternal self-report data sources indicated that no second pregnancy had occurred then we assumed that no pregnancy had occurred. Where GP and maternal self-report were missing and abortions or HSCIC indicated that no second pregnancy occurred, we cannot assume that no event in these two sources indicated that no actual pregnancy occurred. Based on these assumptions, a total sample of 1,289 participants were used for analyses and 329 were missing due to either incomplete follow-up. The missing were withdrawals from the trial or left the GP practice before 24 months (and no subsequent pregnancies recorded from another source) (N=154), and 175 had missing GP or maternal self-report data (and no subsequent pregnancies in HSCIC sources or abortions).

Table 4.24 shows the number of events for each data source and the overall response. For maternal self-report 750 participants had failed to respond to at least one of the follow-up interviews with therefore no subsequent pregnancy recorded. For abortions data, 159 (9.8%) of participants had been matched and identified as having at least one abortion. Of these 159, 74 (46.5%) of these were in the Intervention arm of the trial and 85 (53.5%) were in the Control arm. For the HSCIC data (inpatient and outpatients), seven participants could not be matched with 21% of participants with a subsequent pregnancy recorded in inpatients data and 16.8% from outpatients data. GP records for 951 participants were examined with 501 (52.7%) reporting a subsequent pregnancy found from medical notes.

*Table 4.24 Number (%) of subsequent pregnancies within twenty four months of first birth, identified from each data source (N=1618)*

<b>Subsequent pregnancy?</b>	<b>Maternal self-report</b>	<b>Abortions</b>	<b>Inpatients</b>	<b>Outpatient</b>	<b>GP records</b>	<b>Overall</b>
Yes	453 (52.2)	159 (9.8)	339 (21.0)	271 (16.8)	501 (52.7)	853 (66.2)
No	415 (47.8)	1459 (90.2)	1272 (79.0)	1340 (83.2)	450 (47.3)	436 (33.8)
<b>Total</b>	<b>868</b>	<b>1618</b>	<b>1611</b>	<b>1611</b>	<b>951</b>	<b>1289</b>
<i>Missing*</i>	<i>750</i>	<i>0</i>	<i>7</i>	<i>7</i>	<i>667</i>	<i>329</i>

### 4.4.1 Main analysis

Of the 1,289 participants, 853 (66.2%) had a subsequent pregnancy with no evidence of a difference in event rate between trial arms (Table 4.25).

Table 4.25 Number (%) of participants with a subsequent pregnancy within twenty four months of first birth, by trial arm

	n	%	Adjusted* OR <sup>†</sup> (97.5% CI)	p-value
<b>Intervention (N=643)</b>	426	66.3	1.01 (0.77 to 1.33)	0.920
<b>Control (N=646)</b>	427	66.1		
<b>Total (N=1289)</b>	853	66.2		

\* Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

<sup>†</sup> Intervention compared to Control

### 4.4.2 Sensitivity analyses

#### 4.4.2.1 Effect of missing primary outcome data

To test the impact of excluding the 329 participants in the main analysis, extreme assumptions were made where:

1. participants in the Intervention arm (n=165) experienced at least one subsequent pregnancy and participants in the Control (n=164) did not
2. participants in the Control arm experienced at least one subsequent pregnancy and participants in the Intervention arm did not

The results from these analyses alongside the primary analysis are shown in Table 4.26. Assuming that all formerly excluded participants in the Intervention arm had experienced at least one subsequent pregnancy and those in the Control arm had not increased the OR from 1.01 (97.5% CI: 0.77 to 1.33) to 2.54 (1.99 to 3.24). Assuming the other extremity where the Control arm all experience a subsequent pregnancy (and the Intervention do not), the OR decreased to 0.40 (0.32 to 0.51).

Table 4.26 Effect of FNP visit on subsequent pregnancies within 24 months (N=1618)

		n	%	Adjusted OR* (97.5% CI)
Primary analysis	Intervention (N=643)	426	66.3	1.01 (0.77 to 1.33)
	Control (N=646)	427	66.1	
Intervention arm experienced an event	Intervention (N=808)	591	73.1	2.54 (1.99 to 3.24)
	Control (N=808)	427	52.7	
Control arm experienced an event	Intervention (N=808)	426	52.7	0.40 (0.32 to 0.51)
	Control (N=808)	591	73.0	

\* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

#### 4.4.2.2 Adjusting for additional baseline imbalances

In light of no differences in participants' baseline variables that were likely to be associated with subsequent pregnancies further adjusting for any variables exhibiting marked imbalance at baseline was not necessary.

#### 4.4.2.3 Impact of data source

Since several data sources could be used to detect a more accurate rate of subsequent pregnancies, the impact of using these data sources was examined. Using only maternally reported subsequent pregnancies or those detected through GP records, a lower event rate is detected, although in the maternal report a greater proportion is reported from those randomised to the Control arm and vice versa for the GP records (Table 4.27).

Table 4.27 Percentage of participants with a subsequent pregnancies within twenty four months of first birth, by trial arm

		n	%	Adjusted OR* (97.5% CI)
<b>HSCIC (Inpatients and Outpatients)</b>	Intervention (N=450)	194	24.1	0.85 (0.63 to 1.15)
	Control (N=418)	211	26.1	
<b>N=1611</b>				
<b>Maternal Self-report only</b>	Intervention (N=450)	223	49.6	0.78 (0.58 to 1.07)
	Control (N=418)	230	55.0	
<b>N=868</b>				
<b>GP records only</b>	Intervention (N=471)	257	54.6	1.17 (0.87 to 1.57)
	Control (N=480)	244	50.8	
<b>N=951</b>				

\* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

The non-responders to the maternal interviews (N=750) were more likely to not be in education, employment or training (NEET) (45.2% non-responders vs 38.2% responders) and more likely to have difficulty with life skills (30.4% non-responders vs 23.9% responders). On average they also had a higher deprivation score (mean (SD) =40.1 (18.2) non-responders vs 38.3 (18.2) responders). Participants who did not have their GP notes accessed (N=667) were more likely to have difficulty with basic skills (30.1% notes not accessed vs 24.2% notes accessed), more likely to be more deprived (mean (SD) =41.0 (18.3) notes not accessed vs 37.8 (18.0) notes accessed) and had a different ethnicity case-mix (more black and mixed background).

#### 4.4.2.4 Treatment efficacy

The number of visits received during the total study period was re-categorised in order to obtain sufficient numbers in each arm. Based on the observed data in the Intervention arm, the percentage of participants experiencing an event generally decreased as the number of visits received increased (Table 4.28). Adjusting the analysis for Intervention receipt we observe a 0.004% increased odds of an event occurring in the

Intervention arm compared to Control for every unit increase in FNP visit received (Table 4.29). The estimated treatment efficacy for participants receiving all expected 64 visits was 1.03, indicating that the odds of an event occurring was 3% higher in the Intervention arm than in the Control but the confidence interval was wide. Therefore after taking account of amount of Intervention received there was no evidence of any difference between the arms.

Table 4.28 Subsequent pregnancies within twenty four months of first birth by total number of FNP visits received (observed data)

Number of visits received (categorised)	Number of participants	Subsequent pregnancy	
		Event	No event
Zero visits	31	27 (87.1)	4 (12.9)
1-10 visits	26	22 (84.6)	4 (15.4)
11-20 visits	36	28 (77.8)	8 (22.2)
21-30 visits	67	49 (73.1)	18 (26.9)
31-40 visits	155	91 (58.7)	64 (41.3)
41-50 visits	211	134 (63.5)	77 (36.5)
51-60 visits	89	53 (59.6)	36 (40.4)
More than 60 visits	28	22 (78.6)	6 (21.4)
<b>Total</b>	<b>643</b>	<b>426 (66.3)</b>	<b>217 (33.7)</b>

Table 4.29 Effect of FNP visit on subsequent pregnancies within twenty four months of first birth

Type of analysis	Adjusted* OR (97.5% CI)	p-value
Primary analysis	1.01 (0.77 to 1.33)	0.920
Efficacy per visit	1.0004 (0.993 to 1.008)	0.914
Efficacy per 64 visits <sup>†</sup>	1.02 (0.63 to 1.65)	0.914

\* Intervention compared to Control. Analysis adjusted for stratification (site) and minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

<sup>†</sup>The expected number of FNP visits received (based on participants entering the study at 16 weeks, giving birth on their due date, and receiving every scheduled visit between)

#### 4.4.3 Subgroup analysis

A pre-planned subgroup analysis was conducted employing appropriate interaction terms in the regression model to ascertain any differential effects of the Intervention and Control groups across the following baseline categories: age (less than 16 years), NEET status, difficulty in at least 1 basic skill and deprivation.

Table 4.30 shows the odds ratio (OR) for the interaction term alongside 95% CIs and p-values from the interaction effect. For age subgroup, an OR of 1.13 shows that the Intervention effect was 13% higher in

participants aged less than 16 years at recruitment than participants greater than or equal to 16 years of age at recruitment. However the 95% CI shows no evidence for this subgroup effect. Likewise, there was no evidence to suggest that any of the baseline factors examined here had any influence on the treatment effect.

Table 4.30 Subgroup analyses – subsequent pregnancies within twenty four months of first birth or not

Subgroup	Adjusted* OR† (95% CI)	p-value
Age (years) at recruitment		
Less than 16 years	1.13 (0.45 to 2.79)	0.799
NEET status		
Yes NEET	0.84 (0.50 to 1.41)	0.508
Difficulty in at least 1 basic skill		
Yes	1.24 (0.72 to 2.14)	0.439
Index of Multiple Deprivation		
Quintile 1 = least deprived	Reference category	0.627
2	1.23 (0.59 to 2.57)	
3	1.03 (0.49 to 2.17)	
4	1.44 (0.66 to 3.11)	
5 = most deprived	1.68 (0.80 to 3.54)	

\* Intervention compared to Control. Analysis adjusted for gestational age (weeks), smoking status at recruitment, and first or preferred language

† Odds ratio for the interaction between subgroup and Intervention arm – compares the Intervention effect in the presented subgroup (e.g. Age < 16 years) and the subgroup arm or reference category (Age ≥16 years)

## 5 Results: Secondary Outcomes (Maternal)

### 5.1 Socioeconomic

#### 5.1.1 Not in Education, Employment or Training (NEET) status

All participants reported their education, employment or training status at baseline and at 6, 12, 18 and 24 months follow-up and NEET status could only be considered in participants aged between 16 and 24 years. The odds ratio (OR) is the odds of not being in education, employment or training in the Intervention arm compared to the Control arm with an OR greater than one indicating a greater proportion of participants reporting being NEET in the Intervention than the Control arm. There was no evidence of a differential intervention effect over time and so was excluded from the model, although there was evidence of an increase in the odds of NEET status over time, best illustrated by Figure 5.1. There was no overall Intervention effect (across all four follow-up time points) in reporting NEET status (Table 5.1).

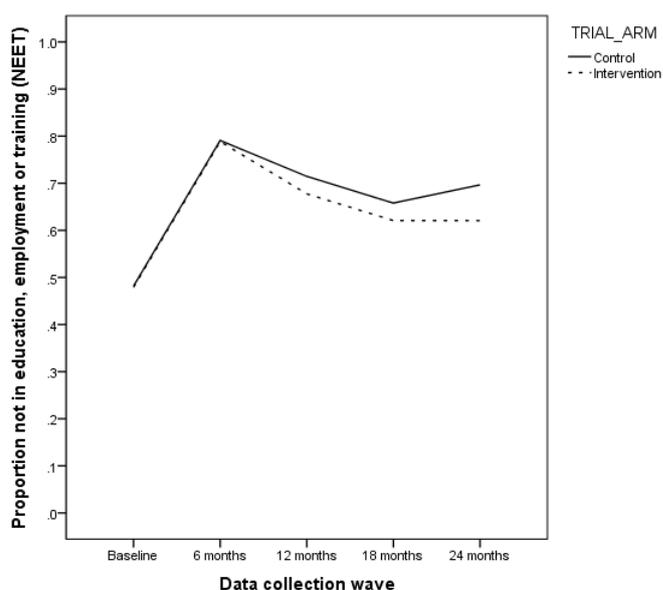
Table 5.1 Number (%) of participants reporting NEET at each follow-up and by trial arm

	Baseline N=1618 (I=808, C=810)	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 <sup>†</sup> (I=595, C=559)	Adjusted* OR (95% CI)	p-value
N (%) NEET							
Intervention	333 (47.9)	369 (78.9)	336 (67.7)	306 (62.1)	368 (62.1)	0.86 (0.60 to 1.23)	0.410
Control	330 (48.2)	344 (79.1)	333 (71.5)	300 (65.8)	388 (69.7)		
Missing							
Intervention	2	26	10	4	0		
Control	2	18	6	4	0		
Academic age <16 at interview							
Intervention	111	17	8	4	2		
Control	123	17	11	6	2		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language) and NEET status at baseline. Participants with no responses at any time point are missing.

<sup>†</sup> N=32 (I=11, C=21) short form 24 month paper questionnaires collected did not include question on education by formal education establishments

Figure 5.1 Proportion of participants reporting NEET at each follow-up and by trial arm



### 5.1.2 Hours in formal education

Participants were asked at the 6, 12, 18 and 24 month interviews whether they were currently attending any of the following formal education establishments: mainstream college/further education college, learning support unit, pupil referral unit, or teenage mums support unit, and, if so, the number of hours per week they attended for. Table 5.2 and Figure 5.2 show the number and proportion in education at each time point by trial arm. The proportion in formal education peaked at 18 months in both arms but had declined by 24 months. The odds of reporting being in formal education were 27% lower in the Intervention arm compared to Control but confidence intervals were wide indicating no evidence of a difference (Table 5.2). There was no evidence of differential intervention effect over time. Of those in education there was no evidence of an adjusted mean difference in mean hours worked per week between trial arms (Table 5.2, Figure 5.3).

Table 5.2 Number (%) in formal education\* at each follow-up and by trial arm

	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 <sup>†</sup> (I=595, C=559)	Adjusted <sup>‡</sup> OR (95% CI)	p-value
N (%) in formal education						
Intervention	62 (13.0)	84 (17.0)	99 (20.4)	101 (17.7)	1.09 (0.75 to 1.60)	0.652
Control	66 (14.7)	78 (16.6)	90 (19.5)	74 (14.0)		
Missing						
Intervention	35	19	16	23		

Control	22	13	5	32		
	6 months N=128	12 months N=162	18 months N=189	24 months N=175	Adjusted <sup>‡</sup> difference <sup>§</sup> in means (95% CI)	p-value
Of those in education hours / week Mean (sd)						
Intervention	17.8 (8.9)	17.5 (9.0)	16.6 (7.4)	18.4 (9.4)	-0.98 (-3.01 to 1.06)	0.347
Control	19.0 (8.6)	18.9 (8.1)	18.5 (9.0)	18.7 (10.0)		

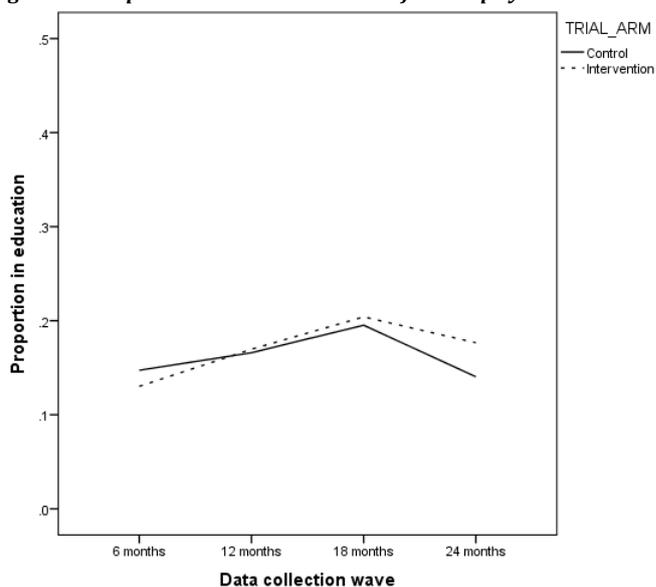
\* Numbers based on participant spending time at mainstream college/FE college, learning support unit, pupil referral unit, teenage mums support unit

† N=32 (I=11, C=21) short form 24 month paper questionnaires collected did not include question on education by formal education establishments

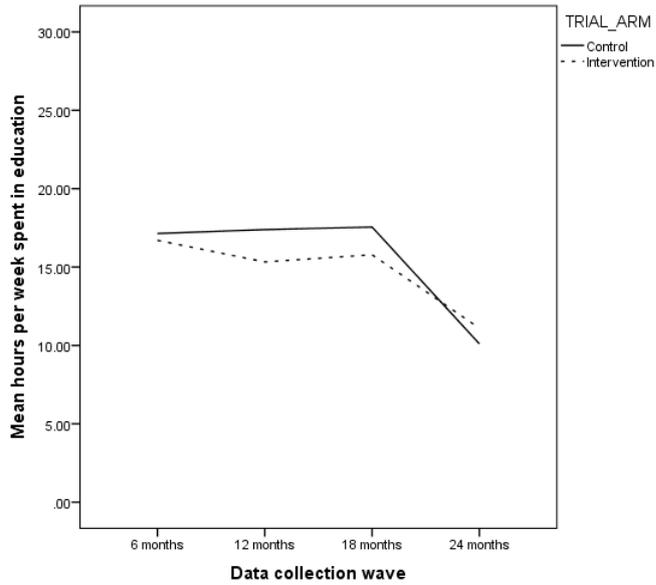
‡ Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing.

§ Intervention minus Control

**Figure 5.2 Proportion in education at each follow-up by trial arm**



**Figure 5.3 Mean hours spent in formal education at each follow-up by trial arm**



### 5.1.3 In paid employment

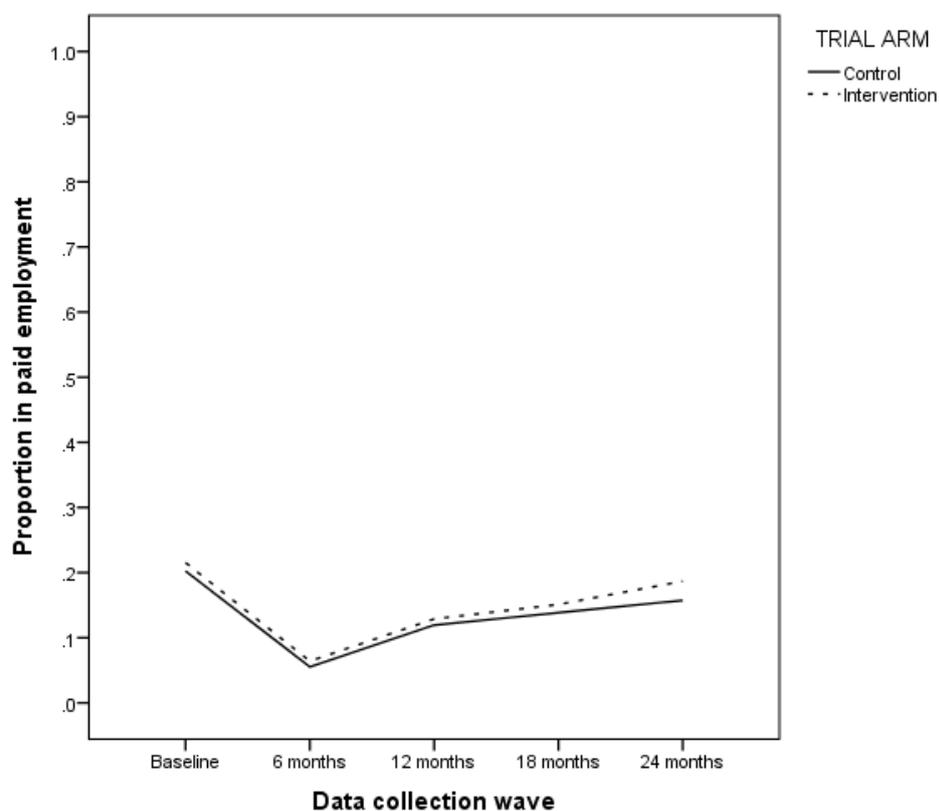
Participants were asked at baseline and 6, 12, 18 and 24 months whether they were in any type of paid employment. The proportion in paid employment by trial arm and over time are shown in Table 5.3 and Figure 5.4. The majority of responders were not in employment (around 80-90%). The proportion in employment is highest at baseline, with a trough at 6 months post-birth with a steady increase until 24 months. Although proportions were consistently higher in the Intervention than Control arm there was no evidence of a between arm difference (Table 5.3). There was however evidence of a change in the odds of participants in paid employment over time with increased odds of being in paid employment at every follow-up time point when compared to 6 months. There was no evidence of differential intervention effect over time.

Table 5.3 Number (%) in paid employment at each follow-up and by trial arm

	Baseline	6 months	12 months	18 months	24 months	p-value	
	N=1618 (I=808, C=810)	N=981 (I=511, C=470)	N=997 (I=514, C=483)	N=967 (I=501, C=466)	N=1154 (I=595, C=559)	Adjusted* OR (95% CI)	
N (%) in paid employment							
Intervention	174 (21.5)	31 (6.4)	65 (12.9)	75 (15.1)	111 (18.7)	1.15 (0.76 to 1.74)	0.506
Control	164 (20.2)	25 (5.5)	57 (11.9)	64 (13.9)	88 (15.7)		
Missing							
Intervention	0	28	10	5	1		
Control	0	18	5	4	0		

\*Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language), and baseline employment status. Participants with no responses at any time point are missing.

Figure 5.4 Proportion in paid employment at each follow-up and by trial arm



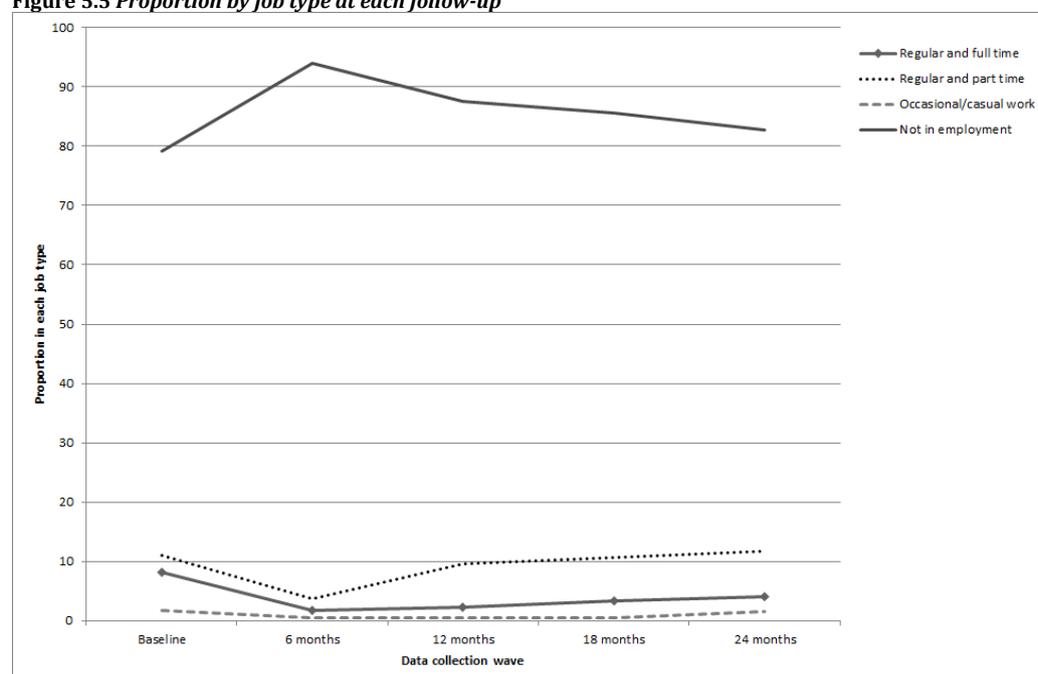
### 5.1.4 Type of employment

Participants in employment were classed as being in regular and full-time work, regular and part-time work, or in occasional/casual work at each time point. Of those in employment, being in regular and part-time work was more common with around 10% of participants in this category (Table 5.4 and Figure 5.5). Occasional or casual work accounted for a very small proportion of the participants (under 2%).

Table 5.4 Number (%) of participants in employment by type of employment at each follow-up

	Baseline N=1618 (I=808, C=810)	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=559)
Type of employment					
Regular and full time	132 (8.2)	16 (1.7)	23 (2.3)	32 (3.3)	47 (4.1)
Regular and part time	178 (11.0)	35 (3.7)	94 (9.6)	101 (10.6)	135 (11.7)
Occasional/casual work	28 (1.7)	5 (0.5)	5 (0.5)	5 (0.5)	17 (1.5)
Not in employment	1280 (79.1)	879 (94.0)	859 (87.6)	819 (85.6)	955 (82.8)
Missing	0	46	16	10	0

Figure 5.5 Proportion by job type at each follow-up



### 5.1.5 In receipt of benefits

Participants were asked at baseline and 24 months whether they were in receipt of any state benefits or payments (such as Income Support, Jobseekers Allowance, Housing Benefit, Council Tax Benefit, DLA and Incapacity Benefit, other care grant from Social Fund). At 24 months the majority of participants (N=1,011, 87.9%) were in receipt of some sort of state benefits or payments (Table 5.5). At baseline, in the same population, only 584 (36.1%) were in receipt of these benefits. A total of 1,150 participants responded at both baseline and 24 months interview (complete case set) and proportions in receipt of benefit were similar. By type of benefit, at baseline the majority of the participants in receipt of any benefits were receiving Jobseekers Allowance whilst at 24 months Income Support, Housing Benefits and Council Tax Benefit were more prevalent. The results are presented as proportions by trial arm and the ORs are the odds of *not* being in receipt of benefits in the Intervention arm compared to the Control arm (Table 5.6). There was no evidence of a difference between trial arms at 24 months after adjusting for baseline.

Table 5.5 Number (%) in receipt of state benefits or payments at baseline and 24 months by trial arm – all participants

	Baseline N=1618		24 months N=1154	
	Intervention N=808	Control N=810	Intervention N=595	Control N=559
Received any benefits?				
All participants				
Yes	301 (37.3)	283 (35.0)	517 (87.2)	494 (88.5)
No	507 (62.7)	525 (65.0)	76 (12.8)	64 (11.5)
Missing	0	2	2	1
Complete case set	N=593	N=557	N=593	N=557
Yes	212 (35.8)	196 (35.2)	517 (87.2)	494 (88.7)
No	381 (64.2)	361 (64.8)	76 (12.8)	63 (11.3)
Type of benefit received*	N=301	N=283	N=517	N=494
N (%) yes				
Income support	75 (24.9)	71 (25.1)	369 (71.4)	354 (71.7)
Jobseekers allowance	177 (58.8)	167 (59.0)	51 (9.9)	50 (10.1)
Housing benefit	96 (31.9)	85 (30.0)	382 (73.9)	383 (77.5)
Council Tax Benefit	50 (16.6)	51 (18.0)	374 (72.3)	354 (71.7)
Disability Living Allowance	18 (6.0)	14 (4.9)	15 (2.9)	30 (6.1)
Incapacity benefit	10 (3.3)	12 (4.2)	4 (0.8)	9 (1.8)
Other Care Grant from the Social Fund	13 (4.3)	10 (3.5)	58 (11.2)	53 (10.7)

\*Participants could choose multiple options

Table 5.6 Number (%) in receipt of state benefits or payments by trial arm – complete case set

	Intervention N=593	Control N=557	Total N=1150	Adjusted* OR (95% CI)	p-value
24 months					
Yes	517 (87.2)	494 (88.7)	983 (87.8)	1.17 (0.81 to 1.68)	0.401
No	76 (12.8)	63 (11.3)	136 (12.2)		
Baseline					
Yes	212 (35.8)	196 (35.2)	397 (35.5)		
No	381 (64.2)	361 (64.8)	722 (64.5)		

\*Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language), and state benefits or payments received at baseline

### 5.1.6 Other financial support

Participants were asked at baseline and 24 months about any other regular payments that they may be receiving, such as education grants, maintenance support, or regular cash from parents or relatives. A total of 1,122 participants responded to this question at both the baseline and 24 months interview with 49.2% at 24 months receiving regular payments compared to 46.7% at baseline (Table 5.7). The source of these payments at baseline was mainly from parents but changed at 24 months and were mainly from other sources. A total of 330 (29.4%) participants did not receive other regular payments at baseline and 24 months; 284 (25.3%) who were in receipt at baseline were still receiving them at 24 months; 268 (23.9%) who weren't receiving regular payments at baseline were at 24 months and 240 (21.4%) who were receiving regular payments at baseline, were not at 24 months. The results are presented as proportions by trial arm and the ORs are the odds of *not* being in receipt of regular payments in the Intervention arm compared to the Control arm. There was no evidence of a difference between trial arms at 24 months after adjusting for baseline.

Table 5.7 Number (%) in receipt of regular payments at baseline and 24 months by trial arm - complete case set

	Intervention N=584	Control N=538	Total N=1122	Adjusted* OR (95% CI)	p-value
24 months					
Yes	279 (47.8)	273 (50.7)	552 (49.2)	1.19 (0.91 to 1.55)	0.211
No	305 (52.2)	265 (49.3)	570 (50.8)		
Baseline					
Yes	290 (49.7)	234 (43.5)	524 (46.7)		
No	294 (50.3)	304 (56.5)	598 (53.3)		

\* Analysis adjusted for stratification (site), minimisation variable variables (smoking status and gestation age only), and regular payments received at baseline

### 5.1.7 Ever been homeless

Participants were asked at each time point (except late pregnancy) whether they had moved house since the last interview and, if so, whether they had ever been homeless, reflecting on the time since the last interview. An overall binary outcome was constructed to indicate whether the woman had ever been homeless during the duration of the trial (since but not including baseline up until 24 months). Participants responding over the four time points (6, 12, 18 and 24 months) were included as were participants who had indicated that they had been homeless for at least one time point (but may not have responded to view and had missing data). Participants who had missing data (and had not responded to at least one of the interviews) and in those in which they had responded had reported that they had not been homeless were excluded from this analysis. At baseline, a greater proportion of participants in the Control arm reported ever being homeless and this continued across the period of the study (Table 5.8). The proportion of participants ever been homeless since baseline is presented by trial arm alongside the odds of ever been homeless in the Intervention arm compared to the Control arm. There was no evidence of clustering of outcome at Family Nurse level and a two-level model was retained. Neither was there evidence of a difference in the proportion of participants in reporting as ever being homeless over the study period between trial arms (Table 5.9).

Table 5.8 Number (%) reporting as being homeless at each follow-up and by trial arm

	Ever been homeless				
	Prior to baseline* N=1618 (I=808, C=810)	Between recruitment and 6 months N=981 (I=511, C=470)	Between 6 and 12 months N=997 (I=514, C=483)	Between 12 and 18 months N=967 (I=501, C=466)	Between 18 and 24 months N=1122 (I=584, C=538)
N (%)					
Intervention	144 (17.8)	40 (7.8)	38 (7.4)	35 (7.0)	46 (7.9)
Control	170 (21.0)	47 (10.0)	35 (7.3)	38 (8.2)	59 (11.0)
Missing					
Intervention	0	0	2	1	0
Control	0	0	3	1	1

\* Includes participants still homeless at baseline interview

Table 5.9 Number (%) ever been homeless during the study period by trial arm

	Ever been homeless (between baseline and 24 months) N=1337 (I=674, C=663)	Adjusted* OR (95% CI)	p-value
N (%)			
Intervention	123 (30.4)	0.76 (0.55 to 1.05)	0.093
Control	136 (36.3)		
Missing <sup>†</sup>			
Intervention	269		
Control	288		

\* Analysis adjusted for stratification (site), minimisation variable variables (gestational age and smoking status at recruitment, and first or preferred language) and baseline homeless status. Language was not included due to small numbers and restricted the model to converge

† Missing due to no response at any of the four follow-up time points and any valid responses were recorded as not being homeless (hence unable to determine whether they had been homeless over the study period)

## 5.2 Maternal health and well-being

### 5.2.1 General health status (EQ-5D)

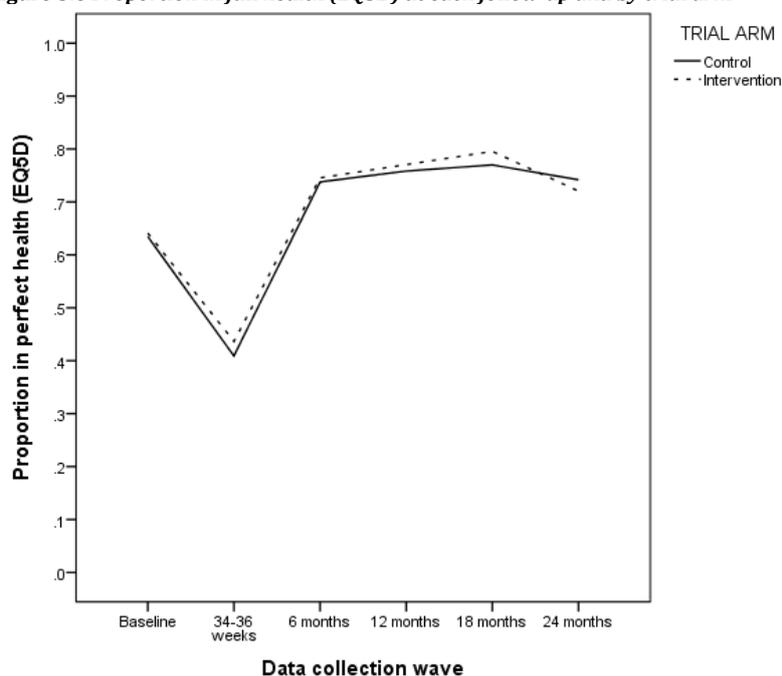
EQ5D was reported at each data collection time point. Due to the distribution of the data the response was categorised into Full (score of 1) and not in full health (score less than 1). The proportion of participants reporting full health at each time point by trial arm is shown in Table 5.10 and Figure 5.6. There was no evidence of a between arm difference in the odds of reporting full health (Table 5.10).

Table 5.10 Number (%) of participants with full health (EQ5D) at each follow-up and by trial arm

	Baseline N=1618 (I=808, C=810)	34-36 weeks N=1237 (I=617, C=620)	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=559)	Adjusted* OR (95% CI)	p-value
N (%) full health								
Intervention	518 (64.1)	268 (43.6)	378 (74.6)	393 (77.1)	397 (79.6)	428 (72.1)	1.07 (0.86 to 1.32)	0.547
Control	512 (63.4)	252 (40.9)	346 (73.8)	364 (75.8)	358 (77.0)	414 (74.2)		
Missing								
Intervention	0	3	4	4	2	1		
Control	3	4	1	3	1	1		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language), and baseline EQ5D. Participants with no responses at any time point are missing.

Figure 5.6 Proportion in full health (EQ5D) at each follow-up and by trial arm



## 5.2.2 Maternal weight

Maternal weight at baseline was derived from two sources: the first from the maternal booking data and if missing then supplemented by self-report at baseline. A total of 1425 (88.1%) weights came from the maternity booking data, with 154 (9.5%) from the baseline self-report; 9 (2.4%) were missing in both sources. At 24 months follow-up, weight was self-reported at interview and non-response was much greater at this time point, with 682 responders (Table 5.11). A total of 671 participants had weight recorded at both time points. There was no evidence of a difference in the mean weight of participants at 24 months follow-up after adjusting for baseline between trial arms.

Table 5.11 Mean (sd) weight (kg) of participants at baseline and 24 months and by trial arm

	Intervention	Control	Total	Adjusted* difference† in means (95% CI)	p-value
All participants					
24 months	N=338 63.7 (13.3)	N=344 63.9 (14.2)	N=682 63.8 (13.8)		
Baseline	N=790 62.7 (13.8)	N=789 62.5 (14.4)	N=1579 62.6 (14.1)		
Complete case set					
24 months	N=334 63.6 (13.4)	N=337 63.9 (14.3)	N=671 63.7 (13.8)	0.47 (-0.88 to 1.83)	0.490
Baseline	N=790 59.9 (11.3)	N=789 60.6 (13.6)	N=1579 60.2 (12.5)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language), and baseline weight. Participants with no responses at any time point are missing

† Intervention minus Control

### 5.2.3 Psychological distress

Psychological distress is measured using the Kessler Psychological distress scale, a ten item scale scored from 1 to 5 (scores range from 10 to 50) where a low score indicates a low level of psychological distress. This was measured at both the baseline and 24 months follow-up. Of the 1,122 participants who responded at 24 months, 1,116 responded at baseline.

Figure 5.7 shows the summary measures for the scale at both baseline and 24 month follow-up. At baseline, the distribution was normal but at follow-up there was a shift to the left with a skew to the right indicating that participants had shifted their scores to a lower level of psychological distress. There was no evidence of clustering at Family Nurse level and a two-level model was retained (adjusting for site and smoking status, language and gestational age). There was no evidence of a difference in the mean Kessler score at 24 months follow-up after adjusting for baseline between trial arms (Table 5.12).

Figure 5.7 Distribution of Kessler Psychological Scale score at baseline and 24 months

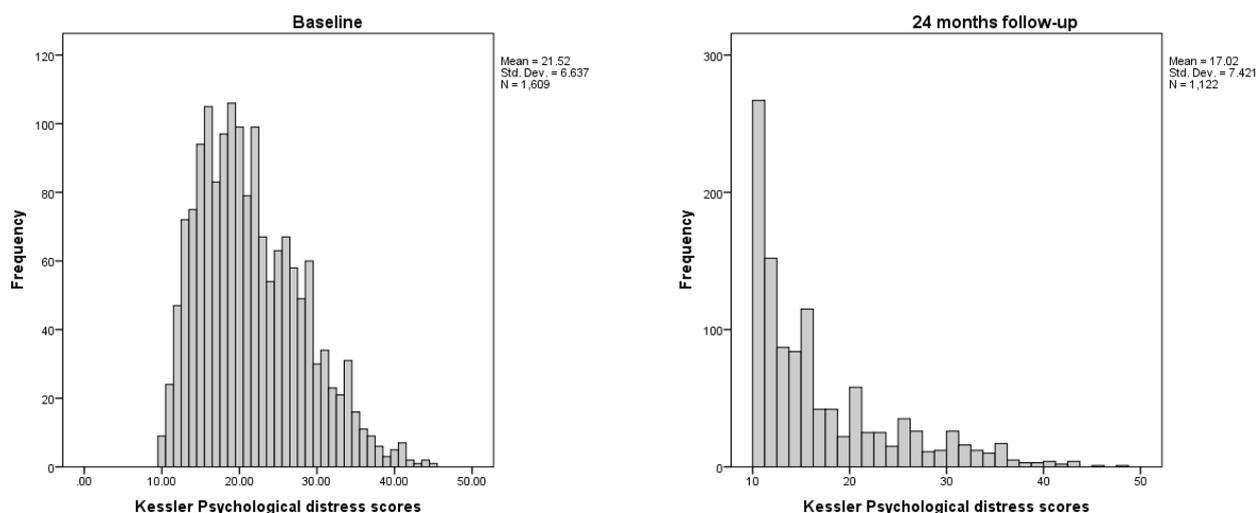


Table 5.12 Kessler Psychological Distress Scale at baseline and 24 months (complete N=1,116)

	Intervention N=580	Control N=536	Adjusted* difference in means (95% CI)	p-value
Kessler Psychological distress score <sup>†</sup> (10-50)				
Mean (sd)				
24 months	16.86 (7.65)	17.19 (7.19)	-0.39 (-1.19 to 0.40)	0.333
Baseline	21.37 (6.53)	21.28 (6.44)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language) and baseline Kessler score

<sup>†</sup> low score = low level of psychological distress

### 5.2.4 Depression

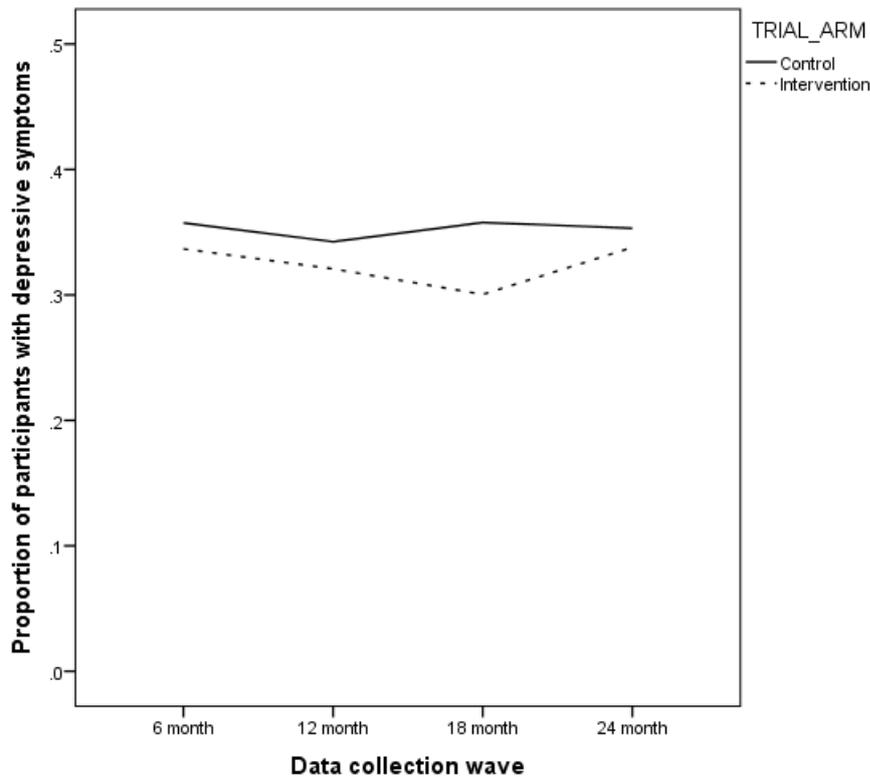
At 6, 12, 18 and 24 months, participants were asked two items about symptoms of depression using the Whooley Depression Screening tool. A positive response to both items indicated that the participant was displaying depressive symptoms, and if no to either or both then no depressive symptoms were displayed. As illustrated by Table 5.13 and Figure 5.8, the proportion of participants reporting depressive symptoms was consistently lower in the Intervention arm across all waves of data collection. The odds of reporting depressive symptoms were 20% lower in the Intervention arm compared to control. However, the confidence intervals were wide and therefore there was no evidence of a statistical difference between arms.

Table 5.13 Proportion of participants reporting depressive symptoms at each follow-up and by trial arm

% depressive symptoms	6 months N=952 (I=496, C=456)	12 months N=984 (I=505, C=479)	18 months N=960 (I=496, C=464)	24 months N=1121 (I=583, C=538)	Adjusted* OR (95% CI)	p-value
Intervention	167 (33.7)	162 (32.1)	149 (30.0)	197 (33.8)	0.80 (0.60 to 1.05)	0.107
Control	163 (35.7)	164 (34.2)	166 (35.8)	190 (35.3)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables

Figure 5.8 Proportion of participants reporting depressive symptoms at each follow-up and by trial arm



### 5.2.5 Postnatal depression

Postnatal depression was assessed at 6 months using the Edinburgh Postnatal Depression Scale (EPDS). This is a 10 items scale ranging from 0 to 30 where higher scores indicate more depressive symptoms. A binary outcome was also used with scores of greater than 13 categorising mothers that are likely to be suffering from, a depressive illness of varying severity. A total of 981 participants responded to the 6 month telephone interview of which 949 (97%) answered the question relating to the EPDS. Scores ranged from 0 to 27 and the distribution was skewed to the right indicating that the majority of participants didn't have depressive symptoms (Figure 5.9). Examining the score as a binary variable, 114 (12.0%) had a score of greater than 13 indicating that they were likely to be suffering from a depressive illness of varying severity. Due to the skewness of the continuous score a square root transformation was

found to result in linear residuals (Figure 5.9). However, using the transformed data did not result in a different result and so the raw scores were used for ease of interpretation. There was no statistical evidence to suggest a difference in EPDS score between participants randomised to Intervention and Control (Table 5.14).

Figure 5.9 Distribution of the Edinburgh Postnatal Depression Score at 6 months by trial arm

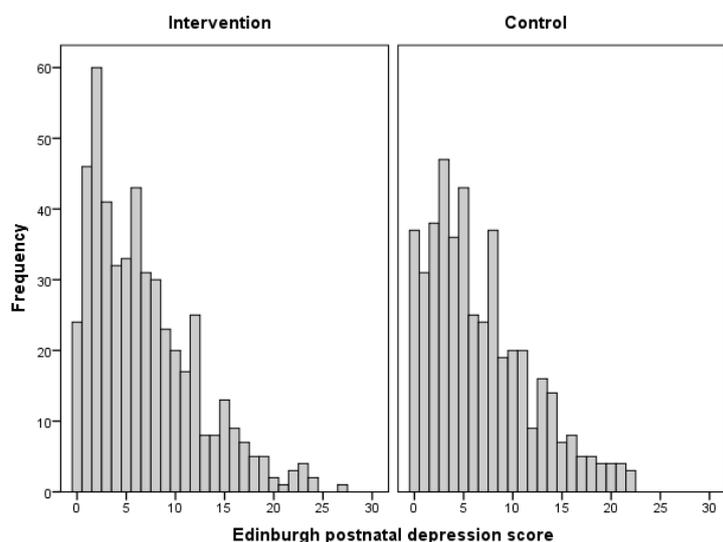


Table 5.14 Edinburgh Postnatal Depression Scale Score at 6 months by trial arm

	Intervention N=511	Control N=470	Adjusted* OR / difference in means (95% CI)	p-value
EPDS Score (range 0 to 30) <sup>†</sup>				
Mean (sd)	6.78 (5.35)	6.66 (5.16)	0.11 (-0.56 to 0.78)	0.761
Missing	18	14		
EPDS – binary				
≤13 (0)	433 (87.8)	402 (88.2)	1.03 (0.69 to 1.52)	0.901
>13 (1)	60 (12.2)	54 (11.8)		
Missing	18	14		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

<sup>†</sup> Higher score indicates more depressive symptoms

### 5.2.6 Self-efficacy

The Generalized Self-Efficacy Scale is a ten-item psychometric scale used to assess optimistic self-beliefs to cope with a variety of difficult demands in life with total score ranges from 10 (low self-efficacy) to 40 (higher self-efficacy). The distributions are skewed at each time point (Figure 5.10). Median self-efficacy scores in the Intervention arm are only

slightly higher at 6, 12 and 18 month time points, but are the same at baseline and 24 months (Table 5.15). There was no evidence of a differential intervention effect over time and so was excluded from the model. There was some evidence of a difference in adjusted mean self-efficacy score between arms over all time points but this adjusted difference was very small, equating to a 0.44 point difference in arms.

Figure 5.10 Distribution of the Generalized Self-Efficacy Scale Score by follow-up

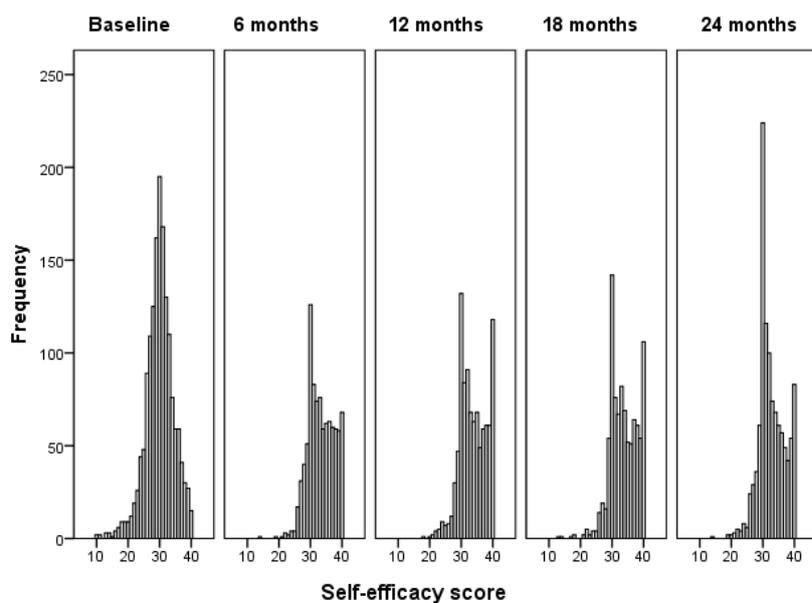
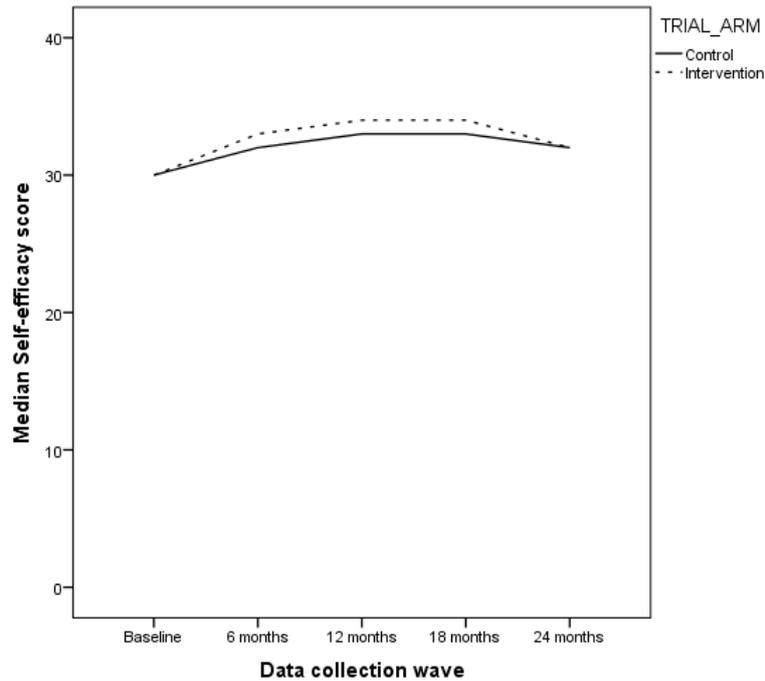


Table 5.15 Median (25th to 75th centiles) Generalized Self-Efficacy Scale Score at each follow-up and by trial arm

	Baseline	6 months	12 months	18 months	24 months	Adjusted* difference in means (95% CI)	p-value
	N=1592 (I=798, C=794)	N=943 (I=487, C=456)	N=980 (I=503, C=477)	N=949 (I=491, C=458)	N=1109 (I=578, C=531)		
Intervention	30 (28 to 33)	33 (30 to 37)	34 (31 to 38)	34 (30 to 38)	32 (30 to 36)	0.44 (0.10 to 0.78)	0.011
Control	30 (27 to 32)	32 (30 to 36)	33 (30 to 37)	33 (30 to 37)	32 (30 to 35)		

\* Analysis adjusted for stratification (site), participant, minimisation variables (gestational age and smoking status at recruitment, and first or preferred language) and baseline. Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables.

Figure 5.11 Median self-efficacy score at each follow-up and by trial arm



### 5.2.7 Adaptive functioning

Eight binary items were asked at baseline and 24 months regarding the participants' adaptive functioning and combined to make three binary subscales: Difficulty with basic skills, burden and deficiency in life skills. The proportion of participants with these difficulties decreased over time in all three areas but there was no evidence of a difference between trial arms (Table 5.16).

Table 5.16 Adaptive functioning subscales at 24 months and baseline by trial arm

	Intervention	Control	Total	Adjusted* OR (95% CI)	p- value
Difficulty in at least one basic skill	N=581	N=536			
24 months	127 (21.9)	116 (21.6)	243 (21.8)	0.91 (0.66 to 1.24)	0.542
Baseline	152 (26.2)	120 (22.4)	272 (24.4)		
At least one life burden	N=573	N=531			
24 months	99 (17.3)	97 (18.3)	196 (17.8)	0.95 (0.70 to 1.31)	0.764
Baseline	164 (28.6)	167 (31.5)	331 (30.0)		
Three or less life skills	N=578	N=534			
24 months	76 (13.1)	76 (14.2)	152 (13.7)	0.93 (0.65 to 1.32)	0.688
Baseline	131 (22.7)	142 (26.6)	273 (24.6)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

### 5.2.8 Intimate partner violence

Intimate partner violence was assessed using the Composite Abuse Scale (CAS). There are four subscales: physical abuse (score 0 to 35), emotional abuse (score 0 to 50), harassment (score 0 to 20), and severe combined abuse (0 to 40), and one overall score (0 to 145). A total of 1,122 interviews were conducted at 24 months of which 1,044 were face to face and 76 conducted by telephone by PRC (Table 5.17). The CAS was only administered in face-to face interview and where the participant was alone (in 607 participants). A greater number of participants in the Intervention arm were able to answer the composite abused scale questions (56.6% vs 51.6%). A greater number of participants randomised to Control received a telephone interview as opposed to a face-to face interview (9.1% vs 4.6%). The participants who were able to answer the composite abuse scale questions did not appear to be a biased sample and were relatively similar to those who did not answer the questions (Table 5.18). There are small differences in that the non-completing sample are more likely to be separated at baseline, more likely to be NEET, have slightly higher deprivation scores based on postcode and have more difficulties with adaptive functioning.

Table 5.17 Summary of responders to the 24 month follow-up for the composite abuse scale by trial arm

	Intervention N=584	Control N=538	Total N=1122
Telephone interview	27 (4.6%)	49 (9.1%)	76 (6.8%)
Face to face interview			
Alone at time of interview			
Yes	330 (56.6%)	277 (51.6%)	607 (54.2%)
No	226 (38.8%)	211 (39.3%)	437 (39.0)
Missing	1	1	2

Table 5.18 Participants' demographics by CAS completion

	CAS completed N=607	CAS not completed N=1011	Overall N=1618
<i>Demographics</i>			
Age at recruitment (years)	18.0	17.7	17.8
Median (25th to 75th centile)	(17.1 to 19.0)	(16.8 to 19.0)	(16.9 to 18.8)
<i>Ethnicity</i>			
White background	534 (87.9)	891 (88.2)	1425 (88.1)
Mixed background	38 (6.3)	51 (5.0)	89 (5.5)
Asian background	14 (2.3)	13 (1.3)	27 (1.7)
Black background	20 (3.3)	51 (5.0)	71 (4.4)
Chinese or Other background	1 (0.2)	5 (0.5)	6 (0.4)
<i>Relationship status</i>			
Married	8 (1.3)	12 (1.2)	20 (1.2)
Separated	46 (7.6)	119 (11.8)	165 (10.2)
Closely involved/boyfriend	475 (78.8)	743 (73.5)	1222 (75.5)
Just friends	74 (12.3)	137 (13.5)	211 (13.0)
<i>Live with father of baby</i>			
Yes	145 (23.9)	223 (22.1)	368 (22.7)
No	418 (68.9)	694 (68.6)	1112 (68.7)
Not answered	44 (7.2)	94 (9.3)	138 (8.5)
<i>Socio-economic</i>			
<i>NEET status*</i>			
Yes	231 (42.9)	432 (51.0)	663 (47.9)
No	306 (56.9)	411 (48.6)	717 (51.8)
Not answered	1 (0.7)	3 (0.4)	4 (0.3)
<i>Overall Index of Multiple Deprivation Score<sup>†‡</sup></i>			
Median (25th to 75th centile)	(23.1 to 50.5)	(26.0 to 53.0)	(25.1 to 52.0)
<i>Maternal health and well-being</i>			
<i>Generalized self-efficacy scale</i>			
(score 10 to 40) <sup>§</sup>	30.4	29.7	30.0
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(28.0 to 33.0)	(27.0 to 32.0)	(28.0 to 33.0)
<i>Adaptive functioning</i>			
<i>Difficulty in at least one basic skill</i>			
Yes	137 (22.6)	293 (30.0)	430 (26.6)
No	470 (77.4)	715 (70.7)	1185 (73.2)

	CAS completed N=607	CAS not completed N=1011	Overall N=1618
Not answered	0	3 (0.3)	3 (0.2)
Three or less life skills			
Yes	137 (22.6)	297 (29.4)	434 (26.8)
no	469 (77.2)	709 (70.1)	1178 (72.8)
Not answered	1 (0.2)	5 (0.5)	6 (0.4)
At least one life burden			
Yes	171 (28.1)	305 (30.2)	476 (29.4)
No	432 (71.1)	699 (69.1)	1131 (69.9)
Not answered	5 (0.8)	7 (0.7)	12 (0.7)
Health behaviour – Ever smoked			
Yes	487 (80.2)	807 (79.8)	1294 (80.0)
No	120 (19.8)	204 (20.2)	324 (20.0)

\* Definition of NEET status: Not in education employment or training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)

† Higher IMD score indicated more deprivation

‡ Mean IMD Score for England in 2010 is 21.67 Wilkinson, Dawn Louise, Falko F. Sniehotta, and Susan Michie. 'Targeting those in need: Baseline data from the first English National Health Service (NHS) Health Trainer Service.' *Psychology, health & medicine* 16.6 (2011): 736-748.

§ Higher score indicates higher level of self-efficacy

Data from the composite abuse total score and subscales were all skewed to the right with 362 (60.6%) of the 597 participants that had complete data reporting no abuse (score of 0). The remaining 2,135 had a score ranging from 1 to 103. These data could not be analysed using linear assumptions and residuals were nonlinear. A binary model was therefore used for participants who had a score of 0 (reporting no abuse) and those with a score at >0 (showing some degree of abuse). The results are presented as proportions by trial arm for the overall CAS score and by subscales. There was no evidence of clustering at Family Nurse level and a two-level model was retained (adjusting for site, smoking status and gestational age). There was no evidence of a difference between arms in the proportion of participants reporting abuse at 24 months follow-up in the overall score or in any of the subscales (Table 5.19).

Table 5.19 Number (%) reporting abuse (overall and by subscale) at 24 months by trial arm

	Intervention N=330	Control N=277	Total N=607	Adjusted* OR (95% CI)	p-value
<b>Overall Composite Abuse Scale</b>					
Reported abuse <sup>†</sup>	122 (37.7)	113 (41.4)	235	1.17 (0.84 to 1.63)	0.365
No abuse	202 (62.3)	160 (58.6)	362		
Missing	6	4	10		
<b>Emotional</b>					
Reported abuse <sup>†</sup>	115 (35.5)	106 (38.4)	221	1.14 (0.82 to 1.59)	0.444
No abuse	211 (64.7)	170 (61.6)	381		
Missing	4	1	5		
<b>Physical</b>					
Reported abuse <sup>†</sup>	61 (18.7)	69 (24.9)	130	1.44 (0.98 to 2.14)	0.066
No abuse	266 (81.3)	208 (75.1)	474		
Missing	3	0	3		
<b>Harassment</b>					
Reported abuse <sup>†</sup>	65 (19.9)	66 (24.0)	131	1.24 (0.77 to 2.01)	0.382
No abuse	261 (80.1)	209 (76.0)	470		
Missing	4	2	6		
<b>Severe</b>					
Reported abuse <sup>†</sup>	34 (10.4)	28 (10.1)	62	0.96 (0.57 to 1.63)	0.876
No abuse	293 (89.6)	248 (89.9)	541		
Missing	3	1	4		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

<sup>†</sup> Score of at least 1

## 5.3 Health behaviour

### 5.3.1 Smoking cessation methods

The data collection did not allow an accurate assessment of smoking cessation; therefore, smoking reduction is examined as an alternative outcome.

### 5.3.1.1 Late pregnancy

At late pregnancy participants who were classified as current smokers at baseline and those who had changed their smoking habit since baseline were asked how many cigarettes they smoked in the 2nd trimester and in the 3rd trimester. A total of 275 of 542 (51%) participants had reduced the amount smoked between the 2nd and 3rd trimesters. Of these, 231 (84%) reported reducing the amount of cigarettes on their own (Intervention 117/139(84.2%), Control 114/136(83.8%)) and the remainder reported help such as smoking cessation counsellor or nicotine replacement therapy. The adjusted OR for reducing smoking on their own in the Intervention arm compared to Control was 1.07 (95% CI: 0.55 to 2.07, p-value=0.844).

### 5.3.1.2 6 months

At 6 months 528 of 981 participants were identified as a current smoker (including those who previously self-reported or had declared a change in status from quitter to current smoker). Of these 528, 237 (44.9%) reported that they had reduced the number of cigarettes smoked. A total of 225/235 (95.7%) of these participants reduced the number smoked without the help of a counsellor (Intervention 120/123 (97.6%), Control 105/112 (93.8%), two participants had missing data). The adjusted OR for reducing smoking on their own at 6 months in the Intervention arm compared to Control was 3.14 (95% CI: 0.75 to 13.17, p-value=0.118).

## 5.3.2 Smoke in home

At each interview point after birth the participant was asked whether anyone had smoked in their home even with doors and windows open. The results in Table 5.20 show that there is little variation between the arms at each time point. We can also see that as the baby gets older there is an increase in participants who report that there has been smoking in the home, ranging from 14% at 6 months interview to nearly 40% at 24 month interview. We felt that the most important question was whether anyone had ever smoked in the home during the study period following the birth of the baby. The results in Table 5.20 show that there is lower chance of smoking in the home in the Intervention arm compared to the Control arm but this is non-significant.

Table 5.20 Number (%) reporting that anybody has smoked in the home at each follow-up and by trial arm

	Smoking in the home by anyone even with doors and windows open in last 6 months			
	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=559)
N (%)				
Intervention	69 (14.3)	91 (18.2)	105 (21.5)	220 (37.7)
Control	65 (14.5)	100 (21.2)	100 (22.0)	215 (40.0)
Missing				
Intervention	29	13	13	11
Control	21	11	12	22

Table 5.21 Number (%) ever had people smoking in the home at each follow-up and by trial arm

	Ever had smoking in home (between 6 and 24 months) N=1319 (I=784, C=735)	Adjusted* OR (95% CI)	p-value
N (%)			
Intervention	298 (61.3)	0.82 (0.62 to 1.09)	0.175
Control	290 (65.2)		
Missing†			
Intervention	180		
Control	208		

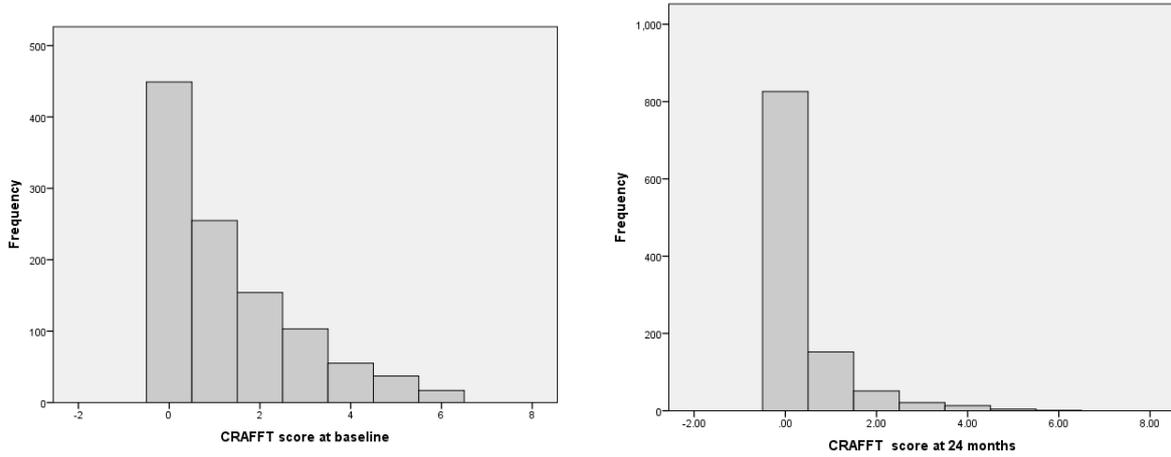
\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

† Missing due to no response in at least one of the 4 follow-up time points and where any valid responses were recorded as not having smoking in the home (hence unable to determine whether they had people smoking in the home over the study period).

### 5.3.3 Problem alcohol and drug use (CRAFFT)

The CRAFFT substance and abuse screening test was administered in participants (at baseline and at 24 months) who had ever used alcohol or drugs. Higher CRAFFT scores indicate a greater risk of problems related to drug and alcohol use. Of the 1,122 that responded at 24 months, 1,120 participants responded to all 6 CRAFFT items (2 missing a follow-up response). Of these, 49 (4.4%) were not asked the question at baseline as they had stated that they had not ever drunk alcohol but had responded at 24 months (scores ranging between 3 and 6). A total of 3 participants were missing at baseline but responded at 24 months; thus 1,068 participants had a CRAFFT score at both baseline and 24 months. Figure 5.12 shows the summary measures for the CRAFFT score at both baseline and 24 month follow-up. The distribution for the CRAFFT score at baseline and 24 months were both skewed. There was no evidence of a between arm difference in mean score (Table 5.22).

**Figure 5.1 Distributions of the CRAFFT score at baseline and at 24 months**



**Table 5.22 Mean (sd) CRAFFT score at baseline and 24 months by trial arm (complete case set - N=1,068)**

	Intervention N=554	Control N=514	Adjusted* difference in means (95% CI)	p-value
Baseline CRAFFT scale (score 0 to 6)				
24 months	0.37 (0.84)	0.37 (0.83)	-0.03 (-0.12 to 0.07)	0.586
Baseline	1.31 (1.55)	1.27 (1.47)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language) and baseline CRAFFT

### 5.3.4 Contraceptive use

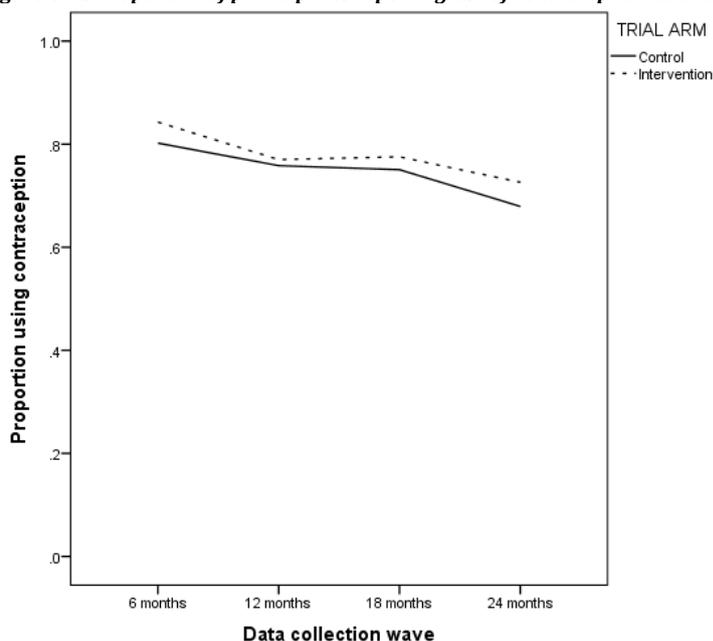
At each time point after birth participants are asked whether they are using contraception and there are three possible responses; yes, no, not having sex. The results in Table 5.23 show that at both 6 month and 24 month interview there is a higher percentage of contraceptive use in the Intervention arm compared to the Control arm. At 12 month and 18 month interviews there is little difference between arms. The adjusted odd ratio for using contraception is 1.25 for the Intervention arm compared to the Control. The confidence interval and p-value show that this is close to being significant at the 5% level. There is a downward trend in use of contraception over time but there is no evidence of a significant interaction effect between time and trial arm (Figure 5.13).

Table 5.23 Number (%) reporting use of contraception at each follow-up and by trial arm

	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=559)	Adjusted* OR (95% CI)	p-value
N (%)						
Intervention	424 (84.3)	392 (77.0)	387 (77.6)	432 (72.6)	1.25 (0.98 to 1.60)	0.078
Control	373 (80.2)	370 (77.2)	349 (75.1)	379 (67.9)		
Missing						
Intervention	8	5	2	0		
Control	5	4	1	1		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables.

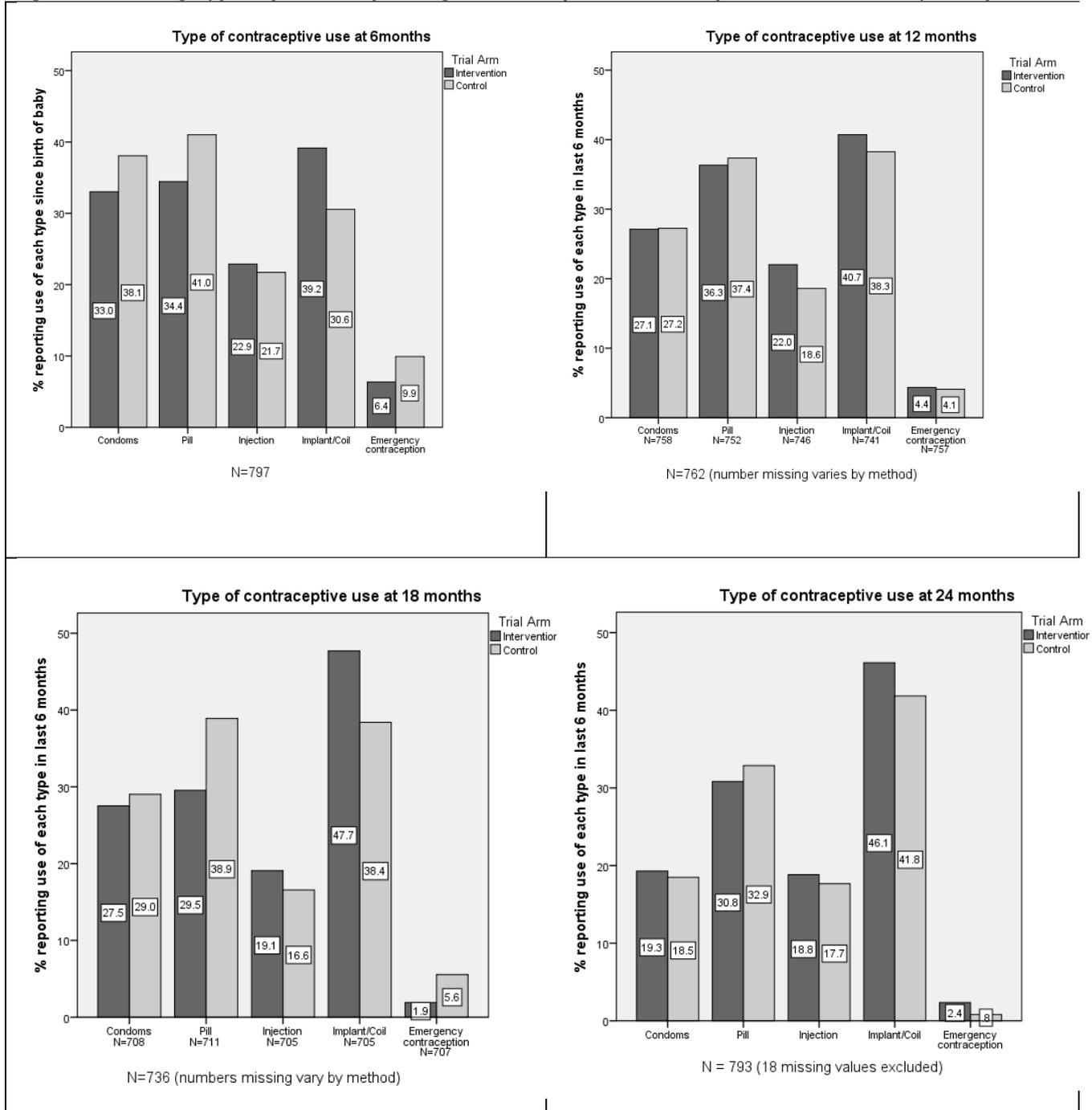
Figure 5.13 Proportion of participants reporting use of contraception at each follow-up and by trial arm



### **5.3.5 Contraceptive method**

Where participants reported use of contraceptives they were subsequently asked which methods they used and were able to choose more than one method if appropriate. The percentage reporting usage by method at each time point is presented in Table 5.23 by trial arm. Numbers using cap and rhythm method were extremely low and hence were excluded from these analyses. As seen in the Figure 5.14, women in the Intervention arm more frequently use longer-acting contraception (injection, implant, coil) than women in the Control arm), whereas women in the Control arm more frequently use short-term contraception (condoms, pill) than women in the Intervention arm.

**Figure 5.14 Percentage of participants who report using each contraceptive method in the previous 6 months at each follow-up**



## 5.4 Pregnancy and birth

The primary source for the birth outcomes is the maternal records. Of the 1,498 participants that we had permission to collect data at birth, a total of 1,510 babies were born (live or stillborn) of which 1,486 were singletons and 12 sets of twins.

Delivery gestation was recorded in the Birth CRF for each participant. Participants were included in this analysis if they had a stillbirth or live baby (N=1498, Intervention=735, Control=763). The distribution of delivery gestation was negatively skewed and very similar for the trial arms (Figure 5.15 and Table 5.24).

Figure 5.15 Distribution of delivery gestation (weeks) by trial arm

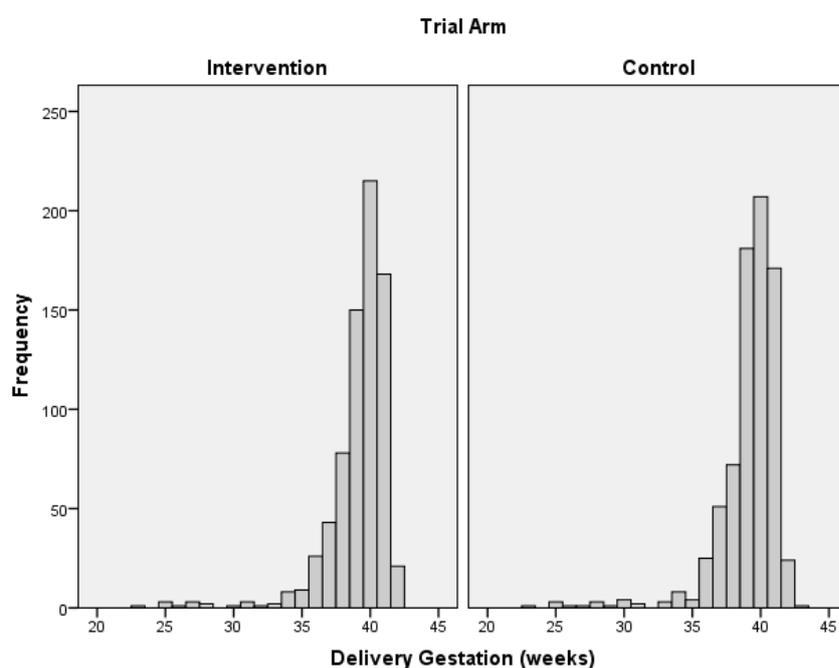


Table 5.24 Mean (sd) delivery gestation (weeks) for live and stillbirths only (N=1,498) by trial arm

	Intervention N=735	Control N=763	Adjusted* difference in means (95% CI)	p-value
Delivery gestation				
Mean (sd)	39.156 (2.325)	39.163 (2.305)	-0.005 (-0.239 to 0.230)	0.968

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

### 5.4.1 Place of birth (planned and actual)

Data on planned and actual place of birth were obtained on 1475 (98.2%) and 1493 (99.7%) participants respectively (Table 5.25). The majority of participants planned to have their baby at an obstetric unit (85%) and a greater proportion gave birth there. The numbers in categories such as Home birth, and birth centre (stand-alone) were too small to be analysed using a multinomial regression model.

Table 5.25 Number (%) planned and actual place of birth at each follow-up and by trial arm

	Intervention N=735	Control N=763	Total N=1498
<b>Planned place of birth</b>			
Home	4 (0.6)	4 (0.5)	8 (0.5)
Birth centre (stand-alone)	16 (2.2)	17 (2.2)	33 (2.2)
Birth centre (alongside)	88 (12.2)	92 (12.2)	180 (12.2)
Obstetric unit	611 (85.0)	643 (85.1)	1254 (85.0)
Missing	16	7	23
<b>Actual place of birth</b>			
Home	5 (0.7)	7 (0.9)	12 (0.8)
Birth centre (stand-alone)	5 (0.7)	6 (0.8)	11 (0.7)
Birth centre (alongside)	55 (7.5)	68 (8.9)	123(8.2)
Obstetric unit	666 (91.1)	678 (89.0)	1344 (90.0)
Born before arrival	0 (0.0)	3 (0.4)	3 (0.2)
Missing	4	1	5

### 5.4.2 Antenatal hypertension

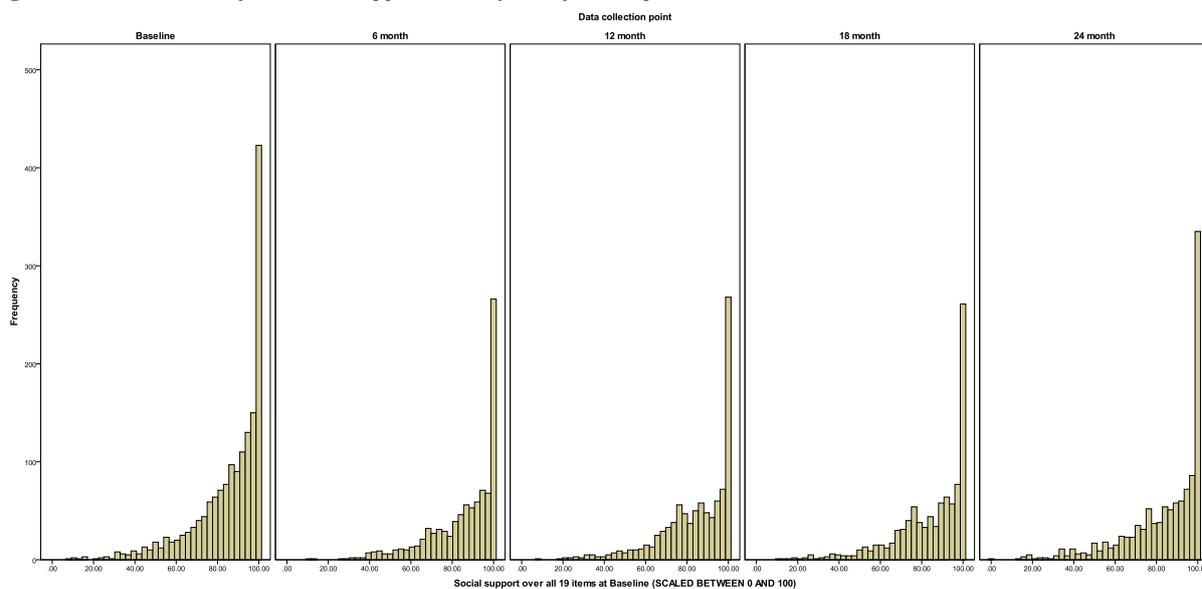
Data on antenatal pre-eclampsia / hypertension were obtained from the maternal record. Of the 1,542 participants, 147 (9.5%) required monitoring, treatment or delivery due to pre-eclampsia / hypertension. There was no difference between trial arms with 80/766 (10.4%) in the Intervention group and 67/776 (8.6%) in the Control group (OR= 1.26 (95% CI: 0.90 to 1.79),  $p=0.182$ ).

## 5.5 Social support

### 5.5.1 Social support networks

Complete social support outcome data were obtained at each data collection point for 593 participants (36.7% of all participants). As shown by the panel of figures below, the overall score for social support displays considerable left skew that will not be amenable to transformations (Figure 5.16). The decision was taken to re-code the score as a binary variable based on the maximum score versus other scores. The maximum score corresponds to a participant rating every item in the scale as 'all of the time' (i.e. they have the maximum possible level of social support available). As illustrated by Figure 5.16 and Table 5.26, the proportion of participants reporting maximum social support availability begins to noticeably differ between arms (lower in the Control arm) around the 12 month data collection wave. There was no evidence of a differential intervention effect over time and so was excluded from the model. There was weak evidence of a between arm difference in the odds of reporting maximum social support availability.

**Figure 5.16 Distribution of the Social Support score by each follow-up**

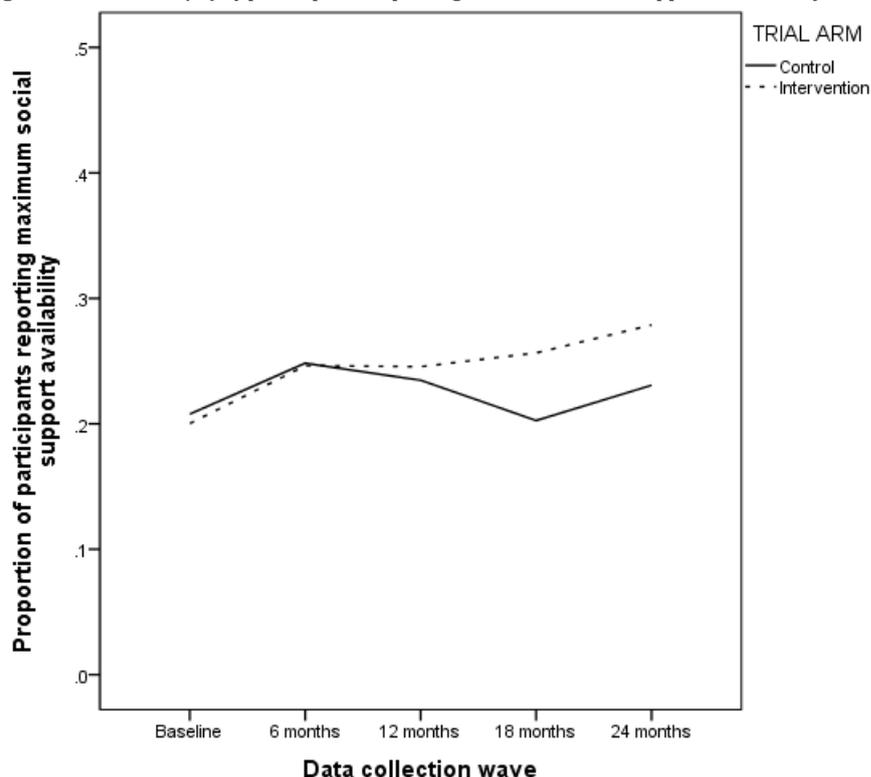


**Table 5.26 Number (%) of participants reporting maximum social support availability split by time point and trial arm**

	Baseline N=1603 (I=799, C=804)	6 months N=926 (I=479, C=447)	12 months N=978 (I=505, C=473)	18 months N=954 (I=495, C=459)	24 months N=1114 (I=581, C=533)	Adjusted OR (95% CI)	p- value
<b>Maximum social support</b>							
Intervention	160 (20.0)	118 (24.6)	124 (24.6)	127 (25.7)	162 (27.9)	1.50 (1.06 to 2.12)	0.023
Control	167 (20.8)	111 (24.8)	111 (23.5)	93 (20.3)	123 (23.1)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables.

Figure 5.17 Number (%) of participants reporting maximum Social Support availability at each follow-up and by trial arm



### 5.5.2 Family resources

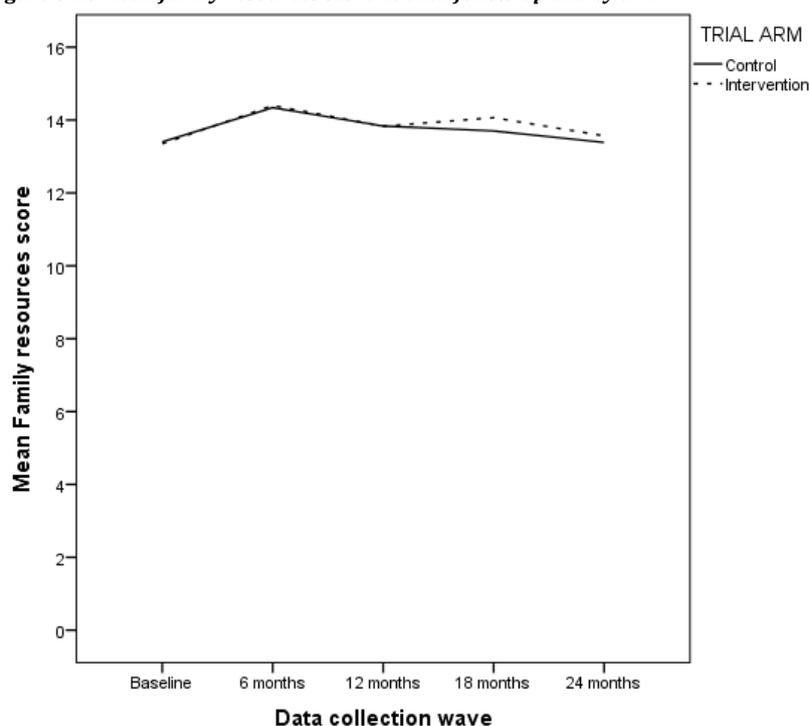
The Family Resources scale was a four-item scale, with a score ranging from 4 to 20 (a higher score indicating more family resources). As demonstrated by Table 5.27 and Figure 5.18, there was a slight decrease in mean family resources score over time. There was no evidence of a differential intervention effect over time and no evidence of between-arm difference in the mean family resources score.

Table 5.27 Mean (SD) family resources score split by each follow-up and by trial arm

	Baseline N=1551 (I=775, C=776)	6 months N=877 (I=452, C=425)	12 months N=959 (I=492, C=467)	18 months N=943 (I=490, C=453)	24 months N=1096 (I=567, C=529)	Adjusted difference in means (95% CI)	p- value
Family resource score Mean (sd)							
Intervention	13.4 (4.2)	14.4 (3.7)	13.8 (3.9)	14.1 (3.8)	13.6 (3.9)	-0.03 (-0.51 to 0.45)	0.894
Control	13.4 (4.2)	14.3 (3.9)	13.8 (4.0)	13.7 (3.7)	13.4 (3.6)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables.

Figure 5.18 Mean family resources score at each follow-up and by arm



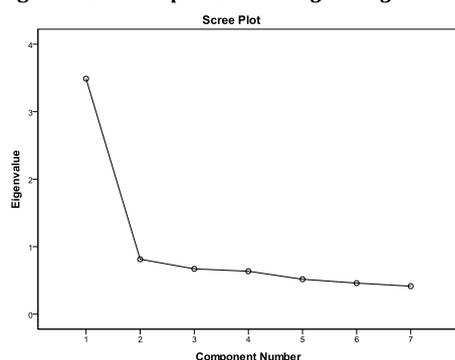
### 5.5.3 Relationship quality

The seven relationship quality items used in the Building Blocks study come from a 28-item scale that had been used in previous research (the Golombok Rust Inventory of Marital State). As it was the intention to represent the seven items as one summary score, the individual items of the baseline total relationship quality score were checked for internal consistency using Cronbach’s alpha, and the validity of combining items into a single scale / score was investigated using factor analysis. The seven-item scale demonstrated high internal consistency (Cronbach’s alpha = 0.826). Item-total correlations were reasonably high, with no items less than 0.2. The effect on alpha of removing items was minimal (range 0.788 to 0.826). Table 5.28 displays the item-total correlations and values for alpha if the corresponding item were deleted. By Kaiser’s rule (eigenvalues > 1) and a visual inspection of the scree plot, a single factor was deemed appropriate (Figure 5.19).

Table 5.28 Item-total correlation and alphas for the baseline relationship quality scale

Baseline relationship quality items	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Sensitive (reverse-coded)	0.587	0.801
Listen	0.555	0.806
Lonely	0.533	0.811
Joy (reverse-coded)	0.670	0.788
Affection	0.628	0.793
Split	0.629	0.795
Argument (reverse-coded)	0.424	0.826

Figure 5.19 Scree plot illustrating the eigenvalues for the various components

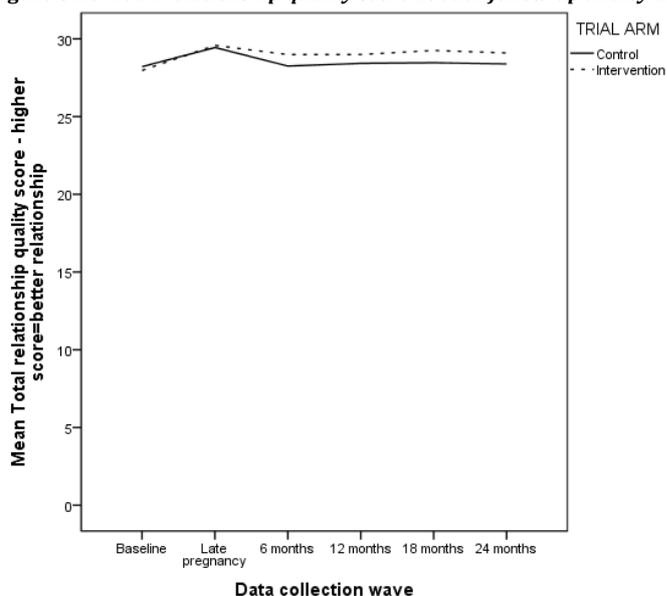


The relationship quality scale was only collected from participants who were in relationships. As this was not a static state (i.e. participants could be in and out of relationships at the various time points), responses were obtained from a participant across all waves very rarely (13, or 0.8% of all 1,618 participants). Drop-outs primarily consisted of participants who provided a response at baseline but not at any of the other waves (24.5%) or provided no response at any of the waves of data collection (9.8%). The remaining 64.2% of participants provided intermittent data on relationship quality. The overall relationship quality scale score ranged from 7 to 35. As shown by Table 5.29 and Figure 5.20 relationship quality was slightly higher on average for participants in the Intervention arm than those in the Control arm from six months onwards. There is no evidence of a differential Intervention effect over time with some weak evidence of a difference in mean relationship quality between arms, although this difference is small (at most 1.20 points on the relationship quality scale).

Table 5.29 Mean (SD) relationship quality score at each follow-up and by trial arm

	Baseline N=1277 (I=637, C=640)	Late pregnancy N=79 (I=45, C=34)	6 months N=640 (I=330, C=310)	12 months N=579 (I=312, C=267)	18 months N=529 (I=288, C=241)	24 months N=714 (I=374, C=340)	Adjusted difference in means (95% CI)	p- value
Relationship quality scores Mean (sd)								
Intervention	28.0 (4.8)	29.6 (4.1)	29.0 (4.5)	29.0 (4.3)	29.3 (3.8)	29.1 (4.4)	0.74 (0.28 to 1.20)	0.002
Control	28.2 (4.8)	29.4 (4.0)	28.3 (4.7)	28.4 (4.5)	28.5 (4.6)	28.4 (4.4)		

Figure 5.20 Mean relationship quality score at each follow-up and by trial arm



## 5.6 Use of services

### 5.6.1 Dental care

A total of 1,154 participants were asked at the 24 month face-to-face interview whether they had been to the dentist for a routine check-up since their children had been born. The results are presented as proportions by trial arm and the ORs are the odds of been to the dentist for a routine check-up in the Intervention arm compared to the Control arm. Overall, 66.5% of participants had been for a routine dental check-up but there was no evidence of a difference in proportions between trial arms (Table 5.30).

Table 5.30 Routine dental check-up at 24 months by trial arm

Routine dental check-up?	Intervention N=595	Control N=557	Total N=1152	Adjusted* OR (95% CI)	p-value
Yes	393 (66.1)	373 (67.0)	766 (66.5)	0.96 (0.75 to 1.22)	0.722
No	202 (33.9)	184 (33.0)	386 (33.5)		
Missing	0	2	2		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

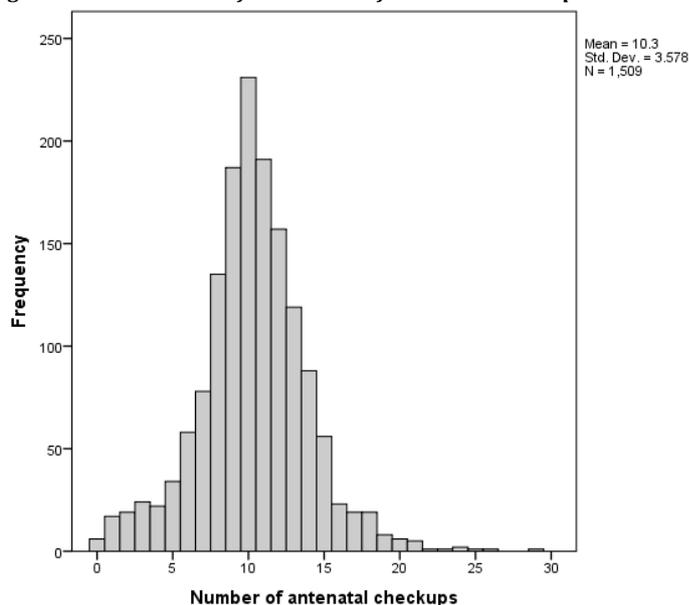
## 5.6.2 Antenatal care

The data source for these following outcomes was the maternal record for all 1,578 mothers consenting to be in the study.

### 5.6.2.1 Total local / hospital check-ups

Numbers of check-ups ranged from 0 to 29 (Figure 5.21) with evidence of counts being normally distributed with an average of 10.30 check-ups (SD=3.58). There was evidence of clustering of number of antenatal check-ups at both the site and Family Nurse levels and a two-level Negative Binomial regression model was retained (due to evidence of over-dispersion where the variance > mean). The results are presented in Table 5.31 as an adjusted incidence rate ratio (IRR) in mean rate of attendances in both trial arms, with an IRR <1 indicating more attendances in the Control arm and an IRR >1 indicating more check-ups in the Intervention arm. There was no statistical evidence of a difference in the number of antenatal check-ups between trial arms.

Figure 5.21 Distribution of the number of antenatal check-ups



### 5.6.2.2 Antenatal care attendances

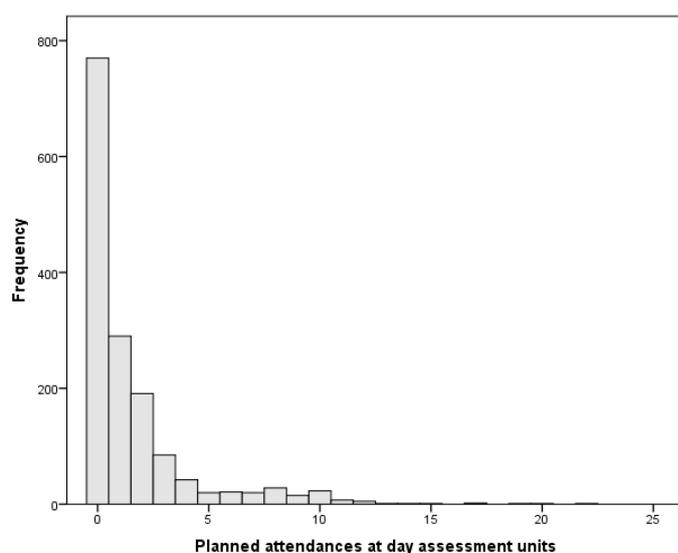
The total number of planned antenatal attendances at day assessment units (or similar) and unplanned hospital attendances were recorded from maternal records (Figure 5.22 a and b). Planned antenatal attendances at day assessment units ranged from 0 to 22 and unplanned hospital attendances from 0 to 16. A total of 50.5% and 34.8% had no planned antenatal attendances and no unplanned hospital attendances respectively. There was evidence of clustering of number of antenatal check-ups at the site level but not the Family Nurse level and a two-level negative binomial regression model was retained. There was no statistical evidence of a difference in the mean rate of antenatal attendances between trial arms (Table 5.31).

Table 5.31 Antenatal care based on participants' maternal records by trial arm

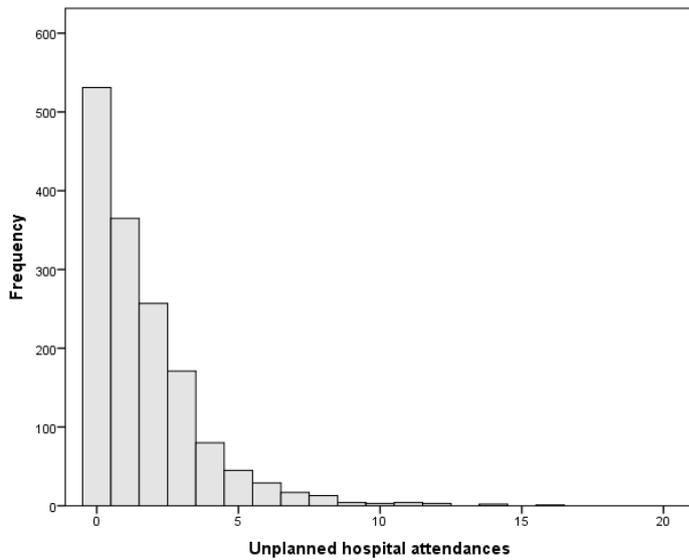
	Intervention N=782		Control N=796		Adjusted* IRR† (95% CI)	p-value
	n	Mean (sd)	n	Mean (sd)		
Number of antenatal check-ups	749	10.38 (3.69)	760	10.22 (3.47)	1.02 (0.98 to 1.05)	0.317
Missing	33	-	36	-		
Number of planned attendances at day assessment units	757	1.45 (2.42)	768	1.59 (2.80)	0.95 (0.82 to 1.11)	0.547
Missing	25	-	28	-		
Number of unplanned hospital admissions	757	1.68 (1.99)	768	1.63 (2.00)	1.04 (0.93 to 1.17)	0.492
Missing	25	-	28	-		
Number of antenatal hospital admissions	757	0.71 (0.05)	768	0.76 (0.05)	0.96 (0.81 to 1.13)	0.607
Missing	25	-	28	-		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). † IRR <1 indicating more attendances in the Control arm and an IRR >1 indicating more attendances in the Intervention arm.

Figure 5.22 Distribution of the number of antenatal care attendances (a) planned assessments at day assessment unit



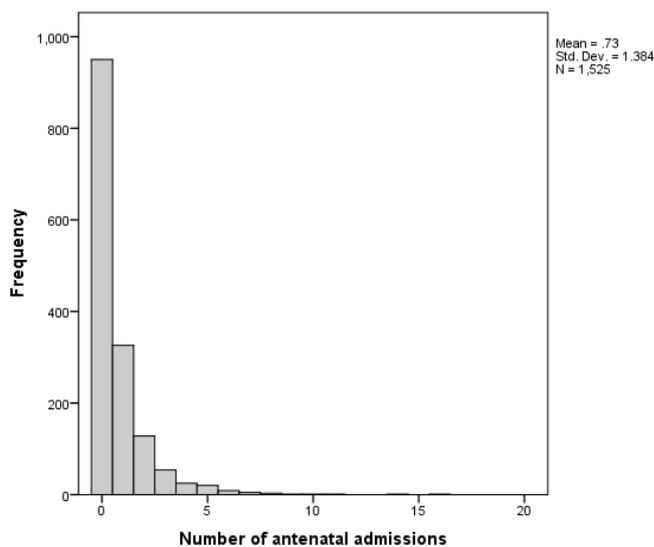
*(b) unplanned hospital admissions*



**5.6.2.3 Antenatal hospital admissions**

The total number of antenatal hospital admissions were recorded from maternal records and ranged from 0 to 16 (Figure 5.23). A total of 62.3% of the participants had no antenatal hospital admissions. Again there was evidence of clustering of number of hospital admissions at the site level and Family Nurse level and a three-level regression model was retained. There was no statistical evidence of a difference in the mean rate of antenatal attendances between trial arms (Table 5.31).

Figure 5.23 *Distribution of the number of antenatal hospital admissions*



### 5.6.3 Primary care consultations over 2 years follow-up period

The data source utilised for maternal primary care consultations was the GP CRF. A total of 951 (59%) participants had their primary care notes examined, although 929 (97.7%) had complete follow-up data and were included in the analysis. The Intervention arm on average displayed a greater number of consultations than the Control arm (Table 5.32, Figures 5.24 and 5.25). A small proportion of participants had no consultations over the period in the trial. It should be noted that consultations are those for GP and Nurse visits and do not include antenatal visits. The results were presented as incidence rate ratios (IRRs) with associated 95% confidence intervals and p-values (Table 5.33). There was no evidence to suggest a difference between arms in the number of events.

Table 5.32 Descriptive statistics for maternal primary care (GP and nurse) consultations by trial arm

	Intervention N=461	Control N=468	Total N=929
Overall consultations Mean (sd)	12.00 (10.2)	10.91 (9.13)	11.45 (9.67)
Zero consultations N (%)	25 (5.4)	28 (6.00)	53 (5.7)
At least one consultation N (%)	436 (94.6)	440 (94.0)	876 (94.3)
Mean (sd)	12.69 (10.02)	11.61 (8.98)	12.15 (9.52)
Median (25 <sup>th</sup> to 75 <sup>th</sup> centiles)	10.0 (5.0 to 18.0)	10.0 (5.0 to 15.75)	10.0 (5.0 to 17.0)

Figure 5.24 Distribution of total maternal primary care (GP and nurse) consultations by trial arm

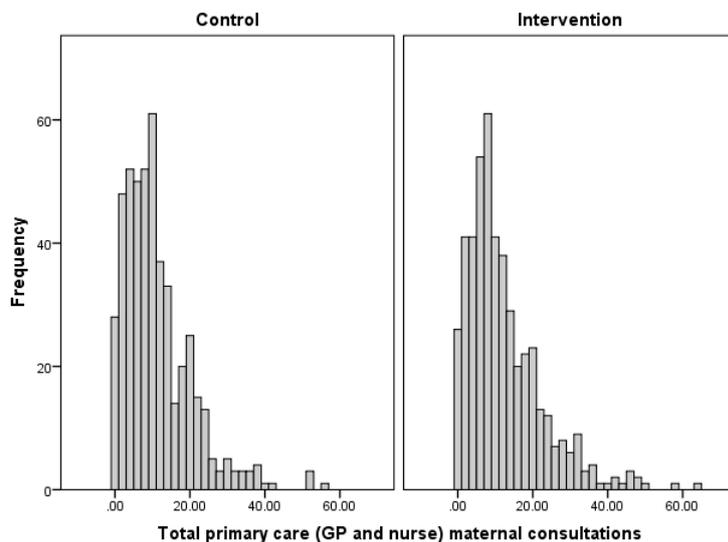


Table 5.33 Incidence rate ratio (IRR) of total maternal primary care (GP and nurse) consultations

	Adjusted IRR*	95% CI for adjusted IRR	p-value
Intervention	1.09	0.98 to 1.21	0.125
Control			

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language) and duration

#### 5.6.4 Emergency attendances and / or admissions

Maternal emergency attendances and admissions were examined over the whole study period, excluding any events relating to the birth of the Building Blocks child. This included any A&E attendances or admissions *relating* to the first pregnancy before the baby was born and any A&E attendances or admissions after the birth. In total, there were 5,301 attendances/admissions (2,156 A&E only, 2,723 Inpatients only and 422 where the A&E attendance resulted in an admission). Of the inpatient episodes, the majority (N=2974, 4.5%) were general episodes and 171 (5.4%) were deliveries (subsequent pregnancies). The distribution of the number of attendances and admissions per participant were skewed with on average 3.28 (sd=4.07) attendances / admissions over the period of follow-up (from recruitment to baby's second birthday or withdrawal date) (Table 5.34). The majority of participants had at least one emergency attendance/admission (80.4% overall) with a higher proportion in the Intervention arm than the Control arm. However, there was no evidence of a difference between trial arms (Table 5.35).

Table 5.34 Descriptive statistics for maternal emergency attendances/admissions care by trial arm

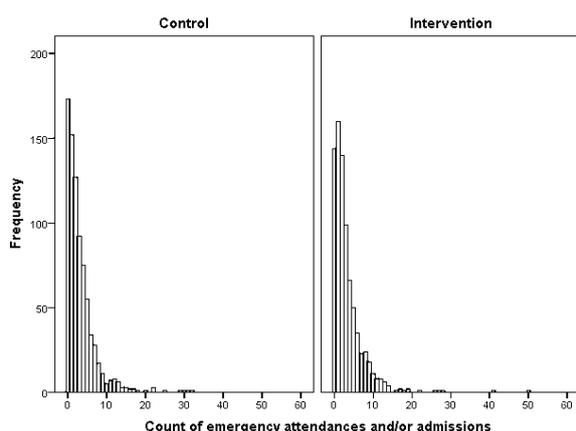
	Intervention N=808	Control N=810	Total N=1618
Overall emergency attendances/admissions			
Mean (sd)	3.35 (4.17)	3.21 ( 3.96)	3.28 (4.07)
Zero emergency attendance/admission N (%)	144 (17.8)	173 (21.4)	317 (19.6)
At least one emergency attendance/admission N (%)	664 (82.2)	637 (78.6)	1301 (80.4)
Mean (sd)	4.07 (4.26)	4.08 (4.05)	4.07 (4.16)
Median (25 <sup>th</sup> to 75 <sup>th</sup> centiles)	3 (2 to 5)	3 (2 to 5)	3 (2 to 5)

Table 5.35 Incidence rate ratio (IRR) of total maternal emergency attendances / admissions care

	Adjusted IRR*	95% CI for adjusted IRR	p-value
Intervention	1.26	0.98 to 1.62	0.069
Control			

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

**Figure 5.25 Distribution of total maternal emergency attendances/admissions care by trial arm**



### 5.6.5 Contact with a Connexions personal advisor

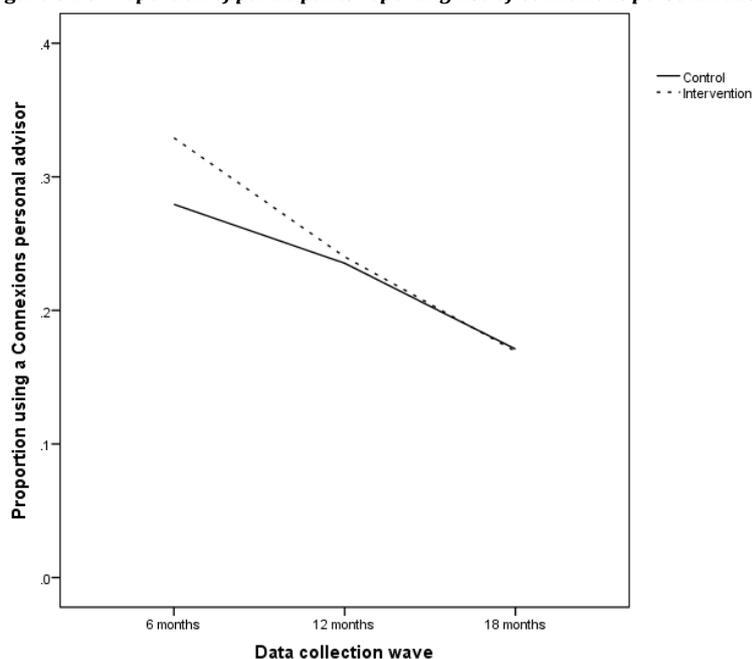
Participants were asked at 6, 12 and 18 months whether they had had any contact with a Connexions personal advisor in the last 6 months. Complete Connexions contact data were obtained at each data collection point for 665 participants (41.1% of all participants). As illustrated by Table 5.36 and Figure 5.26, the proportion of participants reporting contact with a Connexions personal advisor is noticeably different between arms at 6 months but converges thereafter. There was no evidence of a differential intervention effect over time and so it was excluded from the model. There was no evidence of a between arm difference in the odds of accessing a Connexions personal advisor (Table 5.36).

Table 5.36 Number (%) of participants reporting use of Connexions personal advisor at each follow-up and by trial arm

	6 months N=934 (I=483, C=452)	12 months N=980 (I=504, C=476)	18 months N=958 (I=496, C=462)	Adjusted OR* (95% CI)	p-value
Intervention	159 (32.9)	121 (24.0)	84 (16.9)	1.15 (0.85 to 1.53)	0.364
Control	126 (27.9)	112 (23.5)	79 (17.1)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

Figure 5.26 Proportion of participants reporting use of Connexions personal advisor at each follow-up and by trial arm



### 5.6.6 Additional non-health services (education, social, children)

Participants were asked at each time point what other non-health services were accessed over the past 6 months. The proportion accessing each service by trial arm is shown in Table 5.37 and Figures 5.27 to 5.30. The majority of services were rarely accessed by the participants and due to small numbers these are only reported descriptively. For the four services analysed (children’s centre, toddler group, social worker, crèche and day nursery), there was no evidence of a differential intervention effect over time and so was excluded from each of the models. There was no evidence of a difference in the proportion of contact in any services between trial arms.

Table 5.37 Number (%) of participants in contact with non-health resources at each follow-up and by trial arm

Contact with...	Arm	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=559)	Adjusted* OR	95% CI for adjusted OR	p-value
School nurse	Intervention	7 (1.4)	4 (0.8)	0 (0.0)	3 (0.5)	-	-	-
	Control	7 (1.5)	2 (0.4)	4 (0.9)	5 (0.9)			
Child development centre	Intervention	3 (0.6)	2 (0.4)	4 (0.8)	6 (1.9)	-	-	-
	Control	3 (0.7)	8 (1.7)	7 (1.5)	14 (1.7)			
Leaving care service (for young women leaving care)	Intervention	7 (1.4)	9 (1.8)	7 (1.4)	12 (2.1)	-	-	-
	Control	2 (0.4)	5 (1.1)	3 (0.7)	5 (0.9)			
Fostering service	Intervention	3 (0.6)	2 (0.4)	3 (0.6)	2 (0.3)	-	-	-
	Control	1 (0.2)	2 (0.4)	0 (0.0)	2 (0.4)			
Youth Offending Team	Intervention	4 (0.8)	1 (0.2)	2 (0.4)	2 (0.3)	-	-	-
	Control	4 (0.9)	1 (0.2)	0 (0.0)	0 (0.0)			
Alcohol /drug support unit	Intervention	3 (0.6)	1 (0.2)	0 (0.0)	2 (0.3)	-	-	-
	Control	0 (0.0)	1 (0.2)	2 (0.4)	3 (0.6)			
Family Information Service	Intervention	10 (2.1)	6 (1.2)	11 (2.2)	8 (1.4)	-	-	-
	Control	11 (2.4)	12 (2.6)	14 (3.0)	8 (1.5)			
Young people centre/ youth service	Intervention	25 (5.2)	14 (2.8)	9 (1.8)	11 (1.9)	-	-	-
	Control	33 (7.3)	19 (4.0)	9 (2.0)	9 (1.7)			
Children's centre	Intervention	187 (38.7)	184 (40.0)	142 (32.9)	206 (35.3)	1.18	0.94 to 1.48	0.146
	Control	172 (38.1)	172 (38.8)	140 (33.3)	149 (27.7)			
Toddler group	Intervention	40 (8.3)	64 (12.9)	81 (17.2)	114 (19.5)	1.01	0.78 to 1.30	0.956

Contact with...	Arm	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=559)	Adjusted* OR	95% CI for adjusted OR	p-value
	Control	37 (8.2)	53 (11.4)	71 (16.3)	120 (22.3)			
Social worker	Intervention	54 (11.2)	38 (7.8)	41 (8.6)	78 (13.4)	1.44	0.87 to 2.38	0.160
	Control	47 (10.4)	36 (7.8)	29 (6.5)	54 (10.1)			
Crèche/day nursery	Intervention	55 (11.4)	79 (16.0)	-	-	1.19	0.73 to 1.95	0.486
	Control	47 (10.4)	71 (15.1)	-	-			

\* Analysis adjusted for stratification (site), FNP nurse, minimisation variables (gestational age and smoking status at recruitment, and first or preferred language).

Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables.

Figure 5.27 Proportion of participants reporting contact with children's centre at each follow-up and by trial arm

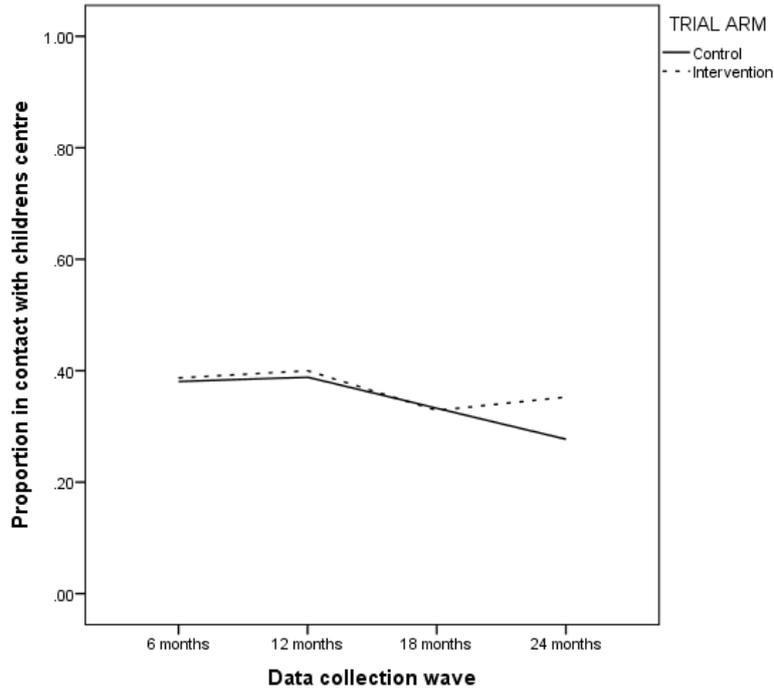


Figure 5.28 Proportion of participants reporting contact with toddler group at each follow-up and by trial arm

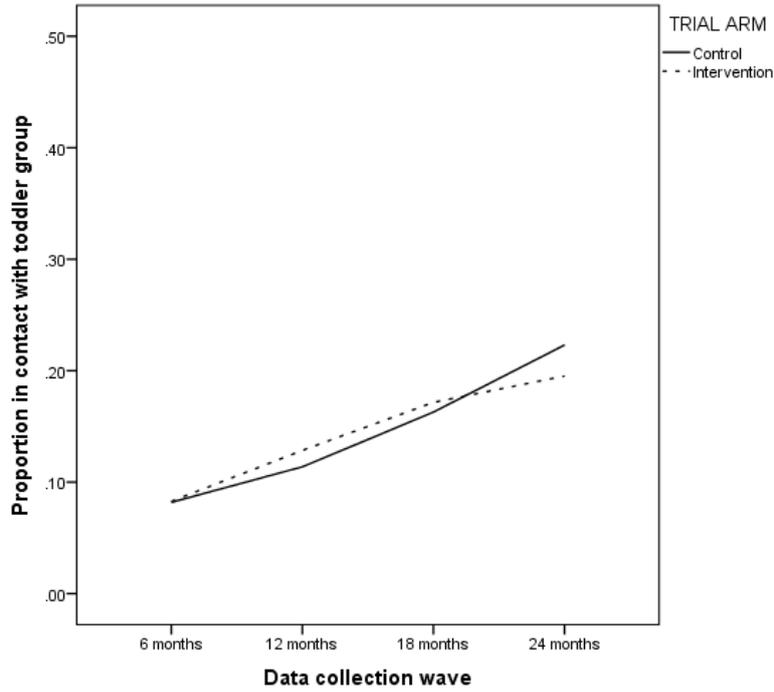


Figure 5.29 Proportion of participants reporting contact with social worker at each follow-up and by trial arm

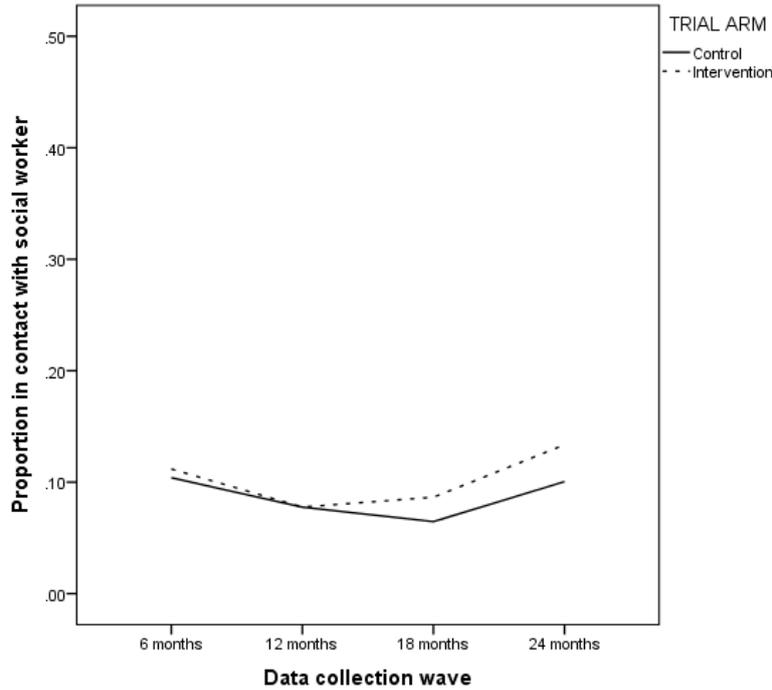
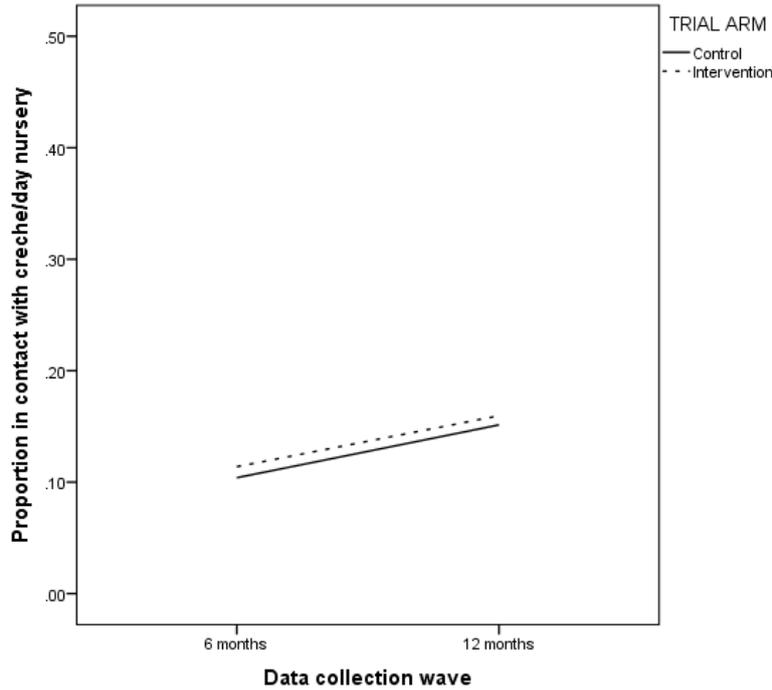


Figure 5.30 Proportion of participants reporting contact with crèche/day nursery at each follow-up and by trial arm



### 5.6.7 Foster care

Participants were asked at 6, 12, 18 and 24 months whether they or their child needed to be in foster care over the past 6 months. Foster care numbers were too small to be analysed using a repeated measures multivariable model and thus the outcome examines being in foster care at least once over the study period. Table 5.38 shows that the majority of participants and their children did not need to be in foster care.

Table 5.38 Number (%) reporting ever needing to be in foster care or not over the study period and by trial arm

	ever needing to be in Foster care over the study period	Not in foster care	Total
Participant			
Intervention	2 (0.6)	327 (99.4)	329
Control	7 (2.3)	291 (97.7)	298
Baby			
Intervention	5 (1.5)	323 (98.5)	328
Control	7 (2.3)	291 (97.7)	298
Participant and Child together			
Intervention	2 (0.6)	326 (99.4)	328
Control	4 (1.4)	291 (98.6)	295

## 6 Results: Secondary Outcomes (Parenting and Child)

### 6.1 Parenting beliefs, feeding intentions and prenatal attachment

The main data source for the next four subsections was the late pregnancy (34-36 week) telephone interview. A total of 1,237 (76.5%) participants responded to this interview (from the 1,618 participants at baseline). Of these, 40 (3.2%) babies had been born with 1,197 participants remaining to respond to questions regarding their parenting beliefs, feeding intentions and prenatal attachment.

#### 6.1.1 Anticipatory parenting

The anticipatory parenting score was a five-item scale in which a response is given on a five-point Likert scale (1='Strongly agree' to 5='Strongly disagree'). The 6<sup>th</sup> option given to a responder of 'Can't say' was recoded as 3='Neither Agree or Disagree'. The sum of the five items created the anticipatory parenting score with a range from 5 to 25 where a low score indicated more structured childrearing practices and a high score indicated a less structured environment. A total of 1,183 (95.6%) participants chose to answer all five items completely and 14 missed at least one item. The mean (sd) score was 8.70 (2.0) and ranged from 5 to 14, indicating that participants favoured a more structured upbringing for their children. This shift in score was true for all the individual items ('pick up baby when crying', 'develop a regular pattern of feeding and sleeping with a baby', 'stimulated if they are to develop well', 'talking to your baby', 'cuddling a baby is important'). The results are presented in Table 6.1 as an adjusted difference (Intervention minus Control) in mean score in both trial arms, with a negative difference indicating more structure in the Intervention arm (lower score). There was no evidence of a difference in the adjusted anticipatory parenting score between trial arms.

Table 6.1 Anticipatory parenting scores, prenatal attachment and infant feeding intentions at late pregnancy

	Intervention N=597	Control N=600	Total N=1197	Adjusted* difference in means (95% CI)	p-value
Anticipatory parenting score (score 5 to 25) <sup>†</sup> Mean (sd)	8.60 (2.03)	8.80 (1.97)	8.70 (2.00)	-0.20 (-0.43 to 0.02)	0.080
Missing	4	9	14		
Prenatal attachment score (score 8 to 32) <sup>‡</sup> Mean (sd)	11.58 (3.17)	11.73 (3.15)	11.65 (3.16)	-0.09 (-2.10 to 1.92)	0.931
Missing	10	11	21		
	Intervention N=597	Control N=600	Total N=1197	Adjusted* OR (95% CI)	p-value
Infant feeding intentions					
Bottlefeeding or undecided	245 (41.6)	293 (49.6)	538 (45.6)	ref	
Breastfeeding or mixed	344 (58.4)	298 (50.4)	642 (54.4)	1.32 (1.02 to 1.70)	0.036
Missing	8	9	17		
Intended breastfeeding duration					
Less than 6 weeks	34 (10.2)	34 (11.8)	68 (11.0)	ref	
6 weeks or more	300 (89.8)	253 (88.2)	553 (89.0)	1.22 (0.73 to 2.03)	0.449
Missing	10	11	21		

\* Adjusted for site and randomisation balancing factor (smoking status, gestation and language)

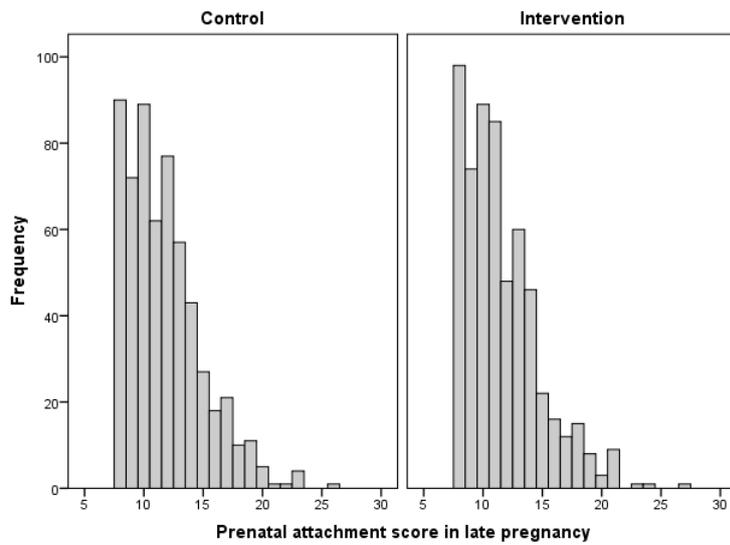
<sup>†</sup> A low score indicates more structured child rearing practices and a high score indicated a less structured environment.

<sup>‡</sup> A low score indicates lower attachment

### 6.1.2 Prenatal attachment

The prenatal attachment score was an eight-item scale to measure how often the participant thought of certain aspects of the baby and a response given on a four-point scale (Almost always, Often, Sometimes, Almost Never). These responses were summed to give a score from 8 to 32. This score was skewed positively (Table 6.1) and ranged from 8 to 27, indicating a tendency for low prenatal attachment amongst these participants. Transforming the data did not help the distribution and thus the raw scores were fitted. There was no evidence of a difference in prenatal attachment between trial arms (Figure 6.1).

**Figure 6.1** *Distribution of prenatal attachment score at late pregnancy by trial arm*



### 6.1.3 Infant feeding intentions

Mothers' feeding intentions were considered as a binary variable, combining participants intending to exclusively breastfeed or use a combination of breast and bottle versus participants intending to exclusively bottle-feed or those that were undecided at time of interview. A total of 1,180 participants responded, with 642 (54.4%) planning to either exclusively breastfeed or use in combination with bottlefeeding. The results are presented in Table 6.1 as proportions by trial arm and the absolute and relative effects of exclusively breastfeeding or a combination in the Intervention arm compared to Control. There was statistical evidence of a difference in the proportion of participants intending to breastfeed.

### 6.1.4 Intended breastfeeding duration

For the 642 that intended to breastfeed, the majority (89%) were planning on breastfeeding for more than six weeks. There was no evidence of a difference in breastfeeding duration between arms with 89.8 vs 88.2% planning to breastfeed for more than six weeks.

### 6.1.5 Parental role strain

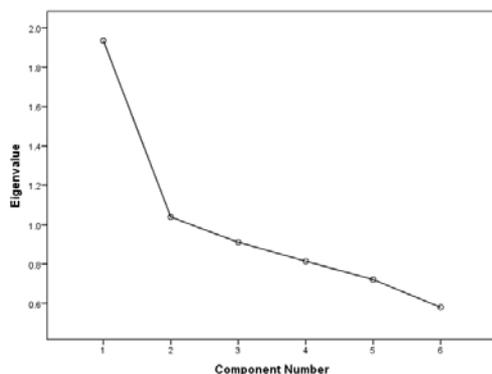
Parental role strain consisted of six items and the responses were combined in to a single measure intended to measure a single underlying construct. Table **Error! Reference source not found.**6.2 shows the proportions responding to the responses indicated in brackets, for example, for the item 'When I am caring for the baby, I get feelings of annoyance or irritation', the proportion responding to 'Almost all the time' or 'Frequently' are displayed by each collection point.

Table 6.2 Parental role strain at each time point

Parental role strain item	6 month N=981	12 month N=997	18 month N=967	24 month N=1122
When I am caring for the baby, I get feelings of annoyance or irritation (almost all the time, very frequently)	6 (0.6)	7 (0.7)	6 (0.6)	9 (0.8)
When I am not with the baby, I find myself thinking about them (almost all the time, very frequently)	867 (88.4)	874 (87.7)	835 (86.3)	868 (77.4)
When I have to leave the baby I often/always feel rather sad	408 (41.6)	409 (41.0)	412 (42.6)	371 (33.1)
When I am caring for the baby I am very/fairly incompetent and lacking in confidence	13 (1.3)	11 (1.1)	11 (1.1)	23 (2.0)
Usually when I am with the baby I am very/a bit impatient	56 (5.7)	67 (6.7)	62 (6.4)	105 (9.4)
Regarding the things that I/we have had to give up because of the baby I find that I resent it quite a lot/resent it a fair amount	31 (3.2)	22 (2.2)	28 (2.9)	23 (2.0)

It was the intention to represent the six items as one summary score and therefore four of the items were reversed so that a low score was indicative of low parenting role strain. The individual items of the baseline total relationship quality score were checked for internal consistency using Cronbach's alpha, and the validity of combining items into a single scale / score was investigated using factor analysis. Using the 6 month data, the six-item scale demonstrated moderate internal consistency (Cronbach's alpha = 0.56). Item-total correlations were reasonably high, with no items less than 0.2. The effect on alpha of removing items was minimal. By Kaiser's rule (eigenvalues > 1) and a visual inspection of the scree plot, two factors were deemed appropriate (Figure 6.2). However the component scores were all greater than 0.50 thus one factor was used with the sum of the items constructed (low score indicating low parental strain) (6 to 29).

Figure 6.2 Scree plot for parental role strain



Mean parental role strain score increased over time indicating that participants' strain increased. This is best illustrated in Table 6.3 and Figure 6.3. A repeated measure analysis showed evidence of an increased score between 6 months and 12, 18 and 24 months. There was no evidence of an overall difference in score between trial arms nor at any of the time points.

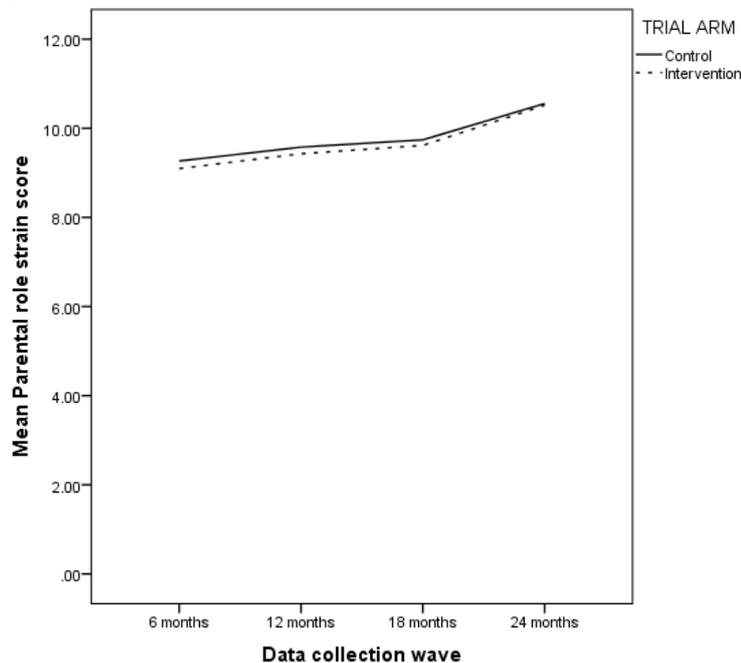
Table 6.3 Mean (SD) Parental role strain score by each follow-up and trial arm

	6 months N=918 (I=477, C=471)	12 months N=967 (I=496, C=471)	18 months N=932 (I=481, C=451)	24 months N=1071 (I=535, C=536)	Adjusted difference in means (95% CI)	p- value
Parental role strain† Mean (sd)						
Intervention	9.10 (2.14)	9.43 (2.27)	9.62 (2.25)	10.52 (2.58)	-0.16 (-0.35 to 0.03)	0.105
Control	9.27 (2.40)	9.58 (2.37)	9.74 (2.52)	10.56 (2.48)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing, as well as data for one participant with no gestational age or language variables.

† low score indicates low parental strain

Figure 6.3 Mean parental role strain over follow-up and trial arm



### 6.1.6 Maternal-child interaction

A total of 508 video recordings were analysed and coded. Five outcomes were constructed as part of this outcome: maternal sensitivity, maternal intrusiveness, child responsiveness, and child positive and negative affect. A comparison

of the participants who completed a recording and those who did not are shown in Table 6.4. Although similar for most baseline demographic and psycho-social characteristics compared, there were some differences between those not completing the video assessment at 24 months and those completing it. Non-completers had a slightly higher rate of being coded as NEET (a difference of 4.1%) and of reporting problems with basic skills (a difference of 3.4%).

Table 6.4 Participants demographics by maternal sensitivity recording completion - N(%) unless otherwise specified

	Recording analysed N=508	Recording not completed N=1110	Overall N=1618
<i>Demographics</i>			
Age at recruitment (years)	17.9	17.8	17.8
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(17.0 to 18.9)	(16.9 to 18.8)	(16.9 to 18.8)
<i>Ethnicity</i>			
White background	456 (89.8)	969 (87.3)	1425 (88.1)
Mixed background	33 (6.5)	56 (5.1)	89 (5.5)
Asian background	9 (1.8)	18 (1.6)	27 (1.7)
Black background	10 (2.0)	61 (5.5)	71 (4.4)
Chinese or Other background	0 (0.0)	6 (0.5)	6 (0.4)
<i>Relationship status</i>			
Married	6 (1.2)	14 (1.3)	20 (1.2)
Separated	46 (9.0)	119 (10.7)	165 (10.2)
Closely involved/ boyfriend	392 (77.2)	830 (74.8)	1222 (75.5)
Just friends	64 (12.6)	147(13.2)	211 (13.0)
<i>Live with father of baby</i>			
Yes	119 (23.4)	249 (22.4)	368 (22.7)
No	356 (70.1)	756 (68.1)	1112 (68.7)
Not answered	33 (6.5)	105 (9.5)	138 (8.5)
<i>Socio-economic</i>			
NEET status <sup>*</sup>	N=441	N=943	N=1384
Yes	199 (45.1)	464 (49.2)	663 (47.9)
No	242 (54.9)	475 (50.4)	717 (51.8)
Not answered	0 (0.0)	4 (0.4)	4 (0.3)
Overall Index of Multiple Deprivation Score <sup>†</sup>	N=505 38.7	N=1101 39.3	39.1
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(24.5 to 51.7)	(25.3 to 52.0)	(25.1 to 52.0)
<i>Maternal health and well-being</i>			
Generalized self-efficacy scale	N=502	N=1090	N=1592

	Recording analysed N=508	Recording not completed N=1110	Overall N=1618
(score 10 to 40) <sup>†</sup>	30.4	29.8	30.0
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(28.0 to 33.0)	(27.0 to 32.0)	(28.0 to 33.0)
<b>Adaptive functioning</b>			
Difficulty in at least one basic skill			
Yes	123 (24.2)	307 (27.6)	430 (26.6)
No	385 (75.8)	800 (72.1)	1185 (73.2)
Not answered	0	3 (0.3)	3 (0.2)
Three or less life skills			
Yes	137 (27.0)	297 (26.8)	434 (26.8)
no	370 (72.8)	808 (72.8)	1178 (72.8)
Not answered	1 (0.2)	5 (0.4)	6 (0.4)
At least one life burden			
Yes	141 (27.8)	335 (30.2)	476 (29.4)
No	364 (71.6)	767 (69.1)	1131 (69.9)
Not answered	3 (0.6)	8 (0.7)	11 (0.7)
<b>Health behaviour</b>			
Ever smoked (Participant self-reported)			
Yes	399 (78.5)	895 (80.6)	1294 (80.0)
No	109 (21.5)	215 (19.4)	324 (20.0)

\* Definition of NEET status: Not in Education, Employment or Training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)

† Higher IMD score indicated more deprivation

‡ Higher score indicates higher level of self-efficacy

Each mother-child interaction recording lasted three minutes and maternal behaviour (sensitivity and intrusiveness) was rated at 30 second intervals using a four-point scale (0-3) designed to reflect no (behaviour), low, moderate and high level during each 30 second period. The summed score for maternal sensitivity and intrusiveness during one interaction ranged from 0 to 18. The summed score for child responsiveness during one interaction could range from 0 to 24 (each 6 x 30 second period rated between 0-4). Child positive and negative affect was rated using three-point scales (0-2) which reflected none, some, or extensive affect during each 30 seconds of free play. The summed score for child positive and negative affect during one interaction ranged from 0 to 24 (each 6 x 30 second period rated between 0-4). There was no evidence of any difference in mother-child interaction outcomes between trial arms (Table 6.5).

Table 6.5 Maternal interaction outcomes

Outcome	Intervention	Control	Total	Adjusted* difference	p-value
Mean (sd)	N=256	N=252	N=508	in means (95% CI)	
Maternal sensitivity score†	11.05 (1.66)	11.06 (1.62)	11.05 (1.64)	-0.07 (-0.41 to 0.27)	0.674
Maternal intrusiveness score†	1.67 (1.85)	1.53 (1.60)	1.60 (1.73)	0.12 (-0.19 to 0.43)	0.438
Child responsiveness score†	18.43 (2.25)	18.60 (2.82)	18.51 (2.55)	-0.26 (-0.77 to 0.25)	0.313
Child positive affect score†	3.13 (1.92)	3.35 (2.24)†	3.24 (2.08)†	-0.23 (-0.59 to 0.13)	0.212
Child negative affect score†	0.89 (1.27)	0.79 (1.11)	0.84 (1.19)	0.09 (-0.12 to 0.30)	0.395

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

† Higher score for maternal sensitivity indicates more sensitive behaviour, lower score for maternal intrusiveness indicates lower intrusion, higher score for child responsiveness indicates greater responsiveness, higher score for child positive affect and for child negative affect indicate higher levels of positive and negative affect respectively. †N=251 (total N=507)

### 6.1.7 Mother and child living apart

At each follow-up time point after birth, the participant was asked whether her child was currently living with her. Table 6.6 shows that only a small number of participants were not living with their child. An overall binary outcome was constructed to indicate whether the participant had ever been living apart from the child during the duration of the trial. Participants responding over the four time points (6, 12, 18 and 24 months) were included, as were participants who had indicated that they had been living apart for at least one time point (but may not have responded to at least one interview and had missing data). Participants who had missing data (and had not responded to at least one of the interviews) and in those in which they had responded had reported that they had not been living apart were excluded from this analysis. Although an absolute difference showed that the Control arm had slightly greater proportion of participants living apart from their child (2.0%), there was no statistical evidence to show a difference between arms (Table 6.7).

Table 6.6 Number (%) of participants reporting living apart from child at each follow-up and by trial arm

	6 months N=977		12 months N=997		18 months N=967		24 months N=1122	
	Living apart	Living together	Living apart	Living together	Living apart	Living together	Living apart	Living together
Intervention	5 (1.0)	504 (99.0)	5 (1.0)	509 (99.0)	9 (1.8)	492 (98.2)	13 (2.2)	570 (97.8)
Control	4 (0.9)	464 (99.1)	6 (1.2)	477 (98.87)	9 (1.9)	457 (98.1)	14 (2.6)	524 (97.4)

Table 6.7 Number (%) ever lived apart at each follow-up and by trial arm

	Living apart N=51	Living together N=620	Adjusted* OR (95% CI)	p-value
Intervention	24 (6.7)	335 (93.3)	0.73 (0.41 to 1.32)	0.300
Control	27 (8.7)	285 (91.3)		

\*Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

## 6.2 Neonatal outcomes

The primary data source for birth and neonatal outcomes were the maternity records. For all models, there was no evidence of clustering and a two-level model was retained (adjusting for site and randomisation balancing factors). The results for all outcomes relating to birth and neonatal period are reported in Table 6.8.

### 6.2.1 Birth outcome (live birth)

All 1,510 babies had an outcome recorded (live or stillbirth) with 99.7% live born. There was no evidence of a difference between trial arms.

Table 6.8 Birth and neonatal outcomes (complete case analysis)

	Intervention N=742	Control N=768	Total N=1510	Adjusted* odds ratio (95% CI)	p-value
<b>Birth outcome</b>					
Stillbirths (0)	3 (0.4)	2 (0.3)	5 (0.3)		
Live births (1)	739 (99.6)	766 (99.7)	1505 (99.7)	0.65 (0.11 to 3.88)	0.633
Missing	0	0	0		
<b>Apgar score at 1 minute</b>					
<7 (low) (0)	68 (10.0)	78 (11.2)	146 (10.6)		
≥7 (normal) (1)	614 (90.0)	621 (88.8)	1235 (89.4)	1.14 (0.81 to 1.61)	0.456
Missing	60	69	129		
<b>Apgar score at 5 minute</b>					
<7 (low) (0)	15 (2.2)	14 (2.0)	29 (2.1)		
≥7 (normal) (1)	666 (97.8)	686 (98.0)	1352 (97.9)	0.91 (0.44 to 1.90)	0.801
Missing	61	68	129		
<b>NNU admission (direct or subsequent)</b>					
Yes (0)	80 (10.9)	69 (9.0)	149 (10.0)		
No (1)	653 (89.1)	695 (91.0)	1348 (90.0)	0.81 (0.58 to 1.14)	0.229
Missing	9	4	13		
	Intervention N=742	Control N=768	Total N=1510	Adjusted† difference in means (95% CI)	p-value
<b>Head circumference (cm)</b>					
Mean (SD)	33.9 (2.1)	34.1 (1.8)	34.0 (1.9)	-0.14 (-0.41 to 0.14)	0.336

\* Adjusted for site and randomisation balancing factor (smoking status, and gestation)

† Adjusted for site, Family Nurse, and randomisation balancing factor (smoking status, gestation and language)

### 6.2.2 Apgar scores at 1 and 5 minutes

The Apgar score is recorded at 1 and 5 minutes, and captures the child's condition at birth. The Apgar score is measured on a scale of 0 to 10 and for the purpose of this analysis has been recoded into a binary variable: 0-6 (low), 7-10 (normal). A total of 1,381 (91%) of children had an Apgar score recorded at 1 and 5 minutes with 129 (9%) missing. The majority of these scores were normal (score ≥7); 89.4% at 1 minute and 97.9% at 5 minutes. The results are the ORs are the odds of low scores in Intervention arm compared to Control. An OR >1 indicates that Intervention had a greater proportion of normal Apgar scores than Control. There was no evidence of a difference in the proportion of normal scores between trial arms at either time points.

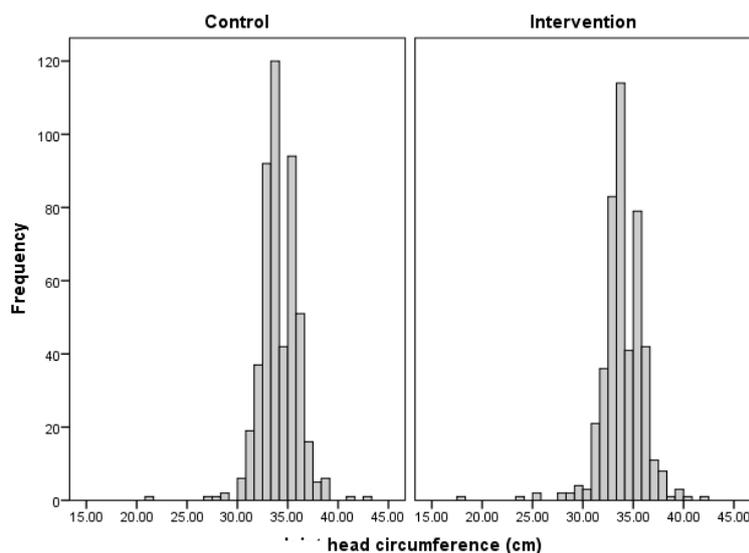
### 6.2.3 NUU admissions

Whether or not a baby was admitted directly or subsequently to a NNU was recorded for 1,497 (99.1%) babies with nine (0.9%) missing. There was no statistical evidence of a difference in the proportion of admissions to NNU between trial arms.

### 6.2.4 Head circumference

Head circumference (cm) was recorded in 951 (63.2%) children, the main source of which was from the maternal record (N=924) and the remainder supplemented from the GP notes. Values ranged from 18 to 43 cm with a mean (sd) overall value of 34.0 cm (1.9 cm) and distributions appeared similar in each arm (Figure 6.4). There was significant variation in head circumference between Family Nurse and sites. There was no evidence of a difference in the adjusted mean head circumference (cm) between trial arms.

Figure 6.4 Distribution of head circumference by trial arm



## 6.3 Feeding and development

### 6.3.1 Feeding method and duration

In the birth CRF the feeding method at birth was recorded for 1,476 babies and the between arm comparison is shown in Table 6.9. A greater proportion of participants in the Intervention arm were exclusively breastfeeding or using a combination of breast and bottle compared to the Control arm (43.8 vs 41.4%). There was no evidence of a difference between trial arms. At 6 months self-reported data on breastfeeding initiation and duration was obtained from participants for 990 babies. Of these babies breastfeeding was initiated in 531 (53.6%) and by 6 months 477/531 (89.8%) of these babies were no longer breastfed and this is approximately equal by arm (Intervention 90.4% and

Control 89.2%). The hazard ratio in Table 6.10 and Figure 6.5 shows little variation in days to cessation of breastfeeding between arms although the Intervention arm do breastfeed for slightly shorter duration.

Table 6.9 Number (%) of feeding method at birth by trial arm

	Intervention N=742	Control N=768	Adjusted <sup>i</sup> odds ratio (95% CI)	p-value
Breastfeeding or Mixed	317 (43.8)	312 (41.4)	1.10 (0.89 to 1.37)	0.374
Bottle feeding	406 (56.2)	441 (58.6)		
Missing	19	15		

<sup>i</sup> Adjusted for site and randomisation balancing factors.

Table 6.10 Cessation of breastfeeding in days at 6 month interview

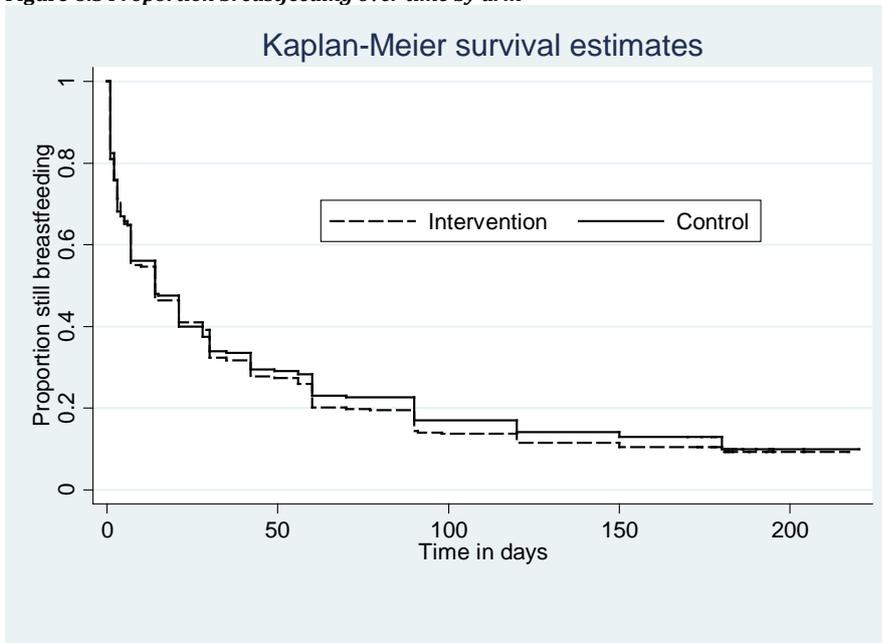
	Median duration in days (25 <sup>th</sup> centile to 75 <sup>th</sup> centile)*	Adjusted <sup>†</sup> hazard ratio (95% CI) N=531 (I=281, C=250)	p-value
Intervention	N=254 7 (2 to 31)	1.03 (0.86 to 1.24)	0.76
Control	N=223 14 (2 to 42)		

<sup>†</sup> Adjusted for site and randomisation balancing factors.

\* excludes those still breastfeeding

NB babies who breastfed for less than one day are recorded as feeding for 0.5 days for purpose of cox regression

Figure 6.5 Proportion breastfeeding over time by arm



### 6.3.2 Introduction of solids and duration

At the 6 month interview participants were asked whether each baby had started solids. Results in Table 6.11 show no evidence of a difference between trial arms.

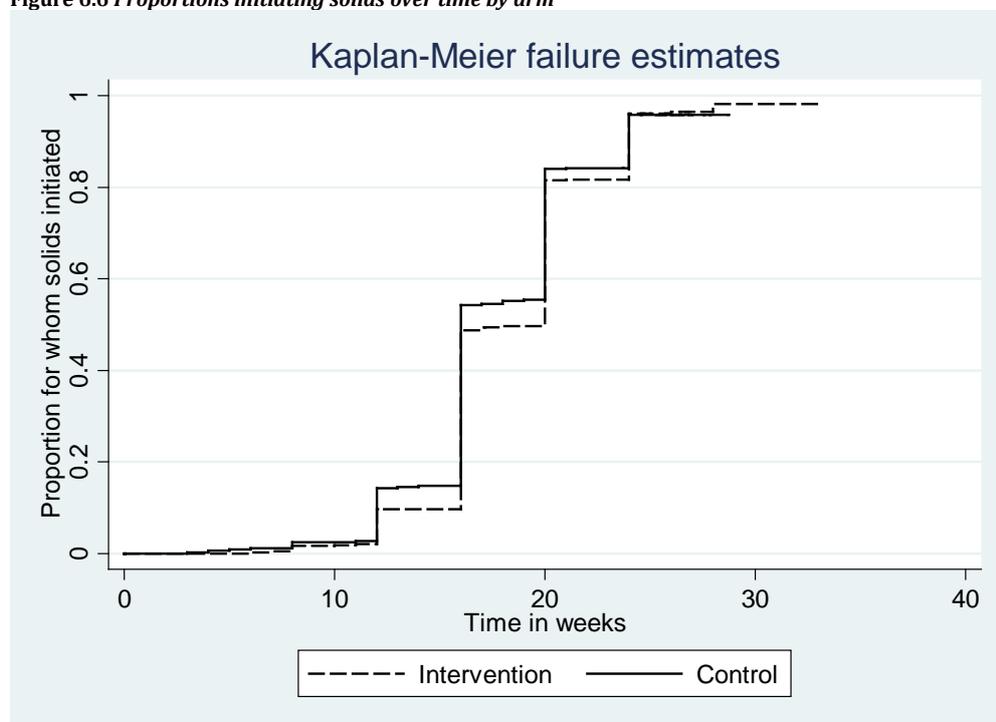
Table 6.11 Number (%) of babies where solids were introduced by 6 month interview

	Intervention	Control	Adjusted <sup>†</sup> odds ratio (95% CI)	p-value
Solids introduced	471 (96.5)	435 (95.6)	1.24 (0.63 to 2.45)	0.540
Solids not introduced	17 (3.5)	20 (4.4)		
Missing	28	19		

<sup>†</sup> Adjusted for site and randomisation balancing factors.

The unadjusted median time to initiation of solids was 16 weeks (25<sup>th</sup> centile to 75<sup>th</sup> centile; 16 to 20) in both arms. The Kaplan Meier graph in Figure 6.6 illustrates some evidence of a delayed initiation of solids in the Intervention arm. The cox regression (adjusted for site and minimisation factors) showed no evidence for an effect with a hazard ratio of 0.92 (95%CI; 0.81 to 1.05) for the Intervention arm compared to Control.

Figure 6.6 Proportions initiating solids over time by arm



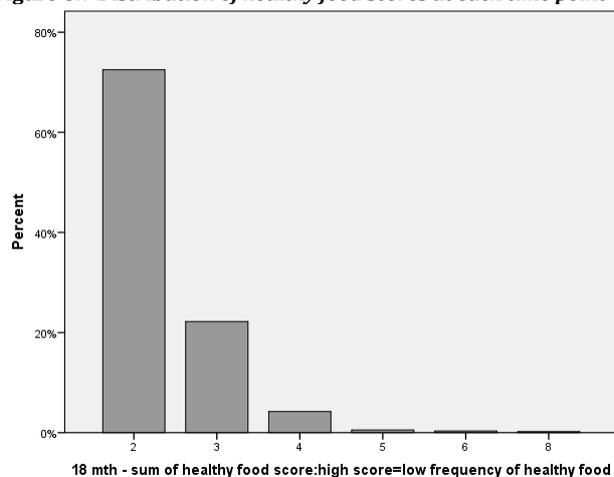
### 6.3.3 Baby diet

Five questions were asked at both 18 and 24 months regarding the frequency of eating home-cooked meals, fruit and vegetables, cake, biscuits or sweets, fast food and drink fizzy pop, sweetened tea or squash. Responses were coded on a Likert scale 'Every day', 'Every week', 'Every month' and 'Never'. Questions were recoded so that a low response indicated a better diet (low cake, pop, fast food and high home-cooked food and fruit and veg). An exploratory factor analysis was conducted (using 18 m and 24 m data separately) to investigate whether the number of items used could be reduced and whether all the items were required to calculate an overall score. This indicated that two factors were present; one for home cooked and fruit and vegetable items and another for the questions related to unhealthy foods. Therefore two scores were calculated to represent healthy food and unhealthy food.

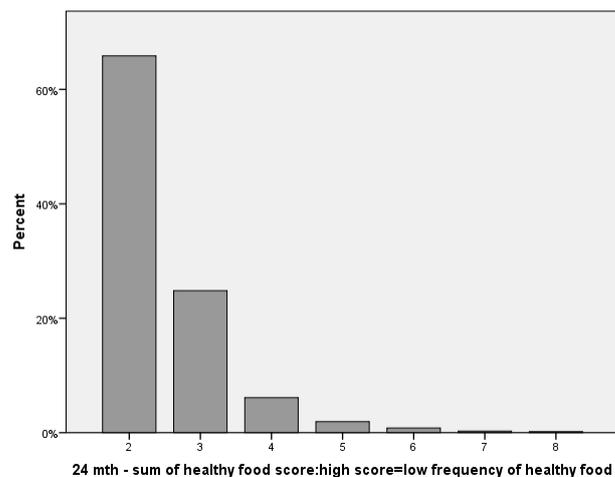
#### 6.3.3.1 Healthy food

The distributions of the scores at each time point can be seen in Figure 6.7. The distributions indicate that most participants give their babies healthy food everyday (score=2) with the remainder having a score of 3 or more. Hence we decided to dichotomise this score for analysis purposes. The results in Table 6.12 show that there is very little difference in percentage reporting giving healthy food to their babies between trial arms at each time point.

Figure 6.7 Distribution of healthy food scores at each time point



N=946 (26 missing)



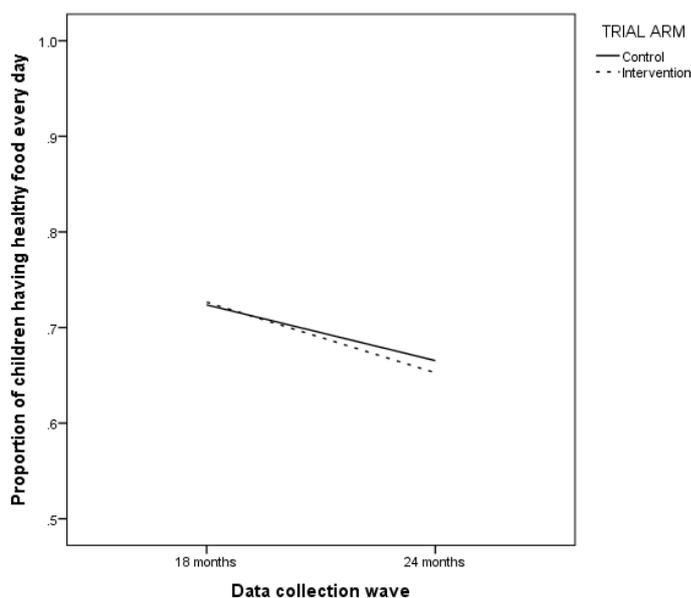
N=1096 (35 missing)

Table 6.12 Number (%) children having healthy food every day

	18 months N=972 (I=505, C=467)	24 months N=1131 (I=590, C=541)	Adjusted* OR (95% CI)	p-value
N (%)				
Intervention	356 (72.7)	374 (65.3)	0.95 (0.70 to 1.28)	0.723
Control	330 (72.4)	348 (66.5)		
Missing				
Intervention	15	17		
Control	11	18		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing.

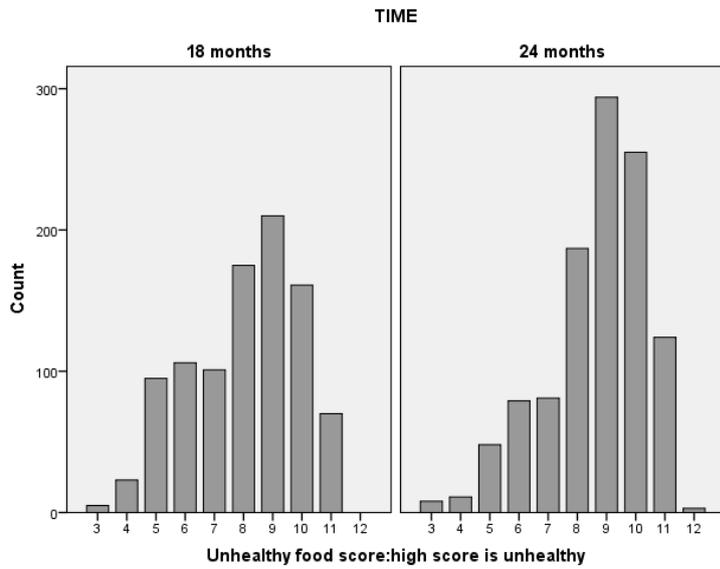
Figure 6.8 Proportion of children having healthy food every day



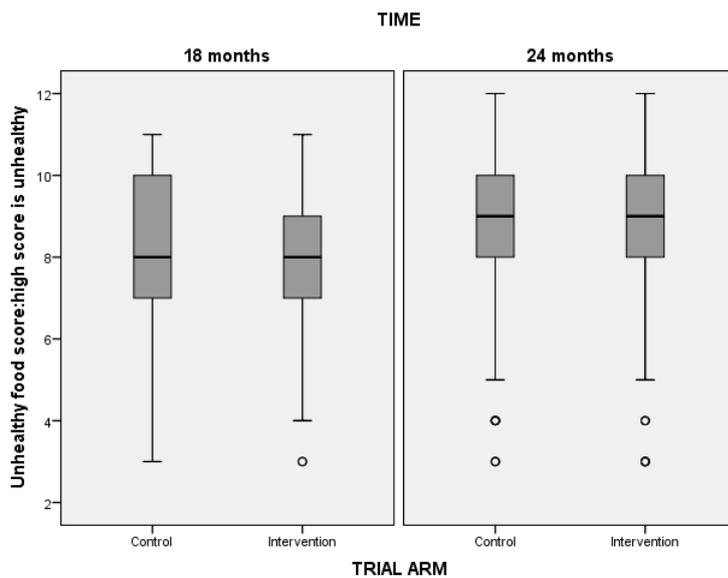
### 6.3.3.2 Unhealthy food score

The distribution of the scores at each time point can be seen in Figure 6.9; we decided to assume normality and analyse these as continuous scores. The boxplot in Figure 6.10 shows little variation between trial arm at each time point. It can also be seen that the median unhealthy food score is greater at 24 months compared to 18 months. A repeated measures analysis was performed adjusting for site, minimisation variables, time and time\*arm interaction. There was no evidence of a differential intervention effect over time and so was excluded from the model. The results showed that the mean difference for Intervention compared to Control was -0.005 (95% CI; -0.197 to 0.19) indicating no evidence of a between arm effect (p=0.957).

**Figure 6.9 Distribution of unhealthy food scores at each time point**



**Figure 6.10 Boxplot comparing distribution for each arm at each time point**



### 6.3.4 Cognitive development

#### 6.3.4.1 Developmental concern

At 12, 18 and 24 months a series of questions from the Schedule of Growing Skills (SOGS – see Appendix 5 for further detail) were asked to each participant for each Building Blocks child that was living with them. At each time point a subset of these questions were used to determine whether a child had any developmental concern. The proportion of children with developmental concern is lower in the Intervention arm compared to the Control arm at all time points (Table 6.13). At 24 months there is evidence that the percentage having cognitive developmental concern is significantly lower in the Intervention arm compared to the Control arm (OR: 0.61, 95% CI 0.40 to 0.90,  $p=0.013$ ).

Table 6.13 N(%) children coded as having developmental concern

	Intervention	Control	Adjusted* OR / difference in means (95% CI)	p-value
<b>12 months</b>				
N	519	485		
Developmental concern n(%)	44 (8.7)	45 (9.5)	0.91 (0.59 to 1.40)	0.657
Missing	15	13		
<b>18 months</b>				
N	506	469		
Developmental concern n(%)	17 (3.5)	26 (5.7)	0.59 (0.32 to 1.11)	0.101
Missing	15	14		
<b>24 months</b>				
N	602	562		
Developmental concern n(%)	46 (8.1)	66 (12.6)	0.61 (0.40 to 0.90)	0.013
Missing	33	40		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

### 6.3.5 Language development

Questions on language development were asked for each baby at 12 and 18 months and the ELM test for each baby was carried out at the face-to-face interviews at 24 months.

#### 6.3.5.1 Language development at 12 and 18 months

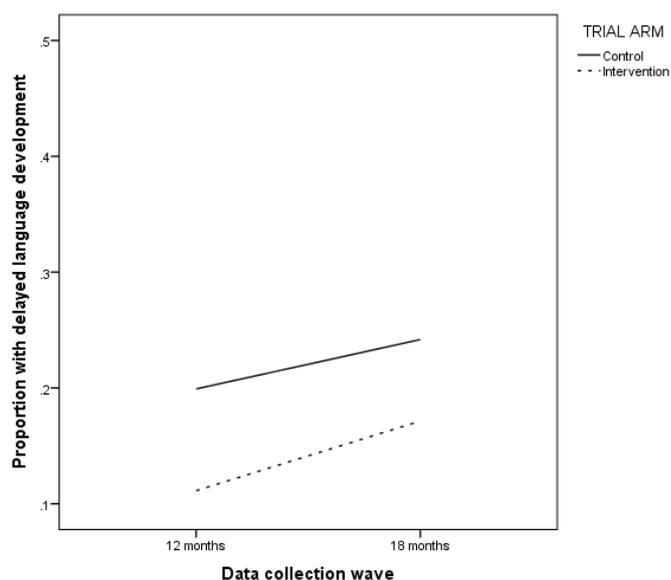
At each time point questions regarding language development were asked for each baby and if the milestone was not reached for any question (at each time point) the baby was identified as having developmental language concern. The level of developmental language concern is lower in the Intervention arm compared to the Control arm at both 12 months and 18 months (Table 6.14).

Table 6.14 N(%) children coded as having developmental language concern

	Intervention	Control	Adjusted* OR (95% CI)	p-value
<b>12 months</b>				
N	519	485		
Language concern n(%)	55 (11.0)	94 (19.9)	0.50 (0.35 to 0.72)	<0.001
Missing	17	13		
<b>18 months</b>				
N	506	469		
Language concern n(%)	84 (17.1)	110 (24.2)	0.66 (0.48 to 0.90)	0.009
Missing	16	14		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

Figure 6.11 Proportion with delayed language development



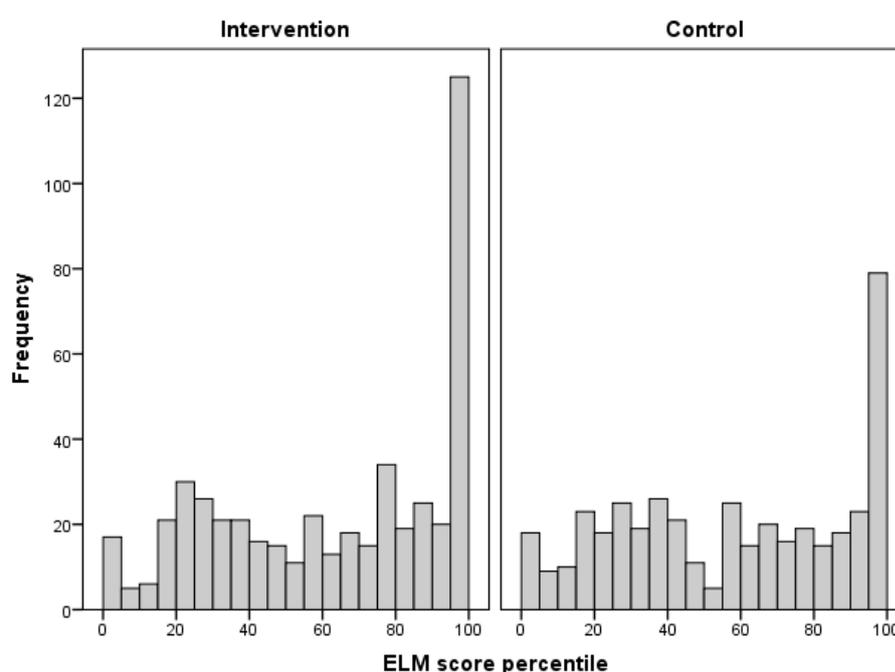
### 6.3.5.2 Early Language Milestones (ELM)

There were 1,046 participants who had a face-to-face interview at 24 months and during these interviews 954 babies were assessed for ELM. A valid score was obtained for 902 of these ELM assessments. The age of the baby and the score were used to obtain an ELM percentile for each baby and this percentile was used to determine whether there was a difference between trial arms. The distribution of the percentile scores were skewed to the left with a large peak at the top of the scale indicating that there were disproportionately more babies at the top end (Figure 6.12). This shows that the babies of our participants have higher values than expected in the normative population. The mean percentile score was greater in the Intervention arm compared to the Control arm with an adjusted difference of 4.49 (Table 6.15) which is significant at the 5% level.

Table 6.15 ELM percentile values by trial arm

	Intervention N=511	Control N=443	Adjusted* difference in means (95% CI)	p-value
ELM percentile				
Mean (sd)	60.8 (31.4)	55.7 (31.4)	4.49 (0.52 to 8.45)	0.027
Median (25 <sup>th</sup> to 75 <sup>th</sup> percentile)	65 (30 to 95)	55 (30 to 85)		
Missing	31	28		

Figure 6.12 Histogram comparing distribution of ELM percentiles between arms



### 6.3.6 Child safety

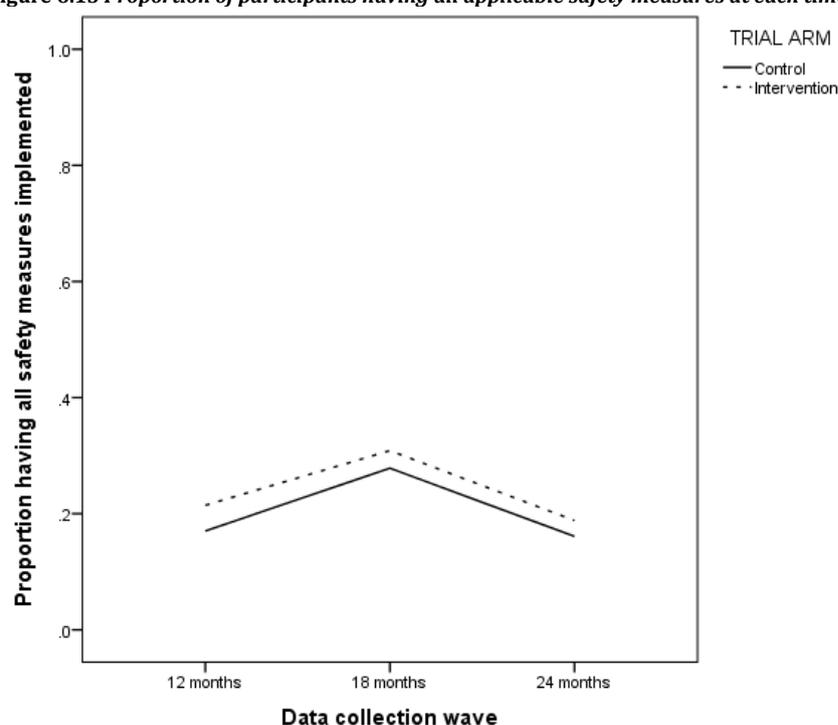
At 12, 18 and 24 months participants were asked whether they had safety features installed within their home. Participants who responded positively to having each applicable safety feature were coded as having a 'safe home'. Table 6.16 shows that there is a peak at 18 months in the proportion using all applicable safety measures. At all time points the percentage is greater in Intervention compared to Control, but there is no evidence of a difference between trial arms (Table 6.16). There is a significant increase in use of safety measures at 18 months compared to 12 months but no Intervention effect was apparent at the time points.

Table 6.16 N(%) participants reporting a positive response to all applicable safety feature questions

	12 months N=997 (I=514, C=483)	18 months N=967 (I=501, C=466)	24 months N=1154 (I=595, C=558)	Adjusted* OR (95% CI)	p-value
N (%)					
Intervention	100 (21.5)	142 (30.9)	96 (18.8)	1.26 (0.97 to 1.62)	0.080
Control	77 (17.0)	120 (27.8)	79 (16.1)		
Missing					
Intervention	48	41	85		
Control	31	35	68		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language). Participants with no responses at any time point are missing.

Figure 6.13 Proportion of participants having all applicable safety measures at each time point



## 6.4 Health and use of services

### 6.4.1 Childcare

Participants were asked at the 6, 12, 18 and 24 month interview whether their child had spent any time in childcare over the past 6 months. Table 6.17 shows the proportion accessing childcare at each time point. There was no evidence of a between arm difference in the odds of use of childcare. There was evidence of a decrease in the odds of accessing

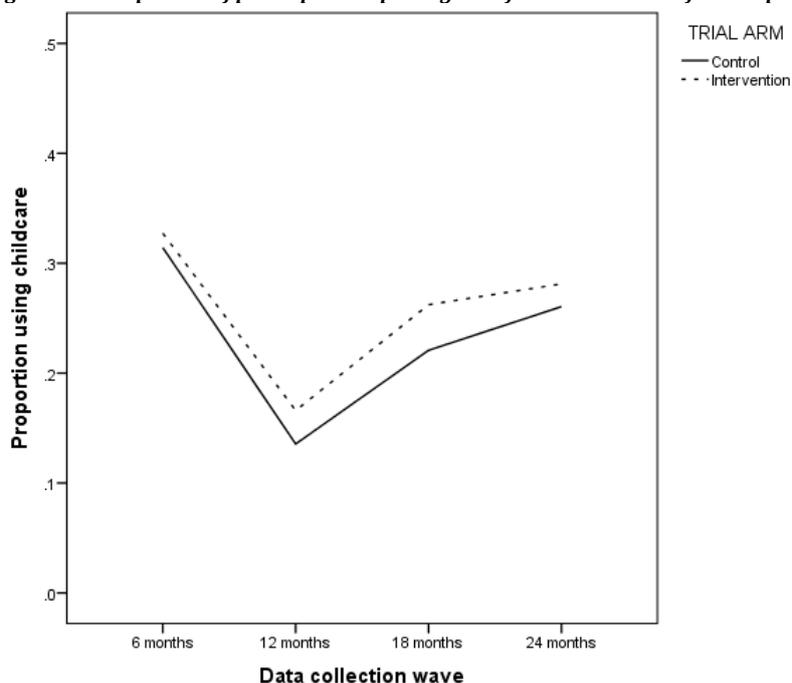
childcare over time, especially between 6 and 12 months, best illustrated by Figure 6.14. There was no evidence that the slope of the trial arms differed from each other.

Table 6.17 Number (%) spent time in childcare at each follow-up by trial arm

	6 months N=981 (I=511, C=470)	12 months N=997 (I=514, C=470)	18 months N=967 (I=501, C=466)	24 months N=1122 (I=584, C=538)	Adjusted <sup>i</sup> odds ratio (95% CI)	p-value
<b>N (%) in childcare</b>						
Intervention	36 (32.7)	83 (16.6)	128 (26.2)	160 (28.1)	1.28 (0.90 to 1.83)	0.176
Control	33 (31.4)	64 (13.6)	100 (22.1)	136 (26.1)		
<b>Missing</b>						
Intervention	401	14	13	15		
Control	365	11	13	16		

<sup>i</sup> Adjusted for site and randomisation balancing factors (smoking status, gestation and language)

Figure 6.14 Proportion of participants reporting use of childcare at each follow-up and by trial arm



## 6.4.2 Immunisations

Data on immunisations were taken from child health systems and supplemented with GP data. There were a total of 1,505 births in which immunisation data were available for 1,063 (70.6% of all live births). The immunisations schedule

is shown in Table 6.18. The two outcomes examined here are the percentage of immunisations received (from a maximum of 10) and also the proportion attending a visit at each time point, analysed as repeated measures over time.

Table 6.18 Immunisation schedule up to 12 months

Vaccine (diseases protected against)	Visit 1	Visit 2	Visit 3	Visit 4
	2 months old	3 months old	4 months old	12/13 months old
5-in 1 (DTaP/IPV/Hib ) Diphtheria, tetanus, pertussis (whooping cough), polio and <i>Haemophilus influenzae</i> type b (Hib)	✓	✓	✓	
Pneumococcal conjugate vaccine (PCV) Pneumococcal infection	✓		✓	✓
MenC Meningitis C		✓	✓	
Hib/MenC <i>Haemophilus influenzae</i> type b and Meningitis C				✓
MMR Measles, mumps and rubella (German measles)				✓

#### 6.4.2.1 Proportion of immunisation received

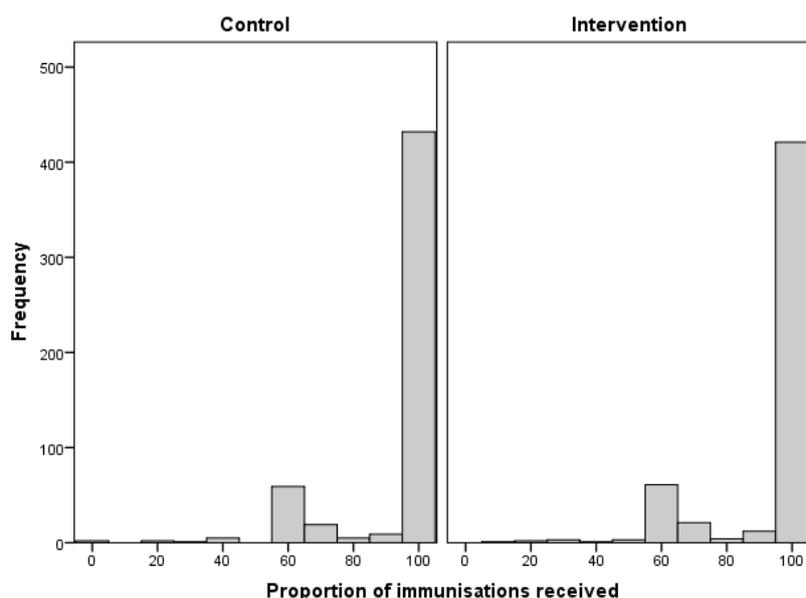
The majority of children received all ten immunisations (N=853, 80.2%) (Figure 6.15). Due to the skewed distribution of the data, it was felt that using a binary outcome of receiving all ten immunisations or not would be used. Overall, 80.2% of children with immunisation data received all ten of their immunisations (Table 6.19). The proportion of children receiving all ten immunisations was similar between trial arms with no evidence of a difference.

Table 6.19 Number (%) of children receiving all ten of their immunisations by trial arm

Immunisations received	Intervention	Control	Total	Adjusted* OR (95% CI)	p-value
< 10	108 (20.4)	102 (19.1)	210 (19.8)	ref	
All 10	421 (79.6)	432 (80.9)	853 (80.2)	0.94 (0.60 to 1.46)	0.770
Total	529 (100.0)	534 (100.0)	1063 (100.0)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language).

Figure 6.15 Distribution of proportion of immunisations received over the four visits



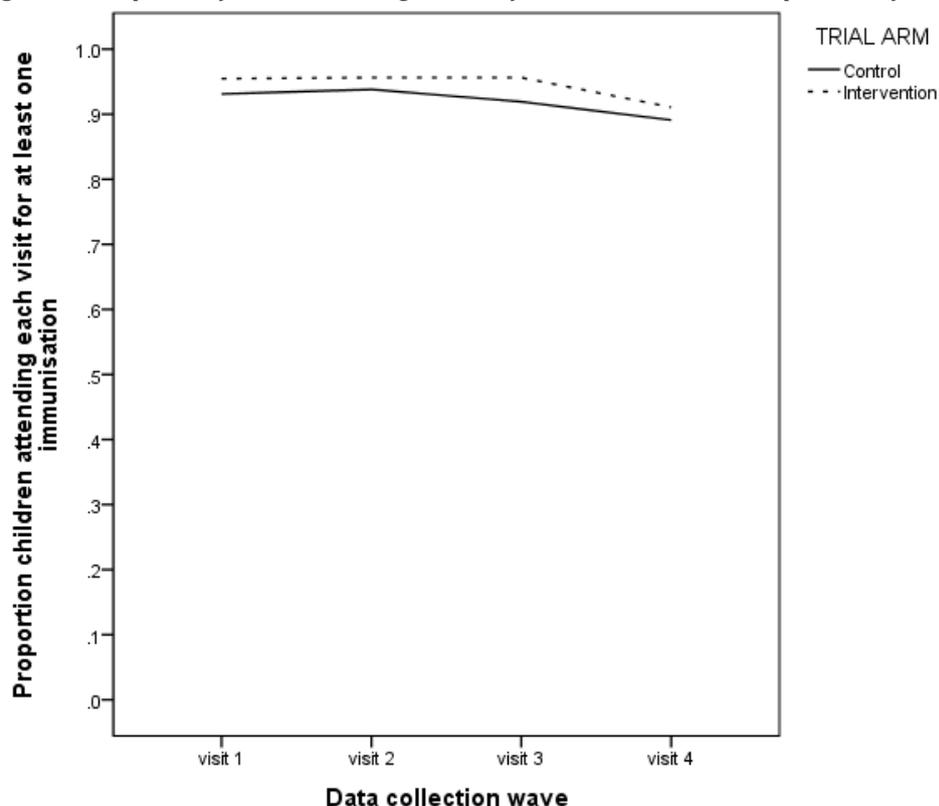
#### 6.4.2.2 Proportion attending a visit over time

The proportion of children who attended each visit and received at least one immunisation at each visit was high across all visits (Table 6.20). There was no evidence of a between arm difference in the odds of attending a visit (Adjusted OR: 1.59, 95% CI 0.92 to 2.76,  $p=0.099$ ). There was evidence of a decrease in the odds of attending a visit over time especially at visit 4 when compared to visit 1 (OR: 0.53, 95% CI 0.34 to 0.82,  $p=0.004$ ). There was no evidence that the slope of the trial arms differed from each other (Figure 6.16).

Table 6.20 Number (%) of children attending for at least one immunisation per visit by time point by trial arm

	Visit 1		Visit 2		Visit 3		Visit 4	
	Attended	Did not attend						
Intervention	464 (95.5)	22 (4.5)	525 (95.6)	24 (4.4)	525 (95.6)	24 (4.4)	500 (91.1)	49 (8.9)
Control	473 (93.1)	35 (6.9)	530 (93.8)	35 (6.2)	523 (91.9)	46 (8.1)	507 (89.1)	62 (10.9)

Figure 6.16 Proportion of children attending each visit for at least one at each time point and by trial arm



### 6.4.3 Emergency department consultations for injuries and ingestions

#### 6.4.3.1 Events to 6 months

Of the 38 participants that withdrew at some point over the 24 months, 24 withdrew after the 6 month period and 14 before 6 months. Of these 14, none had experienced an injury or ingestion before 6 months and all were excluded. Since we cannot say for certain that they would not have had an event if they had continued in the study, they were treated as missing data and were excluded. This left 1,486 children to analyse (1,486 completers at 6 months – with or without an event). A greater proportion of children in the Intervention arm had an injury or ingestion when compared to the usual care arm (4.1 vs 2.8%) (Table 6.21). The odds of attending A&E were 52% higher in the Intervention arm compared to Control but the confidence interval was wide (95% CI: 0.86 to 2.70,  $p = 0.153$ ).

Table 6.21 Number (%) of children attending A&E with an injury or an ingestion by 6 months by trial arm

Injury /ingestion	Intervention	Control	Adjusted* OR (95% CI)	p-value
None recorded	701 (95.9)	734 (97.2)	Ref	
At least one recorded	30 (4.1)	21 (2.8)	1.52 (0.86 to 2.70)	0.153

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language).

### 6.4.3.2 Events to 24 months

Complete outcome data was obtained from 1462 children with 38 withdrawing before the 2 year follow-up. Of these 38, only 3 experienced an injury and / or ingestion up to the point of withdrawal and were therefore included. The remaining 35 were excluded from the analysis, leaving 1,465 children to analyse (1,462 completers at 24 months – with or without an event and 3 non completers with an event). A greater proportion of children in the Intervention arm had an injury or ingestion when compared to the usual care arm (30.8 vs 27.8%) (Table 6.22). The odds of attending A&E were 16% higher in the Intervention arm compared to Control but the confidence interval was wide (95% CI: 0.92 to 1.46, p = 0.204).

Table 6.22 Number (%) of children attending A&E with an injury or an ingestion by 24 months by trial arm

Injury / ingestion	Intervention	Control	Adjusted* OR (95% CI)	p-value
None recorded	499 (69.2)	537 (72.2)	Ref	
At least one recorded	222 (30.8)	207 (27.8)	1.16 (0.92 to 1.46)	0.204

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language).

## 6.4.4 Primary care consultations (injuries and ingestions)

### 6.4.4.1 Events to 6 months

Consultations regarding an injury or ingestion were recorded from GP records for each child. A total of 950 records were accessed and examined with only 14 injuries recorded before the child was 6 months old (Table 6.23). There were no ingestions recorded in the same 6 month period. No further analysis was carried out due to the small number of events.

Table 6.23 Number (%) of children with an injury or an ingestion recorded in GP notes by 6 months by trial arm

Injury / ingestion	Intervention	Control	Total
None recorded	461 (98.3)	475 (98.8)	936 (98.5)
At least one recorded	8 (1.7)	6 (1.2)	14 (1.5)

### 6.4.4.2 Events to 24 months

Consultations regarding an injury or an ingestion were identified from GP records for each child. A total of 950 records were accessed and examined, of which 18 children had partial follow-up (due to withdrawal or the mother leaving the GP practice before the child's second birthday) and no event and were therefore excluded from the analysis. A total of 932 children's records remained of which 103 (11.1%) had an injury or an ingestion recorded (6.24). There was no evidence of a difference in the proportion of injuries and ingestions recorded in children between arms.

Table 6.24 Number (%) of children with an injury or an ingestion recorded in GP notes by 24 months by trial arm

Injury / ingestion	Intervention	Control	Adjusted* OR (95% CI)	p-value
None recorded	413 (89.6)	416 (88.3)	Ref	0.530
At least one recorded	48 (10.4)	55 (11.7)	0.87 (0.58 to 1.33)	

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

## 6.4.5 Secondary care consultations for injuries and ingestions

### 6.4.5.1 Events to 6 months

At 6 months, of the 38 children that withdrew at some point, 24 withdrew after the 6 month period and 14 before 6 months. Of these 14, one had experienced emergency admissions with an injury or ingestion before 6 months and is included. The remaining 13 had not experienced an event up to withdrawal and were thus excluded since we cannot say for certain that they would not have had an event if they had continued in the study. This leaves 1,487 children to analyse (1,487 completers at 6 months – with or without an event). A greater proportion of children in the usual care arm were admitted to hospital with an injury or ingestion when compared to the Intervention arm (2.4 vs 1.9%) (Table 6.25). The odds of having an emergency admission were 21% lower in the usual care arm compared to Intervention but the confidence interval was wide (95% CI: 0.39 to 1.60,  $p = 0.509$ ).

Table 6.25 Number (%) of children admitted with an injury or an ingestion by 6 months by trial arm

Injury / ingestion	Intervention	Control	Adjusted* OR (95% CI)	p-value
None recorded	717 (98.1)	738 (97.6)	ref	
At least one recorded	14 (1.9)	18 (2.4)	0.79 (0.39 to 1.60)	0.509

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

### 6.4.5.2 Events to 24 months

From the 1,500, complete outcome data were obtained from 1,462 children with 38 withdrawing before the 2 year follow-up. Of these 38, only 5 experienced an injury and/or ingestion as an inpatient up to the point of withdrawal and were therefore included. The remaining 33 are excluded from the analysis, leaving 1,468 children to analyse (1,462 completers at 24 months – with or without an event and 5 non-completers with an event). A greater proportion of children in the usual care arm had an injury or ingestion when compared to the Intervention arm (6.6 vs 4.8%) (Table 6.26). The odds of having an emergency admission with an injury or ingestion were 28% lower in the Intervention arm compared to Control but the confidence interval was wide.

Table 6.26 Number (%) of children admitted to hospital with an injury or an ingestion by 24 months by trial arm

Injury / ingestion	Intervention	Control	Adjusted OR (95% CI)	p-value
None recorded	687 (95.2)	696 (93.4)	ref	
At least one recorded	35 (4.8)	49 (6.6)	0.72 (0.46 to 1.12)	0.147

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

## 6.4.6 Social Services contact

### 6.4.6.1 Referred to a non-NHS service

Participants were asked at the 24 month interview whether their child have ever been referred to a non-NHS service. A greater proportion of participants from the Intervention arm had been referred than in the Control (20.9% vs 17.7%) but there was no evidence of a statistical difference between arms (Table 6.27).

### 6.4.6.2 Referred to Social Services

Participants reporting a referral for their child to Social Services were taken from the 24 month interview. A total of 210/911 (23.1%) children were reported as having a Social Services referral with a greater proportion of children in the Intervention arm reported than in the Control arm. There was no evidence of a difference in referral between arms (Table 6.27).

### 6.4.6.3 Recording of Safeguarding events

Data were abstracted for any documented safeguarding event in the child's primary care record. Of the 945 children that had their GP notes examined, 102 (10.8%) had a safeguarding procedure recorded in the GP notes with a higher proportion in the Intervention arm compared to Control. There was strong evidence of a difference between arms (Table 6.27). Although similar for most baseline demographic and psycho-social characteristics compared, there were some differences between who did and did not have their child's GP records accessed. Non-accessed participants had a slightly higher rate of being coded as NEET (a difference of 6.5%) and of reporting problems with basic skills (a difference of 6.4%) (Table 6.28).

Table 6.27 Non-NHS referral and referral to Social Services at 24 months by trial arm

	Intervention	Control	Adjusted* OR (95% CI)	p-value
Referral to non-NHS service (n=1125)				
No	461 (79.1)	446 (82.3)	1.23 (0.91 to 1.66)	0.187
Yes	122 (20.9)	96 (17.7)		
Referral to Social Services (n=1121)				
No	461 (79.5)	450 (83.2)	1.27 (0.93 to 1.73)	0.127
Yes	119 (20.5)	91 (16.8)		
Safeguarding procedure (n=945)				
No	405 (86.4)	438 (92.0)	1.85 (1.02 to 2.85)	0.005
Yes	64 (13.6)	38 (8.0)		

\* Analysis adjusted for stratification (site), minimisation variables (gestational age and smoking status at recruitment, and first or preferred language)

Table 6.28 Participants' demographics by access to GP notes for the child (re: safeguarding) - N(%) unless otherwise specified

	GP records accessed N=945	GP records not accessed N=560	Overall N=1505
<b>Demographic</b>			
Age at recruitment (years)	17.9	17.7	17.8
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	(17.0 to 18.9)	(16.8 to 18.7)	(16.9 to 18.8)
<b>Ethnicity</b>			
White background	848 (89.7)	476 (85.0)	1324 (88.0)
Mixed background	48 (5.1)	38 (6.8)	86 (5.7)
Asian background	16 (1.7)	9 (1.6)	25 (1.7)
Black background	30 (3.2)	34 (6.1)	64 (4.3)
Chinese or Other background	3 (0.3)	3 (0.5)	6 (0.4)
<b>Relationship status</b>			
Married	7 (0.7)	9 (1.6)	16 (1.1)
Separated	96 (10.2)	59 (10.4)	154 (10.2)
Closely involved/boyfriend	710 (74.1)	426 (76.1)	1136 (75.5)
Just friends	132 (14.0)	67 (12.0)	199 (13.2)
<b>Live with father of baby</b>			
Yes	206 (21.8)	128 (22.9)	334 (22.2)
No	663 (70.2)	377 (67.3)	1040 (69.1)
missing	76 (8.0)	55 (9.8)	131 (8.7)
<b>Socio-economic</b>			
NEET status*	N=828	N=459	N=1287
Yes	376 (45.4)	238 (51.9)	614 (47.7)
No	452 (54.6)	218 (47.5)	760 (52.1)

	GP records accessed N=945	GP records not accessed N=560	Overall N=1505
missing	0 (0.0)	3 (0.6)	3 (0.2)
Index of Multiple Deprivation Score <sup>†</sup>	N=938	N=554	
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	37.9	41.1 (25.9 to 54.4)	39.1 (24.9 to 52.1)
Generalized self-efficacy scale (score 10 to 40) <sup>‡</sup>	N=930	N=554	
Median (25 <sup>th</sup> to 75 <sup>th</sup> centile)	30.1 (28.0 to 33.0)	29.9 (27.0 to 33.0)	30.0 (28.0 to 33.0)
Adaptive functioning			
Difficulty in at least one basic skill			
Yes	223 (23.6)	168 (30.0)	391 (26.0)
No	721 (76.3)	390 (69.6)	1111 (73.8)
missing	1 (0.1)	2 (0.4)	3 (0.2)
Had 3 or less life skills (out of 5)			
Yes	242 (25.6)	154 (27.5)	396 (26.3)
no	699 (74.0)	404 (72.1)	1103 (73.3)
missing	4 (0.4)	2 (0.4)	6 (0.4)
At least one burden			
Yes	274 (29.0)	174 (31.1)	448 (29.8)
No	664 (70.3)	383 (68.4)	1047 (69.6)
missing	7 (0.7)	3 (0.5)	10 (0.6)
Health behaviour			
Ever smoked (Participant self-reported)			
Yes	756 (80.0)	450 (80.4)	1206 (80.1)
No	189 (20.0)	110 (19.6)	299 (19.9)
Missing	0	0	0

\* Definition of NEET status: Not in Education, Employment or Training (applicable only to those whose age at end of previous academic year at time of baseline interview was >16)

† Higher IMD score indicated more deprivation

‡ Higher score indicates higher level of self-efficacy

# 7 Stakeholder Involvement

## 7.1 Why involve stakeholders?

A model of stakeholder involvement was developed for use in the trial, which facilitated the contribution of both lay and professional people. This chapter describes the model used, and focuses specifically upon the lay stakeholder contribution.

Public involvement in health and social care research provides benefits that are increasingly being recognised by researchers and supported by funders. Such benefits include research aims and objectives that have greater relevance to the study population, more appropriately designed participant materials, more appropriate recruitment strategies and more relevant approaches to dissemination.<sup>143</sup> Such public involvement can apply both in research governance, most commonly through membership of formal trial steering and data monitoring committees and in research delivery. The latter encompasses the generation of outputs through processes of research co-production.

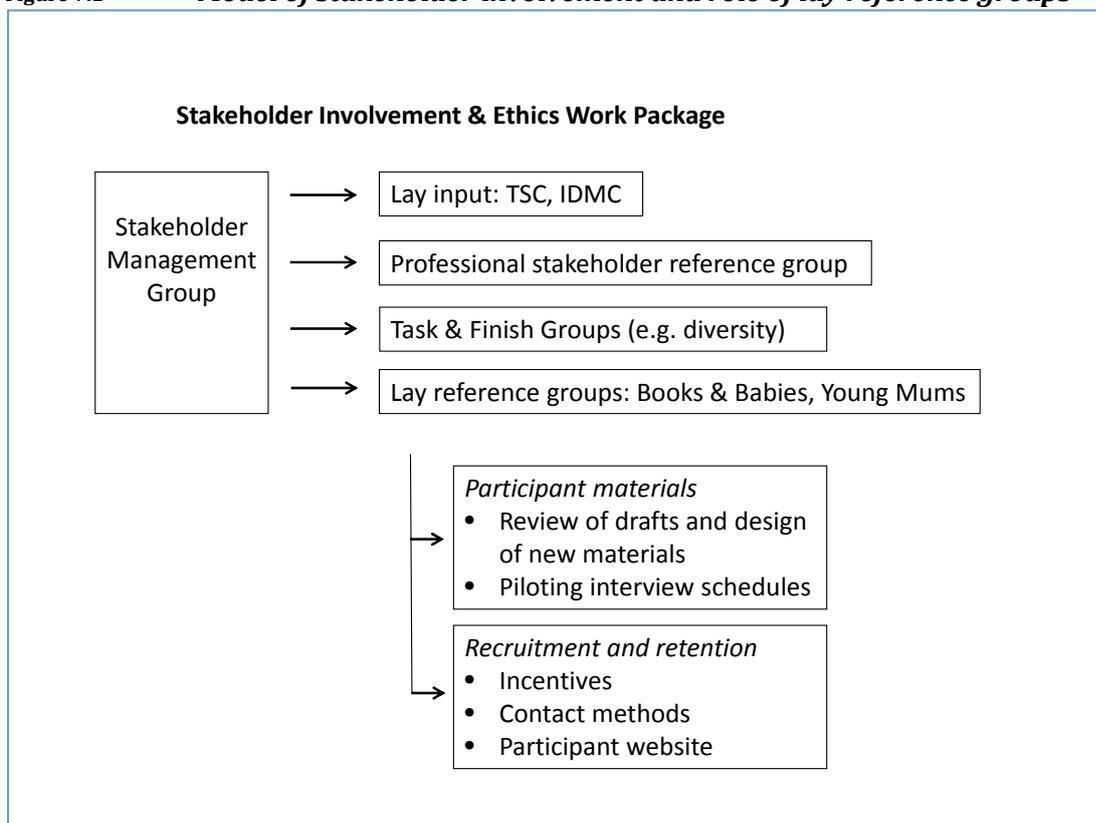
Several features of the Building Blocks trial meant that public involvement had a particularly important role to play, e.g. the complexity of the intervention being evaluated, the duration and range of assessments, and the daily life experiences of the study population. The FNP programme requires a high degree of contact between client and health professional over an extended period of time and addresses a wide range of clinical content. This places a burden on clients and poses a challenge in terms of achieving rapid initial engagement of participants with the trial. The corresponding evaluation required intermittent assessments over a two and a half year period planned to be undertaken using a variety of approaches (e.g. personal interview by telephone and face-to-face, collection of routine data and urine sample collection to calibrate smoking self-report). Pregnant teenagers and young mothers may face particular vulnerabilities associated with relatively disadvantaged social and economic circumstances (e.g. instabilities in accommodation and family support, younger teenage girls where statutory rape is apparent).

The trial therefore would encounter questions that required clarification and timely solutions. An approach to stakeholder involvement was developed to support engagement (both recruitment and retention) of all eligible participants and thereby to ensure the scientific and ethical implementation of the trial. Understanding how to engage and retain this population of young mothers should account for different circumstances, experiences and knowledge that they would encounter, e.g. future parenting, health and social care services, family, father of the child, ethical, legal and equality issues. These issues needed to be acknowledged in the methods of approach for engagement, consent, data collection, retention of participants (especially in the Control arm), safety monitoring and reporting of findings.

## 7.2 Stakeholder Involvement & Ethics Work Package

A Stakeholder Involvement and Ethics Work Package (SIEWP) was formed as a cross-cutting trial platform (Figure 7.1). Central to this was the Stakeholder Management Group (SMG) which included representatives of the trial team, members with a focus upon equality and diversity, and included lay and professional stakeholders. Stakeholder Management Group members engaged with external stakeholder reference groups set up to respond to the needs of the research team in various aspects of the development of documentation, engagement, outcomes, diversity and dissemination. Other elements of the Work Package included contributions to standard trial governance structures such as the Independent Data Monitoring Committee (IDMC) and Trial Steering Committee (TSC), and coordinating specific Task & Finish Groups (e.g. for Equality & Diversity).

Figure 7.1 **Model of stakeholder involvement and role of lay reference groups**



A request was made to 'Involving People' (Cynnwys Pobl) for a representative for the Stakeholder Management Group. A description of the proposed trial and requirements of the post was circulated to members of 'Involving People' who subsequently reported their interest in the topic / trial. To enable active participation in the trial, the selected lay representative was financially supported for their time and expenses and was able to attend meetings in person or via audio-link. The Stakeholder Management Group also sought advice from other stakeholders, e.g. safeguarding leads in the charity sector (e.g. NSPCC, Barnardo's) with knowledge of working with teenage mothers and children. A key initiative of the SIEWP was working alongside a Teenage Mothers educational class who acted as a reference group to the trial.

### **7.3 Teenage Mothers class: Books & Babies**

'Books & Babies' was an educational class set up by one local authority in South Wales for teenage mothers / mothers-to-be. Participants in the class included young women aged from 12 to 16 years of age, joined on occasion by former students. The group was supervised by a teacher and one classroom assistant, with one administrator and occasional input from outreach workers. Initially, it was considered that the role of this group would be to advise on issues such as literacy, consent, trial documentation, participant information sheets, recruitment and retention and incentives for participants. However, they were also encouraged to develop a more creative and proactive role such as designing a poster for recruitment and leaflets.

Approaching the Books & Babies class was suggested by a local health visitor working with the Stakeholder Management Group. An initial meeting was held with members of staff responsible for running the class, and a subsequent meeting with the students was attended by the lead and the lay member from the Stakeholder Management Group. Written information leaflets about the study were provided for the students alongside a verbal description.

Work with the group was always face-to face to be able to respond to their queries about any set task. This was important because language used by researchers may not always have been understood by teenagers. These sessions varied in frequency and length according to the needs of the trial and space in the students' curriculum. For the development of the poster and leaflets for the trial a newly qualified art teacher worked with the group in the development of their ideas and sessions ran over two afternoons. Critiquing the website covered two morning sessions, one for presentation and format of the website and another for discussing ease of use after initial website design had been completed. The lead, at times with the trial's process evaluation researcher, attended these sessions with the young mothers and provided feedback to the SMG. The trial team's responses to their support such as the making of their posters and other activities were fed back to the young mothers. The Books & Babies group became fully engaged with the challenges they were given. They were enthusiastic and on completion took pride in their achievements, as was clear from their comments during the focus group session that rounded off their involvement. Importantly, the tasks set such as the critique of the content of leaflets, design of posters, discussions on issues around recruitment and retention of participants, and their assessment of the usability of the website could be incorporated within their study requirements, especially regarding English language, art and information technology.

Work with the class commenced in March 2009 but the educational programme itself was wound up by the local authority in July 2011 and an alternative educational group for young teenage mothers (Young Mums) was recruited in another local locality within the South East of Wales. However, the original Books & Babies students met again to continue to assist with the trial at the local YMCA despite the official group being disbanded. It was recognised that the teenage mothers lay reference groups would be dynamic as the membership naturally refreshed during the course of the trial. However, it was gratifying that Books & Babies students who had moved on to college returned for the trial session to continue to be part of the initiative, and an indication of the value they placed on their own contribution.

Across the course of the Building Blocks trial, a number of specific activities were undertaken by the Books & Babies students in support of the trial and are described below.

### **7.3.1 Activity 1: Design of participant materials**

Draft participant recruitment materials were reviewed by the students. Their initial reactions were that participant leaflets contained too many words and had insufficient visual content. As part of their input to drafted recruitment materials, the students went on to design a poster which was subsequently used at trials sites to promote recruitment (Appendix 11 Recruitment poster). The students drew upon the original study materials, to include key questions in the text, added their own visual imagery and provided relevant contact numbers for the Local Researcher. A shared student perspective was that the trial would benefit young first time mothers, who they felt were often 'left in the dark' and not given full information. The poster was circulated to trial sites and also displayed in their centre and when visitors or new students came they explained with pride their involvement in the trial.

Incidentally, they shared insights into prejudices they encountered as teenage mothers. The students described examples of everyday experiences as teenage mothers / mothers-to-be, including instances which they considered reflected common discrimination or abuse.

### **7.3.2 Activity 2: Piloting telephone interviews**

Several students volunteered to test the late pregnancy and 6 month postnatal telephone interviews. This highlighted some of the difficulties for telephone interviewers in contacting this young age group (e.g. lack of response when called, frequent turnover in mobile phone numbers).

### **7.3.3 Activity 3: Advertising on recruitment and retention to the trial**

The initial participant engagement strategy devised for the study was formally reviewed by the Trial Management Group during the recruitment phase, in part due to observed variations across sites in recruitment. The Stakeholder Management Group and in particular the Books & Babies students were asked to contribute to the refinement of the developing strategy. Their input into some of the key elements of the strategy is described below and included the use of incentives, approaches to maintaining participant contact details and the development of a participant website. Other suggestions by the students included greater use of the internet, pictures on Facebook, entertainment DVDs for the baby, vouchers for disposable nappies, wet wipes, baby cream and bath products. All suggestions for maximising retention were considered by the Trial Management Group although not all could be implemented for reasons of feasibility or safety (e.g. use of Facebook). Involvement of fathers was discussed but was generally considered problematic due to prior bad experiences by the teenage mothers themselves.

**Incentives:** Telephone pre-payment cards were initially offered to study participants. However, the students in Books & Babies thought this could be problematic as many of them had contracts with telephone providers. They considered

telephone cards ‘too much hassle’ as instructions needed to be followed and ‘inconvenient’ because some existing call credit was required to make the card operational. In addition, the card could not be used for texting, a method of communication often preferred by young people. However, they did develop a draft leaflet making the telephone card instructions more user-friendly, using cartoon drawings with bubble writing and emphasising the ‘FREE’ call time.

Instead, high street retail vouchers were favoured to enable recipients to obtain infant related goods and services. Other suggestions included book vouchers and vouchers for centres with activities for children, where the mother and child could play and eat. This informed the introduction of high street vouchers for later waves of study data collection (£25 for the 12 and 18 month telephone interviews and £40 for the 24 month interview, reflecting the different interview durations). It was considered that the increasing value of the vouchers would have a positive impact on retention of participants. Information leaflets, explaining the new voucher scheme, were developed by the group.

**Contact details:** Up-to-date contact details were important to retain participants on the trial. All members of the Books & Babies group had internet access at home and on their mobile phones. The group suggested in the first instance to send a letter, requesting participants’ current addresses, an address of somebody close to them, e.g. a relative or close friend, the participants’ telephone number and an alternative number, and the participants’ email addresses and thereby endorsed the trial strategy for maximising participant contact details.

In its review of engagement strategies, the trial team considered the use of social media for communicating with trial participants; however, the Books & Babies group subsequently discounted this approach due to previous experience that resulted in targeting of abuse by ‘internet trolls’. Nevertheless, the Books & Babies mothers suggested using email addresses as a means of contacting participants on a one-to-one basis through Facebook.

Table 7.1 Ideas for participant website suggested by Books & Babies students

<b>Category</b>	<b>Content</b>	<b>Website</b>
<b><i>Information for mothers</i></b>	Announcement of events with reminders including where there are ‘freebies’ vouchers available for products (e.g. nappies, wet wipes, bath products, baby cream), Links and useful numbers, Benefits Banking, Borrowing, Health, Exercise	The maternal stakeholders (first the Books & Babies and then
<b><i>Means of communication and exchange of ideas</i></b>	Live blog page, Adverts, Problem page, Relationships, Recipes	
<b><i>Activities with or for the child</i></b>	Tummy time, Sing along tunes, Stories, Suggestions for baby birthday parties, Tips for recipes for the babies first birthday cake, T-shirts and banners with child’s name, Name that tune (competition) including theme tunes to programmes, children’s tunes and chart hits	
<b><i>General Information</i></b>	Fashion, Holidays, News, Gossip, Celebrity mothers.	

the Young Mums group) were consulted about the development of a trial participant website. Potential benefits of such a website cited by the students were support, ability to talk to others, and the development of community through exchange of ideas, problems, experiences and stories, which they felt would make teenage mothers feel less alone and part of a community. They recommended password-restricted access to the website, which, because it concerns teenage pregnancy, could be a target for abuse and criticism. Views from the groups were sought on content, design layout, format, colour scheme. Consensus from the teenage mothers lay reference groups, following review of the prototype website, was that information should be briefly presented, to the point, with relatively less writing and more pictures and coloured text, presented in bubbles and highlighting what is to be read. Some of their ideas about content are presented in Table 7.1.

### **7.3.4 Acknowledgement and thanks**

Certificates acknowledging the Books & Babies group's participation in activities for the trial were produced and presented to members at the closing celebrations for the group. These could be inserted in their 'Record of Achievement' folders, which are for presenting certificates, diplomas, accreditations and any other mark of achievement. A Thank you card also included high street gift tokens for £40 in recognition of their contribution. Similarly, the Young Mums group received vouchers for testing the participant website competition questions and were provided with lunch at some of their meetings.

### **7.3.5 Evaluation of the lay reference group**

The role and contribution of the Books & Babies lay reference group was retrospectively assessed using focus groups.<sup>7</sup> One focus group included the local authority staff with usual responsibility for running the educational group and the other with the teenage mothers themselves. The focus groups were conducted separately - with teachers and one member of the support staff during the last session before closure, and with young mothers at the closing of the group. The topic guide for the focus group discussions was designed by the two facilitators and focused on three main areas; (i) research participation (motivations, expectations, engagement over time), (ii) reflections on participation outcomes, and (iii) relevance of Building Blocks to participants' lives. The focus group sessions were audio-recorded, responses summarised and, where necessary, clarified. The principal aim of the focus groups was to explore with both teaching staff and students their experiences of participating in the study as stakeholders. Reflections from focus group participants were summarised and presented descriptively.

**Teaching Staff focus group:** Educational staff for the Teenage Mothers group described how they continuously tried to optimise students' exposure to new ways of learning and they thought that participating in the research would be something new, relevant and interesting for the students. Their initial concerns included how outsiders might present

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<sup>7</sup> Although the later involvement of the Young Mums group was shorter than that of the Books & Babies group, they did participate in an independent evaluation of public involvement in research led by the University of the West of England: Evans, D., Laterza, V. et al.. (2014). 'Public Involvement in Research: Assessing Impact through a Realist Evaluation'. Peer-reviewed project report. Funder: National Institute of Health Research, UK.

themselves, a possible lack of response or unreliable attendance by the teenage mothers, and the students being unable to deliver. However, their impression was that the teenage mothers enjoyed participating, particularly because 'their views were obviously respected'. Participation was considered to have increased the confidence of the students.

There were some areas where views of staff and students diverged, for example, the use of phone cards as an incentive. The staff stated that when contributing to the development of the posters and phone card leaflets, the students were really interested and got on with their tasks. Different issues covered by the students became part of their portfolio of work to obtain their BTEC and GCSE qualifications and their Youth Achievement Awards (<http://www.youthachievementawards.org/index.aspx>). What was considered particularly useful was the analytical approach required by students to access existing materials and develop new ideas, which was considered empowering particularly in terms of 'language and imagery', which linked to the students' English GCSE coursework.

**Teenage Mothers focus group:** One student in the group remarked that following the initial explanation about the study they 'did not know what the researcher was talking about'. In addition, the group initially thought it would be boring, but paradoxically, were also excited about being invited to participate. Nevertheless, they all actively participated in the process and subsequently stated they enjoyed their involvement in the study, especially thinking up and developing ideas. It was considered 'challenging but enjoyable'. With no prompting, there was consensus from the students that they would take part in research again. They thought that they had gained new skills such as contributing to the website design and posters and they felt good about helping other people. They felt that being part of the study had helped them with writing their coursework. The students were particularly excited that their poster was used nationally and showed their achievements to new students joining the group.

## 7.4 Reflections from lay members on their participation in the trial

Lay members contributed to the trial governance committees (TSC, IDMC) and the Trial Management Group. Two of the lay members of these trial committees were asked to provide their own reflections about contributing to the trial. These observations are presented collectively below.

**Experience of Lay stakeholders:** Stakeholders described the satisfaction of both being invited to participate in their respective roles and also carrying that through over the course of the study. The challenges that incurred were also reflected in their comments. For some of them involvement in the study provided a new insight into the process of research in general and to the operation of the specific intervention being evaluated (box 1).

### Box 1 General comments from lay stakeholders

"In the beginning I was honoured to be asked then wondered did I know enough and there were times when I felt a bit lost." (Lay representative A)

"I am really glad I have seen it right through as I have gained a lot from it. It helped me a lot

personally. It was worth it, it really was.” (Lay representative A)

“Fascinating and interesting ... discussions from a lay person to understand the difficulties of a trial to really get the samples needed for testing.” (Lay representative B)

“It has given me a better understanding especially when everybody talks about evidence.” (Lay representative B)

“For me it was all positive and relative to my job. Everybody talks about FNP, so now I have an insight into FNP and research required.” (Lay representative B)

#### **7.4.1 Raised awareness of government investment in research**

It was noted by one lay member that as the trial progressed, the realisation of the size and detail of the project in terms of the number of participants, the complexity of the trial, the research nurses’ workload and that of the research team that it would cost a lot of money.

“Hearing the amount of money that it was going to cost was unbelievable that a trial would cost so much money but when you see what the trial entails then you realise that it does take a phenomenal amount of money”. (Lay representative A)

Another issue raised was that there was a lack of awareness by the public that the Government provides funding for these types of trials to see if different care provision makes a difference in practice. Related to this was the comment that:

“you hear of what is thought to be a good project closing down, but being part of this trial has made me realise that maybe the project did not work and that is the reason why but you are not told the reason just that there is a cut back. You’re never really told the bigger picture”. (Lay representative A)

It was considered that if people do not know about this research activity, there is a need for more public relations and dissemination to the public by the government.

#### **7.4.2 Expertise and training**

One lay member initially felt nervous but said “I do not know if someone who had not the experience of attending meetings would feel and able to cope with the conversation” (Lay representative B). Another lay stakeholder felt that if a lay person was trained for the role, ‘raw’ thoughts would be unobtainable. One stakeholder commented, “The only thing as a lay person...data and data analysis was way over my head” (Lay representative A). The other commented, “There were times when things felt over my head. But in all honesty I would have contacted you and I have. There was someone there that I could ask” (Lay representative B).

### **7.4.3 Discipline within a RCT**

The lay stakeholders felt they had learnt a lot about the 'rigidity' and effort of data collection, e.g. that data can only be used for what participants have consented to. When they heard about the data being collected, their initial thoughts were that the data would be widely used but subsequently realised that the dataset 'is huge but not free to use'.

### **7.4.4 Meetings**

Documentation was reported to have arrived in time for consideration before meetings and the atmosphere in meetings was considered formal due to the content but informal enough to be inclusive. Lay representatives felt sufficiently informed, and that their contribution was valued rather than tokenistic. Lay representative A commented that there were, "times I was glad to be there to put my point of view forward."

### **7.4.5 Young mums a challenging topic**

The lay stakeholder representative working with the Books & Babies teenage mothers group felt challenged by her own perceptions of modern-day lack of stigma attached to teenage pregnancy (Lay representative A). The lay member stated 'the picture often painted is of teenagers getting pregnant is to get a house, get extra money and benefits'. However, after listening to them telling their stories, realised how hard some of their lives have been and abuse that they have received. The lay member stated that 'no matter why they got pregnant, we should support them'. They considered that "what was happening was at the time when they are finding out who they are". In the past it was considered "acceptable to be married at 17 but youngsters are brought up and not encouraged to be mature. On one hand encouraged to go out to nightclubs but not to stand on their own two feet". There was thought to be a lack of stability in their lives exemplified by swapping phones and changing addresses. The venue used for the young mother's education was perceived by the lay member as a building where they were being "hidden away".

## **7.5 Discussion**

Stakeholder Involvement and Ethics was one of the four trial Work Packages (alongside Trial, Health Economics and Process Evaluation) and took responsibility for ensuring appropriate representation in standard trial governance committees as well as working with an ongoing lay reference group. The lay reference group provided a continuing forum of teenagers able to advise on developing trial activities and requirements. The trial team benefited from the existing structure and organisation of this group to refine and innovate materials and strategies. In turn, participants felt positively about their contribution to the study and were able to add to their educational record of achievement.

Models of lay involvement in trials are often defined by, and limited to, standard governance structures such as independent Trial Steering Committees and Data Monitoring Committees. Building Blocks provided this too, but in addition worked with two standing reference groups of teenage mothers. The group was previously initiated by a local authority to provide education to teenage mothers or mothers-to-be. This had several advantages in that the group was already established, was coordinated by education staff, had regular meetings and an existing venue. The educational

focus of the group was congruent with the activities generated by working with the trial team. Tasks could be easily constructed and integrated with their learning curriculum, and inputs to the trial provided achievements for their own educational portfolios. Alternate models of lay input for this age group exist in Cardiff University, for example, CASCADE Voices, a group of care-experienced young people who advise on social care research projects<sup>144</sup> and ALPHA, a public health research advisory group of young people aged 14-20.<sup>145</sup> The unfamiliarity of the research process was an initial barrier for the Books & Babies group and groups established specifically to input to research may find such initial orientation more straightforward. Nevertheless, the input of the researchers to the Books & Babies group overcame any early unfamiliarity. As the Books & Babies students closely reflected the trial population they may be considered to have provided a particularly valuable source of insight to the trial.

Lay involvement will provide challenges to the research team which, in part, is its benefit. Two examples from the work of the Books & Babies group demonstrate this. First, the trial team suggested the use of a participant website to support study engagement, particularly in relation to retention (for example, by providing a means of capturing changing contact details for participants). The students provided a number of suggestions for the website including the opportunity for participants to interact directly with each other. Parallel moderated fora were therefore introduced that maintained separation of Intervention and Control arm participants and thus avoided contamination between trial arms. Second, the trial team had initially considered the use of social media but the decision not to pursue that option due to potential harms for users was confirmed by the lay stakeholder group. In both examples researcher and lay perspectives came together effectively in trial decision-making. Understanding and respecting the context for decision-making by training is key to an effective working relationship.

We hoped that a key impact of lay involvement was in supporting participant engagement, a common motivation for public involvement in research.<sup>143,146</sup> We considered that this would have been achieved both indirectly (for example, by developing, piloting and refining participant recruitment materials and interview schedules) and directly (for example, by contributing to the range of retention strategies employed in the study such as the participant website). It is not possible to estimate the effect of this input, certainly in a quantifiable manner. Although we could have empirically tested such strategies, it was considered more appropriate to roll-out such low cost interventions to all trial participants. What remains tangible, however, are the innovations led by the students, such as the recruitment posters, revised recruitment leaflets and their ideas implemented in the participant website.

Partnership in research has an impact for lay representatives. This was evident for both lay stakeholder groups and also the lay representatives in the governance and management groups of the study. This included a raised awareness of research policy, governance and practice, sometimes of surprise to the individuals concerned (for example, the cost). Although not apparently problematic, some of this could have been anticipated and supported by more formal induction and training, in line with more recent developments in UK clinical research (e.g. via Involving People). It is also clear that some communication within meetings could have been modified to make discussion more accessible to lay representatives. There were also clearly benefits for lay participants themselves. This included the greater understanding of research and practice mentioned above, and is consistent with findings from other examples of public

involvement.<sup>147,148</sup> What is noticeable, and maybe less frequently reported, were the tangible benefits accrued by the students contributing to the study in terms of enhanced feelings of self-worth and educational credits arising from the project-like activities conducted as part of their contribution to the study.

# 8 Core Model Elements and Fidelity Goals

## 8.1 Introduction to the Core Model Elements and Fidelity Goals

This chapter describes the quality of intervention delivery specifically assessed against programme Core Model Elements (CMEs) and Fidelity Goals (FGs). This component of the trial's process evaluation will establish the extent to which the intervention has been delivered as intended, and therefore whether the trial results are a firm basis for drawing conclusions about programme effectiveness. Table 8.1 summarises each CME and FG and where reported, and which could not be assessed as data were not available. Data were principally drawn from the FNP Information System. Only some CMEs and FGs are retrievable through that source, and where an assessment against these criteria was not possible this is indicated. Other trial-specific process evaluation components (e.g. MITI assessment of MI in chapter 10) will build upon this base.

Table 8.1 Family Nurse Partnership: Core Model Elements (CME) and Fidelity Goals (FG)

Core Model Elements / Fidelity Goals	Criteria	CME	FG	Reported
<b>Client enrolment, recruitment and engagement</b>	Enrolment is voluntary	✓		Chapter 8
	Eligible / 100% of clients enrolled are first-time mothers only	✓	✓	Chapter 8
	Eligible clients are high risk mothers only (criterion: 19 years or younger at LMP)	✓	✓	Chapter 8
	Sites enrol at least 60% of clients by the end of the 16 <sup>th</sup> week of pregnancy and 100% no later than the 28 <sup>th</sup> week	✓	✓	Chapter 3
	75% of eligible clients who are offered the programme are enrolled		✓	Chapter 8
	Each client enrolled is visited by the same Family Nurse throughout her pregnancy and the first 2 years of her child's life	✓		Chapter 8
	Each Family Nurse enrolls 25 families (or pro rata) within 9 months of recruitment		✓	
<b>Family Nurses</b>	Registered with the Nursing and Midwifery Council (NMC), are educated at degree level and meet the person specification for a Family Nurse	✓		
	Follow the FNP learning programme and attend all FNP specific essential training	✓		
	Follow the FNP home visit guidelines: 1) visit schedule: frequency and timing of visits	✓	✓	Chapter 8
	Follow the FNP home visit guidelines: 2) desired structure and content of each visit	✓	✓	Chapter 10
	Follow the FNP home visit guidelines: 3) programme assessments and interventions to be used	✓		Chapter 10
	Apportion home visit time among content domains	✓	✓	Chapter 10
	Actively participate in FNP supervision as specified	✓		
	Be trained in specific approaches for establishing therapeutic relationship and motivating clients for positive behaviour change	✓		Chapter 11
	Carry a caseload of no more than 25 families per full-time employee	✓		
	Work at least 3 days/20 hours a week on the programme	✓		
	Participate in FNP programme data collection (activity, visit content etc.)	✓		
	Work exclusively on the programme			
<b>Programme supervisors</b>	Registered with the NMC, education and training at least equivalent to Family Nurses, preferably masters degree; meet person specification requirements	✓		
	Follow FNP learning programme and attend all FNP essential training	✓		
	Follow supervisor training and action learning sets	✓		
	Supervisory load of no more than 8 Family Nurses (per full-time supervisor)	✓		
	Carry a small clinical caseload (2-3 families)	✓		
	Work at least 3 days/20 hours per week on the programme	✓		

<b>Core Model Elements / Fidelity Goals</b>	<b>Criteria</b>	<b>CME</b>	<b>FG</b>	<b>Reported</b>
	Use programme reports to access and manage areas where systems, organisational, or operational changes are needed to enhance programme quality and inform reflective supervision	✓		
	Meet one-on-one with each Family Nurse at least weekly	✓		
	Conduct at least 4 team meetings per month	✓		
	Develop opportunities for learning within the team and involve experts from other disciplines in case discussions where necessary	✓		
	Make a minimum of one home visit every 4 months with each Family Nurse	✓		
<b>Administrative support</b>	Ensure that data about Family Nurse activity, visit content, mothers and children are submitted completely and accurately on a timely basis Provide general administrative support			
<b>Interpreter support</b>	Not relevant to Building Blocks because of RCT exclusion criteria			
<b>Recruitment and enrolment</b>	Each Family Nurse enrolls 25 families (or pro rata) within 9 months of recruitment	✓		
<b>Attrition</b>	Cumulative programme attrition is 40% or less through to the child's second birthday <ul style="list-style-type: none"> <li>• 10% or less during the pregnancy phase</li> <li>• 20% or less during the infancy phase</li> <li>• 10% or less during toddlerhood</li> </ul>		✓	Chapter 8
<b>Dosage</b>	On average, length of home visits is around 76 minutes		✓	Chapter 3

## **8.2 Client enrolment, recruitment and engagement**

### **8.2.1 Voluntary enrolment**

Voluntariness of enrolment is not directly reported within the FNP IS but is affirmed in FNP guidance, training and policy documents. However, informed consent was required for all women entering the trial, and women allocated to FNP were informed that their participation in any aspect of the study was voluntary.

### **8.2.2 Eligible clients are first-time and high risk mothers only**

Being a first-time mother was not directly reported, this was assessed locally by supervisors, midwifery records and other referrers. As part of the FNP inclusion criteria clients had to be 19 years or younger at the date of their last menstrual period (LMP) (the criterion for high risk being applied in England). Age at enrolment/first visit was collected on the FNP IS; there were no clients who were aged over 19 years of age at the date of their LMP.

### **8.2.3 Enrolment**

A core model element of the FNP programme is that 75% of eligible clients who are offered the programme should be enrolled. During the recruitment phase of the Building Blocks trial the only way a client could enter the FNP programme at trial sites was through randomisation. Data taken from the FNP IS dataset showed that 89% (719/808) of women randomised to receive the intervention and offered FNP were enrolled onto the programme. Of the 719 (89%) that were randomised and enrolled, 716 (99.6%) received at least one valid visit (with a total of 27,853 valid visits) and three (0.4%) women did not receive a valid visit (as defined in section 3.7.1). The following analyses is based on the 719 FNP enrolled participants and the visits that they received from FNP nurses.

A core model element of the FNP programme is that sites enrol at least 60% of their clients by the end of the 16<sup>th</sup> week of pregnancy and 100% no later than 28 weeks gestation. Sites were encouraged to put systems in place to facilitate early recruitment into the trial but this was limited by individual site procedures for booking women into maternity care, which proceeded referral to the Local Researcher. As it was appreciated that there would be an inevitable time period between recruitment into the trial and enrolment into FNP, it was aimed, whenever possible to recruit women into the trial prior to 16 weeks gestation. During the baseline interview participants provided a self-reported gestation, with 58% (416/719) reporting their gestation to be less than 16 weeks (Table 8.2). Across sites the proportion of women recruited into the trial under 16 weeks ranged from 29.2% to 77.3%. Based on the difference in calendar dates, there was subsequently an average 22 days between recruitment into the trial and the first FNP home visit. The FNP IS system provided data relating to gestation at enrolment into FNP and this is presented in chapter 3.

Table 8.2 Gestation at randomisation of Building Blocks Intervention arm participants (from randomisation data)

<b>Weeks' gestation at randomisation N(%)</b>				
<b>Site Number</b>	<b>Missing</b>	<b>Under 16 weeks</b>	<b>16 weeks or over</b>	<b>Total</b>
1	0	17 (77.3)	5 (22.7)	22
2	1	7 (29.2)	16 (66.7)	24
4	0	32 (50.8)	31 (49.2)	63
5	0	11 (57.9)	8 (42.1)	19
7	0	13 (50.0)	13 (50.0)	26
8	0	10 (62.5)	6 (37.5)	16
9	0	13 (61.9)	8 (38.1)	21
10	0	31 (64.6)	17 (35.4)	48
21	0	30 (68.2)	14 (31.8)	44
22	0	14 (43.8)	18 (56.3)	32
23	0	22 (44.9)	27 (55.1)	49
24	0	14 (34.1)	27 (65.9)	41
25	0	48 (71.6)	19 (28.4)	67
26	0	8 (50.0)	8 (50.0)	16
27	0	43 (72.9)	16 (27.1)	59
28	0	34 (54.8)	28 (45.2)	62
29	0	35 (63.6)	20 (36.4)	55
30	0	34 (61.8)	21 (38.2)	55
<b>Total</b>	<b>1</b>	<b>416 (57.9)</b>	<b>302 (42.0)</b>	<b>719</b>

### 8.3 Continuity of Family Nurse

It is the aim that each FNP enrolled client should be visited by the same Family Nurse for the duration of the programme. The majority (70.9%) of clients (restricted to the 716 that received a valid visit) were visited by one Family Nurse only and the remainder saw two or more nurses for their visits (Table 8.3). Two clients received programme visits from five different individual Family Nurses, with the number of visits per nurse ranging from 1 to 20.

Table 8.3 Number of Family Nurses per client over the programme duration

<b>Number of Family Nurses per client</b>	<b>N (%)</b>
1	508 (70.9)
2	172 (24.0)
3	30 (4.2)
4	4 (0.6)
5	2 (0.3)
<b>Total</b>	<b>716 (100.0)</b>

### 8.4 Visit schedules

Clients should receive at least 80%, 65% and 60% of expected visits during the pregnancy, infancy and toddlerhood periods respectively. The frequency of visits received by participants by phase is described in section 3.7.4. In

summary, 413 women (57.7%) received 80% or more of expected visits during pregnancy whilst in the infancy and toddler phases, 53% and 43.6% attained the target of 65% or more and 60% or more, of expected visits respectively (Table 8.4).

Table 8.4 Distribution of the percentage of expected visits received by phase

Percentage of all expected visits	All enrolled clients who started the pregnancy phase		All clients starting the infancy phase		All clients starting the toddler phase	
	N (%)	Cumulative %	N (%)	Cumulative %	N (%)	Cumulative %
<10%	9 (1.3)	1.3	40 (5.8)	5.8	100 (14.6)	14.6
10-19%	12 (1.7)	2.9	11 (1.6)	7.3	19 (2.8)	17.4
20-29%	13 (1.8)	4.7	16 (2.3)	9.7	29 (4.2)	21.6
30-39%	13 (1.8)	6.6	28 (4.0)	13.7	36 (5.3)	26.9
40-49%	30 (4.2)	10.8	46 (6.6)	20.3	60 (8.8)	35.7
50-59%	44 (6.1)	16.9	101 (14.6)	34.9	142 (20.8)	56.4
60-69%	77 (10.8)	27.7	133 (19.2)	54.0	100 (14.6)	71.1
70-79%	105 (14.7)	42.3	155 (22.3)	76.4	96 (14.0)	85.1
80-89%	146 (20.4)	62.7	99 (14.3)	90.6	49 (7.2)	92.3
90-100%	175 (24.4)	87.2	46 (6.6)	97.3	27 (3.9)	96.2
101-120%	67 (9.4)	96.5	113 (1.9)	99.1	14 (2.0)	98.2
121+%	25 (3.5)	100.0	6 (0.9)	100.0	12 (1.8)	100.0
<b>Total</b>	<b>716 (100.0)</b>	-	<b>694 (100.0)</b>	-	<b>684 (100.0)</b>	-
<b>N (%) reaching fidelity goal of:</b>	<b>80% +</b>		<b>65% +</b>		<b>60% +</b>	
	413 (57.7)		368 (53.0)		298 (43.6)	

## 8.5 Training and working practices - Caseload

Each Family Nurse should enrol 25 families within nine months of recruitment and carry no more than 25 families per full-time Family Nurse. Within our cohort of clients randomised and recruited to FNP, 106 Family Nurses had a trial caseload of between 1 and 20 clients. Some Family Nurses would also have had women recruited prior to the commencement of recruitment within their caseload, but these numbers could not be determined.

## 8.6 Attrition

FNP fidelity goals for attrition are that cumulative attrition should be 40% or less through to the child's second birthday, with ≤10% during the pregnancy phase, ≤20% during the infancy phase and ≤10% during the toddlerhood phase. Table 8.5 describes attrition rates from FNP during the various phases of the programme, which were all within fidelity goal levels being 3.6% during pregnancy, 10.1% during infancy and 7.9% during toddlerhood.

Table 8.5 Attrition in the Building Blocks Study

Site ID	N randomised to FNP (%)	N did not enrol in FNP (%)	Enrolled in FNP (%)	Pregnancy phase N=719			Infancy phase N=693			Toddlerhood phase N=623			Total attrition	Total Completers*	Missing data
				Leavers†	Inactive‡	Total	Leavers	Inactive	Total	Leavers	Inactive	Total			
1	23 (2.8)	1 (4.3)	22 (95.7)	0	1	1	2	1	3	2	0	2	6	15	1
2	26 (3.2)	2 (7.7)	24 (92.3)	0	0	0	5	1	6	2	0	2	8	16	0
4	72 (8.9)	9 (12.5)	63 (87.5)	4	1	5	5	3	8	2	0	2	15	47	1
5	19 (2.4)	0 (0.0)	19 (100.0)	0	0	0	1	1	2	0	0	0	2	16	1
7	26 (3.2)	0 (0.0)	26 (100.0)	0	0	0	0	0	0	6	0	6	6	20	0
8	20 (2.5)	4 (20.0)	16 (80.0)	0	0	0	3	0	3	4	0	4	7	9	0
9	25 (3.1)	4 (16.0)	21 (84.0)	1	0	1	0	2	2	1	1	2	5	16	0
10	57 (7.1)	9 (15.8)	48 (84.2)	2	1	3	6	0	6	0	0	0	9	37	2
21	55 (6.8)	11 (20.0)	44 (80.0)	0	0	0	1	1	2	4	0	4	6	38	0
22	35 (4.3)	3 (8.6)	32 (91.4)	1	0	1	1	0	1	2	0	2	4	28	0
23	49 (6.1)	0 (0.0)	49 (100.0)	2	0	2	2	1	3	2	1	3	8	40	1
24	46 (5.7)	5 (10.9)	41 (89.1)	0	2	2	3	1	4	2	2	4	10	31	0
25	75 (9.3)	8 (10.7)	67 (89.3)	0	1	1	1	5	6	6	2	8	15	50	2
26	18 (2.2)	2 (11.1)	16 (88.9)	1	0	1	0	2	2	0	0	0	3	13	0
27	69 (8.5)	10 (14.5)	59 (85.5)	3	1	4	5	3	8	0	3	3	15	41	3
28	69 (8.5)	7 (10.1)	62 (89.9)	0	0	0	5	0	5	2	2	4	9	52	1
29	58 (7.2)	3 (5.2)	55 (94.8)	0	0	0	3	2	5	2	0	2	7	34	14
30	66 (8.2)	11 (16.7)	55 (83.3)	4	1	5	2	2	4	1	0	1	10	44	1
<b>Total</b>	<b>808 (100.0)</b>	<b>89 (11.0)</b>	<b>719 (89.0)</b>	<b>18</b>	<b>8</b>	<b>26 (3.6%)</b>	<b>45</b>	<b>25</b>	<b>70 (10.1%)</b>	<b>38</b>	<b>11</b>	<b>49 (7.9%)</b>	<b>145 (21.2%)</b>	<b>547 (76.1%)</b>	<b>27</b>

\* Client has completed the FNP programme, as indicated by completing the UK004B form.

† Client has moved out of service area as indicated by completing the UK004B form.

‡ Recorded in UK004B as 'INACTIVE' and INACTIVE COMPLETERS'. INACTIVE means that the client has had no Family Nurse contact for 6 months and INACTIVE COMPLETERS are clients for whom 2 years has passed after infant date of birth and the client is in a programme status of INACTIVE.

# 9 Fidelity to Programme Content

## 9.1 Aims and Background

- i. To identify the extent to which Family Nurses (FNs) across FNP are delivering client visits according to the programme fidelity targets for percentage time spent on five content domains.
- ii. To examine the measurement method of self-reporting visit content with a nested validation study using an FNP-informed objective measurement approach.

### 9.1.1 Content domains and target percentages in FNP

The visit by visit protocol for the NFP included the development of six broad content domains for the visits (Korfmacher 1999), which are part of the protocol for FNP. These six domains are condensed into five for the purposes of domain coding and record keeping in FNP as any discussion of domain six, 'health and human services', is considered to arise because of a need identified in one of the other content domains, so a separate category for time spent discussing community resources is not included (FNP data management manual). The proportion of time spent on these five domains during visits is regarded as an indicator of programme fidelity and so there are 'stretch objectives' within the core model which are the target percentages the Family Nurses are aiming to achieve in the long-term (referred to here as 'the target percentages'). The five specified content domains and the target percentages for average percentage of time to be spent in each domain across the phases are detailed in Table 9.1. The changes in percentages over the three phases are designed to reflect the variation in developmental needs of the clients over time.

Table 9.1 Content of Home Visits: Target Percentages across the phases

Phase	Personal Health %	Maternal Role %	Friends and Family %	Life Course%	Environmental Health %
<b>Pregnancy</b>	35-40	23-25	10-15	10-15	7-10
<b>Infancy</b>	14-20	45-50	10-15	10-15	7-10
<b>Toddlerhood</b>	10-15	40-45	10-15	18-20	7-10

Following each visit to a client the FN completes a 'Home Visit Encounter Form' UK001 which includes an estimate of percentage time spent on the topics covered from the specified content domains and these data are collated by the FNP National Unit (FNP NU). The Family Nurses are given instructions on this process in a variety of ways. It is included in the guidance on data collection that they receive and work through individually and as part of team learning. It is also included in the supervisor learning programme and there are regular reports on the FNP Information System showing how much visit time each FN has spent on each domain with each of her clients. This can be reviewed and discussed in

individual and team supervision. The FNs are told that the purpose of the task is to help determine whether the FN has been able to cover programme material that both the FN and client planned to cover. It is made clear that in order to agenda match with the client, the FN has the flexibility to move topics included in the home visit guidelines from one visit to another. However, the aim of the target percentages is to avoid allowing crises to dominate and that planned content is the focus the majority of the time. It is also recognised that these are estimates of time so it is assumed that values will be rounded to the nearest 5%.

### **9.1.2 Domain coverage in the Implementation Evaluation**

Between 2009 and 2011 Jacqueline Barnes and colleagues conducted the Implementation Evaluation of the FNP programme in ten sites in England.<sup>107</sup> This evaluation included an analysis of the content of the visits based on FNs' estimates of time spent on the domains reported in the Home Visit Encounter Form. In the pregnancy phase the content covered in the visits was described as being predominantly in line with the target percentages. During the infancy visits the percentages of estimated time spent on Personal Health and Environmental Health were slightly higher than the target range and slightly lower than the target range on Maternal Role, which was designed to be the major focus of infancy. The authors also commented on the significant variation between sites. In toddlerhood the aim is that attention shifts to the mother's life course. The stretch objective for this domain in toddlerhood is that 18 to 20% of the time in visits should cover the life course but in the implementation evaluation the average time overall was 13%, with no site average reaching 18%. In contrast, in all but one site, the average percentage of time per visit estimated as being spent on the mother's Personal Health was above the 10-15% target range, with an overall average of 18%.

## **9.2 Methods**

### **9.2.1 Content of all valid visits across trial sites**

The content data for all valid visits to women randomised to FNP were collated from the FNP IS.

### **9.2.2 Recorded home visits**

The aim in this section of the process evaluation was to gather audio recordings of FNP client sessions across the three phases from randomly selected Family Nurses. Following consultation meetings in April and July 2010 with FNP supervisors and a representative of the FNP National Unit to explain the purpose of recording home visits, two Family Nurses in each of the 18 trial sites were asked to submit a minimum of two recorded consultations each per phase: pregnancy, infancy and toddlerhood. The FNs were eligible for selection for this recording task if they had clients in the pregnancy phase at the time of the first wave of data collection and had been delivering the programme for at least six months. This was to ensure they had received all elements of their introductory training and were well versed in the FNP programme. The FNs were free to determine which clients they wanted to approach and were told they could record as many consultations as they wished and select what they considered the two most representative examples in each phase. They were informed that the aim of the recordings was twofold; (i) to determine the degree of fit between the activities identified in the programme manual and what was practical or feasible during the actual visit and (ii) to

examine the impact of the Motivational Interviewing skills training on practice. It was emphasised that the aim of the analysis was not to determine 'good' or 'bad' practice, but to compare theory and real-life application. The FNs were asked to take written consent from clients at the start of the visit or during a previous visit. Both clients and Family Nurses consented for the visit to be recorded and for anonymised data to be used by the research team.

Data were collected between July 2010 and May 2012 using encrypted digital audio recording devices which were returned to Cardiff at the end of each recording period, together with recording log forms detailing client and Family Nurse ID numbers, date of visit, visit number according to the FNP manual and who was present during the visit. In addition, FNs could add free text to comment on aspects of the recorded home visits they wanted the Cardiff researchers to be aware of, an option that was used rarely, mainly to explain procedural matters relating to the recording.

### **9.2.3 Methods for analysis of content domains**

To retain the authenticity of home visit interactions as much as possible it was decided not to have the recordings transcribed but to code the data straight to audio. Files were uploaded to NVivo 8 and content coded to reflect FNP domains by two experienced qualitative researchers, one of whom had attended five days of FNP training sessions in order to familiarise herself with the FNP approach, the other a trained nurse. The FNP National Unit provided the research team with a list of 'verbal anchors' reflecting potential consultation topics per content domain.

### **9.2.4 Coding framework**

To content code the data, individual coding categories (main codes and sub-codes) were taken from the 'Assessment and planned guidance' section in the FNP manuals for each phase of home visiting. While coding, the researchers at all times referred to the detailed manual instructions to ascertain correct assignment of codes. Data were first coded into subcategories of the main domains and only at the point of reporting incorporated into overall domain timings. This allowed for greater specificity in the coding of content than a 'broad brush' coding to main domains, as must inevitably happen when Family Nurses report visit content on the prescribed form.

Initially, coders also referred to the list of verbal anchors for each content domain which had been provided by the FNP NU team to enhance coding accuracy. However, as it was found that Family Nurses often rephrased the more technical vocabulary provided in this list and that the manual provided a more detailed and accurate guide, it was only sporadically referred to when coding the infancy and toddlerhood data.

In addition to the five FNP main content domains the researchers added codes labelled 'Introduction', 'Closing', 'Procedural, and 'Other'. At the point of analysis, when calculating percentages of time spent on the main domains, the non-FNP codes were excluded from consideration. This replicates the process by which the FNs estimate percentage time spent on the domains, by only including domain-focused content in their percentage calculations. The coded sound file percentages per domain were then compared with the self-reported percentages of time spent on each of the domains.

### 9.2.5 Intercoder reliability and agreement

As coding categories were taken directly from the FNP manuals they were clearly defined and anchored in the detailed instructions for Family Nurses provided there. This enabled the researchers to reach a high degree of 'negotiated agreement'<sup>149</sup> when uncertainty about assignment of codes arose. Regular data coding discussion meetings were held throughout the coding process.

In addition, while the coding process was ongoing, the two qualitative researchers double coded 20% of the available sound files (Pregnancy 15 files, Infancy 10, Toddlerhood 5). Results were compared and a minimum score of 96% agreement was achieved for assigning main codes and sub-codes in all categories (including the non-FNP content domains) across the three phases (P=98%, Inf=96%, Tod=97%). To ascertain whether coders were in agreement on the main content domains, a further coding comparison was run which showed that the pre-set aim of a minimum of 95% agreement between coders was attained (P=95, Inf=96, Tod=96).

### 9.2.6 Methods for statistical analysis

The distribution of the percentages across all recordings was examined for each domain using histograms and summarised using appropriate summary statistics. To examine the agreement between the two sources, the Bland and Altman method was used.<sup>150</sup> This method plots the difference in the percentages for each recording against the average of the two percentages for each domain thus resulting in separate plots for each domain. Examination of these plots allows exploration of the level of agreement and also if there is bias in a particular direction.

## 9.3 Results

The content of visits is based on all the valid visits to the 808 participants randomised to FNP (described here as 'trial dataset'). Of the 808, 716 (89%) participants received at least one valid visit. The results across the three phases are included in Table 9.2 (pregnancy), Table 9.3 (infancy) and Table 9.4 (toddlerhood).

Table 9.2 Core model objectives and summary statistics for whole trial dataset, self-report and coded data in pregnancy

Data Source		Personal Health %	Maternal Role %	Friends and Family %	Life Course %	Environmental Health %
Core Model Objectives	Target	35-40	23-25	10-15	10-15	7-10
	Median (25 <sup>th</sup> to 75 <sup>th</sup> centiles)	34.7 (27.6 to 39.5)	25.8 (22.9 to 29.1)	15.0 (12.9 to 18.5)	12.7 (10.0 to 15.2)	12.3 (9.5 to 16.0)
	Mean (SD)	33.7 (7.8)	26.0 (5.6)	15.7 (4.4)	13.0 (4.3)	12.9 (4.7)
Self-report N=47	Median (25 <sup>th</sup> to 75 <sup>th</sup> centiles)	35.0 (25.0 to 40.0)	30.0 (25.0 to 35.0)	15.0 (10.0 to 20.0)	10.0 (5.0 to 15.0)	10.0 (5.0 to 15.0)

<b>Coded N=47</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	41.3 (22.7 to 58.3)	30.2 (15.8 to 60.5)	6.8 (0.0 to 21.8)	1.4 (0.0 to 7.0)	0.0 (0.0 to 0.6)
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\*N=3 participants did not receive a valid visit in the pregnancy phase

Table 9.3 Core model objectives and summary statistics for whole trial dataset, self-report and coded data in infancy

Data Source		Personal Health %	Maternal Role %	Friends and Family %	Life Course %	Environmental Health %
<b>Core Model Objectives</b>	<b>Target</b>	14-20	45-50	10-15	10-15	7-10
<b>Whole Trial N=669*</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	20.9 (18.6 to 24.3)	40.5 (35.0 to 46.0)	14.1 (11.7 to 16.7)	12.3 (10.0 to 15.0)	12.3 (10.1 to 15.7)
	<b>Mean (SD)</b>	21.8 (5.1)	40.3 (8.2)	14.5 (3.8)	12.4 (3.7)	13.1 (4.1)
<b>Self-report N=44</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	15.0 (10.0 to 20.0)	40.0 (40.0 to 50.0)	15.0 (10.0 to 20.0)	10.0 (10.0 to 15.0)	12.5 (10.0 to 20.0)
<b>Coded N=44</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	6.0 (1.7 to 16.3)	63.6 (52.0 to 74.5)	6.3 (0.0 to 17.2)	3.5 (0.0 to 9.3)	7.7 (2.5 to 19.5)

\*N=21 withdrawals in the pregnancy phase, N=26 participants did not receive a valid visit in the infancy phase

Table 9.4 Core model objectives and summary statistics for whole trial dataset, self-report and coded data in toddlerhood

		Personal Health %	Maternal Role %	Friends and Family %	Life Course %	Environmental Health %
<b>Core Model Objectives</b>	<b>Target</b>	10-15	40-45	10-15	18-20	7-10
<b>Whole trial N=606*</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	17.1 (14.1 to 20.8)	40.5 (35.7 to 44.5)	14.7 (12.8 to 17.4)	15.0 (12.2 to 18.0)	13.0 (10.5 to 16.4)
	<b>Mean (SD)</b>	17.8 (5.8)	40.2 (8.0)	15.2 (3.8)	15.0 (4.7)	13.7 (5.2)
<b>Self-report N=44</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	15.0 (10.0 to 20.0)	43.5 (40.0 to 50.0)	10.5 (10.0 to 18.8)	15.0 (10.0 to 20.0)	10.0 (10.0 to 15.0)
<b>Coded N=44</b>	<b>Median (25<sup>th</sup> to 75<sup>th</sup> centiles)</b>	4.8 (0.0 to 15.7)	59.9 (46.1 to 71.5)	6.3 (1.3 to 14.9)	9.7 (0.3 to 17.7)	4.9 (0.8 to 14.6)

\*N=30 withdrawals in the pregnancy or infancy phase, N=80 participants did not receive a valid visit in the toddler phase

Comparing the medians of the percentages for all valid visits in the trial dataset to the stretch objectives across the three phases, six of the 15 median percentages fell inside the target ranges, six were above the target range (by 0.8%-3%) and three were below the target range (by 0.3%-4.5%). The three medians of Friends and Family were all in the target range, the medians for Environmental Health were all above the target range and the medians for the other three categories varied across the phases in relation to their target ranges.

### 9.3.1 Recordings received

A total of 154 sound files were received from 56 nurses from 17 centres across the three phases (see Table 9.5). There were several reasons why the total number of submitted recordings did not reach the intended target. Seven sites finished recruitment to the trial at the end of March 2010 and participant numbers in these sites were low. The site with the lowest number of recruits overall, by the time the pregnancy phase recording was initiated, reported that they no longer had any pregnant clients who consented to having their visits recorded. As this trend continued throughout the next two waves of fidelity assessment data collection, we did not receive any home visit recordings from this one site. Other low recruiting sites also struggled to provide the full complement of requested recordings, although the second lowest recruiting site did manage to record four visits in each phase.

Of the total of 154 files received, one was inaccessible and one was inaudible, nine files could not be matched to the data held on the FNP database (different dates, times of appointments etc.) and four files did not cover a complete visit so these 15 files were excluded, leaving 139 files for analysis.

Table 9.5 Sound files available for inclusion in the analysis

		Pregnancy	Infancy	Toddlerhood
<b>Total number of sound files received</b>		<b>51</b>	<b>48</b>	<b>55</b>
<b>Files excluded from analysis</b>	Sound files inaccessible/inaudible	<b>1</b>	<b>0</b>	<b>1</b>
	Sound files do not cover complete visit	<b>0</b>	<b>0</b>	<b>4</b>
	Unable to match ID/link by data on UK001	<b>3</b>	<b>4</b>	<b>2</b>
<b>Total sound files included in analysis</b>		<b>47</b>	<b>44</b>	<b>48</b>

### 9.3.2 Family Nurse self-report data on the recorded visits

Tables 9.2-9.4 include the descriptive statistics for the content domains as reported by the FNs for the recorded visits.

#### 9.3.2.1 Pregnancy Phase

In the pregnancy phase (Table 9.2) the Personal Health and Maternal Role domains have a higher percentage of time spent on them than the other three domains, as would be expected from the stretch objectives, with medians of 35% and 30% respectively compared to medians of 15% on Family and Friends and 10% on Environmental Health and Life Course. The medians in this subset are similar to those in the trial dataset with the biggest difference being found in Maternal Role (subset median 30%, trial dataset median 25.9%).

#### 9.3.2.2 Infancy Phase

In the infancy phase (Table 9.3) the Maternal Role domain had a substantially higher percentage of time spent on it, with a median of 40%, compared to the other four domains which have medians of 15% (Personal Health) or less, with

Life Course covered least (10%). Although Maternal Role was the dominant domain, the median is still 5% below the stretch objective of 45-50%. Overall, the self-report medians in the recorded subset are broadly consistent with the trial dataset medians (with differences within domain ranging from 0.2% -2.3%) with the exception of Personal Health (15% in the subset, 20.8% in the whole dataset).

### **9.3.2.3 Toddlerhood Phase**

In toddlerhood (Table 9.4), the dominance of the Maternal Role domain persists as would be expected from the stretch objectives, with a median of 43.5% of time spent on this domain, whilst the other domains have medians of 15% (Personal Health and Life Course) or less. The greatest difference between the subset medians and the trial dataset is in Friends and Family (10.5% and 14.7%) but both medians are in the target range. Four of the subset medians fall in the target ranges. The only subset median to fall outside the target range is Life Course with both subset and whole dataset medians of 15% falling below the target of 18-20%.

Across the three phases in both the subset and trial dataset, for all domains except Personal Health in pregnancy, the lower and upper quartiles only differ by 11%, indicating that for half of the recordings, the FNs report spending within 11% of the same percentage of time as each other on each of these domains.

Overall, comparing the subset percentages to the FNP targets across the three phases, 11 of the 15 median self-report percentages fell inside the target ranges. The four that were outside were outside the range by 5% or less. In the pregnancy phase, percentage of time spent on Maternal Role (median 30%) was above the target of 23-25% but in the Infancy phase (median 40%) it fell below the target of 45-50%. Percentage of time spent on Life Course was below the target range in the toddlerhood phase (15% compared to target of 18-20%) and in the infancy phase the median for Environmental Health (12.5%) was above the 7-10% target range.

Using the median values of the self-report percentages in both the subset and the whole dataset, the relative weighting of time spent in the domains broadly fits with the pattern of the stretch objectives. There are two seemingly minor exceptions both involving the Life Course domain. In the infancy phase the Life Course target percentage is higher than Environmental Health but in the trial dataset these are reversed. Secondly, in the toddlerhood phase the targets put greater focus on Life Course (18.20%) compared to Personal Health (10-15%) and in the self-reported percentages their medians are either the same (15% in the recorded subset) or Life Course is lower (trial dataset).

## **9.3.3 Coded home visits**

Tables 9.2-9.4 show the descriptive statistics from the percentage of time as coded from the recorded home visits.

### **9.3.3.1 Pregnancy Phase**

In the pregnancy phase (Table 9.2) the Personal Health and Maternal Role domains have on average a higher percentage of time spent on them than the other three domains, with medians of 41.3% and 30.2% respectively

compared to medians of 6.8% or less in Friends and Family, Environmental Health and Life Course. The 25<sup>th</sup> to 75<sup>th</sup> centiles for Personal Health and Maternal Role in particular are wide, indicating individual visit variation.

### **9.3.3.2 Infancy Phase**

In the infancy phase (Table 9.3) the Maternal Role domain had a substantially higher percentage of time spent on it, with a median of 63.6%, compared to the other four domains which have medians of 7.7% (Environmental Health) or less, with Life Course covered least.

### **9.3.3.3 Toddlerhood Phase**

In toddlerhood (Table 9.5), as also found during the infancy phase, the Maternal Role domain had a considerably higher percentage of time spent on it (median 59.9%) than the other four domains which have medians of 9.7% (Life Course) or less.

Looking at the coded percentages compared to the FNP targets across the three phases only one of the 15 medians fell within the target range (Friends and Family in the Pregnancy phase). The median percentage time spent on Maternal Role was always above the target range and Life Course was always below the target range. The lowest median percentage time spent was on Environmental Health in pregnancy (median 0% with 25<sup>th</sup> to 75<sup>th</sup> centiles of 0.0-0.6%).

The relative weighting of the domains in the coded visits in terms of percentage time spent fits with the pattern targeted by the FNP programme, with the exception of Environmental Health in the infancy phase, which has the second largest median percentage of time (7.7%) after Maternal Role. However, with the high percentage of time spent on Maternal Role in infancy and toddlerhood, the differences in percentages in the other four domains were small in both these phases.

## **9.3.4 Comparison of coded and self-reported data**

In the pregnancy phase (Table 9.2) the medians for percentage time spent on Maternal Role are very similar: 30.2% for coded and 30% for self-reported data. However, there is a big difference in the size of the 25<sup>th</sup> to 75<sup>th</sup> centiles: 15.8% to 60.5% for coded and much smaller centiles of 25% to 35% for self-reported data. The medians for Personal Health in the pregnancy phase are higher in the coded data compared to self-report (41.3% and 35% respectively). However, for the remaining three domains the self-report median is higher than the coded median with the measurement differences ranging from 8.2% (Friends and Family) to 10% (Environmental Health). Overall, the results suggest a lack of agreement between the two data sources and the data arising from the external coding showing more variation.

In infancy (Table 9.3) the median of the self-reported percentage of time spent on Maternal Role was 23.6% lower than the coded visit data. Consequently, the percentage of time spent on the other four domains was higher in the self-report data than in the coded visit data. The 25<sup>th</sup> to 75<sup>th</sup> centiles were similar across most domains in the two approaches with the exception of the Maternal Role domain. The 25<sup>th</sup> to 75<sup>th</sup> centile for maternal role was 52% to 74.5% in the coded data and 40% to 50% in the self-report data. Overall there is wider variation in the coded data.

In the toddlerhood phase (see Table 9.4) the self-report median percentage of coverage of the Maternal Role domain was 16.4% lower than in the coded data. Other domains had smaller differences (from 4.2% to 10.2%) and similar 25<sup>th</sup> to 75<sup>th</sup> centiles across the two approaches.

### **9.3.5 Levels of agreement**

#### **9.3.5.1 Difference in scores between the coded and the self-reported data**

The differences between the reported percentages (coded home visit minus the self-reported values) were calculated to show the level of agreement and any bias (i.e. the degree to which one measurement approach is systematically different to another). A negative difference indicates a greater self-reported percentage than that found through coding the same recording (which, if we take the coded measurement approach as the nominal standard, would be described as 'over-reporting' by the FN) and a positive difference indicates a lower self-reported percentage (which, using coding as the standard, would be described as 'under-reporting' by the FN).

In pregnancy, over the 47 recordings, there is a positive difference (10.9 and 6.1 respectively) for Personal Health and Maternal Role, which would suggest under-reporting by the FNs. The remaining three domains on average have negative differences suggesting over-reporting by the FNs.

In the infancy phase the largest observed difference is for the Maternal Role domain. On average, the coding method generates percentages over 20% higher than self-report. All other domains have negative differences, indicating that on average the coding method reports a lower percentage of time spent covering these domains than self-report.

In the toddlerhood phase the difference between coded visits and self-reports is again considerably larger for the Maternal Role domain compared to the remaining four, with a mean difference of 16.5%. While the mean differences for the remaining domains are comparatively small (ranging from 3.0 to 5.4%), there is a lot of variability, with individual differences as much as 50.0% being reported.

#### **9.3.5.2 Bland and Altman plots**

Bland and Altman plots use the difference in percentages and plot against the average of these percentages. The two outer black lines on these plots are the limits of agreement (LOA), the middle black line is the overall mean of the differences and the red dotted line represents the case of no difference between the two data sources, at  $y=0$ .

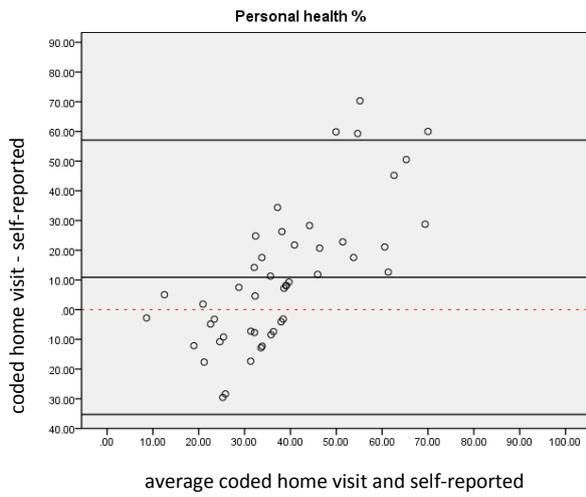
Using the graphs from the pregnancy phase to illustrate (See Figure 1 a to e), many of the points do not lie across or near the red line and the limits of agreement are wide. The graphs illustrate that more time is spent on the Personal Health and Maternal Role domains than on the other three domains. In the Personal Health, Maternal Role, and Friends and Family domains, there is a positive correlation between the average score and the difference (coded home visits greater than self-report associated with a higher average percentage). This suggests that the FNP nurses are over-

reporting in home visits where they have not spent much time discussing topics in these domains, and under-reporting in home visits where they have spent the most time discussing topics in these domains.

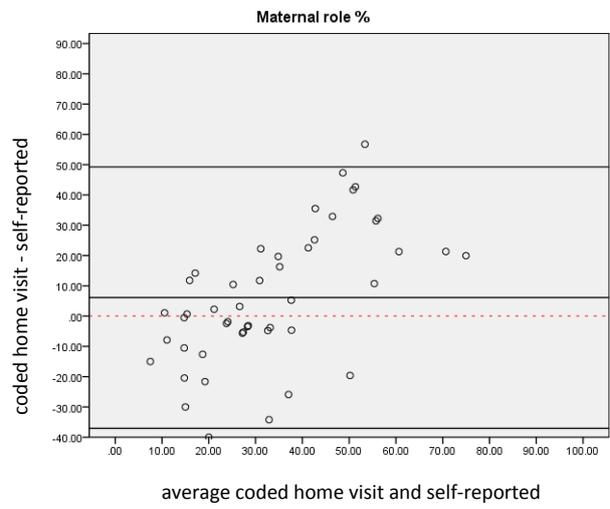
In the infancy and toddlerhood phases (see Figures 9.2 and 9.3), the plots demonstrate a strong systematic reporting bias of the percentage of time spent covering the Maternal Role domain. In all other domains the mean differences observed are smaller (Personal Health included as an example) with a fairly random scatter of points either side of the origin.

**Figure 9.1 (a) to (e) Bland and Altman plots in pregnancy**

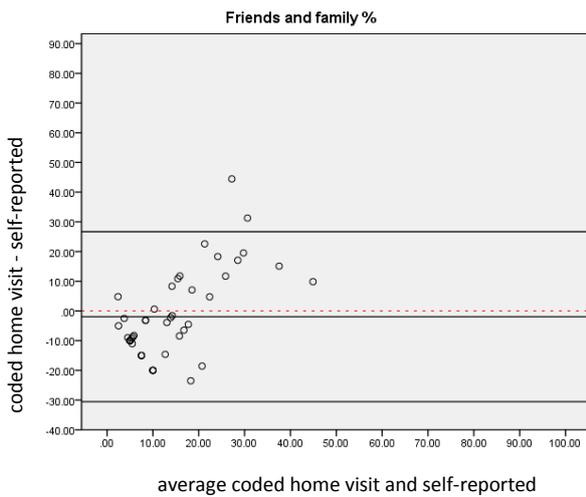
**(a) Personal Health**



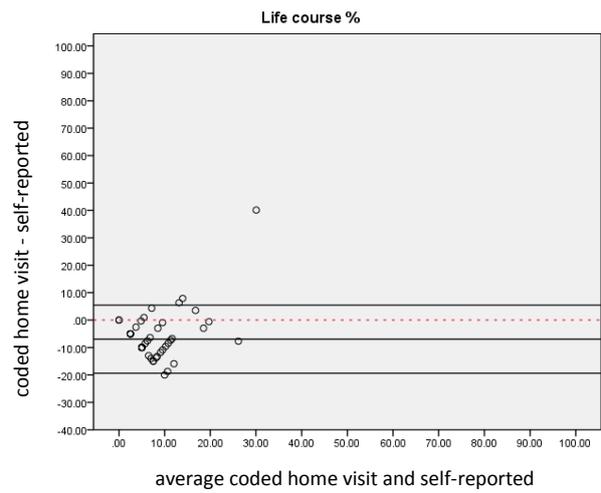
**(b) Maternal Role**



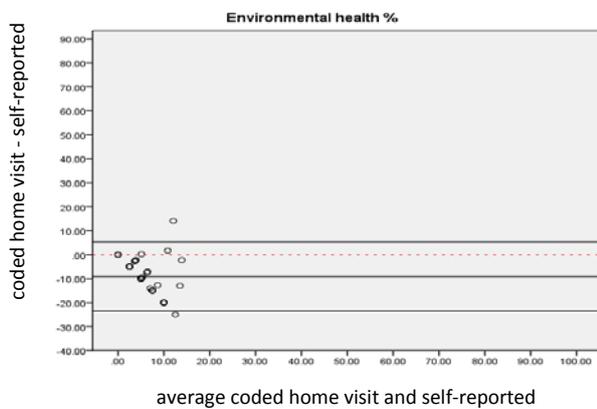
**(c) Friends and Family**



**(d) Life Course**

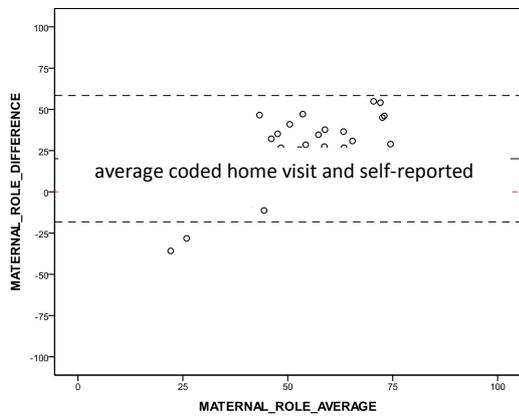


**(e) Environmental Health**

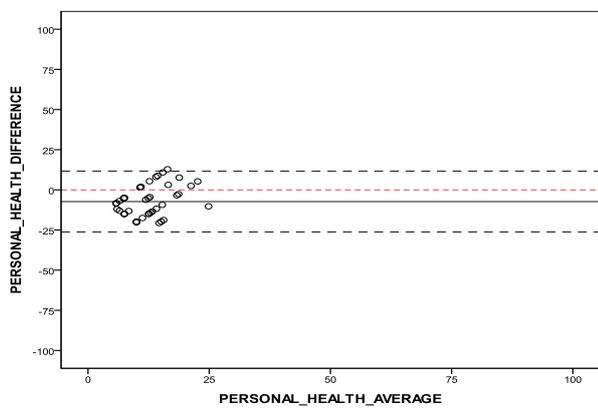


**Figure 9.2 a and b Infancy Phase Maternal Role and Personal Health**

(a) Maternal Role

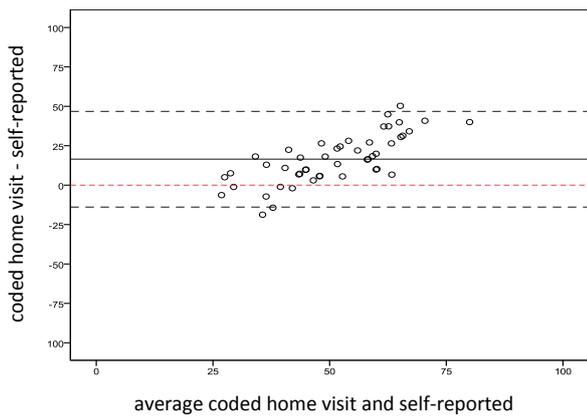


(b) Personal Health

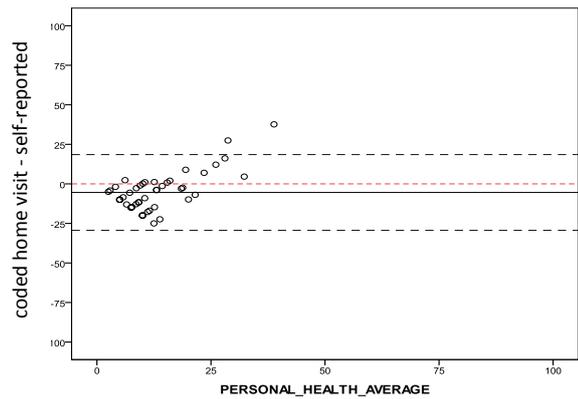


**Figure 9.3 a and b Toddlerhood Phase Maternal Role and Personal Health**

(a) Maternal Role



(b) Personal Health



## 9.4 Discussion

The aim of this aspect of the process evaluation was to identify the extent to which the Family Nurses were delivering the programme in line with fidelity targets related to domain coverage and also to examine the method of self-report with a nested validation study using an objective measurement approach.

### 9.4.1 Fidelity to domain coverage

Overall, across the trial dataset the self-report of time spent on each of the five domains is broadly in line with the stretch objectives: six of the 15 medians are in the target range and the remaining nine are within 5% of the target range. The balance of relative coverage of the domains reflects the weightings of the domains in the stretch objectives, with the possible exception of Life Course which tended to be under-represented in the trial data. With a maximum inter-quartile range of 11% the data suggests consistency of programme delivery across the Family Nurses in percentage coverage.

### 9.4.2 Representativeness of the recorded subset of visits

Based on these data, the subset of recorded sessions seems to be representative of the trial visits. The medians of self-report percentages in the subset are broadly in line with the trial dataset. In the pregnancy phase the biggest difference between subset and trial dataset is in Maternal Role (4.1%), in infancy the difference is greatest in the Personal Health domain (5.8%) and in toddlerhood it is in the Friends and Family domain (4.2% difference). Both the subset and the trial dataset present a similar balance of the different domains which also broadly tracks the relative weighting of coverage in the stretch objectives for the three phases. The small differences between the subset and the trial dataset become more apparent when looking at the number of medians in the target range, with 11 of the 15 in the subset falling in the target ranges and only six of the trial dataset doing so. There was also a digit preference with the Family Nurse reported percentages, where they were rounding up or down their estimates to the nearest 5%.

Some of these areas of difference may be explained by the recording process. For example, in the pregnancy phase, the data in the subset indicate a greater focus on Maternal Role which could in part be because, with the added time required to incorporate the consent process, these visits tended to be later on in pregnancy. The Family Nurses, in deciding on percentage coverage after the visit would have been aware that the session was recorded so they may have been more influenced by the target ranges in determining their estimates (hence the higher number of medians in the target range) and this could also have influenced the numbers used.

### 9.4.3 Comparison of the two measurement approaches

The pattern of percentage time spent across the five domains across all visits was similar using both the coding and the self-report measurement approaches. In the pregnancy phase most time was spent on the Personal Health and Maternal Role domains, with less time spent on the other three domains. In the infancy and toddlerhood phases time spent on Maternal Role dominated, while time on Personal Health decreased, bringing it more in line with the percentage time spent on the other three domains.

Comparing the data from the two methods to the FNP stretch objectives, the self-report medians of percentage time spent in the domains fall much closer to the target range than those in the coded approach. Across all three phases in the coded data, percentage time spent on Maternal Role was higher than the target range and the median percentage time spent on Life Course was below the target.

The Bland and Altman plots illustrate that there is a relationship between the average and the difference, implying that there is a switch from over-reporting domain coverage when the average is small, to under-reporting domain coverage when it is large. There may also be a central tendency bias in which respondents avoid marking at the extreme of the scale and instead opt for something in the middle, this may be a deliberate strategy or it may be unintentional.

These were two very different approaches to measurement. The FNs estimated time spent on the domains after the visit so digit preference would be a reasonable strategy to help manage that process. In order to make sure the totals add up to 100%, once there is some under-reporting in some domains there will need to be over-reporting in others to add up to the 100% required.

The self-report data from the Family Nurses was very similar to that found in the Implementation Evaluation so their conclusions regarding the data could also hold true for the overall impression from these self-reports. One of the main conclusions in the Implementation Evaluation, that there was less focus on Life Course in the toddlerhood phase than would be desirable, remains the case in the trial dataset here. From the coded data it needs to be considered that this may also be an underestimate of the divergence from the target as the coded data had the lowest median for Life Course. The authors of the Implementation Evaluation suggested that as in many cases FNs had a professional background as Health Visitors this might make them more inclined to focus on health related matters and less confident and comfortable addressing Life Course. It may also be that with the approach of agenda matching, Life Course issues were not central to the clients' agenda resulting in a reduced focus on this domain. However, given the consistency of this finding across the two studies, the FNP programme may want to explore the possible reasons and implications of the limited exploration of Life Course domain.

In considering the differences between the two types of measurement approaches there are several factors to take into account. The use of retrospective self-report will inevitably result in estimates with a degree of inaccuracy. It has been suggested that people commonly recall less than half of their communications measured either on amount of detail or frequency<sup>151</sup>. Recency of recall and record-keeping does enhance the accuracy but not to a significant degree. Memory is affected by transience, lapses in attention, misattributions, suggestibility, bias etc<sup>152</sup>. When asked to recall events or experiences this intrapersonal process will also be affected by interpersonal factors such as social desirability bias, i.e. people will tend to report what they believe the researcher expects to see, or what reflects positively on their own abilities, knowledge, beliefs, or opinions.

Self-report on the part of practitioners is the most pragmatic and therefore a widely used approach to record keeping in health and social care. In a systematic review of adherence to practice guidelines in healthcare the impact of self-report bias was evaluated<sup>153</sup>. In comparisons of objective and self-report measures in relation to the same action, e.g., performance of a particular test, response bias was identified in the majority of studies with an overestimate by practitioners of adherence to recommended norms. The main types of bias suggested to be underlying these results were: (i) social desirability with the suggestion that those with the greatest exposure to guidelines are more susceptible to this type of bias and (ii) interview bias. Other explanations for overestimation included memory errors but these would be expected to be random, resulting in over and underestimating, which was not the case in most instances. In FNP the targets for the percentage time on different content domains are explicit and are part of everyday data management and supervision so it would be expected that Family Nurse self-report would be strongly influenced by these figures.

The future implications of these findings for FNP depend on the way in which they wish the self-report aspect of domain reporting to function. The results suggest that broadly, as an average across all visits, the balance across the domains fits with the pattern required by the protocol of the programme. However, there may be a tendency to avoid extremes of reporting and the range of coverage of the domains is much wider than the self-report data captures. It may be that recognising the limitations of the approach, self-report of domain coverage would remain a useful tool in supervision to facilitate discussion of themes without getting into the detailed content. It could operate as an organisational shorthand to enhance communication between staff members and to ensure individual Family Nurses are keeping the whole programme in mind. However, if the content domain coverage is regarded as a form of performance target, then the method for measuring those rates needs to be valid and reliable. There has not been any published work describing the method by which FNP nurses specifically derive their estimates or any evaluation of how good their estimates are, therefore, the approach has not been formally validated. Also the way in which the estimates were derived in this trial are essentially comparable to the US trials so assuming that any bias in self-report would be the same in both settings lessens the likely impact on outcomes.

The detailed analysis has been done on a sample of a relatively small number of visits. What is important in terms of programme delivery are the average rates across each phase. The comparisons between the subset and trial dataset indicate that they are representative of the broader delivery. This study now provides some evidence which can be interpreted as showing that for some domains self-report can be quite different from an objectively derived measurement and that there may be some consistent biases. If this was replicated across all consultations then what happens in practice may be quite different from what Family Nurses report to the FNP National Unit. In terms of impact this may not be important and it may suggest that one option would be to place less emphasis on such precise targets, or broaden the targets to reflect the agenda-matching aspects of the programme.

# 10 Motivational Interviewing Competencies Amongst Family Nurses

## 10.1 Introduction

The aim of this aspect of the process evaluation was to explore the extent to which the Motivational Interviewing skills taught to the FNP practitioners were deployed in audio recorded home visits between the Family Nurses and their clients.

In the US NFP it became apparent that client retention and completion of home visits was lower in programme delivery than in the original trials of NFP, with considerable variation between sites. Sites with the lowest levels of participant retention were also those where nurses used more directive, prescriptive approaches to working with clients. In contrast, nurses at the low attrition sites more often adapted the programme to clients' needs.<sup>154</sup> This finding led to the introduction of the principles of Motivational Interviewing (MI) into the intervention, a modification which has subsequently been tested in a quasi-experimental pilot study across 17 sites in the US.<sup>155</sup>

Since FNP was introduced in England in 2007, the training and ongoing supervision of the Family Nurses has included skills training in MI, 'a person-centred counselling style for addressing the common problem of ambivalence about change'<sup>156</sup>. MI comprises four broad processes: engaging, focusing, evoking and planning, all within the context of a collaborative relationship in which the client's autonomy is fully accepted by the practitioner. MI is often used as a stand-alone intervention but also as an adjunct to other approaches, in particular to promote engagement with an intervention.<sup>157</sup> The description of the relationship between the model of FNP and MI from the perspective of the FNP National Unit is presented in box 1. The MI training for Family Nurses comprises a two-day workshop on the core principles and skills of MI including asking open-ended questions, delivering affirmations, reflective listening, summarising, agenda setting and planning for change. In addition, there are four half-day team sessions for the Family Nurses to consolidate their learning, a skills development day with the trainer, and the team supervisors receive an additional two-days' training on incorporating MI skills into their supervisory practice.

**Box 1****The Relationship between Family Nurse Partnership and Motivational Interviewing:****Anne Rowe Clinical Director FNP National Unit**

The Nurse Family Partnership programme model is always evolving in response to the research evidence, including findings emerging from a programme of model improvement research led by the Prevention Research Centre at the University of Colorado, Denver. As a result of this research, particularly work around client retention, MI has become a core element of the NFP programme model, and a central part of FNP nurse education when the programme was introduced in the UK. In practice, the design and nature of the programme with its principles of strength based approaches, client-centred collaboration, working from the innate intrinsic motivation of first time parents and its anticipatory, forward looking structure and content make for a positive 'fit' with both the spirit and practice of MI. Nurses in the programme learn to take a predominantly 'guiding' communication style with a client, which enables them to explore their ambivalence regarding change, respecting their autonomy, whilst providing information and a structure for decision making. This approach is often in great contrast to the 'expert knows best' model of practice nurses have been expected to use in previous roles.

## 10.2 Methods

Audio recordings were collected across the three phases (see section 8.2 for methods of data collection).

### 10.2.1 The Motivational Interviewing Treatment Integrity Scale

The Motivational Interviewing Treatment Integrity Scale (MITI)<sup>158</sup> is an instrument in use since 2005 to measure integrity to the method of MI through the coding of practitioner utterances.

The MITI (version 3.1.1) has two components (see Table 10.1)

- i) Behaviour counts, which tally seven specific behaviours as defined by the rating scale's manual (without judgement of quality or intent): MI Non-adherent (MINA), e.g., 'you must go to all your antenatal appointments', MI adherent (MIA), e.g., 'you know yourself best so what do you think ought to be on your birth plan?', Closed Question (CQ), e.g., 'Is your mum joining us?', Open Question (OQ), e.g., 'How might that happen?', Simple Reflection (SR), e.g., 'So things are going pretty well at the moment', Complex Reflection (CR), e.g., 'You are feeling that all your hard work has paid off', and Giving Information (GI). The behaviour codes are mutually exclusive so each utterance

receives one code. However, consecutive utterances, even if they occur in the same sentence, may each receive different codes.

- ii) Global scores based on the rater’s overall impression of the practitioner’s delivery on five dimensions (Evocation, Collaboration, Autonomy Support, Direction, Empathy) during the consultation segment being coded. Each dimension is rated 1-5 and specific anchors for the scores are given in the manual. In addition, there is a score for ‘MI spirit’ a summation of three of the five global scores (Evocation, Collaboration and Autonomy Support).

*Table 10.1 Individual behaviour counts and global scores on the MITI*

<u>Behaviour Counts</u>	<u>Global Scores</u>	
MINA: MI Non-Adherent	Evocation	} <u>MI Spirit</u>
MIA: MI Adherent	Collaboration	
CQ : Closed Question	Autonomy-support	
OQ: Open Question	Direction	
SR : Simple Reflection	Empathy	
CR: Complex Reflection		
GI: Giving Information		

There have been attempts to understand the mechanisms of change to guide the search for the practitioner behaviours that are key to client change. The most consistent finding in a review summarising the evidence for these mechanisms was that MI-inconsistent behaviours (which would be coded as MI Non-Adherent, i.e. MINAs) were associated with poorer client outcomes<sup>159</sup>. Similarly, a study of the influence of MI counsellor skills concluded that the overall MI consistent ‘gestalt’ of practitioners is most important.<sup>160</sup>

Therefore, in reviewing the findings of the MITI coding, the key foci in terms of fidelity and impact were global clinician rating (the average score across the five global scores capturing the ‘gestalt’), MI adherence, and MI non-adherence. The other individual behaviour counts provided information on the skills implementation of the nurses and also a snapshot of the blending of the approach of MI with the structure of the FNP programme.

### **10.2.2 MITI Coding**

The MITI coding is conducted on 20 minute segments of the recorded interaction, and the start-time of the segment was selected by using a random number generator. The coding team comprised five coders from a range of backgrounds (two qualitative researchers, one research assistant, one administrator and one clinical psychologist) who attended a three-day workshop learning MITI coding (December 2010) and then developed their coding skills through individual practice on sample recordings and attendance at regular coding meetings.

We found increasingly complex verbal interactions in the infancy phase recordings, with three-way and nurse-child / mother-child communication that could be ascribed to the developmental stage of the child. As the MITI was developed for assessing dyadic interactions the decision was made not to analyse the toddlerhood phase recordings.

### **10.2.3 Coder inter-rater reliability**

Inter-rater reliability on the MITI was measured regularly, 20% of randomly selected recordings were double-coded and reliability was also measured against an independent coder, external to the Building Blocks coding team, to ensure fidelity to the coding system.

On the 20% double-coded recordings inter-rater reliability was 'excellent'<sup>161</sup>, with intraclass correlation coefficients (ICC) ranging from 0.83-0.99 for both global scores and behaviour counts across the pregnancy and infancy phases of the FNP programme. At the completion of coding the overall inter-rater reliability with an external independent coder was 0.83 (95% CI=0.62 to 0.97).

### **10.2.4 Practitioner Competency Variables**

In addition to the five global scores and counts of the seven behaviours, a number of derived practitioner competency variables (Table 10.2) were created by the MITI authors<sup>158</sup> to capture the therapeutic aspect of MI practice (e.g., the balance between questions and reflections which is central to skilful MI).

Table 10.2 Practitioner Competency: Derived Variables

<i>Practitioner Competency: Derived Variables</i>	
<u>Variables created</u>	<u>Components of the variables</u>
Total Questions	CQ + OQ
Total Reflections	SR + CR
Reflections: Questions	Total reflections/total questions
% Open Questions	OQ/(OQ+CQ)
% Complex Reflections	CR/(CR+SR)
% MI-Adherent	MIA/(MIA+MINA)
Global Clinician Rating	Average of the 5 global scores
MI spirit	Average of scores on Evocation, Collaboration and Autonomy support

To help interpret the MITI ratings, we used established competency benchmarks for the derived variables (Table 10.3). Levels 2 and 3 met the MITI manual thresholds for ‘beginning proficiency’ and ‘competency’ thresholds respectively, whilst level 1 indicated when scores did not reach the first threshold of ‘beginning proficiency’ in MI. For example, to achieve level 2 ‘beginners proficiency’ on the balance of questions to reflections the practitioner would need to have a 1:1 ratio and to achieve a level 3 competency threshold on types of questions asked the practitioner would need 70% or more of their questions to be classified as ‘open’.

Table 10.3 Recommended proficiency and competency thresholds for practitioners

<i>Recommended proficiency and competency thresholds for practitioners</i>		
<u>Behaviour Count or Summary Score</u>	<u>Thresholds</u>	
	<u>“Beginners proficiency” Level 2</u>	<u>“Competency” Level 3</u>
Global Clinician Ratings	Average of 3.5	Average of 4
Reflection to Question Ratio	1	2
% Open Questions	50%	70%
% Complex Reflections	40%	50%
% MI-Adherent	90%	100%

## 10.3 Results

### 10.3.1 Family Nurses’ eligibility and total number of recordings submitted

A total of 61 FNs were eligible to submit recordings across the 18 sites at the planned start of the data collection with the range being 2-6 nurses per site. Forty-two (69%) nurses submitted recordings for either one or both phases.

Pregnancy phase: A total of 48 recordings of visits during the pregnancy phase were received from 17 sites. Recordings were submitted by 31 Family Nurses (range of 1-3 nurses per site). The mean number of recordings received per site was 3 (range 1 to 5). The average recording length was 73 minutes (range 46-91 minutes). On one recording the randomly selected 20 minute segment consisted entirely of a DVD being played so it was excluded from the analysis resulting in 47 to analyse.

Infancy phase: A total of 45 recordings from the infancy phase were received from 16 sites for analysis (the nurses in the other two sites did not have any clients in the infancy phase during the recording period). Recordings were received from 30 nurses and the average number of recordings received per site was 3 (range 1 to 5). The average recording length was 64 minutes (range 24-98 minutes)

### 10.3.2 Frequency of individual behaviours

As can be seen in Table 10.4 the frequency of individual behaviours was the same across both phases: Closed Questions were the most common type of utterance (33.3% pregnancy phase and 30.2% infancy phase) followed by Giving Information (30.6% in pregnancy phase and 23% infancy phase). MI non-adherence was the least common behaviour.

Table 10.4 Frequency of behaviour as a proportion of all counted behaviours (ranked from lowest to highest)

Behaviours	Pregnancy Phase (N=47)			Infancy Phase (n=45)		
	Median (%)	25 <sup>th</sup> to 75 <sup>th</sup> centile	Range (%)	Median (%)	25 <sup>th</sup> to 75 <sup>th</sup> centiles	Range (%)
<b>MI Non-Adherent</b>	0.0	0.0 to 1.0	0.0 to 7.3	0.0	0.00 to 0.5	0.0 to 7.69
<b>MI-Adherent</b>	5.1	2.8 to 7.4	0.0 to 14.8	4.0	1.7 to 6.4	0.0 to 12.0
<b>Complex Reflections</b>	5.8	2.5 to 9.5	0.0 to 16.7	5.6	4.0 to 9.6	0.0 to 18.9
<b>Open Questions</b>	9.8	6.23 to 15.3	3.7 to 26.4	7.9	3.2 to 15.0	0.0 to 33.0
<b>Simple Reflections</b>	16.0	9.3 to 20.4	2.0 to 30.9	22.0	17.8 to 28.6	11.1 to 39.7
<b>Giving Information</b>	30.6	19.1 to 37.3	5.4 to 50.7	23.0	16.8 to 32.8	6.2 to 54.3
<b>Closed Questions</b>	33.3	25.2 to 40.6	8.0 to 59.8	30.2	24.4 to 37.1	13.3 to 49.3

### 10.3.3 Practitioner competencies

As shown in Table 10.5, the median rate of MI adherence was 100% in both phases and the global clinical rating remained very similar (4.0 in pregnancy and 3.8 in infancy). In the pregnancy phase a median of 25.0%

of all questions were coded as Open (range 5.8 to 66.7%) and a median of 26.7% of all reflections were coded as Complex (range 0.0 to 66.7%). There were also twice as many total questions as total reflections (median ratio 0.5, range of 0.1 to 1.5). In the infancy phase the reflection to question ratio had increased from 0.5 in the pregnancy phase to 0.7. The percentage of open questions and complex reflections dropped slightly from the pregnancy phase to 18.8% for both.

Table 10.5 Descriptive statistics of clinical competency

Derived Variable	Pregnancy Phase (N=47)			Infancy Phase (N=45)		
	Median	25 <sup>th</sup> to 75 <sup>th</sup> centiles	Range	Median	25 <sup>th</sup> to 75 <sup>th</sup> centiles	Range
<b>Global Clinician Rating</b>	4.0	3.6 to 4.2	2.6 to 4.8	3.8	3.4 to 4.1	2.6 to 5.0
<b>Reflections : Questions<sup>i</sup></b>	0.5	0.3 to 0.8	0.1 to 1.5	0.7	0.5 to 1.2	0.4 to 2.0
<b>% Open Questions</b>	25.0	16.1 to 34.5	5.8 to 66.7	18.8	11.8 to 32.0	0.0 to 66.7
<b>% Complex Reflections</b>	26.7	18.2 to 40.0	0.0 to 66.7	18.8	13.3 to 33.3	0.0 to 46.7
<b>% MI-Adherent<sup>ii</sup></b>	100.0	85.7 to 100.0	0.0 to 100.0	100.0	80.0 to 100.0	16.7 to 100.0
<b>MI spirit</b>	3.7	3.3 to 4.0	2.0 to 5.0	3.3	3.0 to 4.0	1.7 to 5.0

<sup>i</sup>a value <1 indicates a higher number of total questions than total reflections, value >1 indicates a higher number of total reflections than total questions. <sup>ii</sup> N=46 as one home-visit scored MIA=0 and MINA=0

### 10.3.4 Thresholds for proficiency

As shown in Table 10.6 Family Nurses achieved a score that placed them at level 2 proficiency or higher on the global clinician rating in 80.9% of the recordings in the pregnancy phase and 71.1% in the infancy phase. On the MI-adherent scale there were 34 (73.9%) at level 2 or above in the pregnancy phase and 32 (71.1%) in the infancy phase. In the pregnancy phase there was no evidence of level 2 proficiency in most of the recordings for the variables based on specific behaviours, i.e. the reflection: question ratio, percentage of Open Questions, and percentage of Complex Reflections. The infancy phase proficiency scores were similar, with the

exception of the reflections to questions ratio in which 15 (33.3%) showed level 2 proficiency, more than double the percentage (14.9%) that achieved level 2 in the pregnancy phase.

Table 10.6 Number and proportion of visits in which the Family Nurse meets the level 1, 2 and 3 thresholds for proficiency

	Pregnancy Phase (N=47)			Infancy Phase (N=45)		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Global Clinician Ratings</b>						
<b>Global</b>	9 (19.1)	13 (27.7)	25 (53.2)	13 (28.9)	14 (31.1)	18 (40.0)
<b>Reflections :</b>	40 (85.1)	7 (14.9)	0 (0)	30 (66.7)	15 (33.3)	0 (0)
<b>% Open Questions</b>	42 (89.4)	5 (10.6)	0 (0)	42 (93.3)	3 (6.7)	0 (0)
<b>% Complex Reflections</b>	35 (74.5)	5 (10.6)	7 (14.9)	39 (86.7)	6 (13.3)	0 (0)
<b>% MI-Adherent<sup>†</sup></b>	12 (26.1)	1 (2.2)	33 (71.7)	11 (28.9)	0 (0)	27 (71.1)

<sup>†</sup> N=46 in pregnancy phase as one home-visit scored MIA=0 and MINA=0 and N= 38 in infancy phase as seven visits scored 0 on both MIA and MINA

## 10.4 Discussion

The aim of this fidelity assessment was to examine the level of competency in MI skills the Family Nurses displayed in the recorded home visits, as measured by the MITI. Global ratings and the absence of MI-inconsistent behaviours have been shown to be key in assessing impact on outcomes.<sup>159</sup> The primary focus in competence analyses should therefore be on the global clinician rating, avoidance of MI non-adherence and MI adherence. We found that the global clinician rating of the median level of skilfulness of the participating FNs was above level 2, described in the MITI manual as ‘beginning proficiency’. The median on MI non-adherence was 0% and on MI adherence the median was 100% with the majority of recordings evidencing level 3 competency. Therefore, based on these global measures of fidelity the FNs demonstrated skilfulness in key aspects of MI practice.

The individual behaviour counts provide detailed information on MI implementation but also on how MI and the structure of FNP blend. The two most frequent behaviour codes are related to information exchange, i.e. Closed Questions (used to seek specific information) and Giving Information. This compares, for example, to a study of nurse practitioners delivering Motivational Enhancement Therapy to improve diabetes control<sup>162</sup> where the most frequent codes were Complex Reflections and Closed Questions. We expected that Giving Information would be a frequent behaviour, given a high informational component to the FNP programme. The key issue with giving information in an MI-consistent manner is the way in which it is done, i.e. does the client feel they were having advice imposed on them or do they experience it as receiving information they were seeking, with the practitioner having carefully established that they were interested in receiving that information and that choices were given? One measure of this is the levels of 'MI non-adherent' codes as this incorporates advice-giving without seeking permission. Given that 'MI non-adherent' was the least common behaviour code, information exchange in these home visits was conducted in this more collaborative way in the majority of cases, which is consistent with the MI approach.

The use of reflection and the balance of reflections to questions are central to MI practice. Reflections represented less than a third of coded behaviours in both phases and most were simple rather than complex, which reduces the rating of practitioner competency in this aspect of practice. In contrast to simple reflections, complex reflections add substantial meaning, conveying a deeper or more complex aspect of what the client has said (e.g., the client said 'I am just so angry I can't believe what they did' and the practitioner might say 'you're furious about this' (simple reflection) or 'this is the last straw for you' (complex reflection)). It would be an interesting point of discussion with Family Nurses whether this represents an area where they feel they need more skills development and whether higher levels of complex reflections might or might not fit with their work.

In terms of the ratio between questions and reflections, only a minority of home visits contained the 1:1 ratio required for beginning proficiency level as defined by the MITI manual. It might be difficult to achieve more reflections than questions, given the high number of questions that are an essential part of the intervention (e.g., health-related questions). This is one of the areas where having a structured intervention may well impact on the nature of the utterances, making it more difficult for the FNs to achieve the ratios recommended for skilful MI practice. Future detailed analyses of the interactions in the recordings with higher ratios might shed light on this.

The reliability of the raters in our study was good with a consistent team who were well trained and maintained a good level of scrutiny with ICCs at several points, double coding, use of an external 'gold standard' and regular group meetings.

The analysis can only reflect the material presented and with a 65% return rate from 69% of eligible practitioners in this study there may be concerns about the representativeness of the recordings. Practitioners

are often reluctant to expose their practice for evaluation.<sup>163</sup> For example, the average rate of consultation recording return was less than 50% in two other studies of MI.<sup>164</sup> The submission rate in our study was comparatively high. There were also practical considerations such as availability of opportunities to record that affected return rates. Whilst Family Nurses were initially randomly selected to submit recordings, difficulties matching FN and client willingness and availability with the appropriate recording period meant that sites were asked to invite all eligible FNs to submit recordings if they had eligible and willing clients. The FNs were asked to select recordings that they felt best represented their work and they were aware of the purpose of the task so we might assume the recordings represent a picture of 'best practice' in MI terms. However, client availability, willingness to consent and practitioner anxiety may also have biased the sample of submitted recordings in ways that are hard to identify, e.g., it could be their estimation of 'best practice', 'easiest client' or 'least amount of communication'. One possibility that might need to be considered in light of the high Giving Information content is that the least complex home visits (in terms of interpersonal content) may have been submitted for analysis and those home visits could simultaneously be the most information-driven.

The FNs had received substantial training input in MI, combining didactic teaching, coaching and supervision on casework to enable the training to be integrated into practice, which has been shown to be the most effective training model in MI.<sup>165</sup> In applying the MITI (designed for rating MI interventions and coaching MI practitioners) to FNP data, we set the bar high and the levels of competence in MI achieved using the MITI manual definitions were relatively low. However, the FNs were focused on delivering a structured, complex intervention with a lot of informational content, several potential target behaviours, often in difficult circumstances. Furthermore, competency levels detailed in the MITI manual are for guidance and based on expert opinion rather than evidence on client outcomes.

In a study in which one social worker worked with people with Multiple Sclerosis to improve exercise experience<sup>166</sup>, the mean reflection: question ratio (2.6) and percentage of Open Questions (56.7) are significantly greater than in our study (although the specificity of the intervention in terms of therapist and number of sessions per client does make this a very different intervention to FNP). Compared to a study in which four graduate practitioners worked with substance misuse<sup>167</sup> there were some similarities (e.g., mean reflection question ratio was 0.72), although the use of Complex Reflections and Open Questions was higher than in our study.

There are difficulties in comparing findings as studies have used different versions of the MITI, and also there have been concerns raised about cultural differences in language impacting on coding. For example, in the UK, where relatively few studies have used the MITI, McCambridge et al. identified the example of questions being coded as 'closed' (e.g., 'Can you tell me a bit more about that?') when in practice they function as open questions.

This evaluation will inform endeavours to integrate MI principles into FNP practice. The high level of MI spirit is reassuring. However, the types of questions asked, the level of reflection and the frequency of Complex Reflections may be a focus for future training. Our analysis was not intended to assess an individual practitioner's competency, the timing of the recordings in relation to that practitioner's training, or the phase of delivery. Thus it is not possible to determine whether the slight differences seen between phases of programme delivery are important. However, it may raise an area of development for the teams to be thinking about planned maintenance and development of MI skilfulness over time and how the supervision can address this. Frequency of MI supervision may also be relevant. This is commonly weekly<sup>162,166</sup> or fortnightly<sup>168</sup>. The training in MI in the FNP has changed since this evaluation in that the MI trainers are now part of the FNP National Unit.

#### **10.4.1 Conclusions and future study**

Family Nurses have demonstrated ability to consult according to principles of MI. Our results indicate that some behaviours and derived variables measured by the MITI may not always be entirely consistent with the structure and context of particular programmes, while the spirit of the approach might well be. This analysis is the starting point with much more to be gleaned about the inter personal processes of client-practitioner communication. It provides feedback that can be incorporated into supervision and skill development. Also with the knowledge of the growing evidence that practitioner behaviours and communication style relate to client outcomes<sup>159,160</sup>, it is important to take a broader perspective on the database of recordings which could enable a detailed examination of the impact of different nurses' approaches to the blending of information exchange with highly skilled communication, possibly using other measures which have been developed to capture the client-practitioner interaction and other ingredients such as change talk which may play a part in client behaviour change. This would be of relevance in many different contexts in responding to health and social care challenges which require the delicate balance of expert knowledge and complexity of agendas.

# 11 Mapping and Assessing Usual Care

## 11.1 Introduction

The ability of FNP to improve outcomes for clients in any setting is dependent upon being able to bring ‘added value’ to that provided by existing services. Where service provision is limited, FNP could be expected to have a greater potential to improve outcomes than in settings where ‘usual’ care itself offers a comprehensive support package. In order to contextualise the trial of FNP in England, be able to critically interpret trial results by being explicit about the control condition, and understand potential similarities and differences between the English setting and that of the US and European trials of FNP, we needed to understand the totality of the package of care being provided to trial participants. As FNP is multifaceted, intended to improve a wide range of outcomes for both mother and child, it was necessary to describe the range of services and support, outside of FNP, that had potential to impact upon the range of outcomes of interest. The complexity of this task was further compounded as trial participants were often living in circumstances of deprivation with potential engagement with multiple and diverse agencies. Thus, in order to describe the care which FNP was both enhancing and being compared to, it was necessary to undertake a service elicitation exercise to describe available services as comprehensively as possible and identify mechanisms to capture engagement of trial participants with such services.

Some agencies providing services to trial participants captured data pertaining to service delivery through routine mechanisms accessible to the trial. For example, Hospital Episode Statistics (HES) provided by the Health and Social Care Information Centre (HSCIC) provided data on inpatient, outpatient and accident and emergency department attendances. Similarly, data relating to FNP delivery to trial participants were available via the FNP information system. Some data, such as that relating to financial benefits provided to trial participants, is held by agencies but was inaccessible to the trial, and for most services with which trial participants would engage, routine systems of data collection did not exist. Even where routinely collected data were known to be ongoing, at the study outset, and for much of its duration, it was not known if access to data would be granted. For this reason self-reports of service use were incorporated into the follow-up interviews to capture this data, some of which was later duplicated from other sources.

Some universal services, such as antenatal care,<sup>169</sup> postnatal care<sup>61</sup> and the Health Child Programme,<sup>31</sup> were known to be available to all trial participants, but although well described by national minimum standards, were still anticipated to be subjected to local variations in delivery and individual engagement. Thus due to the range of services available, lack of consistency in provision between sites and little routine data collection of service engagement, trial specific data collection including through self-report, was required to describe service provision at trial sites and quantify service engagement.

This aspect of the study had three objectives: to describe care in England, which FNP was enhancing and being compared to (service elicitation exercise); to describe self-reported service usage amongst trial participants, and assess the degree to which receiving FNP affected client usage of other services.

### **11.1.1 Usual care provision in trials of NFP**

The settings of the US based trials of NFP, the trial in the Netherlands and Building Blocks differed in terms of the provision and organisation of usual maternity and early years' child health programmes, and these differences could potentially affect the efficacy of the intervention. In contrast to the UK where community-based GPs, midwives and health visitors are available to all families, in the US trials of NFP, antenatal care was provided by office-based obstetricians, with child development screening and emergency care being provided by paediatricians or hospital emergency departments. Within the three US trials of NFP, participants in control groups were provided with obstetric antenatal care, child surveillance, and access to emergency medicine. In the Elmira based trial,<sup>85</sup> the community was reported to be '*well served from the standpoint of health and human services*' with provision of a free antenatal clinic sponsored by the health department. Women in both the intervention and control groups received a mean of 10.5 antepartum visits. Participants in the Memphis based trial of NFP were recruited at a mean of 16 weeks gestation and subsequently had six prenatal visits.<sup>170</sup> The uptake of antenatal services was not assessed amongst the participants in the Denver based trial, but all participants were provided with referral to paediatric services if indicated following child development screening at six, 12, 15, 21 and 24 months.<sup>171</sup>

In the Netherlands<sup>94</sup> setting of the trial of VoorZorg usual antenatal care consisted of an average four midwifery appointments with referral to an obstetrician if the mother has an underlying medical condition or pregnancy complication. Following birth, each new mother was supported by a maternity care helper for up to a week, who provided home-based support and infant care; and around ten home based or child health clinic visits in the first two years to monitor the child's health and development.

### **11.1.2 Service elicitation exercise aims**

In England an individual pregnant teenager or young parent can receive a complex combination of care, support and financial assistance, provided by various service delivery organisations. The level of support provided to an individual will vary widely depending upon availability, individual circumstances and uptake. It was therefore known that trial participants may engage with multiple services, which, if effective when delivered in the context of usual care, could limit the potential of FNP to further improve outcomes, depending upon the outcome in question.

Apart from the health visiting service which was not available to clients enrolled with FNP, usually provided support was expected to remain available to all trial participants regardless of allocation. Indeed, the role of the Family Nurse included having an in-depth knowledge of locally available resources with referral of clients

to other sectors where indicated. When appropriate the Family Nurse would act as the woman's advocate in communication with other agencies, whilst also aiming to empower clients to themselves access appropriate services and support.

We considered from the outset that three categories of service may be available to study participants: (i) Universal Services, either provided as a statutory requirement or otherwise available in all study sites, (ii) Locally Available Services with a specialist nature, with particular eligibility criteria, but not necessarily designed for teenage parents and (iii) Specialist Services specifically for pregnant teenagers or younger parents.

## **11.2 Services for teenage parents within England**

The Family Nurse Partnership programme is intended to impact upon a wide range of outcomes for both mother and child which extend beyond health to other domains, including education and employment. Relevant supportive services that may influence participant outcomes are therefore likely to be found across a wide range of providers and sectors. Preparatory work for understanding service provision for young parents in England included exploring documents describing relevant policy and guidelines which set minimum requirements for service provision. This literature informed our initial selection of included service domains and provided a basis on which to develop more detailed services descriptions.

A tiered system of local government throughout England has responsibility for services including education, housing and Social Services. For example, across England there are 152 separate Local Education Authorities (LEAs), each of which has responsibility for providing child education in their area. The responsibility for the provision of Social Services and housing will rest with either one of the 152 principal authorities or, particularly in large urban areas, devolved to one of 326 lower tier authorities. Until April 2013, 10 strategic health authorities existed across England, with health care provided through local NHS Primary Care and Hospital Trusts.

### **11.2.1 Health**

The National Health Service (NHS) provides free health care to all. The NHS provides access to family doctors, outpatient and inpatient care, emergency ambulances and accident & emergency departments. There is some limited charging permitted within the NHS, for example for prescriptions and dental care.

The NHS provides maternity care appropriate to each woman's clinical needs. For nulliparous women The National Institute of health and Clinical Excellence (NICE)<sup>172</sup> recommends a minimum of ten antenatal check-ups. Midwives provide antenatal care in community based antenatal clinics. Women with an underlying medical condition or pregnancy complication also receive hospital based antenatal care from obstetric and

associated specialist teams. Women with an uncomplicated pregnancy can choose to give birth at home, or in many areas, in a midwifery-led unit. Women receiving obstetric care give birth in a hospital based obstetric unit. Midwives provide postnatal care in hospital and following discharge up to a maximum of 28 days. All maternity services in England are expected to ensure that midwifery services provide tailored support for teenage mothers<sup>173</sup>, including staff training, accessible services, strong links with other relevant agencies and effective support to prevent a subsequent unplanned pregnancy. Where sufficient demand exists units are encouraged to employ a specialist teenage pregnancy midwife to carry a specialist caseload and lead on ensuring local services meet the needs of teenagers.<sup>174</sup>

All residents of England are encouraged to register with a General Practitioner (GP), a community-based family doctor. Patients have access to appointments with a GP who can prescribe treatment or refer on to specialist consultants. All pregnant women are entitled to free prescriptions and dental care during pregnancy and for 12 months after birth. There is no charge for prescriptions for children under the age of 16 or dental care provided to children under the age of 18.

The Healthy Child Programme (HCP)<sup>31</sup> set out in 2009 and provided details of universal screening, health education, immunisation schedule and support programmes for all pregnant women and children to the age of five. The programme described a package of universal care supported by a progressive programme of more intensive interventions for families identified at greater need.

The universal package of the HCP is provided primarily through the maternity and health visiting services, with involvement of GPs at key time points, for example the baby medical examination at six weeks. Health Visitors offer a limited number of home visits in the early postnatal period, but for more vulnerable families will also engage in promoting sensitive parenting and facilitate signposting to other services and programmes supporting parent-child interaction available within the HCP. FNP is an example of the most intensive level of targeted intervention available within the HCP, and is provided alongside maternity care throughout pregnancy and the early postnatal period. FNP continues to be offered until the child's second birthday, after which the Health Visiting service continues to deliver the HCP, Table 11.1.

Table 11.1 Healthy Child Programme (HCP) – an overview

Universal Support	→	Progressive support intensity
Health and development reviews	Emotional and psychological problems addressed	High-intensity-based intervention
Screening and physical examinations Immunisations	Promotion and extra support with breastfeeding	Intensive structured home visiting programmes by skilled practitioners
Promotion of health and well-being e.g.: smoking diet and physical activity breastfeeding and healthy weaning keeping safe prevention of sudden infant death maintaining infant health dental health	Support with behaviour change (smoking, diet, keeping safe, SIDS, dental health)  Parenting support programmes, including assessment and promotion of parent-baby interaction  Promoting child development, including language	Referral for specialist input  Action to safeguard the child  Contribution to care package led by specialist service
Promotion of sensitive parenting and child development	Additional support and monitoring for infants with health or development problems	
Involvement of fathers		
Mental health needs assessed	Common Assessment Framework completed	
Preparation and support with transition to parenthood and family relationships	Topic-based groups and learning opportunities	
Signposting to information and services	Help with accessing other services and sources of information and advice	

### 11.2.2 Education

LEAs have a statutory duty through the Education Act 2011 to provide 15 hours per week pre-school education to 3 and 4 year olds and full-time education for children aged five to 16. LEAs offer various support schemes to pregnant teenagers and young mothers to enable them to continue their education. Young mothers, under the age of 20, who return to education, are entitled to 'Care to Learn'<sup>175</sup> which assists with the costs of childcare and associated travel (up to £160 per child per week or up to £175 per child per week in London).

### 11.2.3 Housing

Parents or the legal guardian of a child have a duty to care, including provision of accommodation, until the age of 16. Social Services have a statutory duty to provide housing to any child below the age of 18 who can no longer live at home. Housing authorities have a statutory duty under the 2011 Housing Act<sup>176,177</sup> to have a strategy for preventing homelessness and ensuring that accommodation and support are available to anyone

in their district who is homeless or at risk of homelessness. Stronger duties exist to secure accommodation for groups identified as being in priority need, including pregnant women, a person with dependent children, 16 and 17 year olds and persons under 21 who has previously been '*looked after*'. Most Local Authorities have specialist supported accommodation projects for young, single women with babies (sometimes called 'mother and baby units'). Low-cost housing for young parents is in short supply in most areas but for those who are able to secure a flat or house, housing benefit is currently available to assist with rent payments.

#### **11.2.4 Training, employment and financial benefits**

Local Authorities provide wide-ranging support including job centres, and Connexions offices offering specialist careers advice to young people. The value of universal and means tested financial benefits are set by Government in bi-annual budgets. Although the Government have made recent changes to make the benefit system less complex, during the period of the trial the benefits system remained complex with access to individual benefits being determined by factors including age, family structure and income. The range of benefits included Child Benefit, Child Tax Credit, Income Support, Healthy Start Vouchers and Care to Learn. An example of the diversity of benefits and the complexity of eligibility criteria is illustrated in Appendix 13, which gives information on financial benefits possibly available to 16-17 year old study participants.

### **11.3 Service elicitation**

The known complexity and probable geographical variability of support across trial sites indicated that in order to describe the setting of FNP within the English context and describe care to which FNP was being compared it would be necessary to elicit information on the services available at each of the 18 trial sites. As it was intended to encompass services covered by all public sectors available to pregnant teenagers, it was anticipated that multiple informants would be required at each trial site.

#### **11.3.1 Service elicitation - pilot**

A prototype mapping tool in the form of an Microsoft Excel workbook was developed through discussion within the research team. This was designed to gather information regarding services available to young mothers, and pregnant teenagers in particular, across the six domains considered by the research team to cover most available services, midwifery, health visiting, education, housing and social care. An additional domain of 'other services' was added to the workbook to give informants the opportunity to describe other available service sectors not otherwise listed.

For each service available to study participants we aimed to identify: name, description, service provider (e.g., Primary Care Trust, Local Authority), limits on availability / client eligibility, where the service was based (e.g., Children's Centre, hospital), average caseload where relevant, and where each service was delivered, (e.g., home, school). In addition it was considered important to request details on local circumstances that required

particular adjustment to services, for example in areas with a population of diverse ethnic backgrounds with specific needs. It was considered that a manager or senior member of staff for each sector would be needed to provide the level of detail to be requested at individual sites.

Local Building Blocks researchers at three sites piloted the workbook and were selected as a convenience sample. They were requested to ensure that each spreadsheet was populated either by themselves or by the local service manager or nominated contacts. The pilot mapping tools were completed between February and May 2009. The three local co-ordinators provided feedback on the tool and its completion in a semi-structured telephone interview. The interviews confirmed the need for service specific informants and for detailed workbook instructions.

### **11.3.2 Service elicitation – Stage 1 Methods**

An electronic workbook was forwarded to the trial's Principal Investigator at each Primary Care Trust. They acted as the site co-ordinator, distributing the workbook to service heads or managers in their area with a request the workbook be populated with relevant information regarding the types of service provided locally. The contact details of all informants were captured in order that queries could be answered and a pool of local experts at each site identified. We sent a generic email with the workbook to the site co-ordinator, for local distribution to local service heads explaining the exercise, information on the Building Blocks study, and a two-page instruction manual. The site co-ordinator collated the data and returned the completed workbooks within a four month period from August 2009 (i.e. in the first few months of the trial sites opening).

Information in each sheet of the workbook were analysed using the NVivo 8 software package, data were categorised according to the three previously categorised levels of services. Coders met regularly to compare their identification of common services and service delivery themes before coming to a consensus on the final range of services available, assisted where necessary by clinicians or other professionals.

### **11.3.3 Service elicitation – Stage 1 Results**

At sites, the workbooks were completed by the manager, or nominated deputy of each service being described meaning at least six individuals contributed to each site workbook. Completed workbooks were returned from each site and all contained data within each of the six domains. The level of detail provided varied greatly across sites. Many of the services reported by sites within any one domain, despite differing titles, were similar and subsequently grouped together. Following grouping, 161 separate services were identified, some with similar aims. For example, eight different named services were identified, each providing education to pregnant teenagers under the age of 16.

### 11.3.4 Service Elicitation – Stage 2 Methods

A web-based data collection tool was developed and distributed through Bristol Online Survey. The 161 services generated by the coding of Stage 1 were listed, categorised into 12 service domains (the original six domains plus ‘other services’ sub-divided on the basis the Stage 1 responses into childcare, complex needs, Connexions, drug & alcohol services, mental health, third sector services and sexual health). Tick boxes were provided to indicate the current availability or otherwise, of each service. Respondents could also provide details of services that they considered were not otherwise listed. Having good local knowledge of services and key personnel, supervisors of the FNP programme at each study site were requested to complete and return the form in July 2011. The survey generated quantitative data analysed descriptively using SPSS v20.0.

### 11.3.5 Service Elicitation – Stage 2 Results

The online survey was completed for all trial sites. The total number of services reported by individual sites ranged from 52 to 113 (Table 11.2).

Table 11.2 Number of services reported by sites

SITE	Universal services	Combined Locally available and Specialist Services	Total
1	26	26	52
2	43	46	89
4	46	67	113
5	49	39	88
7	41	33	74
8	63	86	149
9	49	64	113
10	30	39	69
21	37	39	76
22	53	46	99
23	40	53	93
24	43	26	69
25	48	63	111
26	46	56	102
27	49	64	113
28	32	46	78
29	50	36	86
30	30	22	52

The 161 individual services described by trial sites were delivered through a variety of providers, including public, private and the third sector who collectively provide direct care, support or guidance. Examples of the ‘Specialist’ and ‘Locally Available’ services are listed in Table 11.3. The services described encompassed direct provision of health care, housing advice and provision and sign-posting to other agencies. It was noticeable that some universal services were not reported by all trial sites, examples included universal education

provision to age 16, obstetric led antenatal clinics for women with complex pregnancies and health visiting access for all new families not in receipt of FNP. It appeared that sites understandably gave priority to providing details of services possibly unavailable elsewhere. In the domains of mental health, addiction, and complex needs provision, a small number of sites reported no additional Locally Available or Specialist Services. None of the trial sites reported specialist health visiting services for teenagers, possibly reflecting investment in FNP in these areas to meet this need. Of the 18 trial sites, 14 reported that they employ a specialist teenage pregnancy midwife.

Table 11.3 Examples of services described by study sites

	<b>Specialist services</b> - specifically for pregnant teenagers or younger parents	<b>Locally Available services</b> - with a specialist nature and eligibility criteria, but not necessarily designed for teenage parents
<b>Education</b>	Schools / colleges with provision for teenage mums Teenage pregnancy support services Accredited courses with free childcare for under 25s	Home learning programmes
<b>Housing</b>	Teenage parents' scheme: training in independent living skills Supported housing for young vulnerable women or teenage parents	Outreach support service aimed at young homeless people under 18 Mother and Baby Hostel
<b>Health Visiting</b>		Antenatal contact at home or in midwife-led antenatal clinics Minor ailments sessions run by health visitors
<b>Midwifery</b>	Teenage pregnancy midwives Antenatal clinics run by midwives in schools	Midwives based in Children's Centres
<b>Social Services</b>	Teenage pregnancy support service	Targeted youth support for vulnerable young people Specialist therapeutic unit for young victims of sexual abuse Family resource service; practical support to access universal services
<b>Connexions Services</b>	Teenage Pregnancy Advisors help young mums-to-be and young families	Provide information and guidance to Looked After young people Provide support and guidance for young people leaving care Provide practical help and advice for young mums who want to go back to college
<b>Drugs, Alcohol and Smoking services</b>		Specialist drugs and alcohol services working with police Community-based young people's drugs and alcohol service Smoking in Pregnancy cessation service
<b>Sexual Health services</b>	Lifestyle services working with teenage parents to prevent second pregnancy	Family planning services for under 25-yr-olds in community settings Sexual health services for teenagers Condom distribution scheme in community settings
<b>Mental Health services</b>		Specialist Children's and Adolescent Mental Health Services for eating disorders Mother-and-baby units in hospitals and prisons Specialist psychiatric unit for postnatal mental illness
<b>Complex Needs services</b>	Support and advocacy for (pregnant) teenagers with complex needs	Child development centre for pre-school children with complex needs Sure Start language therapy team Vulnerable baby service: targeted safeguarding prevention
<b>Childcare provision</b>		Private, voluntary, independent childcare providers Internet database on county-wide childcare provision
<b>Local / third sector projects</b>	Charity funded teen parents projects Peer support sessions for teenage fathers-to-be	Barnardo's Priory Family Centre Charity funded young parents projects Home Start: trained volunteers visit mums for approx. 15 months

The data provided by sites in the service elicitation exercise provided descriptive details of the type and range of services potentially available to trial participants across the range of service providers and sector domains.

This confirmed services to be many and complex with fluid boundaries facilitating multi-professional interaction to achieve service delivery. Each individual service, although provided with similar intent, could vary in content by region, while administrative boundaries between services were shown to be fluid.

## 11.4 Service usage

Although potentially subject to bias in terms of follow-up engagement and recall, we were particularly keen to hear from trial participants themselves about services with which they had engaged. These data were requested during follow-up interviews and are reported, unadjusted, in the remainder of this chapter. Comparative analysis of service usage between trial arms and, where appropriate, across data collection points, is fully presented in chapter 5. There was some overlap between self-reported NHS service usage, and the data relating to NHS service usage obtained from the National Health and Social Care Information Centre and GP records.

The quality of self-reported service usage is limited by participant recall and follow-up bias, although, with similar follow-up rates within both arms of the trial, any influence could be expected to be similar across arms. For some aspects of service usage, for example inpatient hospital stays, the self-report data provided a basic level of information, whilst more detailed data, providing a more comprehensive between arm comparison, was also obtained from other sources. Due to ongoing uncertainties around access to primary and secondary care utilisation data, these outcomes were collected through self-report up until the 18 month interview. It was only by the time of the 24 month interview commencement that access to primary and secondary care utilisation data had been secured, and thus these items were not included in the 24 month interview schedule. For some aspects of services usage such as contact with toddler groups, engagement with education and receipt of benefits, self-reported data was the only available to the trial team, either due to a lack of routinely collected data at sites, ethical or feasibility limitations on access to other data sources.

### 11.4.1 Pregnancy

Table 11.4 describes participant self-reported service usage in the mean 19.3 week period between trial recruitment and the late pregnancy interview, as reported by the 1,237 participants interviewed at this time point. For eight of the 10 categories, service usage was slightly higher for the FNP clients. Participants reported a high uptake of antenatal care in various settings with 93% of participants in both the intervention and Control arms reporting attending for check-ups with a midwife. Around 50% of participants had made a visit to their GP since trial recruitment and over 60% had attended a hospital based antenatal clinic. In addition to routine care lower proportions of women reported the use of other services including counselling, for example for smoking cessation, physiotherapy and A&E attendances.

Table 11.4 Self-reported service use by trial participants (%) between trial recruitment and late pregnancy

	<b>% women using service at least once</b>	
	Intervention n=617	Control n=620
Overnight hospital stays	17.2	15.6
Hospital antenatal clinic visits	62.2	64.0
Unplanned maternity unit visits	40.2	41.6
Attendance at A&E	16.5	14.8
Attendance at Hospital outpatients	10.5	8.9
Midwife visits	93.7	93.1
GP	52.4	50.5
GP Practice Nurse	19.6	16.0
Counselling	9.2	8.4
Physiotherapy	4.5	3.4

### 11.4.2 Health visiting

Women were asked at 6, 12 and 18 months postnatally to recall the number of times they had either had a home visit from a health visitor or seen a health visitor in a clinic, results to these questions for women in the control group are presented in Table 11.5. The proportion of women in the control group who saw their health visitor at home was high, with a mean 3.4 home-based visits in the six months following birth. The number of home-based visits reduced over time to a mean of less than one in the period 12-18 months. There was, however, a wide range in the amount of contact women reported to be having with a Health Visitor. Of participants in the control group, 4.9%, 28.0% and 50.5% respectively, reported at the 6, 12 and 18 month follow-up that they had not seen a Health Visitor either at home or in a clinic in the previous six months.

Table 11.5 Health visitor contacts with women in the Control group

	<b>Follow-up</b>		
	<b>6 months Control n=467</b>	<b>12 months Control n=479</b>	<b>18 months Control n=465</b>
<b>% seen Health Visitor at home in previous six months</b>	89.1	41.7	28.8
Mean (range) number of home visits from Health Visitor	3.4 (0-30)	1.2 (0-24)	0.9 (0-24)
<b>% seen Health Visitor at clinic in previous six months</b>	60.6	48.8	30.9
Mean (range) number of times Health Visitor seen in clinic	3.7 (0-25)	1.7 (0-24)	1.0 (0-24)
<b>% not seen a Health Visitor at home or in clinic in previous six months</b>	4.9	28.0	50.3

### 11.4.3 Housing

At all postnatal follow-up time points, when the question was asked, a greater proportion of participants in the Intervention arm reported that they had received help with finding housing from people outside of their friends and family, (Table 11.6). The proportion in the Intervention arm reporting that help with housing was

provided by their Family Nurse was low at all time-points. Similar proportions in the two trial arms reported having received assistance from their Local Authority Housing Department at each follow-up time point.

Table 11.6 Self-reported proportion of participants reporting help with housing

	Follow-up			
	6 months Intervention n=511 Control n=470	12 months Intervention n=514 Control n=483	18 months Intervention n=501 Control n=466	24 months Intervention n=595 Control n=559
<b>% received help with housing from anyone outside of friends or family</b>				
Intervention	18.0	12.1	9.2	12.1
Control	14.9	9.9	8.4	9.7
<b>% received help from the local Authority Housing Department</b>				
Intervention	7.0	5.1	4.6	6.2
Control	6.6	5.6	4.7	5.9
<b>% received help with housing from Family Nurse</b>				
Intervention	4.1	3.1	2.2	5.4

#### 11.4.4 Healthcare utilisation for baby

Table 11.7 describes the proportion of babies reported by their mothers in a telephone interview to have been reviewed at the GP surgery or at home and the proportion who had attended A&E, in the previous six month period. At the 6, 12 and 18 months follow-up babies receiving FNP had slightly lower attendance rates at their GP practice and GP home visits, but similar proportions had been seen at A&E or had been admitted to hospital. The majority of participants in both trial arms attended the GP surgery for baby care at each follow-up time point. At each follow-up, mothers reported higher rates for taking their baby to A&E for medical review than for being seen at home by their GP. For example, 26.6% of babies attended A&E and 1.7% received a home visit from their GP between 12 and 18 months. In the 12 months postpartum, reported rates of attendance at A&E are higher in the Intervention group than in the Control group, but are similar in the next six month period. Attendance rates in primary care show lower rates for Intervention group compared to the Control group across the whole 18 month period.

Table 11.7 Mothers' reports of the proportion of babies using healthcare

	6 months Intervention n=511 Control n=470	Follow-up 12 months Intervention n=514 Control n=483	18 months Intervention n=501 Control n=466
<b>% baby seen at GP surgery</b>			
Intervention	69.7	64.4	66.7
Control	73.9	69.1	72.1
<b>% baby seen at home by GP</b>			
Intervention	3.3	2.5	1.2
Control	4.5	4.1	2.4
<b>% baby taken to A&amp;E</b>			
Intervention	31.7	29.2	26.1
Control	26.2	26.3	27.3
<b>% baby admitted to hospital</b>			
Intervention	16.8	8.8	7.4
Control	15.1	11.2	6.7
<b>% baby taken to hospital by ambulance <u>since birth</u></b>			
Intervention	Not collected	Not collected	19.8
Control	Not collected	Not collected	14.6

### 11.4.5 Financial support

At the time of the 24 month interview 87.6% (N=1,011) of participants reported being in receipt of financial benefits or other regular financial payments (Table 11.8). A higher proportion of participants in the Control arm reported receiving regular financial support from their parents (15.4%) than in the Intervention arm (8.9%).

Table 11.8 Financial support received by participants

	<b>24 months</b>
	<b>Intervention n=595</b>
	<b>Control n=559</b>
<b>% in receipt of state benefits or payments</b>	
Intervention	86.9
Control	88.4
<b>% in receipt of income support</b>	
Intervention	62.0
Control	63.3
<b>% in receipt of Jobseekers allowance</b>	
Intervention	8.6
Control	8.9
<b>% in receipt of housing benefit</b>	
Intervention	64.2
Control	68.5
<b>% in receipt of council tax reduction</b>	
Intervention	62.9
Control	63.3
<b>% in receipt of disability living allowance</b>	
Intervention	2.5
Control	5.4
<b>% in receipt of Incapacity benefit</b>	
Intervention	0.7
Control	1.6
<b>% in receipt of payments directly from partner or via Child Support Agency</b>	
Intervention	12.8
Control	11.6
<b>% in receipt of regular financial support from parents</b>	
Intervention	8.9
Control	15.4
<b>% in receipt of education grants</b>	
Intervention	5.5
Control	5.9

### 11.4.6 Education

Although the proportion of participants attending school, college or receiving other training increased slightly between 6 and 18 months following the baby's birth, the majority of participants were not engaged in education or training at 24 months. The numbers of participants attending specialist education were low at all time points and across both trial arms (Table 11.9).

Table 11.9 Participants in school, college or training

	Follow-up*			
	6 months Intervention n=511 Control n=470	12 months Intervention n=514 Control n=483	18 months Intervention n=501 Control n=466	24 months Intervention n=595 Control n=559
<b>% In school, college or training</b>				
Intervention	14.5	20.4	22.4	22.5
Control	16.4	19.0	20.6	18.1
<b>% Attending mainstream school or college</b>				
Intervention	11.3	15.0	19.5	16.6
Control	13.7	15.6	18.7	12.7
<b>% Learning support unit</b>				
Intervention	0.6	0.6	0.2	0.7
Control	0.2	0.6	0	0.7
<b>% Attending pupil referral unit</b>				
Intervention	0	0	0	0
Control	0.2	0	0	0.2
<b>% Attending Teenage mums support unit</b>				
Intervention	0.8	0.6	0.4	0.7
Control	1.7	0.6	0.6	1.5

\*Some respondents indicated they were in school, college or training but did not provide further information

### 11.4.7 Sexual health

At the six month postnatal follow-up a greater proportion of women in the Intervention arm were accessing contraception particularly from family planning clinics but this difference was not seen at 12 or 18 months (Table 11.10).

Table 11.10 Proportion of participants accessing contraceptive services

	6 months Intervention n=511 Control n=470	Follow-up 12 months Intervention n=514 Control n=483	18 months Intervention n=501 Control n=466
<b>% obtaining contraception from GP surgery</b>			
Intervention	42.3	41.2	38.5
Control	38.3	44.1	46.1
<b>% obtaining contraception from Family Planning Clinic</b>			
Intervention	26.2	19.6	22.6
Control	19.8	18.6	18.7
<b>% obtaining contraception from Children's centre</b>			
Intervention	1.4	1.0	1.0
Control	0.6	0.8	0.4
<b>% obtaining contraception from Sexual Health Clinic</b>			
Intervention	6.1	4.7	7.2
Control	4.5	4.3	4.5

### 11.4.8 Support with childcare

The proportion of children spending time in any form of childcare increased similarly in both trial arms from 7.0% at 6 months to 25.7% at 24 months with childcare associated with a school or college being most commonly utilised (Table 11.11).

Table 11.11 Support with childcare

	Follow-up			
	6 months Intervention n=511 Control n=470	12 months Intervention n=514 Control n=483	18 months Intervention n=501 Control n=466	24 months Intervention n=595 Control n=559
<b>% of children that spend time in childcare</b>				
Intervention	7.0	16.1	25.5	26.9
Control	7.0	13.3	21.5	24.3
<b>% of children that spend time in crèche at school or college</b>				
Intervention	4.1	8.8	4.8	12.1
Control	4.5	6.6	3.6	12.3
<b>% of children that spend time in day nursery at children's centre</b>				
Intervention	0.8	0	3.6	5.5
Control	0.6	0	2.4	4.3
<b>% of children that spend time with a child-minder</b>				
Intervention	1.8	2.1	3.2	3.2
Control	1.1	1.2	2.4	3.0
<b>% of children that spend time in other forms of childcare</b>				
Intervention	0.8	2.1	8.0	6.7
Control	0.6	2.9	6.9	6.1

### 11.4.9 Support services

The proportion of participants making contact with various support groups and services are reported in Table 11.12. The services reported to be used by the greatest proportion of trial participants were Connexions and Children's centres. Connexions services were reconfigured towards the end of the trial with some areas seeing their service disbanded or merged with other services. Children's Centres vary in the range of support offered to young parents but frequently host parenting preparation and support groups, and early years play groups. At each follow-up a minority of trial participants reported contact with a social worker, with around 10% reporting contact within the first six months following birth.

Table 11.12 contact with support services

	Follow-up			
	6 months Intervention n=511 Control n=470	12 months Intervention n=514 Control n=483	18 months Intervention n=501 Control n=466	24 months Intervention n=595 Control n=559
<b>% contact with Connexions</b>				
Intervention	31.1	23.5	16.8	Not collected as service reconfigured
Control	26.8	23.2	17.0	
<b>% contact with school nurse</b>				
Intervention	1.4	0.8	0	0.5
Control	1.5	0.4	0.9	0.9
<b>% contact with Young People's Centre</b>				
Intervention	4.9	2.7	1.8	1.8
Control	7.0	3.9	1.9	1.6
<b>% contact with Family Information Centre</b>				
Intervention	2.0	1.2	2.2	1.3
Control	2.3	1.5	3.0	1.4
<b>% contact with Children's Centre</b>				
Intervention	36.6	25.8	28.3	34.6
Control	36.6	35.6	30.0	26.7
<b>% contact with child development centre</b>				
Intervention	0.6	0.4	0.8	1.0
Control	0.6	1.7	1.5	2.5
<b>% contact with crèche/ day nursery</b>				
Intervention	10.8	15.4	8.4	17.6
Control	10.8	14.7	6.0	16.6
<b>% contact with toddler group</b>				
Intervention	7.8	12.5	16.2	19.2
Control	7.9	11.0	15.2	21.5
<b>% contact with leaving care service</b>				
Intervention	1.4	1.8	1.4	2.0
Control	0.4	1.0	0.6	0.9
<b>% contact with fostering service</b>				
Intervention	0.6	0.4	0	0.3
Control	0.2	0.4	0.6	0.4
<b>% contact with youth offending team</b>				
Intervention	0.8	0.2	0.4	0.3
Control	0.9	0.2	0	0
<b>% contact with social worker</b>				
Intervention	10.6	7.4	8.2	13.1
Control	10.0	7.5	6.2	9.7
<b>% contact with alcohol / drug support</b>				
Intervention	0.6	0.2	0	0.3
Control	0	0.2	0.4	0.5

## 11.5 Discussion

The aim of this component of the trial was to describe the support available to young parents in England, which FNP was enhancing and being compared to (service elicitation exercise); to describe self-reported service usage amongst trial participants, and to assess the degree to which receiving FNP affected client usage of other services.

The service elicitation exercise confirmed that England has a complexity of services that is difficult to comprehensively describe at either national or site level. The work provided information on, and allowed us to reflect upon, the variety and scope of locally provided services in England. Each individual service, although provided with similar intent, could vary in content between trial sites. The exercise demonstrated services to be many and complex. Many service providers had core functions to deliver a specific service and this was captured by the service elicitation exercise. Although the methods used achieved the aim of capturing service descriptions, it artificially segregated individual services from the far less tangible, but equally important, multi-professional interaction which facilitates service delivery for an individual family.

### 11.5.1 Description of service utilisation

Information provided by stage 1 of the service elicitation exercise, informed the content of the service utilisation domain of the postnatal follow-up interviews, but not the late pregnancy interviews that had required completion prior to the data being available. In addition to providing services required by statute, there were many examples at sites providing specific support to teenagers, particularly through the housing, educations and midwifery services.

In each of the five follow-up periods the usage of services reported by trial participants followed very similar patterns across trial arms. This suggested that FNP was provided to participants, in addition to, rather than in place of usual care. Whilst the FN may have assisted clients to access additional services, or initiate access for themselves, there was no suggestion that FNP clients were obtaining preferential access, or were being denied access, to other services.

Similarly to the US trials of NFP, engagement with antenatal health services was high and similar across study arms, with participants in each study engaging in midwifery, obstetric and GP care during pregnancy. The majority of participants were in receipt of Housing Benefit, but lower proportions indicated that help with housing had been provided by the Local Authority or their Family Nurse, possibly reflecting residency with parents who were themselves in receipt of the benefit.

Trial participants not allocated to receive FNP were expected to be provided with the Healthy Child Programme through the local Health Visiting service. Most women (89.1%) reported that a Health Visitor had made at least one home base visit following the birth of their baby with this reducing over time to 28.8% in the

six months between 12 and 18 months postpartum. Half of the women allocated to the Control group reported that they did not see a Health Visitor either at home or at a clinic between 12 and 18 months postpartum. However, the numbers of contacts with Health Visitors varied widely at each time, with some women reporting frequent home visits or clinic contact.

The service uptake data suggested that whilst the return to education increased over the postnatal period, the majority of participants remained outside of education, with a very small proportion attending specialist teenage mums support units. During the early postnatal period more participants in the Intervention arm obtained contraception from the GP or family planning clinic, than women in the Control group, consistent with the emphasis in the FNP programme of planned pregnancies with encouragement for longer inter-birth intervals.

### **11.5.2 Complexity of service mapping**

Previous reports of UK-based service mapping have demonstrated the potential complexity of such work. The mapping of mental health related services within a single NHS partnership group identified an extensive array of services being delivered both by mental health services and by other specialties including dentistry, maternity and dermatology and identified the need to separate generic from more specialist services.<sup>178</sup> Work conducted to map services available to older people, or those with mental illness also recognized the complexity of the task, overcoming this by separately identifying specialist and generic services through a multi-staged approach to data capture.<sup>179</sup> In addition to the complexity of service mapping such tasks are appreciated to be time consuming for individuals providing data. This challenge previously was recognised by individuals providing data to a national children's services mapping exercise on an annual basis.<sup>180</sup>

Due to the complexity of support available within the trial sites, the reporting of services potentially available to trial participants was necessarily time consuming. One trial site reported to us that the coordinator alone had taken over 50 hours to complete the mapping exercise, with many other individuals providing data and information. The challenge in collecting these data was compounded by a lack of detailed knowledge by any individual as to the full spectrum of locally available services, requiring involvement of many informants at each site. This highlighted the difficulties women and professionals may encounter when navigating the system of support and attempting to access services.

### **11.5.3 Strengths and limitations**

Data were captured from all study sites during both stages of the service elicitation, providing information on a wide range of services and support potentially available to study participants. Whilst data were provided on many services by study sites, some statutory services, such as routine NHS care and school education to 16, went unreported by many sites. This possibly reflected their truly universal availability and site informants, with limited time for form completion possibly placing priority on the reporting of additional services. Whilst the service elicitation was informed by pilot work the method used, of completion of spreadsheets, had

weaknesses. Providing predetermined headers, which was necessary to provide some structure, may have placed unintended boundaries on the data provided by trial sites whilst the completion of the spreadsheets by service leads may have resulted in bias in the description of service provision.

An original plan to capture changes in services over the duration of the trial proved unachievable as services frequently went through a process of evolution rather than definitive commencement or cessation. Services were witnessed to have merged, been renamed or be provided by different organisations. An example of the way in which services evolve in this manner was characterised by Connexions, developed in the late 1990s from the former Careers Service to become increasingly focused on the delivery of targeted services to young people regarded as most in need of help. This service was reported as 'universally available' by trial sites in 2011. With change in Government direction, by 2013 there was no longer an expectation that Local Authorities would provide Connexions as a distinct service, but in some areas the service continued, often under the same title but with increased local variation.

The information on services was provided primarily by the managers or individual service leads at trial sites. The amount and depth of data provided by trial sites varied widely and it was not possible to determine the extent to which the wide variation in reported service provision between trial sites reflected actual service variations or reporting bias. Some service leads had greater engagement with the trial and delivery of FNP at their site trial, possibly increasing personal interest in the exercise, whilst for some the time required for detailed completion may have limited participation.

Despite inconsistency in reporting across individual sites, the service elicitation exercise provided detailed descriptions of the many services potentially available to study participants. Self-reported service utilisation data obtained from the follow-up interviews provided important information to aid understanding of the context in which FNP was delivered in the trial. Our findings identified that within the trial FNP was provided to participants alongside other care and support from multiple agencies. The similarity of service usage found between trial arms suggested that in England FNP is provided in addition to other care available to young parents, and is neither a substitute for, nor a preferential access route into, generic or specialist services.

# 12 Programme Implementation: Stakeholders' Views on Barriers and Facilitators

## 12.1 Aims

Building on the Implementation Evaluation of FNP in 10 pilot sites by Barnes and colleagues the Building Blocks Process Evaluation aimed to:

1. identify contextual factors affecting implementation of FNP within the context of an RCT, addressing the issue of generalisability of trial results to other areas within England
2. capture factors that may have impacted on trial outcomes, and aid our interpretation of these (i.e. factors impacting on engagement / attrition of clients and fidelity of programme delivery)
3. document factors relevant to the wider roll-out of the FNP programme, such as workload issues, team morale, and the interface with universal services.

We therefore organised a series of focus groups to explore the perceptions of relevant professionals (Family Nurses (FN), Health Visitors (HV) and Midwives (MW)) in a sample of trial sites.

We aimed to hold focus group discussion meetings at two different time points in order to capture mid and end of trial perceptions, with Round 1 focusing on recruitment and referral and Round 2 focusing on the toddlerhood stage and handover to universal services. As Midwives were only in contact with trial participants at the start of the programme, they were not included in the Round 2 meetings. However, as some of the sampled sites were wave 1 pilot sites, some focus group participants could contribute experience of the toddlerhood phase and handover to universal services in Round 1 meetings, so this was a shift in emphasis rather than an absolute distinction.

## 12.2 Methods

We chose to gather the views of FNs, MWs and HVs via focus groups as a convenient and feasible alternative to individual interviews. As all three professional groups had regular team meetings, we were able to link into existing group structures.

The focus groups were facilitated by two researchers on the Building Blocks Process Evaluation team who had no direct involvement in trial conduct, and thus no personal stake in the views expressed by participants.

Maximum variation sampling was used to determine focus group sites, with criteria set out in Table 12.1. We recruited participants by contacting professional leads who invited their team members and circulated information sheets and consent forms before the meeting. Wherever possible, the focus groups were arranged to coincide with professional

team meetings to maximise attendance rates and minimise inconvenience to participants. However, in a few cases meetings were organised as stand-alone occasions due to a lack of a regular team meeting or teams' geographical dispersion. At the start of the meeting participants were asked to read the Stakeholder Focus Group Information Sheet and to provide written consent for the meeting to be recorded and anonymised data used. Participants did not receive a monetary incentive to take part.

All sites and all professional groups contacted agreed to take part in the focus group discussions. Attendance ranged from two to 12 participants and a total of 122 professionals contributed to the discussions. One interview with a Health Visitor who arrived too late to participate in the focus group was also included in the dataset. Meetings lasted between 60 and 75 minutes, and were facilitated by usually two, but on occasion just one, experienced qualitative researchers.

Focus group topic guides were developed and discussed within the Building Blocks process evaluation team. The four main discussion questions (adjusted per professional group and per round of data collection) were:

- How has FNP been implemented in this site? What has worked well and what has not?
- What has been your experience of working within a trial? What has worked well and what has not?
- What has changed as a result of having FNP in this area?
- What advice would you give to others considering implementing the FNP programme? What advice would you give to the BB team?

Prompts and follow-up questions explored participants' perspectives on FNP in relation to their understanding of professional roles, their values and their working practices and within the context of current and previous service changes and developments. FN teams were also asked to discuss the experience of training and development of FNP in different waves of programme roll-out.

Table 12.1: Building Blocks Focus Group sampling criteria per site

Site ID	Site sampling criteria	Professional groups	Focus group time frame
G	Wave 1, smaller city/urban character, low trial recruitment	FN, HV, MW	<b>Round 1:</b> 15 March to 7 June 2011  (NB low-medium-high recruitment measured in total number of women recruited)
R	Wave 2b, rural, medium trial recruitment	FN, HV (x2), MW	
N	Wave 1, smaller city/rural character, low trial recruitment	FN, HV, MW	
Q	Wave 2b, large city, high trial recruitment	FN, HV, MW	
H	Wave 1, urban, late* trial recruiting site	FN	<b>Round 2:</b> 26 April to 25 June 2012  (all sites expected to have medium to high number of
J	Wave 1, London, early stop* trial recruiting site	FN, HV	
C	Wave 2b, urban, late trial recruiting site	FN	

I	Wave 2b, rural, medium length* trial recruitment	FN, HV	handovers at time of FG meeting)
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\*early/medium/late refers to length of trial recruitment period which varied across sites: early: recruitment to trial finished by end March 2010, medium: finished by end May 2010, late: finished by end June 2010

All focus group meetings were digitally audio-recorded and transcribed verbatim. Names, places and other potential identifiers were replaced with generic descriptors at the transcription stage and ID numbers were used to indicate sites. For ease of reading, data extracts are here presented using standard orthography. The following transcription conventions apply:

- [word] text added for clarity
- (word) transcriber's guess at unclear speech; generic descriptor
- ((word)) transcriber's description of non-speech sounds
- ... text not directly relevant to topic omitted in data extract
- word- truncated speech; rapid switch to new formulation
- I/I2: interviewer/second facilitator
- FNsp Family Nurse supervisor
- HVld Health Visitor lead

For the Family Nurse focus group data, all eight transcripts were scrutinised independently by the two experienced qualitative researchers who facilitated the meetings. At this initial stage, three broad content areas (key questions, professional perspectives, evaluation of processes), as well as initial lists of thematic codes to fit those content areas were identified. Coding of transcripts was supported by NVivo 8 and a detailed coding framework building on those initial observations was devised by one of the researchers. During the coding process, discussions about the expanding coding framework as well as the assignment of particular codes were held at regular intervals. These were informed by impressions (captured in field notes) taken at the time of data collection by both researchers. As the level of agreement was very high from the start, it was decided not to double code a percentage of the data.

The Health Visitor and Midwife focus group data were analysed by a researcher not involved in data collection. Data were analysed thematically, with themes identified as patterns in the data in response to the research question. The coding frame was finalised after a second qualitative researcher, not on the study team, double coded 25% of the data, i.e. two of the eight data sources for Health Visitors and one of the four data sources for Midwives. Where 95% agreement was reached between the two coders, no action was taken. In other cases the coders reviewed areas of discrepancy and resolved these. There were no coding discrepancies that could not be resolved. Coding comparisons were then rerun to ensure that 95% agreement was reached across all higher level codes.

## 12.3 Results from Family Nurse focus groups

### 12.3.1 Factors affecting delivery of the FNP programme during the trial period

#### 12.3.1.1 Coping with workload pressures

FNs across sites reported envy from their Health Visitor colleagues about their low caseloads, but agreed that such comments were based on misperceptions about the intense nature of FNP and the amount of time and effort spent on keeping clients engaged in the programme. FNs in one rural site had been permitted to have a caseload of 21 instead of the usual 25 clients in recognition of the special challenges posed by travel distances, but still felt pressurised.

- FN1: I think you think of (name county) you don't actually think it's a huge county but the mileage we're doing, they're quite staggered, aren't they, when they find out a lot of our time is taken up with the travelling.
- ALL: mhm
- I: So, does that mean that comparatively you get less client contact than the other nurses?
- FN1: No, no, definitely not.
- I: You're just working longer hours.
- FN1: We're just working harder and longer.
- FN2: Yeah, long hours.
- FN1: We are working very long hours and a lot of our time that- we do computer work and what have you, and data is all done in our own time, a lot of it is. (site R)

FNs in all sites said they regularly worked beyond their contracted hours. Several also said they found it difficult to switch off from their jobs due to the nature of the work, the weight of responsibility and their personal involvement in clients' lives. Good morale within the team, the belief in doing a worthwhile job and advice and support from colleagues when confronted with difficult situations were described as important factors in managing workload pressures and avoiding professional burnout.

#### 12.3.1.2 Workload issues resulting from integration of FNP with existing services

In one site, there was a suggestion that Midwives singled out 'high need' clients for referral to FNP. Family Nurses felt that while they could cope with a couple of 'chaotic' or 'hard to reach' clients on their caseload of 25, having an increased numbers of such 'high need' clients would start to pose a threat to delivering the programme with high fidelity. In addition, several FN teams in Round 2 reported Social Services mandating young parents to have FNP contact as part of child protection orders. The FNs felt conflicted about this as they saw it as going against the spirit of the Family Nurse-client relationship as being voluntary and non-directive. They were also concerned about what would happen to such arrangements at the point of handover back into mainstream services:

- FN1: I think where social care has become involved that's been the trickiest bit to get hold of the clients then.
- I: Yeah, why is that?
- FN2: They have multiple appointments and it seems to be a case of fitting them all in. They see social care as their main priority because they have got to fulfil all those appointments, you see, and because our service is voluntary it's like an add-on, so something might have to give and it might be Family Nurse partnership. But, on the other hand, Social Services will say no you have got to have Family Nurse partnership, so then it becomes not voluntary, it becomes something that they have to do.
- I: Right, so the Social Services make it a condition that they continue?

FN3: Even though when we say you can't do that because it's still a voluntary programme they still, they still write it into child protection packs. (site G)

FNs saw it as part of their role to facilitate their clients' engagement with other services, but some felt that the different ethos of FNP compared to other services could make it hard to find common ground in interprofessional communication.

FN4: I think a lot of the time I find myself keeping these clients going with other services, you know, trying to keep- help them to engage with other services. Do you know what I mean? Why I'm saying that?

FN5: To get them to know the process and to get them to actually engage.

FN4: Yeah.

FN2: To advocate.

FN4: To advocate, yeah, and all the time you're like trying to keep services involved with the client because these clients are really difficult to work with and a lot of these services are 'oh well they're hard work, they're not engaged, they're not coming to appointments' and they discharge them.

FN3: 'Three strikes and they're out', that's what the GP told me.

FN4: Whereas, yeah, we don't work like that, so a lot of the time you find yourself facilitating clients' therapeutic relationships with other professionals, other than yourself, because you know that client needs to work with a social worker, she needs to work with a mental health worker, so you're smoothing it over all the time getting her to help, getting her to appointments, doing the, you know, all the time facilitating that relationship. (site H)

FN4: I would approach it in a different way or say it in a different way and that can be really hard when all the other services are sort of directing a client and going down a particular road and you're trying to come in with a completely different approach that you know works. Uhm, and I think sometimes other professionals think you're on another planet in terms of the way you approach things.

FN2: Because we talk about strengths, don't we?

FN4: Yes.

FN2: They just talk about the challenges and that's the way we've been trained and that's the way we always look at the strengths. (site H)

### **12.3.1.3 Potential threats to programme fidelity**

Delivering the prescribed number of sessions at the prescribed intervals was perceived as challenging by FNs with full caseloads in all the focus group sites. Major challenges described included high client mobility and frequently changing mobile phone numbers and contact details. This led to FNs having to spend considerable amounts of time on 'detective work' to re-locate clients. All teams reported having to contend with some clients with particularly chaotic lifestyles who frequently missed or forgot appointments and therefore took up many more resources than others to arrange and deliver sessions.

While such problems were reported by FNs across all the focus groups, the impact of missed appointments was much greater for those in rural areas (sites I and R) and as they had to invest travel time of up to an hour per client and could not exercise the flexibility of fitting in another client if one had cancelled at short notice.

FN1: I think it does affect the fidelity ... with regard to like, exactly what (other FN) just said, with the fact that if a client cancels us then they have to- generally have to wait until their next maybe fortnightly visit because there is no flexibility within the working week to fit that client in. (site R)

Trying to honour continuity with the same FN when clients moved to other locations within the area was described as having a huge impact on travel times in site 1.

- FN6: I- I think the other thing, because the clients are so spread out, so you try and do your best, like I do maybe I try and do a day in (place name).
- FN2: Yeah, I do.
- FN6: But if I then get a cancellation in (place name) I then can't see that client again, I can't just slot her in somewhere else, because I'll be fifty miles away.
- I: Yeah, so you might be-
- FN6: So it's not going to be possible to do fifty miles there and fifty miles back.
- FN2: And there's no one else you can slot into that place.
- FN6: There's no one else. ((all laugh))
- FN2: Because you have to travel so far and that- I know, and it's frustrating
- FNS: Yes
- FN2: because when they ask for contact numbers, for days, some days on- on Monday I had four booked, two cancelled in the morning.
- FN6: Yeah, yes. So you can't do anything about that.

In the other rural site, R, differential success of recruiting clients onto the trial meant that the staff based in the north had full caseloads early on while their colleagues in the south were unable to share that workload due to the distances involved. The following comment also illustrates the logistical challenge of running a trial around a complex community-based service which is trying to recruit vulnerable clients and where only 50% of recruited participants would be randomised to the intervention.

They [The Building Blocks trial team] couldn't understand and when I was saying 'actually, we're going to have to close the north because we're going we're coming up to full complement', they couldn't understand because I had two other nurses why I was closing the north. And I said, 'I cannot have my nurses in the south travelling two hours to go and see a client, that's the difference'. So I think for Cardiff it's certainly been a challenge having (name county) as an RCT site really. (supervisor, site R)

FNs in site H commented that the actual work and hours they had to spend with some of the more demanding clients as well as the individual progress made would be poorly reflected in terms of overall fidelity rates. The tension between having to meet programme targets and yet address their clients' very real needs is clear:

- FN7: We're being monitored in terms of fidelity, some clients we were talking about, my most particular difficult client I've done over and above the amount of visits, the amount of FNP I've delivered in terms of everything else is probably minimal.
- All: Yeah, yeah.
- FN7: Because of the circumstances where I've got other girls that I can see and I know I can deliver the programme in, in half the time I could for a more difficult one ... I might miss out on one visit and it's not reflected. Do you see what I'm saying? It's not reflecting on terms of the work you're actually doing with the clients because the most difficult clients and the visits that you do there, the time-consuming ones, and you're really working at delivering the FNP programme and you've got your figures on paper. Yeah, we've got 85% fidelity and whatever else and you've missed one because of one visit but actually she didn't need that visit, so sometimes I don't think it really reflects the work that we do. (site H)

#### **12.3.1.4 Competing demands in clients' lives at end of infancy period**

Family Nurses across all sites reported greater difficulties with arranging visits towards the end of the infancy period, as many clients by then would get increasingly busy with work or education and had less free time to fit in appointments.

This was perceived to be the main period during which clients might disengage from FNP, albeit for very positive reasons, i.e. a return to education or employment.

- FN6: And then you get the other girls who are not chaotic, but, like, they're in college or they're in, I've got a girl in university I'm very proud of, and she's cancelled me today because 'I've got an assignment to do', and it's like I really struggle to get in to her. But it's not because there's stuff going on, it's just because she's got her head down and she's getting her uni work done and I know (FN name) has the same problem with a girl that's in college or in school.
- FN7: I've a lot of school girls.
- FN6: Trying to get hold of them after school, and they'll go 'I'm tired I've been in school all day', they cancel.
- FN3: You can't blame them, can you.
- FN5: I've only got two clients that aren't at college or school, which is great isn't it? ((all: mhm)) But it's really hard doing the work.

Apart from competing demands posed by education and training, Family Nurses also describe family difficulties, partners unsupportive of FNP, unwell babies, and transport difficulties as factors that made it difficult to deliver the prescribed number of sessions to clients after the birth of the baby.

#### **12.3.1.5 Location of FNP teams and resources for working**

The teams participating in the focus group discussions had differential access to resources for supporting their activities. Poor office infrastructure, lack of contact with allied professionals, lack of administrative support and outdated IT equipment directly impacted on FNs' ability to consistently deliver the programme

From the very beginning, and we've also found it since the new nurses came on board, that IT is an ongoing challenge, um, originally we- we had nurses in, and still do, have nurses in non-NHS settings, um, so IT has been a challenge with remote access, um, not having printers, printers that don't seem to marry up with- with computers, so it really, that really has been a challenge for the nurses. (supervisor, site I)

In site I, members of the FN team were based in separate venues and the supervisor spent long hours driving around to deliver materials. Components of visits at times failed to be delivered because it had not been possible to photocopy and distribute the required materials in time, or because the FN was too far removed from her office base to look up contacts details or fetch the materials she needed. Working mostly in isolation meant that FNs in site I could not profit from team support as a means of peer-to-peer supervision and thus missed out on the morale boost that was described in other sites. In site R, another rural area with spread-out FNs, similar challenges were described.

In the larger urban areas, a constantly changing service landscape proved challenging not just for forming working relationships with allied practitioners but also for appropriately supporting and referring clients. Several FNs working in large urban areas said they had incomplete knowledge of universal services of relevance to teenage parents. This applied especially to FNs who had moved to the site after their appointment to FNP:

I'd never even worked in (name site) so knowing who's out there and what's out there that's taking a long time and I still don't think I know it fully. So therefore I get stuck with doing things that I probably could (delegate)- so it's a parallel process, I've got to find out what's in the community so then get your clients to find out what's in the community you know because they shouldn't be relying on me to do things, they should be finding their own resources that are there and we're there to facilitate them to get those resources but sometimes when we don't know they're there we take them on board instead. (FN5, site H)

FNs' insufficiently developed knowledge of and relationships with universal services could thereby impact on FN workload. Lack of awareness of relevant and locally available services could have also contributed to the perception of FNP as undermining clients' engagement with universal services that has been reported in Barnes et al.

<sup>107</sup>Implementation Evaluation reports and was also voiced in some of the HV and MW focus groups.

Where Family Nurses were co-located, frequent informal peer support from other FNs was described as an invaluable resource to cope with high caseloads. FNs also described the formal supervision arrangements available to them as vital to performing their role.

FN7: I think the other thing that's important is the infrastructure that's in place to support us really, because it is a quite emotionally demanding role and sometimes you feel that your head's left your body, umm, and it can be quite challenging, so it's nice to have that infrastructure, you know, the clinical supervision, the safeguarding supervision and the psychologist on board as well.

Group: mhm, mhm

FN6: You couldn't do it without that, I couldn't away.

Group: No, no, no

I2: How often are they available to you, is it on demand or do they have- do you have regular meetings with

FN2: We have monthly psychology supervision we have peer supervision once a week in a team meeting and we have uhm supervision safeguarding and clinical supervision from our supervisor once a week as well.

I2: Right

FN3: And then we have access to uhm a specialist safeguarding nurse every three months. (site H)

#### **12.3.1.6 Variations in skills and training between waves, sites and practitioners**

All focus groups included a mix of FNs recruited at different time points: in wave 1 sites, additional staff had joined existing team members for the start of the Building Blocks trial, and in wave 2b sites, staff had joined after the recruitment phase of the trial had closed. This meant that within each team, FNs had undergone training at different time points and they commented how both the training and their own practice had developed over time.

I think we were learning the programme, we were learning how to deliver the programme and at the same time as we had got RCT clients and I think until we kinda-, taking a group of clients through the programme you're kinda- you haven't learnt it. And, you know, all the skills that we pick up along the way, the MI, the PIPE, we're learning. So I think that's got to have an effect on how you deliver the programme and possibly the outcomes. (FN, site G)

Regardless of wave, FNs described their experience of going through training while taking on clients as a 'steep learning curve'. Although the situation described in the following data extract did not involve Building Blocks participants, it illustrates the ever evolving nature of the job:

FN3: ((laughs)) Well, we had to set the service up from scratch, being a wave 1 site, so we had to find the premises, equip it, all the time doing training and and uhm er recruiting clients as well, so it was a steep learning curve, wasn't it girls? Very steep, we learned on the move. But I think as other waves and (name FN) and her wave have come in, I think we have, it's just grown, it's just grown, I mean it's never stayed still, has it? (site G)

Those who had joined existing teams emphasised the value of having the support of more experienced colleagues. However, FNs who had completed their training earlier on also valued newly trained Family Nurses joining the team and said it helped to remind the team about specific aspects of the programme and keep them 'on their toes'.

- FN/Lead: But with the experience we have really managed to look at that and explore other ways of working, but it's been good, new members coming into the team, because they have motivated us again to get on with things and lifted us, you know, so and brought their experience, so it's been really good.
- FN/Sp: Plus all their new ideas, when they come they have had their training and they come with new ideas, it's been brilliant. (site G)

Furthermore, FN colleagues who had been trained during different 'waves' thought the contents of the programme itself had evolved considerably.

- FN6: Every team that, every wave that comes through is going to have a completely different experience and you think from the first pilot sites to when we came through, you know, wave 2b, you know how much they'd tweaked it and you know all the rest of it and changed things and the facilitators, everything was kind of different. So you're not going to get- you're going to get very- two kind of different experiences which is going to result in two very different teams, aren't you really. (site G)

Several FNs commented on how their skills at delivery of the programme had increased from when they first started:

I suppose if you're looking at clients and how we've grown. When you start off with your first client on the RCT to the one- the last client on the RCT, you've learned much more personally. So how you're delivering it to the first client is completely different to the last client because your knowledge base is increasing by such an extent and we're learning all the time. And I bet if we all reflected, all the clients that we've had, we'd probably change how we'd interacted because each interaction we're learning something more. And I suppose from my point of view that makes me so desperate to carry on doing FNP because I know I can be so more effective. (FN3, site H)

#### **12.3.1.7 Clients having different Family Nurses**

All focus group sites had to contend with members of the FNP team going off on long-term sick leave or maternity leave. This put pressure on the remaining team members in terms of increased caseloads. It also meant that clients had to change their Family Nurse, in some cases more than once. However, FNs in site H, where three FNs had gone on maternity leave at the same time, felt that changing FNs should not cause problems in itself if the process was well-managed, and they prided themselves on not having lost any clients due to the necessary change-overs.

In the rural sites I and R, clients sometimes had to be handed over to a different Family Nurse when they had moved away too far away from their FN's base. More often than not though, Family Nurses would try to keep continuity and follow 'their girls', thereby increasing the hours they spent travelling:

- FN2: These girls are transient, they live all over the place.
- FN6: Yeah.
- FN2: So we follow them.
- FN6: Yeah.
- I: So even though somebody moves out of your locality, you
- FN2: We still follow them,
- I: don't hand them over, you still.
- FN2: that's part of the programme, [you see].
- FN5: Well that's not- that's not always the case,

- FN2: No.
- FN5: though, because I've actually handed somebody over this week, to where they've moved out of my area, into another area, so and I discussed that,
- FNSp: Yeah, absolutely, yeah.
- FN5: so, you know, that's
- FNSp: We do look at it in supervision on an individual case basis,
- FN5: Yeah.
- FNSp: but, ideally we like to follow, as we say, follow our girls if we can, because it just keeps that continuity and that trusting relationship.
- FN1 That's part of the programme. (site I)

### **12.3.1.8 Keeping to prescribed programme contents**

FNs from several teams described difficulty keeping to the prescribed programme contents or recommended times for discussing specific issues when there were pressing concerns for the client at the time of their visit:

- FN1: From the studies in the States, I don't think those nurses have the same issues with the environment part of our visits because when you get your reports back you're only supposed to spend a specific amount of time discussing issues around the environment, so when we get our report ours are always in the red to say we're spending too much time in the environment, but those are the issues that the girls are presenting with, you know, housing
- FN4: It's particular for this area.
- FN1: yeah housing, homelessness,
- FN4: It's a (name site) thing
- FN1: all these things, family breakdown, so you can't sit and talk about anything else when that is a massive, massive issue that needs- so housing and homelessness generally is just a really massive problem. (site H)

One FN team described as a constant challenge remaining true to the FNP principles of client-centredness and a guiding style while making sure programme contents would be delivered according to the manual guidelines:

- FN1: Because you have to go with the structure, because it is a manualised programme, and hit the domains and the fidelity and that's the agenda of FNP. But with the motivational interviewing techniques that we're all trained in we sort of have the agenda matching issue of it, so the agenda for the young women is an abusive relationship, or their house is going to be repossessed or whatever, you have to go with that.
- I: You can't just follow the manual.
- FN1: You can't just follow the manual.
- I: And that was a challenge at the start for you, would you say?
- FN1: Constant challenge.
- FN2: Constant.
- FN3: Sometimes, the girls, as well their vocabulary is not great, so it's really a struggle to get them to understand what what the visit is all about, and the programme I suppose.

### **12.3.1.9 Cultural values and educational diversity as challenges for programme delivery**

Ethnic diversity of the client population differed between sites: sites R and I (the two rural areas) had almost exclusively white clients, while the large urban areas (sites H, J and Q) were more diverse, and one of these sites had a very high proportion of black and minority ethnic (BME) clients (site J). However, ethnic diversity was not commented on as a factor influencing programme delivery and one FN explicitly commented on the universal reach of the materials as a particular strength of FNP:

To me it just spells equality. This is a programme for young families regardless of which culture (ethnic background) you are, but the challenges came when we found there were many words many things we were using where we actually had, particularly saying 'we don't

say that' or the interpreters stopping and saying 'how do I say this' or what do I say here so we've had those little hiccups, but they were little hiccups, they weren't very big hiccups. (FN6, Site J)

Cross-cultural translatability of the programme materials was perceived as a minor issue that could be addressed by enhancing the overall client-friendliness of the material rather than making them more 'culturally specific'.

FNs in several focus group sites identified what they labelled as 'cultural factors' that could hinder client engagement with FNP. These factors included extremely close-knit family structures, a distrust of interventions delivered by outside agencies, and low commitment to engage responsibly with the services offered. These problems were encountered by FNs in urban and rural areas alike, regardless of clients' ethnic backgrounds. Where clients were part of extended families, FNs talked about the importance of 'getting granny on side' to pave the way for a productive relationship with the young mum. FNs from site R, which spanned a large geographical area, talked about different cultures in different geographical areas affecting client reliability to keep appointments or getting in touch to cancel a visit. This was partly ascribed to differences in local service culture, as the site spanned several NHS and Social Services administrative areas which had different ways of dealing with issues, and partly to high versus low mobility of inhabitants and the influence of extended families:

- FN1: You know, (place in north of county) is a city, and you've got probably more socially mobile people coming that have moved into the city, so you've got a different mindset al.together because maybe you've not got as much cultural- you know, they've been born, bred, lived there, worked there, ... and that's what you get in the west of the county.
- I: Right
- FN1: Do you know what I mean? So they sort of have a tendency to, ..., have a really set culture. They've got a real extended family there. You've got, you know ..., grandmas, granddads, great-grandparents, all that with our young people, who then influence our young people.
- I: Right, mhm.
- FN1: You know, whereas in the city you've got a different ... (site R)

Family values of having children young and spaced closely together could also come into conflict with the FNP target of avoiding a second pregnancy for several years (see also 'FN views of trial targets' below).

Very different levels of education, reading and writing ability among clients also affected how much work was required to implement particular programme contents. Comments about some aspects of the programme being more time-consuming and complex to deliver than others due to some clients' lower levels of verbal skills or education were echoed across the focus groups:

Also, some of their education background is very limited and not being to senior school for not many years, so their understanding of some of the words that you use, and you have to be very tuned into them. And you don't always know what their literacy skills are like and some of the information and facilitators are quite wordy and involve a lot of writing, so that's a bit of a challenge for some of the girls who can be uncomfortable with that really. (FN1, site Q)

### **12.3.1.10 Contamination between intervention and Control arms**

FNs across sites reported that clients on occasion had friends round during visits so that effectively teenage mums who were in the Control arm or outside the trial could have been exposed to FNP materials. After birth, clients might also share their FNP-acquired knowledge with other mums in local parenting groups or in their circle of friends. In one unique case, pregnant twins living together were randomised to different trial arms, but for practical reasons the Control arm twin also received the intervention:

FN?: It is difficult because sometimes they do want to kind of come in and want to come on your visit and kind of share information through each other or talk to each other on Facebook and all this kind of stuff. This whole social media that, you know, we haven't even caught up with. (site J)

All FNs contributing to the focus groups wholeheartedly believed in the benefits of the programme for clients. From their point of view, therefore, they thought of other pregnant teenagers joining an FNP session with their client as an opportunity to spread helpful knowledge to a wider audience, rather than a 'risk of trial contamination', which was a small risk anyway, given the fact that other pregnant teenagers were not necessarily eligible to be in the trial, or even in the FNP programme:

FN4: I think we were discouraged really from bringing them [RCT clients and their friends] together. And right at the very beginning we were discouraged, really, from letting them share what we were doing with friends who weren't doing it, weren't we?  
I: Right.  
FN4: Yes. Yeah.  
I: Right.  
FN4: Because they felt that, you know, we might be uhm, skewing the research.  
I: Oh, okay.  
FN4: Certainly that's how I felt it. I don't know whether that was right or not.  
FN3: Yeah. Yes. I think- I think we did feel that.  
FN4: (unclear) a lot of work with a client who might be sharing a house with somebody who's on the uhm, on the Control arm.  
FN3: And benefiting from our information. And spoiling the research. ((general laughter)) (site C)

FNs were unable to assess how much of these knowledge transfer activities involved trial participants as they had no knowledge about who had been recruited and randomised to the control group.

In sites where FNP clients had been recruited within a small geographical radius, existing friendship ties between teenagers could at times prove challenging for FNs in terms of maintaining client confidentiality and containing the spread of programme specific content:

Some of the girls that I've got, a group of them that all know each other outside, and they also were kind of in a- they all knew each other from school and used to hang out before. And they all know that I know each other because they talk to each other. Not because I've shared the information, so it puts me in a very difficult situation. (FN?, site J)

Spillage of FNP-specific know-how was easier to limit between FNs and allied health professionals. However, having to maintain 'secrecy' about FNP materials, was described as a major source of frustration by several FNs and was also seen to exacerbate interprofessional conflict and envy, especially between FNs and Health Visitors. A majority of the FNs taking part in the focus groups had previously worked as Health Visitors, and in some instances continued to share

office facilities or social relationships outside work with former colleagues. FNs described having to ward off interest from Health Visitors into FNP training materials and their new areas of expertise.

They [Health Visitors] didn't know what we were doing and because it was surrounded by quite a bit of secrecy because it was an RCT site ((others agreeing)). That doesn't instil any confidence in them either because we couldn't show them any materials, we couldn't, you know. And I think that's caused a bit of distrust possibly with some. (FN, site I)

FNs at times found it hard not to share their knowledge and skills acquired in training (in particular, insights on attachment and cognitive development in early infancy, and engagement strategies for hard-to-reach clients.)

FNs in several sites expressed hopes that in future there would be greater opportunities for interprofessional learning and passing on their knowledge to colleagues. However, they also expressed concerns that the FNP approach should not be 'cherry-picked' by policy-makers and diluted to a point where the professional ethos of FNP was threatened by pressures to deliver aspects of the programme in a more cost-and time-efficient manner.

- FNSp: It's a model that, perhaps, will be looked at and how we can  
I: Yeah  
FNSp: share, share our experiences, um, around strength-based working, motivational interviewing, um, perhaps how we engage with clients, even working with fathers. There's aspects of our role that isn't part of the license, that we could, potentially, share with our colleagues.  
I: Yeah. Yeah, I understand the difficulty about what's the license and what's not, which seems to be  
FNSp: Yes, you know, um, but I- I- I see why, it can just be taken out of context, but, actually some of our skills that we're learning about, engagement and, and motivational interviewing that we do anyway, without putting a name to it, e- if it was explained a bit more, maybe they would, the- the- they'd realise they're doing it.  
FN2: Yeah.  
I: Mm.  
FNSp: If that makes sense.  
FN2: I think as long as it doesn't get watered down to the point where it's ineffective, I think the intensity of this programme is what makes it work. (site I)

FNs in site N felt uncomfortable about the surge in caseloads for their HV colleagues when the trial started and they could no longer provide an FNP service to large numbers of teenage parents so they needed to be seen in universal services instead. They therefore started doing normal health visiting and seeing non-RCT clients in addition to their FN roles and struggled with switching between the two different styles in approach. While there was potential for 'contaminated' service provision in case they unwittingly saw Control arm participants, this was outweighed by the benefit of maintaining a very positive relationship with the health visiting team.

## **12.3.2 What affected client referral and recruitment?**

### **12.3.2.1 Local awareness of FNP**

While wave 1 sites had already worked to put FNP 'on the map' amongst local services, wave 2b teams said that much of their initial time on the job was devoted to raising the profile of FNP. They identified structural and personal factors such as favourable attitudes of commissioners or having a strong local FNP lead as vital for their efforts to be fruitful.

Especially in the larger urban sites raising awareness about the existence of FNP was felt to be challenging due to the higher numbers of hospitals and Midwife and Health Visitor teams as well as more frequent staff turnover in allied professions. This circumstance was reflected in our own failed efforts to convene focus groups with Midwives and Health Visitors in these sites who had actually referred to FNP or encountered trial participants.

‘Spreading the word’ about FNP was described as time-consuming and something that needed to be repeated at regular intervals. Several FNs commented on the difficulty of having to ‘sell’ FNP to allied services before they themselves had acquired an in-depth understanding of the programme:

FN4: It was coming into something that was completely unknown, really, to us, um, and we didn’t have bases at that point, and so that was all, you know we had to set up without- we had to get to know the programme which took quite a while, we had to promote something we weren’t a hundred percent sure about, we didn’t always know everything about the programme when we were going out there to other professionals, so that was always a challenge. (site I)

By contrast, in one urban site with a dedicated maternity hospital and Midwives who specialised in the care of teenagers (site Q), the referral process worked well as only a small number of practitioners needed to be involved and enduring working relationships could be established. Having strong local leads from midwifery and health visiting involved in the FNP programme bid was described as helpful to open doors and facilitate good relationships with practitioners on the ground.

#### **12.3.2.2 Special issues for wave 1 sites**

During Wave 1, ‘selling the service’ to the potential client was done directly by the Family Nurses who would then take on that specific client. During the trial, Local Researchers (LRs) recruited for participation in research first and foremost, and information about FNP therefore needed to be provided in a reasonably neutral manner. This meant that clients were likely to only realise the full extent of the FNP programme when they had been randomised to the Intervention arm and had their first session with a Family Nurse.

For FNs who had been involved in Wave 1, it took some getting used to that they were no longer able to ‘sell’ FNP to the clients but that the process of recruitment was now handled by a trial Local Researcher. In site G, lower than expected referrals led the team to query the LR’s process for identifying eligible clients and they discovered that potentially eligible clients had been missed:

All they looked at was the young people who were eligible for the teenage pregnancy midwife who were the under eighteens so we did have a gap in the under twenties and if we had been involved a bit earlier we maybe would have twigged that or seen that but we were kind of kept out of the loop a little bit. (site G)

Some FNs felt that LR’s might not know enough about FNP to adequately prepare intervention clients for what to expect and there was an underlying feeling of ‘we could have done a much better job’ in some cases. By contrast, FNs in wave 2 sites and a few FNs who had joined after the trial was underway, seemed to appreciate LR’s doing the ground work of getting clients on board, and one nurse expressed slight anxiety over having to recruit her own clients after the end of the trial.



### **12.3.2.3 (Re-)routing of referral and recruitment via Local Researchers**

In several sites, FNs attributed drops in referral or low recruitment during the trial to problems with the Local Researchers. Issues included delays in appointing LRs, LRs working part-time and therefore having limited flexibility to see clients when needed, LRs living out of area or not knowing services in the area well enough, and perceptions about LRs not having the appropriate communication skills to engage young people.

Time elapsing between referrals and LRs' recruitment visits was perceived to contribute to losing clients whose initial willingness to take part might be influenced by family members. In site R, recruitment picked up when an LR who lived out of area was replaced with someone more local who they perceived to be more responsive. In sites G and N, the FN teams felt that the amount of personal information required upfront was likely to have put off some potential clients:

- FN3: The initial interview with the research nurses [Building Blocks Local Researchers], a lot of clients thought that it was far too long.
- FN2: It were taking up to an hour.
- FN3: And they were giving a lot of in-depth information right there and then. Working with these girls now after four years, it can take quite a long time to take in all this information, it was quite sensitive stuff, you know, erm, that would have put a few people off. (site G)

Most teams shared the perception of the trial referral and recruitment process as lengthy and cumbersome, and possibly confusing for clients.

Maybe there's, um, not quite the understanding. It- because they- they agreed to go on the research, they then have the research midwife [=Building Blocks Local Researcher] go out to a- you know, they- they agree to be seen by a research midwife, research midwife goes and does her two hour visit, asking lots and lots of questions, they then get randomised after that, and I- I'm just wondering whether they- sometimes they fully understand the impact of being on the FNP arm. (FN, site C)

### **12.3.2.4 Randomisation as a source of frustration for FNs and referring services**

In wave 1 sites, start of the trial meant that the established referral routes from Midwife teams and Social Services directly to FNP could no longer operate. This was described as frustrating for services who had judged clients as needing support yet could not be assured that the client would receive FNP. FNs discussed how they had had to work hard to rebuild networks and relationships, especially with social care and midwifery services.

FNs themselves also found it hard to witness when clients who in their perception appeared less needy were randomised to the programme while those who they thought could have genuinely benefitted were allocated to the Control arm. However, in spite of the frustration expressed, they were also aware of the need to have the programme independently assessed:

- FN1: Frustrated phone calls.
- FN2: Yeah, yeah, you put the phone down, it's very frustrating and, you know, originally, when we was recruiting for wave 1, every phone call, you know, you could write down and pass on and they'd take it and, you know, uh, frustrating, yeah very frustrating when you put the phone down and you think, you know, you could offer it to them girls and you can't. You're not the person that can make that decision, you know, it's very difficult.
- FN1: But other professions would say 'when is this over'.
- FN2: Yeah, and they knew afterwards, they knew that they didn't want to ring because of the RCT trial, that's what came across to me. I don't know if anybody else felt that but I I definitely felt

that, and even somebody must have said to me on the phone once and they said they didn't ring because of the RCT because they know the girl wouldn't get it, so they obviously waited for another girl to be pregnant. Could be a midwife, whoever, whoever, it rings and they ring and they know that we'd take the referral.

FN1: But it was very hard for us because we understood the importance of the RCT. (site G)

### 12.3.3 Family Nurses' perceptions of factors affecting client engagement

#### 12.3.3.1 Reasons for client disengagement from FNP sessions

Apart from the competing pressures in clients' lives described above, Family Nurses also identified relational and emotional difficulties that could negatively affect clients' willingness to engage with FNP.

FNs across sites were in agreement that the programme's strong focus on continuity with one nurse and the development of a therapeutic relationship that had the potential to address and heal some clients' previous attachment difficulties was a key requisite to keeping clients engaged during challenging periods. However, across sites, FNs found it challenging to maintain the same level of commitment from clients after the end of the infancy period:

FN1: By the time the child is a year, and they are kind of um thinking okay, ah- um is this a bit too intense, do I really want to be visited this much, they look around and see other friends and they're not visited every two weeks,

((murmurs of agreement from others))

FN1: 'what's wrong with me', kind of thing, and then- then you have the, the engagement of of trying to explain that, now s- quite often they're they're quite happy to do that, and and you re-establish the relationship in a different way and a- perhaps even a more mature sense for that last year.

I: mhm yeah.

FN1: But for others, that's the point at which they're saying 'hang on a minute', they're (you know), I'm, I'm, I'm really not sure, and th- and it's generally the girls with the most intense worrying backgrounds that are the ones that find it difficult to sustain the- the relationship really. And that is to do with, a lot to do with these, the- their ability to make relationships per se, it's not necessarily to do with the FNP, I would say. (site I)

A few FNs suggested that some clients might fear a certain stigma from being seen to have regular visits after the baby's birth, suggesting problems with their parenting ability.

FN2: One of my ones was a bit umm disengaged and she'd engaged really well throughout the pregnancy and then during infancy I lost me fidelity with her because she did disen- and I mean she was in contact with me but she'd be putting off visits why I couldn't go so we had a bit of hit and miss and it turned out she actually said something to me like 'my next door neighbours must wonder why I've got the health- they think that you're a Health Visitor and you're coming all the time and what why do you get somebody coming all the time', so it was a bit like- a bit of a stigma. (site H)

One FN described how clients remained engaged with her as a person, but sometimes were no longer keen on the more structured elements of the programme.

FN4: I think actually, I- I think (that) they are are still engaged with me, quite often, but not with the programme. They like me to come round, but they don't want to be doing worksheets. Um, they er j- want me to- they want to catch up and tell me what's happening with their friends and their boyfriend and show me their baby's now got three, four

FN1: teeth

FN4: teeth, and more teeth and that they can walk and, er, and it's more that, that they're kind of wanting me there, but not necessarily wanting the structure, they want to be a bit more in control of their visits. (site I)

Other factors undermining client engagement that were mentioned by FNs included hostile family members and abusive partners, who persuaded clients that they didn't need the programme.

However, Family Nurses across sites emphasised the importance of keeping an 'open door' and commented that while clients might tend to 'go quiet' for a while and not respond to requests for contact, many of these young women could be successfully re-engaged at a later point.

### **12.3.3.2 Reasons for client disengagement from the trial**

Only some Family Nurse teams offered comments on why they thought clients might disengage from the research trial. Some nurses seemed to think that phone vouchers as an incentive had not been helpful and shopping vouchers were a better option. Still, several FNs commented that the phone calls required by the research team seemed very long and placed quite a burden on clients, especially those with chaotic lives or coping with difficult personal circumstances.

FN1: No, I just- I just had one client who got quite irritated with the long phone calls and she just- she didn't want that anymore, but, you know, that was quite sort of difficult.

FN2: Yeah, a couple have said they just didn't want all these phone calls. In fact, the phone would ring, she knew it was the RCT so she wouldn't answer it (site N)

## **12.3.4 Family Nurses' views and understanding of trial targets and procedures**

### **12.3.4.1 Views on inclusion criteria**

FNs across sites thought that the trial inclusion criteria were targeting the right client population by and large, though some of those in wave 1 sites felt that reducing the age limit down to 19 was missing out some slightly older women who could have benefitted. FNs in another site commented that they got better engagement from the younger clients, but felt that the lack of flexibility with regard to ending the relationship after year 2 proved difficult with very young Mums.

FN1 I think it's the younger ones that I've had more problem saying goodbye to. When they've only been fourteen when they've taken them on, one wasn't even seventeen when I was saying goodbye.

I: Mhm

FN1 and still had masses of- of real need.

I: Mhm

FN1 You could have stayed with her for another two years, easily. (site I)

### **12.3.4.2 Views on randomisation**

While Family Nurses understood the need for randomisation in a research trial context from an intellectual point of view, as practitioners who were already convinced of the benefits of the intervention they delivered many struggled with a sense of 'unfairness' when clients who they thought 'didn't really need' FNP were allocated to the intervention and other, more needy, clients had to go without additional support.

FNs also commented that randomising clients had caused problems with referring services. This applied especially to wave 1 sites, where FNs had built good working relationships with Midwives and other services, but then struggled to explain why they could no longer just take on clients that these services had identified as 'in need of FNP':

- FN5: and I know there was a lot of resistance about, I don't know if we've- about the RCT at the time because the service- in one way that was a disadvantage for (place name) because they'd had the Family Nurse partnership so therefore they were used to recruiting and could see the benefits. Then, all of a sudden, they were being asked to- that it wasn't a referral process, it was asking if they would come onto a
- ?: lottery
- FN5: research process and a lot of people thought it was unethical because it was a service and we were saying without the research there will not be a service because we can't prove that it works. (site H)

#### **12.3.4.3 Views on trial outcomes**

Family Nurses talked about the success of FNP and their engagement with clients in terms of clients' individual progress and the difference they felt they had been able to make to clients' lives. Many FNs felt that the trial targets were unlikely to give an accurate reflection of the progress in real terms that some young women had made, often under adverse circumstances.

- FN1: because some of the health outcomes, we're looking, you know, they always tend to look at breastfeeding and smoking. I'm not saying they're not important, but the kind of level of work we're doing, it should be like looking at is this mum keeping her baby, you know, is this baby
- Group: mmm, yeah
- FN1: it's really deep, complex things like
- FN6: is the dad staying out of prison.
- FN1: Yes, social care.
- FN3: Or the attachment, they don't try to measure that at any point, when it's underpinned by attachment theory.
- FN5: And the- another thing that's not- I suppose it is measured, maybe, possibly, but I've had a lot of girls, especially in the RCT strangely enough, that have had domestic violence and they've actually all taken them to court but they've actually all maintained not a relationship for themselves with the dads but they make sure their babies maintained a relationship
- FN4: yeah yeah
- FN5: with the father which is taken, you know, there's sort of a six month period.
- FN2: It's a massive achievement.
- FN6: It is a massive achievement. (site H)

FNs also commented that as outcomes were collected only at specific time points, the trial might miss out on important interim achievements.

FNs in site Q commented that the trial outcomes of smoking cessation and breastfeeding had to be worked towards in the face of cultural resistance from clients' families.

- FN1: We have got a lot of intergenerational smoking so it's a challenge to work on smoking reduction when everybody in the family smokes.
- FN2: They may give up in pregnancy, mightn't they.
- FN1: Yeah
- FN2: Then start again in infancy.
- FN3: If they don't give up they
- I+FN? reduce

- FN1: So there's a strong cultural link to smoking and I think that's been seen in our figures with (name smoking cessation programme), but we have all just done nicotine replacement therapy training to try and address that particular issue. Breastfeeding is a challenge culturally, very low breastfeeding rates.
- FN4: Breast feeders (have had) breast fed as children, so it's another cultural norm, isn't it? They see it as normal, but in a lot of families it's seen as abnormal, it's breaking the trend really.
- I: Is that difficult if they live with their parents?
- FN4: Yeah, I think we could give one example where to talk about breastfeeding had to almost be done like cloak and dagger really, didn't it. (site Q)

Regarding improvements in clients' socio-economic circumstances, FNs commented on the difficulty for clients to take up work if their housing situation was precarious, due to the way in which even small and short-term earnings could affect their benefit entitlements.

- FN3: Housing is a big problem, but the benefits system ((all: mhm, mm)) I don't know if you find it, it's just- the thing is- some of the girls are trying to get jobs and they start a job they obviously come off benefits then the job doesn't work out for some reason and then trying to get the benefits again this puts them off even trying to get into employment then because they're so worried they've got no one else to support them if those benefits are not there for 2 weeks.
- ?: Yeah
- FN6: They're destitute for 2 weeks.
- FN3: They've got nothing and that's just a massive problem and that causes a lot of crisis for them.
- FN5: And we don't have- and because the service as a provision has been cut you know we used to have a, well, a really good benefit advisor who used to go and see people at home and was brilliant. That took a huge chunk out of my work load. (site Q)

FNs also commented on the paradox that having good FNP support and managing well could lead some clients to consider a second pregnancy, which, however, would be seen as undesirable in terms of trial targets. For clients with good family support and living within a culture that values having children at a young age with closely spaced pregnancies, the target of preventing follow-on pregnancies thus seemed questionable from some FNs' perspective.

In terms of fidelity assessment, some FNs commented that the way in which their work was categorised did not reflect the work they had actually put in (see also section: number and spacing of visits).

- FN5: You travel all the way there, get there, they're not in, and not answering the door, you've got then travel back, so you've had that time out of your day,
- I: Yeah.
- FN5: (and you've done) nothing
- FN4: And your contacts don't show that you've (seen)
- FN2: And it's counted an attempted visit, but it's not counted in contacts,
- FN4: No.
- FN2: and yet you have wasted half a day.
- FN4: Mhm
- FN5: Yeah, just trying to see them.
- FN2: I know, just try- so, numbers actually mean nothing without looking into what you've actually done, the story of it. (site I)

## 12.4 Results from Health Visitors and Midwives focus groups

Health Visitors and Midwives intersected with the FNP at different time points. At the start of FNP, contact was usually with the Midwives who were referring into the programme. Both Midwives and Health Visitors had varying levels of contact with FNP while clients were involved in the programme. At later stages of the programme, contact was usually with the Health Visitors, particularly at handover.

The three overarching themes in the focus group discussions with Health Visitors and Midwives reflected the three key questions asked, i.e. (i) the experience of these professionals of the FNP programme (structure, implementation and impact on care as usual), (ii) FNP and the interface with usual care, in particular communication pathways at different stages, and (iii) their views of the Building Blocks trial.

### 12.4.1 Experience of FNP

#### 12.4.1.1 Perception of the FNP programme

Focus group participants varied in the amount they knew about FNP. In general they had little knowledge of the content of the programme, but did know about broad areas that were covered, usually through contact with their clients. Their perception of the FNP programme was coloured therefore by the amount of contact they had with FNs or FNP clients, or by what they had heard from colleagues.

Focus group participants described many positive aspects of the FNP programme, including that it targeted young mums, a group that can be difficult to engage with services, that it offered consistency of contact with a single professional, that it was evidence based, and that it involved working with families, in particular with dads. Time to develop a trusting relationship with the family was seen as another benefit of the programme, and participants also reported that clients seemed to value contact with their FN.

They just say 'oh, the nurse is coming, and oh she's lovely and she's really good and she's telling me all this', so you know that there's a good rapport. So that's important, and, you know, nobody says, 'oh I dread that one woman coming', you know, that type of um attitude hasn't come across, they've all been very welcoming of that service, so, the one, not that many, I haven't been involved with that many. (MW1, site Q).

Aspects of the programme, such as the focus on communication with the baby, were seen as particularly valuable.

Focus group participants also reflected on the amount of misinformation that often gets passed down generationally from parents or grandparents. The difficulty with breaking intergenerational patterns of behaviour was also discussed. For example, it was described how teen pregnancy is often accepted as the norm and that shifting these behavioural patterns would require a shift in the family system to be effective. The capacity of FNs to engage with the family was therefore seen as a real strength of the programme.

However there were also mixed feelings about some elements of the programme. For example, while some focus group participants viewed the structure and materials of the programme as excellent, others felt they were 'prescriptive' and inhibiting the flexibility and the need for professionals to be responsive. Other participants highlighted that, while the

programme content was structured, the FNs had flexibility in how they delivered it, for example the way in which the FNs used their time to maximise client engagement.

FNP seem to be quite- have more flexibility and that does allow them really greater access to clients, where we could be, if someone works full time, we could try three times in a day, they're not going to be in if they're out working, whereas if you know that they are full time workers you can go at half past six in the evening, you can catch them first time and it probably will save a lot of work. ... They're getting a better standard of care really because they're being accessed and engaged with .... (HV1, site Q)

The intensity of the programme was also seen as intrusive. One focus group participant reported that some of her clients had dropped out of the programme because they found it too intense

I've had two that have left um FNP, and they said to me that nurses would visit for two and a half to three hours, um, it was intrusive, they felt like they were just sitting observing their life in the living room, and, and it was just, it was quite difficult for them, for the participant, to accommodate- felt very negative about it and left. (HV1, site Ra)

Participants, Health Visitors in particular, also described frustration at not knowing more about the content of FNP sessions. They talked about FNP staff as being in an 'isolated bubble' seemingly endorsed by senior management and they expressed frustration at not being able to know more about what was involved in the FNP sessions.

HV6: Yes it was almost like a secret society

HVLd: Yes.

HV6: that we weren't part of.

HV3: We weren't told anything, yeah.

HV6: And we- and we couldn't, although we knew the basis, the basic information about what was happening, that was it. And I think that- I would say that's happened over the whole two years. (HV, site I)

Also, while the continuity of the programme was seen as a benefit to clients, and participants appreciated that FNP retained contact with clients when they moved out of area, this also caused difficulties. When FNs were off sick or on leave, for example, usual care services would then be required to step in.

MW4: Because one girl I have just delivered, her Family Nurse has gone off on long term sick and I know that she found that quite, um, well, it's a disappointment at the delivery. After all that for the pregnancy. And obviously there was a gap and then she didn't have anyone, and now that somebody else is in place she's told me- I mean, it can't be helped if it is long term sick, but I wondered if there would be a team rather than- as after you have built up that relationship- I know what a young girl would feel like. They would be disappointed, wouldn't they.

I: It does happen that Family Nurses decide that the job wasn't for them after all and they have left so other Family Nurses have had to step in at that point, so obviously it creates exactly the same type of problems that you are referring to, but it's a situation that can't be helped.

MW4: No, it can't be helped.

I: But it definitely is hard on the client because they have got used to communicating with a particular person and have got a really good bond, and now suddenly they have to bond with someone else and that's not always easy.

MW5: I found that one problem I had with one of them was that, um, the Family Nurse partnership professional was actually on holiday when this lady delivered and then there was a bit of a delay then in the visit. So rather than the visit being between ten and fourteen days it ended up being twenty days by the time she got the first visit. I actually had to ring the Health Visitor up and ask what was happening and they said that she is on holiday at the moment and she will be in contact after, so there was quite a bit of delay with that which I think that the patient weren't really impressed by really.

I: So they had the midwife postnatal visit from you.  
MW5: Yes (MW, site G)

#### **12.4.1.2 Perception of the Family Nurse role**

Focus group participants had mixed feelings about the professional role of the FN. This was a new role and offered an opportunity for career progression as it was a higher banding than many midwifery or Health Visitor posts. However, FNs were not required to have a midwifery or health visiting background, and questions were raised about how this worked in practice. Both Midwives and Health Visitors described needing to offer some level of service to FNP clients – Midwives continue to deliver antenatal care, Health Visitors see the babies and toddlers at their clinics – and this led to role confusion and doubling up of services at times.

MW2: Because I know, I knew this girl I was talking about, she was being visited by someone who was,  
MW3: a midwife  
MW2: who I used to work with, actually, and that's, like, yeah, I suppose that was in the back of my mind, where is she coming from, from a midwifery point of view.  
MW4: And that actually has caused us a problem that, when um, there was a case conference, and someone assumed because the Family Nurse was a midwife she was okay to go to this case conference, and she wasn't, and it should have been somebody else, who went, so I think that did cause confusion  
MW2: (ah right)  
MW4: as to exactly what their role is. (MW, site Q)

The training available to Family Nurses, in particular around attachment theory, solution focused approaches and MI, was seen as particularly valuable.

HVLd: And um, I- I just feel that maybe we're missing a trick in health visitor training, we're not actually focusing on those key skills needed to engage parents and do strength based work, and looking at fathers and, and some of the um, parenting input that the FNP are doing ... health visitor training does not focus on that and I- I would say if we don't start addressing that, we're- we're going off in a big divide.  
HV3: Yeah. Absolutely. (HV site I)

However there was also criticism that FNs were not necessarily up to date with best practice across midwifery and health visiting because they did not have the prior training for these roles.

MW1: I have to say I have come up against a couple of problems where some of my girls are involved were given what really was midwifery advice by sort of you know (official) that were involved in the Family Nurse partnership and it were wrong advice and I found that a little bit of a battle sometimes.  
I: Can you give an example?  
MW1: Uhm one were to do with a lady quite early in her pregnancy who were bleeding and she were given totally wrong advice about what she should do. It didn't cause any problems the lady were fine and it turned out okay  
I: But that worried you.  
MW1: but she rang and I were on day off and she spoke to someone at the nurse partnership and she told her the wrong thing. I found that to be difficult on a couple of occasions. (MW, site G)



### **12.4.1.3 Views on implementation**

Prior to implementation, participants describe mixed reactions to the FNP with some seeing value in the programme and others expressing concern at the level of investment it involved.

- HV1: I- I was jeal- of FNs, really, that um, that they could spend  
HV3: Yeah.  
HV1: all that time with clients, and, and thinking that really this is what we should be doing.  
(HV3and4 agree)  
HV2: I think I felt quite excited, at the thought of it coming, um, (.) ((phone rings)) I had some dubious thoughts as well, around what some of my colleagues have been saying, um, interested to know really how the Department of Health and government have made a decision  
HVLd: Mhm  
HV2: to use this particular model.  
(murmurs of agreement)  
HV2: However, I feel that we have to start somewhere, I think, as a- as a nation, we do absolutely need a far greater input around parenting than we currently do. (HV, site I)

Where FNP was physically co-located with other services, implementation appeared to have worked better. In reflecting on what may have made FNP implementation easier, focus group participants suggested co-locating FNs with usual care teams so that informal opportunities for interaction could be facilitated. For example site N described the FN being based with Sure Start services and this was described positively as there was more effective interprofessional working.

- MW1: In an ideal world we would be having offices not far from each other, maybe sharing a kitchen and popping in and saying 'oh hello, how are you, have you seen so and so'. (MW, site N)

Where participants knew the FN, for example, if she was an ex-colleague, it was also easier for them to trust FNP delivery. Several participants spoke of colleagues and friends who had been recruited to FNP and they demystified and defended certain aspects of the programme. For example, they spoke of colleagues working hard, often beyond their regular working hours, and also described the 'learning curve' these colleagues went through in taking on the FN role.

### **12.4.1.4 Perceived impact on practice**

Caseloads for Midwives and Health Visitors providing universal services are large compared to those of FNP. Health Visitors, for example, describe caseloads of between 200 and 350, but these can also go up to 600 (sites N and J). In contrast, Family Nurses work with a protected caseload of 25. However, the need for smaller caseloads, given the intensity of the FNP programme, was recognised.

Only a proportion of the clients making up the caseloads carried by Midwives and Health Visitors would have met the criteria for inclusion into FNP. Consequently, these professionals did not experience much impact on their caseloads due to FNP involvement. There was frustration that an age band defined the FNP inclusion criteria, rather than criteria being needs led. Usual care practice is to provide services in response to client need, assessed by the Common Assessment Framework (CAF). Professionals increase the intensity of their input in response to this perceived need, and their expectation of FNP, which is based on intensive client input, was that high need clients should have access to it.

- HV1: We still see it that we're prioritising what we have always prioritised but we would have still given them more support and care because they would have been there and would have been under our noses.
- HV2: And we would have identified their needs.
- HV1: Yeah, we would have.
- HV3: It's the numbers as well, isn't it? You know, say there's three children in our area that are currently on the Family Nurse Partnership I can't believe that I would have noticed those three, you know, compared to all the other hundreds I'm trying to do.
- HV1: No, but you would have identified surely when they came through that the mum was 19 or 18.
- HV3: Oh yeah.
- HV1: So you would have just given them more support according to that need that you highlighted. (HV, site N)

This perception was underlined by participants' experience of working in areas of high deprivation and high pregnancy rates. Several of these areas were also multi-ethnic, a group that some participants thought were particularly vulnerable due to language barriers or previous experience of trauma. Participants also felt that deprivation was not necessarily an indicator of high need and gave examples of working in middle class areas where new mothers were perhaps more isolated than younger mothers.

- MW1: And very often, professional mothers are mothers without
- MW4: support
- MW1: without support, because they've, they've been say to university in (place name) and their mothers and their families are living in other cities.
- MW2: Or another country.
- MW4: Yeah
- MW1: Or another co- yeah and, and, they again- you do get lots of postnatal depression because they're struggling, without the support. The teenagers, there's a big family, extended family, round and you know ....
- MW4: I think in (place name) especially, the teenagers are generally very well cared for by their family. (MW, site Q)

Teenagers were seen as an important group to target particularly as it can be difficult for them to engage with services. Participants in site I described this in the context of the rural location with wide distances between services and poor transport links. Signposting services and helping young mums to access these was seen as a challenge arising from the geographical location rather than the particular client group. Participants also described the strengths of this client group, particularly linked with strong social and family relationships. For example, both site Ra and site Q were described by participants as areas of high deprivation but with very supportive families, and participants wondered if FNP might be better suited to some areas than others.

While there was some acknowledgement that FNP influenced everyday practice, for example, some participants described having to provide less input to FNP clients, participants generally experienced little impact of FNP. They did, however, see that the impact of FNP may better be assessed much later in the life of the family, mother and child.

- I: Does it affect what you need to provide for these women at all? Does it make your job easier if they have got a Family Nurse as well, or does it not make a difference.
- Group: I don't think that it makes a difference, really
- MW6: I think that it makes it a little bit easier, because I know that if I have had someone that's been on- having some more input, that they then don't have to go through breastfeeding in as much detail because they are more gelled up on it. I don't need to sit and worry if she

- knows what she's doing with sterilising, making feeds up, bathing babies, because they will have gone through it all with her.
- I: So you felt that you could capitalise on
- MW6: yeah
- I: Most of the others are shaking their heads. You don't really feel you (unclear)
- MW2: It varies with the individual, the client that you got really is- you can't do a broad, you know, scope, it's individualised. (MW, site G)
- MW3: I don't think the statistics that we get from the public health point of view it's not having a massive effect. There's a lot of other things- there's a lot of other things you can look at that, you know, but I don't think it has been massively affected, I think (it's more the case) (unclear) has been affected, I haven't seen any evidence that teenage pregnancy rate is dropping, (place name)'s got one of the highest
- MW2: But maybe it's too soon
- Group: yeah
- MW2: maybe it's early isn't it. (MW, site G)

#### **12.4.1.5 Views on Usual care**

Care as usual services varied across sites. Focus group participants described a range of statutory and non-statutory services that were available to teenage mothers. Some of these were well established, such as Connexions (sites, N, R), Barnardos (site R), or the Salvation Army (site Q). Some were contingent on funding that was available for discrete periods of time, for example, participants in site I talked about a Care to Learn type service that was funded for a year and able to offer free transportation across this rural location. Usual care services were augmented where local health professionals had a particular special interest, e.g., site R described a special interest group in maternal mental health coordinated by a GP and psychiatrist. There were also descriptions of different specialist roles that had been created in different sites. For example, site R had a specialist stop smoking advisor, and site N had a family visitor employed to offer practical support to higher need families. The inequitable distribution of services across the country was described by one HV as a 'geographical postcode lottery' (site I).

Focus group participants described usual care as understaffed, under-resourced and undervalued. They were experiencing a disinvestment in their services and therefore questioned the considerable investment in FNP. There were strong views that if resources were directed at improving existing services then elements of FNP could be integrated into usual care services to good effect. Focus group participants described their work as reactive, like 'firefighting'.

- HV1: It's like we're firefighting the whole time here, we're just seeing case after case after case and problem after problem and then it's very rare that we can sit back and reflect and I think that's a real onus to look back and see are you making a difference, are you doing what your trained to do.
- HV2: Yeah, I think at the moment our practice, well my practice, has become quite defensive actually. I'm busy thinking 'please, if someone kills their child make it look like it wasn't my fault'. Sorry, this is off the subject a bit but I think there's a culture that (provides)- but possibly off the point.
- I: No, that's very relevant actually  
((group laughter and unclear speech))
- I: to have to make this quite strong statement shows the emotion behind
- HV3: I mean every time the phone rings and it's children's services and you know it's not one of yours and it's a name you don't recognise you're like (unclear) ((group laughter)) not like 'oh

gosh, isn't that awful' and, you know, you do become like that, but it's like 'thank goodness it's not one of mine', that's really sad ... .

I: Yes, it is for you as professionals.

HV4: And for the families. It's not giving the service that we want to, it's not that we don't want to do it, we're just exhausted. (HV, site R).

This experience of usual care influenced the perception of staff about FNP, and a Midwife in site N described their service being like a 'poor relation' that had been 'abandoned'. In some areas colleagues were recruited to FNP and, while focus group participants described being pleased for their colleagues, this also meant they had to carry the extra workload while these positions were being filled. As the programme was getting started, efforts to promote it highlighted aspects of the programme that contrasted starkly with usual care services, such as the evidence base and investment of resources. Consequently, FNP was experienced as a threat, both to participants' perceived competence and, practically, to their resources.

It was like they were something better, and wonderful, and were going to offer a service, which was a bit of a kick in the teeth when we've all worked so hard. Uhm, it was almost as though, well, what we're doing is no good at all, but we're going to have these super nurses, that will then come in and work wonders, when they have even now tiny caseloads, compared to what we, what we've already said. (HV2, site Ra)

Participants also described routine services being in a constant state of change. There was some frustration that the essence of the FNP was 'old fashioned health visiting' and that, if properly resourced, the positive aspects of existing services could have been retained.

HV5: As you can see on my form I've been qualified for the longest out of everyone here and, you know, I have to say when we first started health visiting, this is what we were able to offer

HV1: That's what I said before.

HV5: and I think that's what is so sad, because like this is seen as gold standard and yet this is what years ago

HV6: It's old fashioned health visiting, isn't it really?

I: How long are we talking?

HV5: Well, I have been qualified thirty years as a health visitor.

HV6: I'd say even as far back as ten years ago this is what we did. We had the capacity to do the health visiting promotion, the time to visit family on a regular basis

HV5: build up that relationship

HV6: for maybe like four or five years. So we did do that, but we don't have the bodies on the ground. (HV, site R)

In looking forward, focus group participants could see ways in which FNP could be implemented to better complement the service that they offer. Some suggestions included widening the inclusion criteria, changing these criteria so that access was needs led, locating FNs with existing teams, strengthening communication pathways, and sharing resources, in particular the FN training and programme materials.

HV1: I'd like to see more integration and more working with us and using them, the fantastic ways in which the service- work with us and becoming part of our service, a real part of the service, you know, (unclear) really families that benefit can actually be put on and FNP can work with them not instead of us but with us.

I: So linking up

HV1: Yeah, linking up with other services, and it flowing a bit more than it does at the moment.

HV2: More flexibility.

HV1: Yeah

HV3: Make it more accessible as well.

- I: And from a health visiting point of view, what advice would you give other areas that might consider implementing FNP?
- HV4: More communication, I think, and, you know, I don't know what the plans are, you have hinted at something, but maybe some sort of sliding scale at the end of the two years so we are involved, so mums can put a face to a name, so they don't go from lots of support to none, from conceivably universally they could do. (HV, site Q)

## **12.4.2 Experience of the FNP-Usual care interface**

### **12.4.2.1 Referral to FNP and Building Blocks**

Midwives were the main professional group involved in referral to FNP and to the Building Blocks trial. For wave 1 sites the FNP was already established before the Building Blocks trial started, whereas for wave 2 sites the start of the FNP and Building Blocks happened simultaneously. Some participants reported not having referred clients to FNP much even when it was operational prior to the start of Building Blocks. For participants who had been referring to FNP, recruitment to the trial signalled a change in referral procedure. The change in procedure and the difference in referral criteria for FNP and the trial, was described as confusing. Site G, one of the lower recruitment sites, also reported lack of clarity about whether or not they were able to continue referring, and variable communication about this. Site Q had a high recruitment rate and Midwives at this site reported a system that worked well. The Midwives themselves were not necessarily involved in making the referral and they said this was something that had been changed over time to increase the referral rates.

Having materials such as referral packs and pens in particular, reminded focus group participants about FNP and Building Blocks. Participants reported that having materials to offer potential FNP/Building Blocks clients helped to standardise the procedure, and they appreciated having something to give the young person. They also described promoting FNP to young people during the recruitment process as a means of encouraging their referral.

- MW1: You know, a lot of girls are so overwhelmed by the time they get there, then they would agree to anything because they think that's what you want them to do. Others are blasé and don't seem to see what the fuss is about and they don't take all the information in and they need to go away and possibly there's an air of suspicion from one or two that this is a bit intrusive and you're doing this because I'm young and whatever. It's the whole spectrum of reaction really.
- MW2: But if you mention housing and benefits.
- MW1: Well, that's what's- what I'm saying to you, it's a way you promote things, isn't it, in a positive or negative, you know, 'this could be beneficial to you if you sign on the dotted line', it's all promotional, the way you do it really. (MW, site R).

### **12.4.2.2 Interprofessional working during the trial**

In general, the amount of contact that focus group participants had with FNP varied. For each professional group there were different time points when the need for communication was stimulated. For example, if Midwives had a concern during an antenatal visit, or when Health Visitors saw a client in their regular clinics, they would make contact with the FNP. FNs also contacted Midwives and Health Visitors, for example, to give feedback about a client or to ask advice. Where FNs were physically located in the same building as their midwifery or health visitor colleagues, communication was better as there were opportunities for informal conversations. However, communication was often not regular and

was complicated by difficulties in sharing client records. At the second round of focus groups some of these difficulties with information sharing seemed to have been addressed, however.

- HV: I think, um, there has been some change that's resulted in- obviously, the general computerisation, that now we can actually see entries on the computer that FNP nurses have made um, but-
- I: Is that recent, then?
- HV: Yeah, it's recent.
- I: Ah
- HV: Whereas before, that wasn't happening. So you would get someone coming to clinic, and you would have no background information about them at all, except maybe what's written in the red book, but that would be limited information and you'd have no family (information) or anything. (HV, site Ja)

Reports from focus group participants suggested that FN referral to other services was also inconsistent. For example, there were concerns raised by Midwives in site Q that FNP were not referring their clients to the Children's Centres and that this might prevent these young people from meeting other young mums. In contrast, other focus group participants saw FNs as actively supporting referral to local services and encouraging their involvement in social, education and leisure facilities.

Participants also that felt interprofessional communication pathways were unclear. While communication pathways were established with routine care services, such as when a client or their child was admitted to A&E, these pathways did not appear to be operating in the same way with FNP.

- HV2: and, um, I- I can't clearly see where the systems and processes are, around the key things like safeguarding
- HV3: Yeah.
- HV2: and for safeguarding it's there- doesn't seem to be a, anything formal set with a pathway about who you inform
- HV3: Yeah.
- HV2: and who you include, and at what point. Also things like accident and emergency slips, or
- HV3: Yeah
- HV2: hospital admissions etcetera, all of that information will come back to the health visiting team, and there's no process set up for how, how that would be shared, and who keeps the record, and record keeping generally because those clients, I'm discovering, will turn up at an ordinary health visiting child health clinic, for example, but we have to input that data and we haven't got any records held for that family anymore, in, in our teams, so um, I have recently raised that question, um, you know, where- where does- where does that all sit? (HV, site I).

Poor communication between FNP and usual care services was described as having an impact on the care that was provided to clients, and a number of concerns were raised about safeguarding practices. In site Q (MW) a safeguarding incident had escalated and a subsequent investigation highlighted the need for more robust communication procedures to be in place across the agencies involved with the case, including with FNP. A similar situation was described in site Ra.



### **12.4.2.3 Handover from FNP to usual care**

Clients end FNP contact either by choice during the course of the programme or when they have reached the end of the programme. In both instances, once FNP services are ended there is a handover process to Health Visitors who will continue to provide care as usual.

Where handover worked well, there was usually timely communication from FNP, a planned tapering of FNP involvement with clients, and a joint meeting to introduce the Health Visitor and to discuss key aspects of the client's care. However there were also difficulties experienced during handover, particularly in accessing written notes for clients.

- HV: Yeah, I've had er, quite a few of those, and um, what we usually try to do is do a joint visit, as a handover visit from the FNP to mainstream, um, often the families would know of us anyway, because (they'd) be coming to clinic, so, they'd made contact with us, but we'd still do that official handover. What I did find having difficulties actually getting the records from the FNP nurse, once they've ... . So they're sort of, you know, main records that way ...
- I: Did you get them in the end, or not?
- HV: I- I got them in the end, but it wasn't sort of within sort of er a timeframe of a week, or something, sometimes it could take, you know, a few months for the actual records as in their records to come through to us, but as I say, usually we did do er, try and do this joint (unclear) so you did get that background information up front. (HV, site Ja)

Concerns were raised about the intensity of service that clients were used to receiving from FNP that could not then be offered by universal health visiting services. Health visitors felt that it would be harder for them to engage with these young people and that some clients may then 'fall through the gap'. On the other hand, some Health Visitors felt that where FNP had worked well, clients would not necessarily need to be more robustly engaged with services.

- HV1: I've only worked with that one single mum, but from what my experience with her that was quite positive because she was in the programme for two years and she came out and, you know, she started college. She was- she had positive thinking and she had a positive future to look forward to, she was in college, she wanted to become a social worker, she wanted to do things for her child, she never got the opportunity, you know, and I thought that was probably the intense work (with FNP) and her parenting was brilliant.
- HV2: See now I've met both really, I've met a family that have come out of it into the universal and they've not really required anything, not really wanted anything um because they have been through the programme and at the end of it they're all sorted um they're getting on really well, but similarly I've met a family who were quite shell-shocked at the end of the two year process to find the service that we were offering um was so limited compared to the support that they had got [from FNP], but then I do think it is dependent on the success of how the programme has worked for that family really, isn't it. (HV, site N)

## **12.4.3 Experience of the Building Blocks Trial**

### **12.4.3.1 Communication**

Focus group participants generally reported needing more communication from the Building Blocks team. They described periods where communication was good, particularly at the start of the trial when they had contact with a member of the research team. Also they had received some information through newsletters. But this was inconsistent across the groups and it was not clear whether the information had not been received or if it had not filtered down to

team members. Participants were particularly interested in the progress of the trial, including the numbers of participants that had been recruited and what some of the findings might reveal.

- MW4: She does come, she came here did she come over from (place name)? I think she came over, we all got a pack, we all got our referral forms ((group laughter)) and a pen ((group laughter))
- MW2: We've not had anything since then. Did someone come from Cardiff came, yeah, we had somebody else from Cardiff came
- I: So there was some communication at the beginning
- MW2: Yeah, that's- but we haven't- seem to have much since, quite a lot in the set up before it started.
- MW1: I did have communication with them if they were to visit a lady to check that she was still okay in the pregnancy, so I have had a few phone calls for that to say to check the pregnancy was still ongoing and viable but that was in the beginning as well. (MW, site G).

#### **12.4.3.2 Experience of randomisation**

Some participants expressed frustration at the process of randomisation, particularly when clients they had spent time recruiting were not then allocated to receive FNP. This was seen as disappointing for the client. However, other participants felt they had explained the process clearly and so clients knew they had a 50 percent chance of receiving FNP.

- I: And you said that was something you found quite difficult and disappointing.
- MW3: Yeah, it could be if they needed the support. We sold this to them, some of them, you really did have to sell it to them and then when they do accept and give their consent and they don't get on it, yeah, it is disappointing for them.
- MW4: When you compare it to the one that has been accepted.
- I: So did you get any feedback from your clients, your girls, when you saw them again about- did they voice some of their disappointment to you?
- MW4: I think they just accepted it.
- MW3: yeah
- MW4: Truthfully, the ones that didn't get onto the trial, they just didn't get onto the trial.
- MW2: Because they didn't know probably what they were missing. (MW, site R)

A second frustration with randomisation arose when clients who focus group participants felt would really benefit from the FNP, weren't randomised to receive it.

#### **12.4.3.3 Awareness of which client was in the Building Blocks control group**

Many participants reported not knowing if a client they had was part of the control group in the Building Blocks trial. Some described a process of a receiving a letter or phone call and a sticker being placed on the case notes, however, a number of participants mistakenly understood that they were not supposed to know who on their caseload might be in the control group.

- HV2: I thought that we weren't supposed to know. Otherwise, if we knew that they were on the trial, um as, you know, what do you call it, as a placebo or whatever, then we may be treating them differently, us giving them a different service then perhaps our other caseload
- HV1: But in the first two years surely you're meant to, you don't know about them the fact that you don't know about them means you don't know about them
- HV2: I thought it was meant to be like that, we didn't know, thought (HV, site N)



#### **12.4.3.4 Contamination between intervention and Control arms**

The perceived secrecy of the FNP programme was a distinct theme through all the HV and MW focus groups. Participants felt that their own clients could have benefitted from the content of the programme, even if they themselves were unable to provide the same intensity of input. There was little discussion across these groups that suggested contamination between teenage clients receiving FNP and those receiving care as usual. It was acknowledged generally that teenage clients had pre-established friendships that might create potential for contamination. But participants also discussed the potential for FNP clients to be isolated from their peers.

HV1: I feel that there has just been this gap now for two years while they have been on Family Nurse and it's been handed over, and nothing prior to that. You know, it's not like a criticism, they're getting- they're getting really intensive support, that's really positive, but it just seems to be that

HV2: They're not part of the children, the weaning parties, baby massage clinics, they don't come to clinics ... . (HV, site G).

Also, there was little suggestion of a transfer of information between FNs delivering the programme and HVs or Midwives delivering care as usual. The secrecy about FNP materials, training and documentation was understood to be a function of the programme's license, or of the RCT.

The difficulties of it, sorry, being a research project was that it was kind of kept quite separate from mainstream health visiting ((murmurs of agreement)) which I understand, but I think probably from a public relations point of view didn't help greatly. (HVLead, site I)

There was one discrepant case where a HV had returned 15 months previously to a post of team leader after having worked as a FN for three years (site G). In this instance there was greater potential for transfer of information and expertise within the team, particularly as this HV was leading a team.

## **12.5 Discussion**

The views expressed in this chapter were voiced by a representative sample of the professional groups most directly involved in and affected by FNP programme delivery during the Building Blocks trial. Findings reflect the lived experience of these stakeholders and highlight perceived barriers and facilitators to FNP delivery and evaluation by the Building Blocks trial. The focus of the discussions was on professional roles as well as participants' general values regarding role-fulfilment, covering the three aims set out for this component of the trial Process Evaluation, i.e. describing programme delivery in the context of the RCT, pinpointing factors that might aid interpretation of trial outcomes, and illustrating issues relevant to wider roll-out of the programme.

In summary, the main factors affecting FNP delivery, whether during the trial or more in general, were seen to be workload pressures and work infrastructure, with potential threats to fidelity arising from the need to remain responsive to clients' individual needs and circumstances, including geographical location. The integration of FNP with existing services was described as presenting challenges regarding communication, lack of information, and perceived role conflicts as a manifestation of entrenched organisational structures. Experiences of trial participation were mainly discussed in terms of trial targets and procedures. Key findings are set out below.

### **12.5.1 Implementation of FNP within the Building Blocks RCT**

Our first aim was to identify factors affecting the implementation of FNP within the context of an RCT. Being part of an RCT was discussed as having an impact on practice in four main domains. First, trial requirements were seen to impede smooth working relationships between FNs, MWs and HVs when already established procedures had to be changed. Second, questions were raised whether the programme was being delivered to those who needed it most. Third, for FNs a focus on what were perceived to be less relevant trial outcomes led to a sense of being undervalued in their work. And, fourth, there was a clear realisation that transparency and information sharing would be key for future working across services.

#### **12.5.1.1 Referral and recruitment**

Although rigorous scientific scrutiny of FNP programme implementation in England was widely recognised as necessary and desirable, there were some areas where trial participation was described as having impacted negatively on working practices and programme delivery. In spite of the fact that the Building Blocks team worked effectively with local teams and with the FNP NU to identify referral routes into the trial and therefore into FNP, inevitably trial referrals involved a change in procedure for wave 1 sites which put some strain on interprofessional working relationships in those sites. Established referral routes directly into FNP could no longer operate and this caused frustration for professionals who had assessed clients as needing support yet could not now be assured that these clients would be offered FNP. FNs discussed how they had had to work hard to rebuild networks and relationships, especially with social care and midwifery services, an issue highlighted by the MW groups as well. Obviously, this was not the case in wave 2 sites where the first experience of recruiting clients was as part of the RCT, but there as well questions were raised about the effectiveness and appropriateness of the trial Local Researcher (LR) as the first point of contact for potential FNP clients. Some of these study-related tensions involved FN teams feeling sidelined in the client selection process, and, based on their own training, they questioned the LRs' ability to communicate well with the young people they had to deal with. In addition, LRs in some cases were thought to cause delays between referral and first contact as they only worked part-time, or were put in post too late. The initial trial interview, furthermore, was deemed too long and the questions too personal which FNs feared might have discouraged new clients from staying in the programme, although the trial's initial withdrawal figures do not support this supposition. Finally, FNs questioned the extent of the LRs' knowledge about FNP and wondered whether they would have been able to 'sell' the programme in a convincing manner. As some of these issues were recognised by the Building Blocks trial team as potential problems early on, steps were taken to involve local FNP teams where possible, but not all concerns could be addressed as conducting an RCT calls for prescribed *modi operandi*. Thus, for example, the LR in recruiting a participant to the trial could not advocate the proposed intervention, but only present an unbiased account of options. So, although FNs at times wondered to what extent they had been able to reach what they termed the 'right' clients during the period of the trial, their definition of 'right' may have been influenced by their training and their dedication to their work.

### **12.5.1.2 Randomisation**

Trial randomisation caused considerable debate in all the focus groups, with the emphasis on FNP allocations often going to 'wrong', i.e. lower need, clients. FNs felt frustrated when a young woman was prevented from accessing the service because of the trial, a view echoed by MWs who, moreover, felt disappointed if a client they had spent time recruiting did not then make it on to the programme. Focus group participants seemed to share a clear view that FNP was superior to care as usual, even though at the time there was no directly relevant evidence base for the effectiveness of FNP in England. There was an assumption that given the financial investment, which included enhanced training, more intensive personal contact and licensed programme materials, it would be better for their clients to be allocated to receive the intervention.

### **12.5.1.3 Trial outcomes and programme goals**

Interestingly, in questioning what they perceived as aspects of the trial design, the FN focus groups were in fact discussing programme goals. For example, FNs criticised trial (primary) outcomes, and in particular the focus on smoking and second pregnancies, as too narrow and unrepresentative, although in fact these outcomes are based on programme goals and are part of the underlying programme logic model. We would agree that it is not necessarily clear cut that a second pregnancy is a poorer outcome and that the issue needs to be discussed in the context of individual cultural and social values, but FN perceptions were that the trial was not measuring 'what their work was all about'. In a similar way, FNs sometimes commented on the programme monitoring system and the need to meet fidelity targets as trial requirements which to some extent impacted on their working practices. Taken together, there was a perception among FNs that trial outcomes, and even programme targets, were not sensitive to the real value of their work. This is an important consideration that could/should have implications for future evaluations of the FNP programme.

### **12.5.1.4 Sharing information with other health professionals**

A prevalent discussion topic in all focus groups was the perceived requirement for 'secrecy' regarding the sharing of FNP materials and information. For the MW and HV groups this reflected a degree of mistrust and suspicion which was rooted in uncertainties about their own job security and a perception of general disinvestment in their service. The need for 'secrecy' was presented either as a requirement of the RCT or as consequence of delivering a licensed programme with copy-righted materials. It was a clear source of frustration for FNs and other health professionals alike and was described as impacting on good interprofessional working relationships. The trial team did not at any time provide advice regarding materials or programme content but as part of their training FNs and FN supervisors would have been told that the FNP materials were for use in FNP only as they had not been tested in other contexts and might therefore not be appropriate. There may be a question here as to the insistence with which this message was put across in order for it to be upgraded in FNs' perceptions from recommended course of action to a prerequisite they clearly felt uneasy about and for it to be labelled as 'secrecy' with all the negative connotations that entails. It would constitute a key barrier to FNP integration with other services, but one which could easily be overcome with greater transparency and information sharing

## **12.5.2 Contextualising trial outcomes**

Our second aim was to capture factors that may have impacted on trial outcomes. We identified three issues that may be relevant when interpreting trial findings. First, reasons why clients might have chosen to disengage from FNP during the BB trial. Second, the skilfulness with which FNP was delivered by FNs was described as developing over time, so that clients recruited at a later stage of the trial or in wave 2 of the trial sites might conceivably have received a more practiced intervention from their FN. And finally, issues relating to contamination between trial arms were identified.

### **12.5.2.1 Client disengagement**

FNs commented on how it could become increasingly more difficult to engage clients towards the end of the infancy period as many clients would be back in work or had resumed their education. Generally, the period before and just after giving birth was seen as most 'productive' in terms of delivering programme content although delivery was always contingent on clients' practical needs and concerns, with housing issues singled out as frequently needing to be addressed. While acknowledging that they lacked detailed knowledge of FNP, some of the HVs and MWs saw the intensity and what they perceived to be the rigid structure of the programme as too demanding and thought this caused clients to switch to usual care instead. These would be standard features impacting on FNP delivery at any given time. However, longer term disengagement from FNP was also discussed as potentially resulting from clients' dissatisfaction with the trial over time, when telephone interviews were increasingly seen as too long and intrusive and initial incentives not particularly useful. While this may have affected only a minor percentage of FNP clients, any factor impacting on potentially less than complete programme delivery would still have to be taken into account when discussing trial outcomes.

### **12.5.2.2 Emerging skilfulness**

Most FNs taking part in our focus group discussions came from health visiting or midwifery backgrounds, but they described how they brought different levels of experience to their new roles as FNs. Some of them, especially in the wave 2 sites, mentioned getting additional training during the trial period and many indicated how 'learning on the job' remained a constant feature of their practice and referred to the value of regular supervision sessions and informal peer support as invaluable resources in that regard. The discussion of trial outcomes needs to reflect how programme delivery could potentially be subject to this type of emerging skilfulness.

### **12.5.2.3 Contamination**

During the trial, for FNs 'controlling' the spread of knowledge was not always possible, or even deemed desirable. For example, in situations where clients' friends happened to be present during FNP sessions there would be a natural transfer of information across young mothers, who might be in different arms of the trial. FNs had no way of knowing who was in the trial control group and in any case would want any young woman to benefit from the information that was provided as part of the programme. It was not possible, therefore, to prevent or monitor potential contamination across trial arms in this respect. In addition, in one of the focus group sites a FN went back to work as a HV, thereby again introducing a contamination risk as, based on her FN training and experience, she might have tried to deliver 'enhanced quality' standard health visiting. However, it seems unlikely that the action of one health professional not

working to programme targets or using programme materials would have made enough difference to influence trial outcomes in a significant way.

### **12.5.3 Wider roll-out of FNP: barriers and facilitators**

Finally, we aimed to document factors relevant to the wider roll-out of the FNP programme, and identified three areas that present both barriers and facilitators to this process. First, there is a perceived tension between programme fidelity targets, which can be experienced as constraining, and the needs of the clients, which could vary significantly. Managing the inherent challenges that arise when working across services, was a second area identified in our work. Finally, despite the potentially increased workload to effectively engage FNP clients, the attention given to this process of engagement was seen as a real strength of FNP.

#### **12.5.3.1 Focus on fidelity**

Whether as part of FNP daily practice, promoted by the FNP NU to keep the focus on programme content, or influenced by perceived requirements of the randomised controlled trial, a concern with meeting programme fidelity targets seemed to permeate FN discourse. Threats to programme fidelity, especially providing the prescribed number of sessions, were discussed in terms of missed or difficult to arrange appointments because of geographical spread, client mobility or chaotic lifestyles and were compounded by working conditions which were perceived as less than ideal, with poor infrastructure, outdated IT or lack of admin support at the time of start-up. Workload pressures were also mentioned as potentially influencing the FNs' ability to meet targets. Where there was a perception that Midwives singled out 'high need' clients for referral to FNP—entirely reasonable from the Midwives' perspective, who, in any case would keep such clients on their own caseloads—the discussion focused on how having many 'chaotic' or 'hard to reach' clients on FNs' caseloads would pose a threat to delivering the programme with high fidelity, even though, paradoxically, it would be exactly those clients who would reap most benefit from being in the programme. Participants seemed to find it difficult to marry the idea of offering a 'needs led' service, as provided by the Midwives and Health Visitors, with the requirement to follow fairly strict programme guidelines and reaching prescribed targets which is part of the remit of FNP.

This raises the question to what extent the concern with fidelity may be stifling some aspects of the FNs work, and in particular causing tension with the client-centred spirit of the programme. FNs expressed concern, for example, that all too often clients needed to talk about topics that were not part of the agenda for that visit, topics which had to be accommodated even if this was at the expense of meeting fidelity targets. If addressing their clients' very real needs is experienced as somehow 'failing' programme requirements perhaps a case can be made for allowing FNs a greater degree of discretion in their work. In contrast, MWs and HVs described having this flexibility to respond at the level of client need, but experienced a lack of time and resource to do this adequately.

### **12.5.3.2 Working with other services**

There were several areas where working with other services was seen as challenging, a perceived lack of communication and mutual uncertainty about roles impeded smooth working relationships. The need to initially raise awareness of FNP to allied services was described by FNs as time consuming although having had MW and HV leads involved in the original programme bid was seen as an advantage in this respect. Contact with other services was negatively influenced at times by the constantly changing service landscape. In addition, where FNs had been appointed from outside the local areas, insufficiently developed knowledge of and relationships with universal services could impact on FN workload as instead of referring clients FNs would sometimes try to find solutions on their own. Lack of awareness of relevant and locally available services could also have contributed to the perception of FNP as undermining clients' engagement with universal services that was voiced in some of the HV and MW focus groups and was reported in the Birkbeck-led Implementation Evaluation reports. However, most importantly, the discussion of the relationship between FNP and universal and usual care services focused on the tensions involved in integrating FNP with existing service structures given the programme's principles of voluntariness, the strength-based approach and the professional-client relationship that they saw as lying at the core of successful programme delivery. Although FNs considered it part of their task to help transform 'chaotic' clients' ability to develop trust through 'healing attachments', to teach them to accept help from and form relationships with universal services, they also felt that the underlying ethos of universal services was at times in conflict with FNP programme goals.

HVs especially focused on what they described as the disinvestment in usual care which left their service understaffed, under-resourced and under-valued. They saw this in sharp contrast to FNP which especially during the early years of the trial was seen to receive disproportionate funding. This rankled, especially when HV colleagues had been recruited into FNP, leaving HVs to carry extra workloads for a time. However, where usual care teams and FNP teams were co-located or communication channels between services were operating well, interprofessional working was described in more positive terms.

### **12.5.3.3 Client engagement**

FNs described what they termed the strong therapeutic relationship as one of the main factors for keeping clients engaged in the programme. Even though visiting could become more difficult after the birth of the baby, and especially in the infancy period when clients would feel the need for support less acutely and might have re-joined education or employment, disengagement was often with the programme but not with the nurse. General perceptions were that in many cases this disengagement could be overcome by keeping an open door, adjusting the frequency of visits and being flexible with programme content.

Differences in client education levels were described as potentially affecting knowledge transfer, both in terms of effort needed and time involved, but not as impacting on engagement, whereas ethnic diversity was seen to have no noticeable impact. However, 'cultural' diversity and family values and structures were seen to be factors potentially influencing engagement. Intergenerational patterns of behaviour were also described as potentially affecting programme efficacy but, where established, the FN's connection with the whole family, not just the client, was

presented as a strength of the programme. HVs and MWs commented on close family networks as either sources of conflicting advice or a strength which could counter high deprivation. Flexibility was deemed key to dealing with disengagement, whatever its cause. However, flexibility, an essential resource to engage 'hard to reach' client groups, and strongly valued by clients as evident from the client interview data (see chapter 12), could also greatly add to workload pressures. This was particularly the case in rural areas with high travel distances, which might suggest the need for different caseload targets in rural vs urban areas.

#### **12.5.4 In Summary**

The focus group discussions touched upon a wide range of issues related to the provision of the FNP programme in England as part of the Building Blocks trial. To some extent these discussions were curtailed by the research questions asked, and the reporting reflects the analytic focus on the most prominent themes. However, even within those limitations, the key findings provide an insight into FNP delivery at the time of the trial and highlight that future roll-out of the FNP programme can benefit from continued targeted communication with other services and the responsiveness towards clients' needs that is already such a large part of FN practice.

# 13 Views of FNP Clients

## 13.1 Introduction

Barnes et al.'s Implementation Evaluation of the FNP programme reported on the acceptability of the FNP programme for clients. They based their conclusions on structured face-to-face and telephone interviews with a sample of approximately ten percent of clients enrolled on the FNP programme in each of the three programme phases (pregnancy, infancy, toddlerhood). Their main conclusions were that:

- clients had a high regard for their Family Nurse, describing her as a good listener, approachable, non-judgemental and non-threatening, and that they felt accepted, supported and strengthened by their Family Nurse
- clients identified universal services as judgemental and reported that they felt excluded or demeaned by many professionals they came into contact with
- clients valued the learning aspects of FNP, especially as the information provided was often practical and quickly proven to be effective
- some clients found the programme too demanding (in terms of time commitment)
- FNP was acceptable to fathers who both participated in visits and enjoyed working with the materials and activities engaged in during visits
- clients felt they had gained confidence as parents and a greater understanding of their child
- clients felt empowered in their interactions with their child but also in their dealings with other professionals such as hospital staff, social workers and GPs
- clients described clear hopes and aspirations for the future
- most clients found the programme better than expected

As the FNP programme works with a structured curriculum, the Implementation Evaluation team also asked clients to rate FNP materials in terms of usefulness, presentation and general acceptability. They found that most activities and materials were remembered by at least some of the interviewees and that they were valued positively. However, throughout, it was the relationship with the Family Nurse and the recognition of her professional expertise, including the fact that information was discussed rather than just dispensed, that made the learning experience so valuable to them.

In this part of the Process Evaluation we aimed to conduct face-to-face semi-structured interviews with a sample of FNP clients to gain insight into their engagement and satisfaction with the FNP programme as it was being implemented in the trial. The Implementation Evaluation was undertaken some time before the Building Blocks trial and we expected some evolution in programme implementation since then, especially in wave 1 sites where teams and practitioners would have gained more experience and were likely to be in a more

steady state of practice. Furthermore, service delivery is unavoidably influenced by participation in a trial. For example, pathways for entering the programme will be different, clients may experience specific trial requirements as positive or negative and judge the FNP programme accordingly, or practitioners may feel they are under scrutiny from the trial team and adjust their practice.

However, although different in essence, there will be also be a degree of overlap between the work conducted during the Implementation Evaluation and the BB trial. Building Blocks FNP client interviews, therefore, are meant to augment rather than reproduce the work already completed in the Implementation Evaluation.

## **13.2 Methods**

The aim was to interview two FNP clients at all 18 trial sites at two different time points to capture initial and final, overall, impressions of the programme. The first round of interviews was scheduled to take place when clients had been receiving visits from their Family Nurse (FN) for 6 to 9 months, i.e. from three to six months after giving birth. The second round of interviews focused on clients who were about to graduate or had already graduated from the programme, with their first child around two years old.

To facilitate recruitment, FNs identified and approached potential clients. Once clients had indicated to their Family Nurse that they wished to take part, the FN passed her contact details on to the Building Blocks Local Researcher (LR) who then contacted the client to provide detailed information about the interview aims and procedures and set up a meeting. Written informed consent was obtained at the start of each interview.

Interviews were conducted by the Local Researchers who had, in most cases, originally recruited the client into the trial. A small minority of the Local Researchers already had previous experience conducting qualitative interviews but most of them did not. They all received training in appropriate interviewing techniques with follow-up training after the first round of interviews had been completed.

The interview topic guides were designed by the project team and piloted with three FNP clients who had already graduated from the programme. They were designed to leave maximum room for interviewers to explore three main question domains. For the first round of interviews these domains were: (i) how does the client experience the FNP visits, (ii) how does the client experience the FNP programme content, and (iii) how does the client experience being a participant in the Building Blocks trial. For the second round of interviews the focus shifted to (i) the client's experience of motherhood, (ii) the client's experience of being in the FNP programme, (iii) life after FNP, and (iv) research participation. While the interviews were designed to contextualise programme participation during the trial, they also left scope for identifying facilitators or barriers regarding future programme roll-out.

The semi-structured nature of the interviews was meant to provide clients with an opportunity to make their voices heard and to leave scope for elaboration on topics most salient to the clients' own experience. To assist the interviewers, Topic Guide Round 1 provided many discretionary follow-up questions or prompts whereas Topic Guide Round 2 provided main questions only, with interviewers instructed to aim for in-depth exploration of topics.

Interviews were digitally audio recorded and encrypted before being sent to Cardiff where they were transcribed verbatim. All transcripts were fully anonymised and content coded by the process evaluation researcher using NVivo 8 qualitative data software. Ten percent of the data was double coded by a second experienced qualitative researcher. An average of 97 percent agreement was achieved for the main level coding categories. Coding disagreements were discussed and resolved.

When presenting data, key quotes are identified with site ID, interview round (Int 1 or 2) and order of recording (01, 02, 03) in each round. Where narrative summaries of findings are presented, unattributed smaller quotes are often grouped together for illustrative purposes. Transcription conventions follow those set out for the Focus Group data (see Chapter 12). I=interviewer and P=participant

## **13.3 Results**

### **13.3.1 Interview overview**

Round 1 interviews took place between October 2010 and April 2011, with 34 interviews conducted in 17 sites. The average duration of these interviews was 29 minutes. Round 2 interviews were conducted between June 2012 and January 2013. The total number of interviews in this round was 27 across 14 sites. The average duration of interviews was 17 minutes.

### **13.3.2 Description of sample**

At the time the first round of Building Blocks interviews took place, the interviewees had been receiving the programme for about a year, on average, with home visits covering pregnancy and up to six months of the infancy period. The shortest experience of FNP was 6 months and the longest 14 months. Round 2 interviews involved clients who had already graduated from the programme or were on the verge of doing so. Time points for the second round of interviews ranged from two months before the child's second birthday, to four months following a client's graduation from FNP. Although we tried to interview different clients in each round so as not to overburden clients with trial demands, one interviewee took part in the first as well as the second round of interviews.

In spite of our aim to interview FNP clients in all trial sites, practical limitations meant that the full complement of interviews could not be achieved. By the time Round 1 interviews took place one trial site no longer had

clients in the requisite phase of FNP participation. In Round 2 the difficulty in finding volunteers who agreed to be interviewed meant that four sites failed to yield any interview data.

To determine representativeness, we compared our sample to the whole of the FNP cohort on age and number of home visits received. This was particularly important because FNP teams selected potential interviewees. The mean (SD) age for all FNP clients at baseline was 17.8 (1.21). The mean (SD) age at baseline for Round 1 interviewees was 18.3 (0.99) and the mean (SD) age at baseline for Round 2 interviewees was 18.0 (1.16). For the total of Round 1 and 2 interviewees the mean (SD) age at baseline was 18.1 (1.10). Comparing number of valid home visits throughout the programme, we found that the interview sample received a slightly higher number than the whole of the FNP group: Round 1 interviewees received an average of 43 visits (range 15-66), and Round 2 interviewees 42 (range 16-57). The average for the all FNP clients not including the interviewees was 38.1.

### **13.3.3 Main findings**

To do justice to the full range of issues discussed in the interviews, while keeping the focus on identifying potential facilitators or barriers re: participation and maintenance, this presentation of results is divided into three main sections: I. Contextualising participation, II. Contextualising engagement, and III. Impact of FNP. Each section provides a short introduction describing the constituent elements of these three concepts. Finally, there is a brief overview of clients' views on participation in the Building Blocks trial.

#### **13.3.3.1 Contextualising FNP participation**

To contextualise clients' participation in FNP it is useful to know how they came to be involved in the programme and how they experienced practical issues like home visit location and participation, planning and timing of visits, and the content of the programme as they remembered it. Also relevant is an overview of what clients expected from the programme and whether/how these expectations were met. The overview presented in this section is based mainly on information from the first round of interviews (covering the pregnancy and initial stages of the infancy phase), although, where appropriate, Round 2 data (toddlerhood phase/end of programme) have been incorporated.

##### *First introduction to FNP*

Most interviewees first heard about the programme from their Midwife (MW) who either gave them a brief description of what the Building Blocks trial entailed or handed them a leaflet about the study ('My Midwife didn't really say anything about it she just give me the leaflets ... and she just said 'read through as many as you can'. And that was how I got to know about it, she didn't really say much about it'). Many interviewees had little recollection of what exactly they were told about the trial or the FNP programme at the beginning. Some remembered the Building Blocks Local Researcher's explanation about the nature of the trial, i.e. the randomisation processes and the fact that they would be asked to take part in regular interviews. Others remembered being told about particular elements of the programme, for example, the frequency of home

visits and the promise of ongoing support. Only a handful of interviewees heard about FNP from someone other than their MW, i.e. a hospital nurse, Social Services, their grandmother (who was a hospital employee herself), or a friend. In a few instances, interviewees expressed surprise at how little other health professionals seemed to be aware of the FNP programme and what it could offer.

### *Expectations of FNP*

Initial expectations and subsequent experience of FNP diverged widely, with the majority of interviewees commenting on how the programme turned out to be much better than they had originally envisaged. Some had expected it to be boring, didn't relish the thought of a stranger coming to the house so frequently, or had been apprehensive about the programme being prescriptive. In practice, however, they found the programme enjoyable, they felt they got help and support as and when they needed it, and they appreciated the relaxed visits, the wide-ranging information, and the bond they had with their Family Nurse.

#### Key quotes:

'When I met (name FN) they didn't judge you, they kind of helped you along with it but they didn't tell you how you should do it, they almost let you figure it out for yourself, they didn't interfere.' (I-Int2-01)

'In the beginning I was thinking 'oh, I don't really want somebody coming round telling me what to do', but then, like when I started seeing (name FN) she wasn't like that, and I was really actually happy at that. When we used to have our visits I couldn't wait for them because she'd come by and then she'd tell me stuff that I didn't know about babies and I had, like, all these work sheets and, like, she'd give me information that I could read, and I found it really helpful.' (K-Int1-02)

### *FNP visits - Location and participation*

Overwhelmingly, the visits were conducted at the interviewee's place of residence, most often their own home. Family Nurse flexibility was evident, however, from the range of other locations that were listed, with the FN clearly accommodating the needs of clients' specific circumstances. Mentioned in this respect were the client's mother's house, a friend's house or public spaces like a coffee shop, a department store or a park.

#### Key quote:

'whenever I used to stop at (name boyfriend)'s it was, 'well, if you want, I can always come down to (name boyfriend)'s in the morning, if you're not at home'. So, yeah, she's really like, 'yeah, I'll come to you', instead of me rushing home.' (D-Int1-01)

Home visits were described as generally inclusive of anyone who happened to be present at the time. Clients reported the presence of partners/the child's father, members of their wider family (grandmother, mum, sister, aunt) or friends at some, though not all, of the visits. Interviewees commented on how their Family Nurse tended to draw others into the interaction, with special emphasis given to the inclusion of partners/child's dad.

#### Key quote:

'my mum always like talks to (name of FN) and (name of FN)'s like, she's really nice to my mum as well, they get on really good, and my boyfriend, well he, he's usually here, like, when he's not working, he's usually here and he'll, like, talk to (name of FN) and ask her questions ... so he likes it when he's off work and she's here because

he can ask her stuff, and um, like, he'll ask her about stuff like ... things that he- that makes him a better dad, like, 'oh, what should I do with her? Is this okay, is that okay?' (K-Int1-02)

### *FNP Visits - Planning and timing*

Planning and timing of visits was invariably described as flexible and driven by the client's needs and wishes. In that way visits became 'easy to fit in' and 'no problem' to organise. Visit length was described as ranging from half an hour to three hours and to depend on what the client's support requirements were at the time. Only one interviewee said visits were too long. Family Nurses were said to be punctual and not to mind if a visit had to be re-arranged or organised around clients' other commitments like work or college attendance. A few interviewees indicated that the frequency of visits did not quite suit their busy lives and that there was often not enough time in between visits to complete standard programme materials such as questionnaires or checklists. However, they also pointed out that, in spite of this, their Family Nurse's flexibility still allowed them to make best use of what the programme could offer.

#### Key quote:

'She arranged [the visits] the time she came before. She was really good actually, she arranged it around work, so she always came after I'd finished work but not straight after I'd finished. She waited until I'd got in and, you know, got a bath and had a bit of my tea, so that was real good.' (M-Int1-02)

### *Suggestions for improving home visits*

After six to nine months in FNP most interviewees offered no suggestions for improving the visits as 'everything is fine'. If anything, they would like to see their Family Nurse more often. A few issues did come up, however. One client said she would occasionally like to meet her nurse in a different, more convenient, location, although she admitted she had not actually discussed this with her and thought it would probably be no problem to organise. Two interviewees found the programme materials that came in the form of 'worksheets' boring as they were seen as repetitive and reminiscent of their school days. One interviewee would have liked more information for dads included in the programme (although, generally, inclusion of dads was commented on positively). One interviewee would have liked to be able to contact her Family Nurse at weekends, although most commented they could text their nurse at any time and she would always try to get back to them as soon as she could (there were no indicators in the data whether this included weekends as well). One interviewee would have liked to meet up with other families on FNP (although another reported this was exactly what her Family Nurse had organised for her) and one interviewee would have liked the number of visits to suit her own needs instead of programme frequency (whereas most reported that their needs were well met by the visits they received).

At the end-of-programme interview point, visit length was mentioned as a potential area for improvement by one interviewee. One interviewee commented on how she had found the frequent visits during pregnancy and after giving birth 'too intense' and suggested spreading out the visits more evenly over the duration of the programme. Finally, one interviewee thought the programme should be provided for older mothers as well. Most interviewees, however, expressed regret at the fact that their FNP visits had come to an end and wished

they could continue to receive home visits 'for another 2 years'. Across the two interview rounds, the prevailing perception was that during home visits clients' needs were met and their wishes respected as the following, more lengthy quote demonstrates.

Key quote:

- I: Is there anything that (name FN) could do that would make your visits better for you?
- P: Don't speak so loud ((laughs)), I don't know, I don't know to be honest, she, she, she's alright, I, I can't actually find anything wrong with what she does.
- I: Yea, yea
- P: Like sometimes she says things that I think 'ohh, get out'. (unclear)
- I: Like what, can you think of an example?
- P: Well, sometimes she can say, oh I don't know, sometimes, say it'll be about (name boyfriend) or something, like 'has (name boyfriend) found work yet' sort of thing, and then I'll see that as biting at me sort of thing. She's only asking a simple question, but because she knows that we're both on benefits, I don't want to be on benefits and neither does (name boyfriend), we both want to go out working. That's why I'm at college now, you know, and (name boyfriend) is like doing his sort of anger management, going into, hopefully trying to get into college
- I: Yea, yea
- P: uhm, you know, and it's sort of, like, sometimes I think, and I look at her and I think just because you've got a job, and just because you have a decent life doesn't mean you've got to ask me about mine,
- I: Mhm
- P: or his. Because it's nothing to do with you,
- I: Yea
- P: but then again it is,
- I: Yes, yea
- P: so, you know what I mean?
- I: Yes, I know what you mean,
- P: So I, I know where she's coming from, so I do sort of go to her 'oh, you know, shut up, I don't want to, I don't want to talk about this'
- I: Mhm
- P: and then she'll go, 'fine then, whatever' and puts her hands up, and then just gets on with the next thing you know. (O-Int1-02)

### **13.3.3.2 Programme content**

#### *Infancy phase*

Round 1 Building Blocks interviews initially asked a general question about what materials and activities were used during the home visits. The aim was to see which were best remembered and could therefore be deemed to have a longer term learning effect. Follow-up questions concentrated on likes/dislikes and perceived usefulness of FNP materials.

All interviewees said they found it easy to understand programme content. They commented on how the Family Nurse would repeat information for them, explain it in simple terms or break it down into smaller chunks. Clients reported that they felt comfortable asking their nurse about something if they didn't understand, as they knew the nurse would not think them 'stupid' or judge them in any way. Most interviewees also referred to the Family Nurse's use of charts, DVDs and models as very helpful (DVD and

model pelvis for demonstrating the process of giving birth; 'jelly babies' to show different stages of foetal development; dolls in different sizes to practise holding and bathing the baby).

Information sheets and leaflets, and discussing these with the Family Nurse, were most often mentioned as constituting the main source of knowledge transfer and learning during home visits. Next were the models of fetuses and babies used to demonstrate the process of giving birth and the subsequent care of the newborn baby. Interviewees also experienced the bringing of scales and the process of regularly weighing the baby, as well as the questionnaires about the child's development, as an important part of the FNP programme, with the resulting record of the child's development commented upon as a valued resource or future memory. Less frequently remembered, but still mentioned a number of times were (NHS) books with information on raising babies, children's books, toys and games for the baby brought along by the Family Nurse, DVDs with information on giving birth and breastfeeding, and the teaching of baby massage techniques.

Inevitably, specific materials and activities singled out as liked or disliked will to some extent overlap with those simply remembered as being part of the programme, and personal preferences and backgrounds will influence how elements of the programme were experienced. Nevertheless, when asked about dislikes specifically, most interviewees were at pains to point out that 'all is helpful'. They also saw it as very positive that during home visits they were consulted as to what materials or activities they wanted to engage with that day. However, for some interviewees, lack of time or a feeling 'like being back in school' sometimes detracted from the overall benefit they still felt they derived from the programme as a whole, while one interviewee commented on how it made her feel uncomfortable that her Family Nurse always insisted she be more positive about herself, as 'I am just not that kind of person'.

The list of activities and materials liked was long and varied, covering a wide range of programme topics. Aspects of the programme related to learning about the baby's development ('that heartbeat thing', the 'weighing scales') and about interacting with the child were described very positively. Similarly, activities and materials that helped clients explore and improve their role as parents as well as their own personal development were found to be very helpful.

When asked to summarise what they found the most useful aspect of the whole programme it was the close personal relationship with their Family Nurse, in addition to the factual information, that came top of the list. Especially the FN's role as advising, not enforcing, and the continuity of, in most cases, having the same Family Nurse for such an extended period of time were seen to be most beneficial. Negatives were only discussed in terms of personal reservations—frequency of visits that did not suit a personal lifestyle and repetition of information already known or perceived as no longer required ('advice or information about smoking when I'd already stopped').

*Toddlerhood phase*

Although not specifically asked to comment on programme materials, the interviewees who were close to the end of their participation in FNP referred to specific learning activities in their discussion of the programme as a whole. Naturally, they focused slightly more on programme items relevant to dealing with toddlers (potty training, coping with tantrums, how to get funding for childcare) as that was closest to their experience at the time of interview, but programme content from across all three phases, pregnancy, infancy, toddlerhood, was mentioned as useful, enjoyable or memorable. Thus, for example, the breastfeeding and labour DVDs were well remembered, as were the 'jelly baby' foetal models and the baby size dolls that were used to teach nappy changing or bathing techniques. In addition, interviewees remembered how they were taught to play with their child, they remembered advice on weaning and solid foods, and on how to baby-proof the house. Again, reference was made to the programme worksheets not only as providing helpful information but also serving as a record of the child's development 'that will be great for the future to look back on'. A summary statement from one of the interviewees, 'I seem to know a lot more about my child than people who are not in FNP', indicated that interviewees were aware of the impact their participation in the programme had.

Key quote:

'It's endless information that you always need, whether you think you need it or not. You always find out something new ... . It's like an extra support that isn't telling you to do stuff. They're putting it nicely sort of across, so you don't feel like someone is saying to you 'you're a bad mum', and you're going, 'oh okay, I never knew that'. (O-Int2-01)

### **13.3.3.3 Contextualising engagement with FNP**

This section combines views expressed during both the first and the second round of Building Blocks client interviews. Although some of the reflections presented here are not specifically FNP related, they focus on clients' life circumstances and how these may have influenced their initial and continued engagement with the programme.

### **13.3.3.4 Clients' experiences of pregnancy and motherhood**

#### *Within six months of giving birth*

Most interviewees reported that initially they were scared, worried or uncertain when they found out that they were pregnant. Some even reported plans to give up their child or to have an abortion. Only a few said they had always wanted to be a mum and that child rearing 'comes naturally' to them. All, however, reported that they now enjoyed having a baby, and that, although it may have been hard at first, they had now grown into the role.

Key quote:

'I was already pregnant four months when I met (name of FN) ... . I came to a point of terminating my pregnancy, I mean I was going to talk to my husband and everything ... but she in (a) way changed my mind, but not in a bad way. You know, she just said to me, 'you've (already) come to this point'. It's nice because she thought I was able much more than I think and she boost my energy and boost my inner, you know, strength and I went 'oh my god, I really can do it'. And I done it. And it's brilliant. I love her now.(O-Int1-01)

#### *When child is two years old*

Round 2 interviewees, looking back on approximately two years of motherhood, often mentioned that being a mum was hard work and could be stressful but that it was also hugely enjoyable and very rewarding. Often a potentially negative description was counterbalanced by a positive one ('tiring but nice', 'challenging but the best thing I've ever done'). In addition, negatives were often explained in terms of specific and occasionally trying child behaviours rather than as experience of motherhood in general. This ties in with the manner in which clients described how becoming pregnant had changed their lives, as discussed in the next section.

#### **13.3.3.5 Life changes occasioned by pregnancy**

Also in the first round of interviews, when asked how becoming pregnant had influenced their lives, many interviewees voiced their experiences as a negative-positive dichotomy ('more friends and better social life, but can't do as many things as I used to do', 'you grow up in an instant, but I had to stop working', 'fell out with boyfriend but continued college'), the juxtaposition serving to underline their awareness of the change experience. Most interviewees also reported how these changes, while radical, were often for the better ('now more settled and happy', 'it focused my goals, I am now in college and got my own flat'). Of course, there were a few who saw the increased responsibility as irksome ('life is harder with a baby') but overall, although disruptive of previous lifestyle, motherhood was described as a positive experience and clients often portrayed themselves as stronger, more mature, more responsible.

##### Key quotes:

'being pregnant, and, like, having a baby now, it's just made me feel much more responsible ... . I'm really serious about my life now and I'm going back into education and, you know, finish off a course, and then get a job. And, you know, it's just, I don't know, it's like- it's like there's so much on me, because I'm, like, obviously a single mum and it's, like, there's so much on me, and my daughter's going to be depending on me at the end of the day.' (J-Int1-01)

'if I didn't have her then I probably wouldn't be where I am now, like the GCSEs that I got, for example, I wouldn't have them. I would have probably crap GCSEs, well, not crap, probably like Ds and everything, but I haven't. It did it made me knuckle down, like really, loads because, I don't know, I kind of wanted to prove everyone I wasn't gonna be like a stereotypical young mum sort of thing. Because everyone sort of expects young mums to be like diabolically rubbish, but I tried to prove them wrong, and I have.' (I-Int1-02)

#### **13.3.3.6 The FNP and the client's social network**

Clients reported varying degrees of access to social support networks. Some interview discussions revealed how clients initially had only their Family Nurse to support them, while others indicated frequent and wide-ranging contact with partners, family, and friends. At the point of graduating from the programme most interviewees indicated they would mainly be relying on close family and partners for support. A few would turn to friends and only two mentioned their Health Visitor or GP as their first point of contact if they had questions or were worried about their child. When clients talked about FNP to those in their social network it was mainly to explain how the programme worked or to pass on information they had been given by their Family Nurse as advice to other young mothers. The client thus became an FNP advocate and the information provided to one client could have a wider impact in the client's social network. Only a few of the interviewees

said they didn't talk about FNP to their friends as, for example, 'younger friends are not interested and older friends are too busy'. In general, reactions from others to the client's participation in FNP were very positive. Especially mothers and partners, as well as members of the wider family, were reported to comment on how much the programme was benefiting the client.

In addition to discussing already existing personal support networks, clients referred to the role the Family Nurse played in directly facilitating contacts with others, such as mother-and-baby groups at the local Children's Centre or other FNP participants who happened to live in the same area. Clients commented on how they enjoyed meeting these new contacts and how they valued the friendship and support from their peers. Facilitating contact with other FNP clients was suggested as a way to improve the programme. In Round 2 one interviewee described in detail how FNP participation had been instrumental in creating and maintaining the social support network she had gradually come to rely on.

Key quote:

(...) when I look back at what I wrote in the first folder (...), it's really shocking to now, I was like, I- I wouldn't have said like, you know, I wouldn't have gone to all the different groups, and I think, (name FN1) and (name FN2), they're both of them, they really encouraged me to go to the Sure Start groups, and I met all my friends there. So I'm really glad I did because now I've got like a handful of friends, really good friends I can rely on, like, you know, and they always look after (name baby) for me if I'm stuck, and they always pick me up if I'm- you know, if I can't afford fuel, so actually they've, they've kind of made me have a lot friends in (place name), whereas when I first started it, I'd only been living here perhaps a year, so I had no friends, no family here at all so, they were kind of like, well, I suppose they were like part of the family. I could've moved (name FN) in, really, come and stay with me! ((laughs)) (I-Int2-01)

### **13.3.3.7 Clients' experience of their time in FNP**

This section focuses on how interviewees voice what taking part in the FNP programme means or has meant to them. It is less about the practicalities of visits or the relative merits of specific knowledge gained, although these may of course have played a role. It is about constituents and evidence of change in clients' lives as well as their assessment of skills and qualities gained as a result of being in the programme. When asked at the end of programme how they would describe FNP to other young mums, interviewees overwhelmingly stated that they would greatly encourage others to join for the support and information it provides.

Key quote

'You get to be able to ask all the questions that, you know, some family can't really answer for you. And just- I just find it- I found it so helpful where, the way I was feeling, I could talk to somebody about- who could give me information, to help me with how I feel, and, and also, like, pregnancy classes, and parenting courses. You can ask anything like that with them, and you don't get judged either. So it's nice, you can sit there and be yourself and just tell them how you feel, your fears and your excitements about having your (unclear) having (baby's name). So, yeah, it was just really nice. It was also nice that the dad gets to be able to talk and say what his (worries) are and just get a chance to be involved, a lot of- with everything, so, yeah it's [all right].' (A-Int2-01)



### **13.3.3.8 Relationships with health professionals**

#### *Relationship with Family Nurse*

##### Key quotes

'She's not someone that's just coming round to put information into my head, she is there to talk about everything.' (D-Int2-02)

'She cares about you and the baby and it's not just her job, like.' (J-Int1-02)

Across both rounds of interviews the client's relationship or bond with her Family Nurse stood out as the key issue in making the impact of the FNP programme profound and lasting. In almost all cases, Family Nurses were described as having a great personality, being trustworthy and supportive, available and approachable, showing a good sense of humour and being very easy to talk to. FNs were seen as non-judgemental and caring, a friend or family member rather than a nurse. Their style of communicating, as experienced by the clients, fits the Motivational Interviewing approach incorporated into the FNP programme in England (see report Introduction section). There were references, for example, to how the Family Nurse accentuated the positives ('turning negatives into positives') and always tried to 'present a balanced view'. Clients appreciated how 'she asks our opinions', 'allows me to set the terms for the visits' and 'makes me feel positive about my life, baby and marriage'. Throughout the data there were references to how the Family Nurse's support helped to build up self-confidence. In particular, getting confirmation from their Family Nurse that what they were doing as a parent was alright was described as an empowering experience.

Family Nurses were portrayed as being personally involved with the client and her family ('they know you so well') which gave the client the reassurance that they matter: 'she cares about me, she phones me and checks in with me', 'my Family Nurse gets excited about the baby putting on weight', 'we talk about each other's families, she is a mother herself', 'even though she no longer visits we keep in touch by Facebook' (after graduating). The positive nurse-client relationship was also expressed by the interviewees in terms of the scope and availability of the support on offer: 'she is just there for us, we can ring any time', 'she does anything she can to help', 'she talks a lot and uses posh words but makes sure I understand, she is always available when I need her', 'I chat to her between visits as well, this stops me worrying'.

In summary, the Family Nurse was described as a valued and trusted friend, a professional with a human face, someone the clients felt comfortable with and whose advice they were therefore eager to accept. Throughout the total data set there were only two instances where the relationship with the Family Nurse was described in less favourable terms. In one case, a client was assigned a new nurse when the first one left FNP and the interviewee felt that although she had had a very strong bond with her original nurse, she could never quite feel the same about the second one. Another interviewee mentioned falling out with her nurse over a personal matter but then also indicated that the positive relationship was restored over time.

### *Relationship with other professionals*

In contrast, interviewees reported more negative experiences dealing with other health professionals. There was a sense of Midwives or Health Visitors having 'no time to go beyond their job', and at the most basic level clients report not being listened to ('they're not really interested', 'my GP does not respect anything I say, he doesn't care, doesn't listen', 'the Health Visitor keeps putting me down, keeps judging me and making rude remarks, she talks about the baby being underweight and says I'm not feeding him properly'). Perhaps not surprisingly, contacts with other health professionals were defined by how they differed from contact with the Family Nurse and, invariably, this difference was described in negative terms. 'The hospital says we're doing things wrong, the Family Nurse says we're brilliant parents', 'the GP gives you something to fix the problem, the Family Nurse gives advice', 'the Midwife visits are just check-ups, there is no time to talk about what is happening in the world and with me'. Clients said they felt uncomfortable, even 'stupid' for asking their Midwife or GP questions and they also felt that they were being given conflicting information. However, interviewees recognised that the lack of regular contact, with the consequent lack of a personal bond, influenced how they felt about these contacts with health professionals other than their Family Nurse: 'I am not so familiar, don't feel safe to talk', 'Midwives have no time to provide the level of contact they might want to give' which could explain why, generally, the frequency of the FNP visits is described as being valued highly.

The fairly negative assessment of contact with health professionals other than their Family Nurse also came through in the discussion of where clients would turn for support when they had come to the end of their engagement with the programme. Most clients were aware that the support and care role is passed on to a Health Visitor, but some seemed sceptical as to the value of this service: 'Health Visitors are useless for advice, won't bother contacting them', 'I would only contact the Health Visitor if I had to'. Some described alternative ways of seeking information or support: 'I will rely on my own judgement but when it's really bad I'll go to the doctor's or A&E', 'I will look on the internet for information', 'I rely on FNP information in my folder'. The implications of FNP visits coming to an end were felt: 'it's going to be difficult without the Family Nurse', '(name child) will miss her coming round', 'I'll be lost'. But there was also a recognition that FNP participation had put them in a position where they could seek support on their own terms: 'before FNP I wouldn't have gone to a Health Visitor, I didn't trust them, I am now confident enough to contact her', 'the Health Visitor hasn't been in touch yet but I'll try and talk with her'. Finally, four out of the 27 participants in the end-of-programme interviews said that in spite of having an allocated Health Visitor they would still ring or text their Family Nurse if they were worried about their child's health.

#### **13.3.3.9 Hopes and goals after FNP**

One major aim of the FNP programme is to encourage clients' aspirations to build a better future for themselves and their child. The end-of-programme interviews explored clients' dreams and wishes to improve their lives. Hopes ranged from a short-term and modest 'get (name child) to sleep in her own bed' and 'treat myself a bit and spoil my child' to longer-term and more ambitious 'teach (name child) respect and morals and turn him into a good person'. Many interviewees had made plans to start or resume college or university, or

had already done so, others referred to getting their child properly educated, starting with a good nursery place in the very near future. Most often, the locus of these aspirations was the child, while the agency lay with the mother: 'I want to keep up (name child)'s level of development and build up his confidence', 'I teach him to be independent', 'I want her to be happy and healthy'. Clients discussed how they wanted to be a role model for their child, how they wanted to keep growing as a family, and how their own development (going back to work, passing driving test, getting own house) would benefit their child. Only one interviewee indicated she had not given the future much thought.

When asked whether personal hopes and aspirations were influenced or shaped by taking part in the FNP programme, only five interviewees said that this was not the case. Others described how it was their Family Nurse's advice and encouragement that helped them focus on what they wanted to achieve: '(name FN) always talked about how hard it is to have no qualifications and no job, I don't want this for my children', '(name FN) taught me how to encourage my baby's development, emotionally and mentally, he can become independent', 'I always knew what I wanted for my child, FNP taught me how to, I have more an idea of how to do it', '(name FN) encouraged me with anything I wanted to do, including going back to work and college', 'my FN taught me how to save up if I wanted to achieve certain goals'. Again, while highlighting particular elements of programme content, interviewees singled out the personal bond with their Family Nurse as providing the main impetus for making positive life choices.

#### **13.3.3.10 Reflections on ending FNP**

These summary reflections on the impact of FNP were taken from the Round 2 interviews with clients in response to a request to look back on the whole of the programme. Interviewees were not prompted specifically to mention negatives or positives, just to reflect on their general experience. Many of the reflections focused on expressions of self-belief and self-efficacy in two important aspects of the client's life, her parenting skills and her personal and emotional development. Both aspects are captured in comments like 'I am really good at setting (child's name) routines and I'm confident now also about resuming my studies', 'I learned how to take care of (name child). Now I'm pregnant again and I know it will be okay', 'I have learned to understand children, this helps in my work'. The focus on more confident parenting skills in particular came through when an interviewee pointed out how because her interaction with her child had been a lot calmer 'he (now) seems months ahead with his speech'. A few interviewees mentioned that they felt much better equipped to look after their children when they were ill, one said she had learned the skills to 'build' her child to be 'a really good kid', and another reported how she had had no problems tackling potty training on her own when her Family Nurse had been away for a few weeks. Personal and emotional development was evident from references to better anger management and improved mood and stress levels. Interviewees also mentioned increased contact with other people and, sometimes, services ('I learned to trust other people like doctors', 'her encouragement to go to Sure Start groups gave me lots of new friends', 'I'm now part of a support group for other young mums and gave a presentation there last week'). They expressed a general sense of strength and a belief in their own abilities ('I don't think I would be as, like, good as a person, as a

mum, what I am now', 'I learned to stand up for myself', 'I learned how I can still be myself, not just a mum', 'I am more confident now about asking questions, I know my child', 'It's made me who I am today, I ask questions and don't worry if I sound stupid').

The impact of the programme was described as wide ranging and in this group of interviewees there were no dissenting voices as to its overall efficacy. Although, of course, the levels of engagement with the programme differed, each client reported it had been helpful in some way. Some saw FNP as important and life changing while others felt it served more to consolidate skills and qualities they already possessed. All, however, endorsed it as a valuable resource for young mothers and families who might otherwise struggle to care for their child in the best possible way.

### **13.3.4 The Building Blocks Trial**

#### **13.3.4.1 Confusion: Equating BB and FNP**

One issue relevant to both interview rounds was that in spite of the interviewers' best efforts to explain the difference, participants found it hard to distinguish between FNP, the home visiting programme, and Building Blocks, the randomised controlled trial studying the programme. Comments on Building Blocks participation often (though not always) reflected how participants felt about taking part in FNP.

#### **13.3.4.2 Trial participation**

##### *First contact with BB*

In the first round of client interview participants were asked how they first heard about the Building Blocks trial and what they could remember being told. Generally, recollection was vague. Most interviewees remembered some elements of what they were initially told ('it's a 50-50 percent chance', 'you need to be under 19/under 20', 'it was all confidential') but even then the confusion about what was Building Blocks and what was FNP was obvious: 'it was research and a help to young mums', 'Building Blocks helped me see being a young mum isn't so daunting'. Many recalled meeting the Building Blocks Local Researcher at the start of the trial but, perhaps not unsurprisingly, only about ten interviewees manage to provide a short but comprehensive description of the wider aims and goals of the study.

##### *Likes and dislikes*

Any likes or dislikes about the study are difficult to tease out as many interviewees are clearly transferring their positive feelings about FNP when asked to evaluate trial participation. Most interviewees therefore reported there is absolutely nothing they disliked about the study with a few instances of positives being described in terms of 'it is exciting helping to make a change'. However, some positives about trial participation were specifically mentioned, the birthday presents sent to their children at the first and second birthday and the high street vouchers they received as a thank you for agreeing to take part in trial interviews. In addition, clients commented on the fact that trial staff were friendly and polite, and that the telephone interviewers were very flexible in arranging convenient times to call. Although some interviewees found the

telephone interviews a bit daunting ('all the questions bamboozle you a bit', 'I could not remember how often I seen the GP') or struggled to answer sometimes ('the questions were not always relevant for me', 'I felt I didn't know what to say'), and one thought it 'weird doing them over the phone', others reported it made them happy to do the interviews as 'it was someone taking an interest'. The only negatives that were voiced, sometimes only after prompting by the interviewer, were the fact that 'no one knew about it (i.e. the study) when I was in hospital', a few references to interviews being too long, and one instance where the client did not like the Local Researcher asking her about smoking and drinking habits in front of her mum. Generally, clients' reactions to all aspects of trial participation can be summarised in the often voiced 'it was fine, it didn't bother me'.

#### *Reasons for participating in BB*

Interviewees agreed to become part of a research study mainly because they thought it would be helpful to others and it made them feel good to be part of something. Also, they reported that they felt they had nothing to lose, or they simply described themselves as being up for trying anything new. One interviewee saw participation as an opportunity to voice her opinion as a young mum and another said she would have liked to feel more involved in the study. All interviewees found the study worth doing and many said they would take part in research again.

## **13.4 Discussion**

### **13.4.1 Interview findings, programme aims, and previous research**

When relating the interview findings to the processes involved in achieving the three main goals of the FNP programme, the NFP Theory of Change Logic Model provides a useful framework for discussion. The first goal of FNP is to improve pregnancy outcomes. In the interviews women reported being made aware of and endorsing better personal health behaviours. The detailed information about foetal growth and development, as well as the extensive preparations for giving birth, provided to them by a health professional they trusted and liked were seen to be beneficial in alleviating anxiety and enhancing self-confidence. Taken together, these factors can only contribute to improved conditions for safe delivery and subsequent nurturing of the infant.

The second goal of FNP is to improve child health and development. Overwhelmingly, interviewees referred to having gained better insight into how to form attachments with their child, including how to stimulate their child's development, and how to take care of their child in general. In addition, they had come to see themselves as empowered and confident parents who were in the best possible position to enable their child to have a healthy and fulfilled life. The third aim, improving parental life course, had also been addressed, at least for the group of FNP clients interviewed for this Building Blocks study. Most of the interviewees reported

the wish to continue or resume their education, or attempt a return to work, and many had already attained these aims.

Findings from the Building Blocks client interview data are consistent with the key messages set out in the Implementation Evaluation reports. It can be argued that the two studies overlap to some extent, especially in overall aims and methodological approach. However, in the earlier study the main emphasis was on reporting the acceptability of the FNP programme for clients whereas BB client interviews intended to explore client engagement with FNP, what may have influenced that engagement and how delivery of FNP within the context of the trial may have influenced such experiences. There are further differences in that Building Blocks focused on trial participants only, not programme leavers, and had a smaller sample of interviewees overall. In addition, half of the BB sites had been delivering FNP prior to the trial, while the other half were delivering it for the first time. This may have potentially influenced clients' experiences of the programme during the trial. The earlier study did not have to take such influences into account. In the light of these differences, if the later findings in essence substantiate the earlier ones, it can only mean that general acceptability of the programme has remained constant.

#### **13.4.2 Strengths and limitations**

A particular strength of the BB interview study was that the topic guides left scope for uncovering a wide range of client experiences regarding participation in both the FNP programme and the trial. As the interviews were semi-structured to in-depth in nature, participants had the opportunity to freely voice their opinions and make their voices heard. Being listened to and having their opinions appreciated was described as particularly valuable and empowering by clients in describing the interactions with their Family Nurse. It stands to reason that being taken seriously as a trial participant by having their views sought in a personal interview would have a similar effect.

In addition to reporting clients' experiences, the insider perspective was further explored by comparing focus group (Chapter 12) and interview data. Diverging views often help to illustrate the complexity of everyday practice. For example, FN flexibility regarding location and timing of visits was greatly valued by clients but was discussed in the FN focus groups as potentially adding to their workload and out of hours work. Clients experienced flexibility in home visit content as positive and conducive to longer term engagement with the programme. However, FNs discussed agenda matching, in which they aim to match FNP programme content with what the client wants to focus on in the session, as a challenge and described how they sometimes felt the need to impose visit content to achieve fidelity. In a final example, the role of family support, seen as essential by clients, was presented as a potentially negative influence by HVs and MWs. In contextualising the Building Blocks trial outcomes, it is necessary to keep these multiple perspectives in mind.

The study had limitations too. In particular the interviewee selection by FNP nurses which, although we realised it introduced the risk of selection bias, was meant to protect vulnerable participants from any anxiety

that the prospect of being 'examined' in an interview might bring. It was also a practical way of ensuring that we would be able to find enough participants. We had no control over the possible recruitment of potential interviewees for their positive opinion of the programme, and it seems logical to assume that clients the FNs had a good relationship with would be more likely to give their consent for being interviewed. We tried to assess the bias associated with included interviewees and how they might differ from all FNP clients by comparing both client age and the number of visits they received throughout the programme. There were differences in that the interviewee sample tended to be slightly older, although only to a degree that could be considered negligible. However, they had also received a higher number of FNP visits which may indicate a stronger engagement with the programme overall. Not all sites were fully represented at both time points. Reasons provided for this were absence of eligible volunteers as a result of interview timings and the difficulty – also reported in the focus group data – of keeping clients engaged towards the latter part of the programme when life circumstances such as a second baby or a return to work/education put demands on clients' time.

Finally, to enable interviews across all trial sites, local research staff were trained to undertake this task. Research staff were mostly clinically trained and had previous experience in structured data collection from the same trial sample. The semi-structured topic guide used for the first round of interviews was intended to support data collection by relatively less experienced qualitative researchers. This appears to have been borne out with longer average interviews in the first round. The second round interviews were differently structured to allow more responsive questioning from researchers who, by that point, would have accrued more interview experience. However, the observed duration and depth of these second round interviews probably means that some topics could have been more substantially explored. This is not likely to have a bearing upon what would be concluded from the interviews but does indicate that more in-depth questioning may yet provide a more detailed understanding of client experience.

### **13.4.3 Trial participation**

There are two observations about trial processes that are also worthy of comment. First, one interviewee reported discomfort about trial data collection about sensitive topics in front of her mother. All trial participants should have been asked permission at the start of the trial data collection process. Even if this occurred, it may be that the participant felt uncomfortable with subsequently asked questions. It is important to reinforce for researchers collecting data in this way the need to be aware of such sensitivities and signs of discomfort from participants, and to intermittently check that participants are happy to proceed. For some elements of data collection (e.g. items about domestic abuse) automatic prompts in the interview schedule ensured that highly sensitive items were skipped if other people were present.

Second, interviewees reported sharing knowledge gained through the programme with peers, including other young mothers. We are interested in the potential for contamination, that is, where participants in the Control arm are also exposed to the intervention. The most direct and comprehensive example of this would be if Control arm participants were enrolled formally to FNP. This did happen in a few cases as described in Chapter

3, although the numbers were very small and therefore unlikely to be important to our conclusions. Where Control arm participants are recipients of information from Intervention arm FNP clients (as could be possible in the descriptions above, although not confirmed) this is unlikely to have any real equivalence to being enrolled into FNP. Indeed, the most powerfully expressed sentiment from interviewees about the programme was the importance of the personal relationship with the Family Nurse. That relationship, and the receipt of the full scheduled programme were highly unlikely to occur for participants in the Control arm in this trial.

#### **13.4.4 Implications for further roll-out**

Facilitators for FNP participation and engagement were the strong personal bond that most interviewees develop with their Family Nurse, the therapeutic relationship that lies at the heart of the nurse-client encounter. In addition, the strength-based focus of the home visit interactions greatly enhanced clients' sense of self-worth which in turn increased their confidence in 'doing the right thing' for their child and their motivation to be a good parent. The fact that clients had a say in what topics were discussed during visits (agenda matching), as well as the nurses' flexibility in arranging visits around the clients' needs and commitments made for a non-prescriptive, non-intrusive learning experience which put the client in control and thus stimulated continued participation. This ties in with other publications<sup>155</sup> which describe how flexibility in scheduling and content to match the clients' needs showed promise as a means of reducing participant attrition and increasing completed home visits. Finally, the information the FNP programme provided for young mothers was invariably described as useful and helpful, even to the extent where some interviewees took on the role of passing on knowledge to friends who were pregnant or young mothers themselves.

Barriers to engaging with the FNP programme were evident from the interview data were often in the personal domain and dependent on circumstances particular to individual interviewees. Some women found they had sufficient experience from looking after younger siblings or other children, or felt they had enough support from their partner and immediate family. Others were so caught up with work and, by the time of the second round of interviews, raising a second child that they felt they simply could not make time for FNP visits. However, while expressing that they did not need, or did not have time for FNP, they often commented on how they still enjoyed meeting up with their Family Nurse. This then informed their decision to continue their engagement with the programme overall.

# 14 Within-trial Economic Analysis

## 14.1 Introduction

The Family Nurse Partnership (FNP) programme is an intensive, nurse-led home visiting programme for young, first time parents who live in areas with a low socio-economic profile. This programme was developed in the US and was introduced in England by the Department of Health in 2006 with the aim of improving outcomes for health, well-being and social circumstances of young first-time mothers and their children. In the UK, the FNP programme is provided alongside the usual maternity services during pregnancy and the neonatal period<sup>106</sup>. As stated in earlier chapters the aim of the Building Blocks trial is to provide rigorous trial evidence for the FNP in the UK.

Economic evaluation supports decision making in prioritising the allocation of limited health care resources.<sup>105</sup> Economic evaluation alongside clinical trials, as in the Building Blocks trial, therefore can be a valuable tool to help decide what interventions should be implemented based not only on effectiveness but also cost-effectiveness. Moreover RCTs are often the best means for providing unbiased estimates of both health effects and costs.<sup>181</sup>

This chapter reports on the economic evaluation conducted alongside the Building Blocks trial. This is the first UK-based full economic evaluation that has compared the cost-effectiveness of the Family Nurse Partnership (FNP), in comparison with the usual, universal services for young, first-time parents who live in areas with low socio-economic profile.

## 14.2 Methods

### 14.2.1 Overview

Briefly, the Building Blocks trial is an individually randomised controlled trial conducted in 18 centres across England. It involves women, aged 19 or younger, who are pregnant with their first child. The trial seeks to compare the effects of the provision of FNP services from pregnancy up to two years following childbirth. Individual participant data (IPD) collected alongside the Building Blocks trial were used to perform a cost-utility analysis where health related quality of life (HRQoL) was measured in terms of quality adjusted life years (QALYs), which represent years lived in perfect health. Differences in mean costs and mean QALYs at two years following childbirth were used to derive an estimate of the cost-effectiveness of FNP and usual care. Costs and QALYs were evaluated on the basis of costs falling on the NHS and Personal Social Services (NHS perspective) and expressed in UK £ sterling at a 2013 price base. Costs and QALYs were discounted from year one using the

recommended discounting rates according to the current available guidance.<sup>182</sup> The analysis was conducted on an intention to treat basis (ITT), thus the trial arms were compared based on their initial random allocation irrespective of protocol deviations or withdrawal. This section summarises the methods that were used for the within trial economic analysis.

### **14.2.2 Study Sample**

A total of 1,645 participants were randomised in the study. The economic analysis is based on the 1,618 participants recruited to the trial that were not assessed as ineligible or later withdrew their consent to use their data. Participants in the Intervention arm (n=808) received home based visits from the FNP nurse during their pregnancy and in the two years following childbirth. Participants allocated to the Control arm (n=810) received care from the local maternity services in line with usual practice. Details on recruitment and follow-up rates are described in Chapter 3. The data for participants subject to mandatory withdrawal (FNP=26; Usual care = 24) were not included in the primary analysis as those imply cessation of intervention delivery. Those were related to miscarriage (FNP=15; Usual care=13); social termination of pregnancy (FNP=3; Usual care = 8); termination for fetal anomaly (FNP=4; Usual care =2); stillbirth (FNP=3; Usual care = 1); and molar pregnancy (FNP=1). Therefore a total of 1568 women were included in the primary economic analysis (FNP=782; Usual care=786). Nevertheless the data available from those participants were used in the sensitivity analysis to test for the impact in the cost-effectiveness results.

### **14.2.3 Economic data collection**

Data for outcomes and resource use were collected by self-reported questionnaires at various time points throughout the trial: baseline, late pregnancy (34-36 weeks gestation), birth, and 6, 12, 18, and 24 months postpartum. Baseline and 24 month data were collected by face-to-face interview by a research nurse. Follow-up self-reported data were collected via telephone by qualified telephone interviewers for the remainder of the time points. In addition to the above, data related to the use of health care services for each trial participant were collected from Hospital Episode Statistics (HES) and primary care data (general practitioner (GP) records).

The generic data collection process has been described in Chapter 2. A list of data collected for the economic evaluation is presented in Appendices 14 to 16.

### **14.2.4 Health Related quality of life (HRQoL) and quality adjusted life years (QALYs)**

HRQoL was expressed in terms of utilities that were assessed from trial patients using the EQ-5D results at baseline, 34-36 week's gestation, and 6,12, 18 and 24 months after childbirth. The primary outcome measure for the economic analysis was the QALY. The QALY is a measure of health that simultaneously incorporates changes in both morbidity (related to the quality of life) and mortality (related to the quantity of years lived).

The EQ-5D<sup>183</sup> is a standardised and validated generic instrument for the measurement of HRQoL that allows translation of patient utilities into QALYs. As well as being one of the most used generic health status measures, it is the instrument recommended by the NICE appraisal guidance.<sup>182</sup> The EQ-5D considers health (functioning) in terms of five dimensions: mobility, ability to self-care, ability to undertake usual activities, pain and discomfort, and anxiety and depression. Each dimension has three possible levels: no problems, moderate problems or severe problems. This five-domain and three-level system generates 245 mutually exclusive health states, including unconscious and death. In order to estimate HRQoL weights (known as utilities) and to reflect the preferences of the UK population, each of these health states has been validated in a large UK population sample using the time-trade off method ranging from 1 for perfect health (thus the maximum value possible) to -0.594 for severe problems; 0 corresponds to death.<sup>184</sup> Utility values were generated by valuing health status (using a social tariff) as measured using from the EQ-5D system. Mean utilities values were reported for each trial arm, differences in utilities between both trial arms were estimated using ordinary least squared (OLS) regression.

The EQ-5D has been used before in the UK setting within the context of a pregnant population in the economic evaluation conducted alongside the Early Labour Support and Assessment (ELSA) trial.<sup>185</sup>

We converted the utilities derived from the EQ-5D into QALYs for each patient using the area under the curve (AUC) method, following the trapezium rule which assumes linear interpolation between follow-up points.<sup>186</sup>

Incremental mean QALYs between trial arms were estimated with regression models according to treatment allocation. Despite the randomisation process, which ensures baseline variables are balanced between the arms of the trial, in practice (regardless of sample size) it is normal to find imbalance in mean baseline utility. As baseline utility is likely to be correlated with patient's QALYs gained over time, there are robust reasons to control for baseline utilities when estimating QALYs.<sup>187</sup> Therefore, we conducted two models for all of the analysis: (i) based on adjusted baseline utility scores; and (ii) adjusted for a number of covariates. We used the same set of covariates as in the clinical effectiveness analysis: site and the balancing randomisation factors of smoking status, language and gestation.

## **14.2.5 Resource Use**

### **14.2.5.1 Primary care resource use**

There are two sources for primary care data in the trial: (i) self-reported questionnaires and (ii) GP CRF (see section 2.15). GP CRF data were used for the base case analysis whilst data on resource used reported by patients were used for the sensitivity analysis. There are two reasons that support this decision. First, it was hypothesised that GP records would be a more accurate representation of actual resource use. Second, we wished to reduce respondent burden in the self-reported questionnaires at two years by avoiding the need to collect resource use data.

CRF GP dataset provided information on the type of health professional the women in the trial had seen (GP or nurse), where the consultation was held (surgery or home), and the total number of visits during the trial (both antenatal or pregnancy related and postnatal appointments). GP CRF records were available for a total of 951 mothers and their babies in the Building Blocks trial (FNP = 471; Usual care = 480). The data on which health professional was seen at the consultation and/or setting was not always available. From the available data it was observed that there were 80% GP visits vs 20% nurse visits, and 98% clinic visits vs 2% home visits. Therefore for those records in which this information was missing, a clinic based visit with a GP was assumed.

Resource use on community midwife, health visitor and counsellor visits was available from self-report questionnaires. As the resource use for these categories was not available for the last six months of the trial (duration between 18 months and two years) it was assumed that resource use at two years was the same as month eighteen. The same assumption was made for the rest of community and hospital services when the self-reported questionnaires were used in the sensitivity analysis.

Resource use collected in the Birth dataset (surgery/hospital antenatal visits, attendances to day assessment units, antenatal inpatient nights and mode of delivery) was already captured in CRF GP and HES dataset; hence the data collected from the Birth records was not used to estimate resource use for the economic analysis.

### **14.2.5.2 Secondary care resource use**

Similarly there were two data sources on secondary care: (i) self-reported questionnaires and (ii) Hospital Episode Statistics (HES) records. HES data contain details of all admissions to NHS hospitals, all NHS outpatient appointments and all A&E attendances in England. The National Health and Social Care Information Centre (HSCIC) administers HES on behalf of the Secretary of State for Health. HES records include NHS funded patients treated in England NHS trusts and independent providers. It was assumed that HES represented a more accurate basis for the analysis, and more importantly, there was less possibility for missing data as HES records were requested for all the mothers and babies in the trial. Therefore HES data were used as the primary source for the economic analysis. Self-reported data on hospital resource use collected from participant's questionnaires was used in the sensitivity analysis.

HES data were requested from April 2009 to March 2013 (as HES financial years range from April to March). The mothers and their babies were linked to HES data using NHS number, date of birth, gender and postcode. HES data were received as unlabelled csv files for Inpatient (including maternity and adult critical care), Outpatient and Accident & Emergency. HES data dictionaries<sup>188</sup> were used to label variables and value labels, as those dictionaries provides detailed information on the data submitted and the fields derived by HES. Unique patient level identifier and unique record identifier were the variables used to link data. HES data cleaning rules were taken into consideration, using the check variables created by HES to understand the validity of data or presence of errors. All datasets were checked for data quality in order to identify and remove duplicates entries.

Inpatient HES records are based on the time the patient spend under the care of a single consultant -Finish Consultant Episode (FCE)- which constitute the unit of observation in HES. The period of care that the patient receives in one hospital provider is known as a spell. The sequence of spells from first admission to hospital to final discharge is known as CIPs (Continuous Patient Spells) which represent the patient's journey from one hospital to another. For the majority of patients the inpatient pathway is straightforward as FCE=Spell=CIPs. In order to estimate the unit cost associated with each mother and baby, inpatient records were analysed to identify spells and CIPs. HSCIC identifies four methods to estimate spells.<sup>189</sup> From all those methods we used the CHE (Centre for Health Economic, University of York) spells method as it makes best use of available information in HES; and does not rely on inconsistencies or invalid fields. This method allowed us to estimate length of stay (overnight admissions) and day case admissions for the participants in the Building Block Trial.

Outpatient HES records, were analysed to understand the different types of outpatient attendances (first appointments or follow-up). It was seen that while appointments were recorded in HES, it was not necessarily the case that mothers (or babies) were actually seen at the scheduled appointment. Cases in which the participants did not attend or the hospital cancelled the appointment were not considered in the analysis.

HES A&E records were analysed to estimate how many emergency admissions and readmissions there were during the trial. Following the advice given by CHE we used CIPs instead of FCE as they provide a more accurate measure of hospital emergency activity and avoid duplications.

As already stated, self-reported questionnaires also collected information on hospital resource use. Inpatient data collected in the participants' questionnaires allowed us to determine how many nights the mothers and babies were in hospital, the reason for admission and the type of ward they stayed on. Outpatient data recorded total number of appointments and the reasons for the visits. This information was mapped into Healthcare Resource Group (HRG) codes by an epidemiologist and NHS Reference unit costs selected accordingly. Resource usage related to the mothers collected by means of self-reported questionnaires was used as part of the sensitivity analysis.

## 14.2.6 Unit costs and estimation of costs

Resource use was valued in monetary terms and unit costs were reported in British Pounds sterling for the financial year 2012/2013. The cost for each mother and their babies in the Building Blocks trial was calculated by multiplying health care resource usage by their associated unit costs. Costs were discounted from year 2. The sections below give detailed information about the published sources used for the analysis.

### 14.2.6.1 Primary care resource use

Table 14.1 unit costs of all the health care and community services used by the Building Block participants.

Item	Unit	Cost	Reference	Notes
<b>GP</b>	Per Surgery consultation lasting 11.7 min	£45	Unit Costs of Health and Social Care 2013	Including direct care staff costs & qualifications
	Per out of surgery (home visiting) lasting 23.4 min	£114		
<b>GP Nurse</b>	Per Surgery consultation lasting 15.5 minutes	£13.4	Unit Costs of Health and Social Care 2013	Assume same duration as GP home visit
	Per home visiting lasting 23.4 min	£27.3		
<b>Midwife</b>	Antenatal visit (Community)	£51	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Community Health Services – Health Visiting and Midwifery
	Postnatal visit (Community)	£68		
	Home visit (per hour)	£70		
	Midwife episode	£65		
<b>Health visitor</b>	Per hour	£49	Unit Costs of Health and Social Care 2010	Assume same duration as GP home visit
	Per hour of home visiting	£71		
<b>Counsellor</b>	Surgery consultation	£58	Unit Costs of Health and Social Care 2013	
<b>Mental health</b>	Per hour per team member	£36	Unit Costs of Health and Social Care 2013	Community mental health team for adults with mental health problems.
<b>Crisis Resolution team</b>	Per hour per team member	£37	Unit Costs of Health and Social Care 2013	
<b>Support worker</b>	Per hour	£22	Unit Costs of Health and Social Care 2013	

<b>Social worker</b>	Per hour	£79	Unit Costs of Health and Social Care 2013	
<b>Physiotherapist</b>	Surgery session per hour	£34	Unit Costs of Health and Social Care 2013	
	Hospital session per hour	£36		

#### **14.2.6.2 Secondary care resource use**

Costs related to the inpatient hospital activity for the base case analysis were estimated using HRGs codes. HRGs are standard groupings of clinically similar treatments which use common levels of healthcare resource. NHS currently uses HRG 4 (previous HRG 3.5). Therefore HRG4 were requested from HES. HRGs codes associated with each FCE/Spells were determined using the Grouper software provided by the NHS Information Centre.<sup>190</sup> We downloaded and installed the HRG4 Reference Costs Grouper applications corresponding to the specific years for the Building Blocks trial. In order to group data correctly it was necessary to create an input file that matched the sample Record Definition File (RDF) provided with the Grouper installation. In that sense HES inpatient data was cleaned to meet the Grouper specific requirements for the Admitted Patient Care data. The grouper sorts Admitted Patient Care data prior to processing so that records with the same Provider code and Provider Spell number are placed in Episode order. The Grouper assigns HRGs at episode and spell level. The link between episodes in the same spell was made by matching Provider Code and Hospital Provider Spell number. NHS Reference Cost associated with the HRG codes derived by the grouper was used to estimate inpatient costs for the cost-effectiveness analysis. There are NHS Reference costs and Reference Cost Grouper for each specific year, so these were combined accordingly. For example, NHS Reference costs for 2009-2010 were used to estimate unit costs related to the HRG codes derived from the NHS 2009-2010 Reference Costs grouper. HRG4 trim points were used to cost extra length of stay associated with each spell (although as expected this was rare for the Building Blocks trial population). HES inpatient data showed that the majority of the mothers had an unplanned admission, including admissions for maternity or births and emergency admissions. Therefore, it was reasonable to use the non/elective inpatient setting to source unit costs for the analysis. Inpatient stay during the trial was related to delivery/birth, gynaecology or general episodes. Due to the extensive list of HRG unit costs used for the analysis those are not reported here.

Outpatient visits were classified in terms of the service the mothers and their babies were attending (main speciality). Unit costs from the NHS Reference Cost dataset (specific for the corresponding year) were consequently selected (Appendix 17). Unit costs related to Accident and Emergency services were derived as a weighted average of all the activities among services selected based on the type of admissions recorded in HES: (1) Leading to admitted; (2) Not leading to admitted; (3) Minor injury service: Leading to Admitted; (4) Minor Injury Service: Not leading to Admitted; (5) Accident and Emergency Services: Walk in Centres, leading to Admitted, (6) Walk in Centres: Not leading to Admitted, (7) Non 24hr A&E/Casualty Department: Leading to Admitted; or (8) 24hr A&E/Casualty Department: Not Leading to Admitted (Appendix 18).

Unit costs included for the cost-effectiveness study based on self-report data that were used for the sensitivity analysis are included in Appendices 15 and 16. As mentioned before, hospital activity reported by participants was mapped into HRG codes by an epidemiologist. However, when the reason for attending the hospital or the type of ward was missing, then national unit costs averaged across all settings were used for the analysis. These are also reported in Appendices 15 and 16.

### 14.2.6.3 Costing the intervention

The cost of the intervention was assessed on the basis of routine data collected by the FNP nurses that were entered onto the FNP IS. This dataset included information for all the mothers in the Building Blocks trial that received the FNP intervention in the Intervention arm (n=709) and in the Control arm (n=10). This included information directly related to the FNP utilisation such as the number and percentage of valid visits by the FNP nurses as well as their duration, and the number of telephone encounters with the clients. In addition, the dataset includes information on the qualification of the FNP nurses which was used to assess the remuneration bracket of the nurses for the overall costing of this service. The cost of the training in delivery of the FNP programme is not considered as part of the analysis. The staff cost per minute was estimated using PSSRU 2013 (Personal Social Services Research Unit) data for all the staff involved in the delivery of the intervention

Table 14.1 Unit costs used for costing the FNP intervention

Item	Unit	Cost	Reference	Notes
FNP Supervisor Nurse	Clinic or phone visit per minute	£1.34	Unit Costs of Health and Social Care 2013	Qualified nursing, midwifery & health visiting staff by Agenda for change band 8a, NHS England.
	Home visit per minute	£1.62		Ratio of direct time on: Home visits (1:0.45) Client work (1:0.20)
FNP Nurse	Clinic or phone visit per minute	£1.17	Unit Costs of Health and Social Care 2013	Qualified nursing, midwifery & health visiting staff by Agenda for change band 7, NHS England.
	Home visit per minute	£1.41		Home visits (1:0.45) Client work (1:0.20)

#### **14.2.6.4 Base case analysis**

For the base-case analysis total costs constituted the cost of the FNP programme (home based visits from the FNP nurse); GP and nurse visits (recorded in the CRF GP dataset), midwife and health visitor visits (self-reported by mothers); and hospital activity (HES records for inpatient admission, outpatient visits and A&E services).

Family Nurses were mainly health visitors but were occasionally nurses and midwives. Self-report questionnaires asked about the times the mothers had visited community midwife and health visitor for them or their babies. The questionnaires did not ask participants to exclude any visit related to the FNP programme. As the FNP programme is provided alongside the usual maternity services, for the women allocated to the FNP programme all midwives / health visits reported were included in the analysis, both self-reported and DH-recorded. There is a possibility that mothers in the FNP group may have included the FNP visits when asked in the self-reported questionnaires, hence for the sensitivity analysis self-reported midwife visits reported from mothers in the FNP group were excluded in the calculation of total costs.

### 14.2.7 Missing data and Multiple Imputation

In every clinical trial dataset, of either resource usage or outcomes, there is almost always a proportion of missing data irrespective of how well designed the data collection exercise is. There is a multitude of reasons for the presence of missing data and there are different methods for analysing these data dependent on the pattern of data missingness.

The problem of missing data arises when data on some variables (or participants) are not available. This problem is likely to occur in economic evaluations, as the economic analysis has to draw on all the aspects of the study, including resource use and health outcomes. Not only missing forms but also incomplete forms reduce, often considerably, the quantity of data on resource use that are available for analysis. The problem is amplified where there are frequent assessments, as in the Building Blocks trial. Unfortunately, the loss of just one cost component or EQ-5D index result for a participant means that the total cost or total QALYs for that person is lost to the analysis.

The pattern of missingness for the economic evaluation was examined. As expected a situation of multivariate missingness arose, where some but not all of the variables were missing for some of the subjects. That is, there was information available on EQ-5D scores but no information on costs (and vice versa). For the EQ-5D data, the missingness arose for two reasons: (i) trial participants did not complete the EQ-5D instrument at all; and 2) trial participants did not complete all the five domains of the EQ-5D questionnaire. For the total costs, the missingness arose when there were missing data on any cost domain. That is, if one cost variable (e.g. costs due to GP visits) was missing, then there will be a missing data point for the total costs.

Two methods were used for dealing with missing data: (i) Complete case (CC) analysis; and multiple imputation (MI). In CC analysis only observations with complete information on both costs and EQ-5D are used. The main assumption that drives this scenario is that the data are missing completely at random (MCAR). That is, the missing values bear no relation to the value of any of the observed (or unobserved) variables and the complete cases are fully representative of the cases in the original sample. Complete case assessment excludes all participants with any missing data; thus, only participants with an observed total cost and QALY data are included in the analysis. Additional to the resulting sample usually being a much reduced sample of the original data, complete case analysis might be biased if participants included in the analysis are not a random subset of all study participants.<sup>192</sup> An alternative method to address missing data in clinical trials is multiple imputation (MI),<sup>137</sup> which has been recommended as the appropriate method to reflect the uncertainty in the results of the economic evaluation due to missing data.<sup>193</sup> The main assumption that drives this second scenario is that the data are “missing at random” (MAR). That is, the missing values in the dataset may depend on the value of other observed variables in the dataset, but that conditional on those values the data are missing at random. The missing values do not depend on the values of unobserved variables.

MIm resolves the missing data problem by substituting each missing value with a predicted value. The MIm process follows three consecutive steps. First the imputed dataset is created, through the use of regression models to predict plausible values for the missing observations from the observed values. The process includes all the covariates that might be associated with the 'missingness mechanism' (why the data are missing), including balancing randomisation factors and site; costs (primary care and hospital activity) and utilities (at baseline, late pregnancy, six, 18, 12 and 24 months). Costs and utilities were simultaneously imputed in the model rather than imputed separately. Therefore the covariates registered were used for both costs and utilities, where a regression model was fitted for each variable with missing values, with the previous variables as covariates. Based on the resulting model, a new regression model is then estimated and used to impute the missing values for each variable. A random component is included to reflect the uncertainty around the predictions. Thus, MIm reflects the uncertainty in the prediction of missing values while preserving the distribution and correlations in the data.<sup>194</sup> These values are then used to fill in the gaps in the dataset. This process is repeated for a finite number of times  $m$ , creating  $m$  imputed datasets. In the second stage, each dataset is analysed independently using complete case methods. Finally, the estimates obtained from each imputed dataset are pooled together to generate mean estimates of costs and QALYs, variances and confidence intervals (CIs) using Rubin's rules, in such a way that the uncertainty around the predicted values is fully taken into account.<sup>195</sup> Since the Building Blocks trial has missing data for both costs and EQ-5D scores, multiple imputation using chained equations was employed.<sup>194</sup> This way, each variable is predicted with its own regression model. Each imputed dataset is created by running the regression models over several cycles, in which each variable informs the prediction of the other variables.

The correct specification of the regression models is key to ensure that the distribution of imputed values do not differ from that of the observed values, and thus provide unbiased estimates. The specification of the regression models depends on the type and distribution of the variable to be imputed. Costs and QALYs (the variables to be predicted for this analysis) are both continuous and not normally distributed. Two alternative methods are proposed to deal with this difficulty when using MI with chained equations: data transformations and predictive mean matching. Predictive mean matching was used. This method ensures that observed data are used to estimate a predictive model (using the specified covariates) but instead of replacing missing values with the model predicted values, the nearest observed value is used to fill the missing. This guarantees that the imputed values are sampled from values in the original dataset, and therefore no imputed values will lie outside the bounds of the original data distribution.

Given the extent of missing data in the Building Blocks trial, we decided to use the MIm dataset, created using all available data and MIm with chained equations, as the 'base case'. Meanwhile, the use of the complete case dataset was explored in the sensitivity analyses. The multiple imputation data analysis and pooling was performed in Stata release 13.1 (StataCorp 2011, TX, USA).

### 14.2.8 Incremental analysis

This cost-effectiveness analysis aims to guide decision making. Given that total health care expenditure must be covered from a limited and fixed budget, the most informative estimate of cost for decision makers is the mean cost per participant. Also relevant is the mean utility per participant. Therefore the focus of this analysis was to estimate the difference in mean costs and mean QALYs between the two trial arms of the trial.

We used a bivariate modelling approach for the analysis. The incremental mean utility and the incremental mean cost between the two treatments were estimated using seemingly unrelated regression (SUR) equations for data on costs and QALYs. This bivariate method brings efficiency gains over unrelated ordinary least squares (OLS) regression<sup>196</sup> for three reasons: (i) it allows for explicit modelling of both costs and effects while allowing the inclusion of a set of different covariates in the two equations; (ii) exploits the existence of correlation between costs and effects; and (iii) SUR does not require a new regression for every value of cost-effectiveness threshold.<sup>197</sup> Again, the same set of covariates as used in the clinical effectiveness analysis was used. The baseline EQ-5D utility was also included in the utility regression to adjust for possible baseline imbalance.<sup>198</sup> Therefore, for the cost-effectiveness analysis, the mean differences in costs and effects were estimated using SUR and their 95% confidence intervals (CI) estimated using bias corrected and accelerated (BCA) bootstrap methods. Analysis were conducted in Stata version 13.1

The incremental cost-effectiveness ratio (ICER) was estimated as the difference in mean total costs divided by the difference in mean total QALYs from baseline to two years after childbirth. According to standard cost/effectiveness decision rules four different eventualities are plausible when comparing incremental costs and QALYs. If the new intervention provides better outcomes (positive incremental QALYs) at lower costs (negative incremental costs) it is considered a dominant intervention and hence cost-effective. In contrast, if the new intervention achieves poorer outcomes (negative incremental QALYs) at higher costs (positive incremental costs) it is considered a dominated option and hence not cost-effective. Thus, the ICER is considered only if either intervention does not dominate; i.e. both incremental costs and incremental QALYs are positive (or negative). In these last two situations, to determine whether the incremental health gain is worth the incremental cost the ICER needs to be compared against a threshold value. For positive incremental costs and QALYs (the most frequent situation in health technology assessment), an intervention will be considered cost-effective only if the ICER is lower than the threshold. According to NICE, the willingness to pay threshold for an additional QALY ranges from between £20,000 and £30,000.<sup>182</sup> Therefore, if the results of this cost-utility analysis – the estimated cost per QALY – are below this threshold, the FNP intervention would be considered as cost-effective and its use in the NHS recommended.

The ICER can be rearranged in terms of Net Benefit (NB), a more intuitive way of expressing whether the health benefits of the FNP intervention are worth the additional costs.<sup>199</sup> The Net Benefit can be estimated on the cost scale as the incremental health gain expressed in terms of money, minus the incremental cost of the intervention. The health benefits are translated into monetary value using the cost effectiveness threshold;

i.e. incremental QALYs are multiplied by the willingness-to-pay (WTP) threshold. Therefore, the Net Monetary Benefit (NMB) provides an estimation of the gain (or loss) in resources of investing in a particular intervention when those resources might be used elsewhere.<sup>200</sup> Current NICE guidance recommends presenting the NMB using values of £20,000 and £30,000 per QALY for the WTP threshold. Thus, FNP would be considered cost effective only if the NMB is positive.

#### **14.2.9 Analysis of uncertainty**

A range of sensitivity analyses were conducted to test the robustness of the results under different scenarios. These scenarios capture variability in the estimates of cost and outcomes, which resulted from either different methods (e.g. imputation methods) or from different sources of data (e.g. unit cost data). The sensitivity analyses also extend to the different participants' sub-groups within the trial.

As already mentioned, the extent of missing data justified the use of the imputed dataset as the base case scenario. Nevertheless the results of the complete case were tested as part of a sensitivity analysis and the results presented and compared against the imputed results. Complete case analysis offers unbiased estimates only if data are MCAR (missing completely at random; whereas MIIm provides unbiased estimates only if the data is MAR (missing at random). If the MCAR assumption does not hold the results of the complete case analysis might be biased but this would apply to the results of MIIm only if the MAR assumption also did not hold. Thus MIIm has the advantage over complete case analysis in that if data are MAR, MIIm will produce unbiased estimates<sup>201</sup>.

One way sensitivity analyses were conducted to test the impact of (i) excluding midwife visits that mother allocated to the FNP intervention reported in the questionnaires; (ii) including the limited data available for mothers that withdrew due to mandatory withdrawals as part of the imputation; (iii) including resource use exclusively related to mothers (and hence excluding resource use of the babies); and (iv) halving the cost for the FNP intervention.

Finally, we used probabilistic sensitivity analysis to investigate the uncertainty associated with the mean difference in costs and QALYs between both treatment groups. Non-parametric bootstrapping<sup>202</sup> was used to plot the joint distribution of costs and effects (QALYs) on the cost-effectiveness plane and derive the cost effectiveness acceptability curves (CEAC) to express the (Bayesian) probability that the intervention is cost-effective as a function of the threshold willingness to pay.<sup>203</sup> The bootstrap technique was used to sample with replacement from the original observed pairs of costs and effects, maintaining the correlation structure, to create a new dataset with 5,000 observations. For each bootstrapped resample, an estimate of differential costs and QALYs was calculated. The 95% CI for the differential estimates were estimated using bias corrected non-parametric bootstrapping.

### 14.2.10 Validation

In order to validate the results of the analysis two statistical codes (written in Stata) were independently developed and their results compared. The codes were developed by one analyst and checked independently by another. Regarding the imputation process, the distributions of the observed and imputed values were compared graphically to check that the distribution of the data resembled the original one.

## 14.3 Results

### 14.3.1 Participant sample

Complete case analysis was comprised those participants that had data available for the whole trial duration and for all the resource use and cost categories. There were 584 complete cases for utilities (265 in Usual care and 319 in FNP). Similarly complete GP CRF records were available for 951 mothers (480 in Usual care and 471 in FNP). Overall the complete case for the base (considering both mothers and babies data) consisted of 403 complete cases (186 in Usual care and 217 in FNP).

### 14.3.2 Health Related quality of life (HRQoL) and quality adjusted life years (QALYs)

Health related quality of life (HRQoL) is measured by the EQ-5D questionnaire. The EQ-5D was considered as completed only if patients give a response to all its five dimensions, otherwise it was not considered for the analysis. Table 14.2 shows the number of questionnaires returned by participants (including questionnaires with any dimension missing) and the number of EQ-5D completed for each wave. The number of completed questionnaires decreases during the second assessment, corresponding with the late pregnancy interview for the mothers.

Table 14.2 HRQoL: number of completed EQ-5D questionnaires and corresponding proportion of missing data by allocation and follow-up

Follow-up	FNP (n=808)			Usual care 2 (n=810)		
	Completed EQ-5D	Missing EQ-5D (including withdrawals)	Missing EQ-5D (excluding withdrawals)	Completed EQ-5D	Missing EQ-5D (including withdrawals)	Missing EQ-5D (excluding withdrawals)
<b>Baseline</b>	808 (100.0%)	0 (0.0%)	-	807 (99.6%)	3 (0.4%)	-
<b>34-36 weeks</b>	614 (76.0%)	194 (24.0%)	105 (12.9%)	616 (76.0%)	194 (24.0%)	134 (16.5%)
<b>6 months</b>	507 (62.7%)	301 (37.3%)	293 (36.2%)	469 (57.9%)	341 (42.1%)	329 (40.6%)
<b>12 months</b>	510 (63.1%)	298 (36.8%)	294 (36.3%)	480 (59.3%)	330 (40.7%)	325 (40.1%)
<b>18 months</b>	499 (61.8%)	309 (38.0%)	307 (37.9%)	465 (57.4%)	345 (42.6%)	342 (42.2%)
<b>24 months</b>	583 (72.2%)	225 (28%)	221 (27.3%)	537 (66.3%)	273 (33.7%)	272 (33.5%)

The number of partially completed questionnaires is very low. If the questionnaire is answered it is always completed, except for 3 cases in each group (Table 14.3). For those cases where the questionnaires were

invalidated because one dimension was missing this missing dimension was anxiety/depression for all cases in both groups.

Table 14.3 HRQoL: number of completed EQ-5D missing dimensions for invalid questionnaires

EQ-5D	Number of missing dimensions (FNP)					Number of missing dimensions (Usual care)					
	1*	2	3	4	5	1*	2	3	4	5	
<b>Follow-up</b>											
<b>Baseline</b>	0	0	0	0	0	2	0	0	0	1	*When there was only 1 dimension missing, this missing dimension was anxiety/depression for all the cases
<b>34/36 weeks</b>	1	0	0	0	193	0	0	0	0	194	
<b>6 months</b>	0	0	0	0	301	0	0	0	0	341	
<b>12 months</b>	0	0	0	0	298	0	0	0	0	330	
<b>18 months</b>	1	0	0	0	308	0	0	0	0	345	
<b>24 months</b>	1	0	0	0	224	1	0	0	0	272	

Proportions of Level 1 (no problems), Level 2 (some problems) and Level 3 (severe problems) reported for each of the five dimensions are included in Appendix 19.

Table 14.5 summarises the mean EQ-5D scores reported at each wave for all the available cases. The analysis of utilities shows that participants in the FNP group started from a lower HRQoL at baseline (0.90 vs 0.91). At the second assessment the FNP group reports slightly higher utilities on average. The patterns change again and at the end of the trial the utilities are slightly higher for the Usual care group in terms of utilities and QALYs (Table 14.4).

Table 14.4 HRQoL: EQ-5D mean (SD) scores and unadjusted mean difference (95% CI) at baseline and follow-up assessments up to two years following childbirth

Follow-up	FNP Mean (SD)	Usual care Mean (SD)	Difference (FNP – Usual care) (95% CI)
<b>Baseline</b>	0.907 (0.005)	0.914 (0.005)	-0.007 (-0.021; 0.007)
<b>34-36 w</b>	0.836 (0.008)	0.834 (0.007)	0.002 (-0.020; 0.023)
<b>6 months</b>	0.934 (0.006)	0.935 (0.006)	-0.001 (-0.019; 0.016)
<b>12 months</b>	0.937 (0.007)	0.937 (0.006)	0.000 (-0.018; 0.018)
<b>18 months</b>	0.943 (0.006)	0.944 (0.006)	-0.001 (-0.018; 0.016)
<b>24 months</b>	0.927 (0.006)	0.937 (0.006)	-0.009 (-0.026; 0.007)

Table 14.5 shows the difference in utilities adjusted for baseline utility scores. Despite any difference seen in the EQ-5D dimensions across the groups, this translates in very little difference between the FNP and Usual care group in terms of utilities and QALYs (Table 14.6).

Table 14.5 HRQoL: Difference in mean EQ-5D scores (95 CI) adjusted for baseline utility

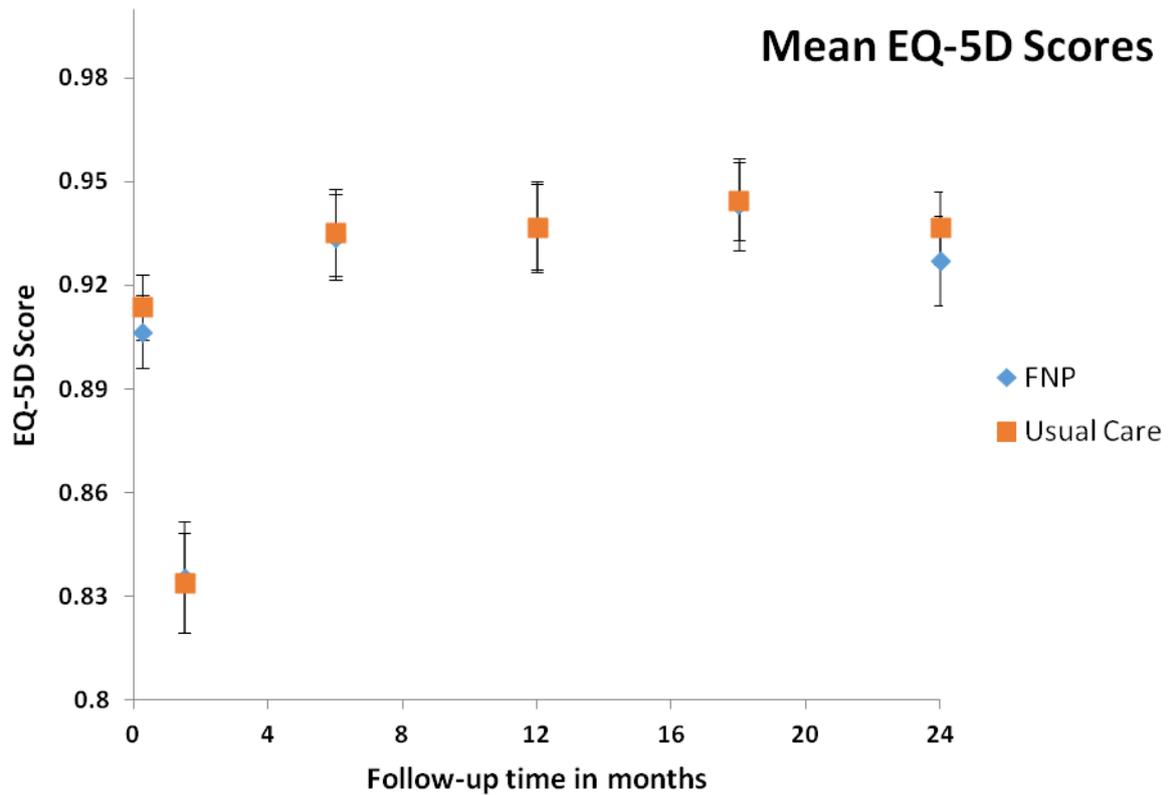
<b>Outcome</b>	<b>Difference (FNP – Usual care) (95% CI)</b>
<b>Baseline</b>	-0.007 (-0.021; 0.007)
<b>34-36 w</b>	0.004 (-0.016; 0.025)
<b>6 months</b>	0.002 (-0.015; 0.019)
<b>12 months</b>	0.001 (-0.016; 0.019)
<b>18 months</b>	0.002 (-0.015; 0.018)
<b>24 months</b>	-0.008 (-0.023; 0.008)

Table 14.6 HRQoL: Total QALYs for all available cases by allocation up to two years following childbirth

<b>Allocation</b>	<b>Total</b>	<b>Mean QALYs (SD)</b>	<b>Min QALYs</b>	<b>Max QALYs</b>	<b>Difference<sup>a</sup> (FNP – Usual care) (95% CI)</b>
Usual care	265	2.047 (0.20)	1.13	2.21	0.008
FNP	320	2.041 (0.22)	0.85	2.21	(-0.225; 0.038)

The distribution of mean utilities for the available cases across the two groups over the duration of the Building Blocks trial shows that patients in the Usual care group reported better quality of life at baseline; subsequently both groups overlap and at the end of the second a very marginal difference is observed. 95% confidence intervals overlap at all of the assessments.

Figure 14.1 Mean EQ-5D scores at baseline and follow-up assessments up to two years following childbirth



### 14.3.3 Health care resource use and costs

The mean levels of resource use over the duration of the trial based on all available data are shown in Table 14.8. There were no clear differences in resource use across the two groups with the unsurprising exception of health visitor visits, as women in the FNP group received this service as part of the intervention. Both groups were also very similar in terms of hospital visits; except for A&E attendances for mothers and babies in the FNP group (especially mothers), who had on average more emergency episodes. Similarly, babies in the usual care group had on average longer inpatient length of stay (overnights) in hospital than those babies whose mothers were randomised to the FNP intervention.

Table 14.7 Mothers and babies average resource use per arm of the trial from baseline up to two years following childbirth

	<b>FNP (n=782)</b>					<b>Usual care (n=786)</b>				
	<b>n</b>	<b>Mean (SD)</b>	<b>Min, Max</b>	<b>Median</b>	<b>Missing</b>	<b>n</b>	<b>Mean (SD)</b>	<b>Min; Max</b>	<b>Median</b>	<b>Missing</b>
<b>GP surgery visits for mothers</b>	471	9.55 (8.40)	0; 48	7	39.76%	480	8.49 (7.81)	0; 48	7	38.93%
<b>GP home visits for mothers</b>	471	0.22 (0.84)	0; 9	0	39.76%	480	0.21 (0.76)	0; 8	0	38.93%
<b>Nurse surgery visits for mothers</b>	471	2.14 (3.61)	0; 36	1	39.76%	480	2.22(3.01)	0; 20	1	38.93%
<b>Community Midwife visits</b>	459	10.40 (5.34)	0;41	10	41.30%	422	10.68 (5.25)	0; 41	10	46.31%
<b>Community Health visitor visits</b>	363	8.60 (13.74)	0; 68	0	53.58%	321	16.25 (12.15)	0;73	13	59.16%
<b>Community Counsellor visits</b>	612	0.29 (1.23)	0;12	0	21.73%	614	0.32 (1.64)	0;20	0	21.88%
<b>Inpatient Length of Stay for mothers</b>	782	3.98 (6.35)	0; 99	3	0%	786	4.09 (6.39)	0;110	2	0%
<b>Day case admissions for mothers</b>	782	3.53 (5.19)	0; 60	2	0%	786	3.57 (5.48)	0;77	2	0%
<b>Outpatient visits for mothers</b>	782	8.61 (8.05)	0; 74	7	0%	786	8.55 (8.05)	0; 70	6.5	0%
<b>A&amp;E attendances for mothers</b>	782	4.54 (2.43)	0; 36	1	0%	786	1.58 (2.55)	0; 29	1	0%
<b>GP surgery visits for babies</b>	471	8.17 (7.10)	0; 70	7	39.76%	480	7.60 (6.20)	0; 51	7	38.93%
<b>GP home visits for babies</b>	471	0.29 (1.25)	0; 17	0	39.76%	480	0.29 (1.61)	0; 20	0	38.93%
<b>Nurse surgery visits for babies</b>	471	0.88 (2.17)	0; 22	0	39.76%	480	0.90 (2.05)	0; 18	0	38.93%
<b>Inpatient length of stay for babies</b>	724	2.82 (21.32)	445 ;0	0	0%	757	3.10 (25.29)	0; 466	0	0%
<b>Day case admissions for babies</b>	724	1.74 (3.42)	0;34	0	0%	757	1.79 (3.31)	0; 32	0	0%
<b>Outpatient visits for babies</b>	724	1.82 (5.29)	0;69	0	0%	757	2.08 (7.03)	0; 135	0	0%
<b>A&amp;E attendances for babies</b>	724	2.58 (3.24)	0; 30	2	0%	757	2.21 (2.53)	0; 15	1	0%
<b>FNP visits/encounters</b>	709	39.28 (15.19)	1; 88	41	10%	10	0.45 (4.26)	0; 53	0	NA
<b>FNP calls</b>	709	6.29 (5.34)	2; 31	4	10%	10	0	0	0	NA

Regarding the FNP intervention itself, there were a total of 28,208 visits regarded as valid during the trial period for 728 participants (718 women randomised to the FNP Intervention and 10 to Control arm). Details on the FNP dosage, schedule of visits and support delivered are Chapter 3. This section reports the mean resource use and costs associated with the FNP intervention, both related to visits and calls.

Women in the Intervention group received 27,853 visits whilst mothers in the usual care group received 355 visits. The analysis was conducted on an intention to treat basis (ITT), therefore all valid visits were costed regardless the Intervention arm the mothers were allocated to. The duration for the visits/calls were estimated in minutes; total minutes were then multiplied using the unit costs per minute listed in Table 14.2 according to the grade of the nurses providing the intervention (supervisor or nurse). Mothers in the Intervention arm had on average 39.28 visits (SD=15.19), with a minimum of 1 visit and a maximum of 88 visits. Mothers allocated to usual care who received the intervention had on average 35.5 visits (SD=14.26), with a minimum of 5 visit and maximum of 53 visits. The average duration of the visit within all the participants that received the intervention was 78.40 minutes. Regarding calls, only women allocated to the intervention received calls from FNP nurses, although only 35% of those used this service, who had 6.29 (SD=5.34) calls on average, a minimum of two and maximum of 31 calls.

The average costs for the FNP intervention for the 719 women that received the intervention during their pregnancy and in the two years following childbirth based on IPD collected alongside the Building blocks trial is £4,270.12 (SD 1,855.57) per woman. This cost includes only staff time estimated based on current salaries for qualified nursing, midwifery & health visiting staff by Agenda for change band 8a (FNP supervisors ) and band 7 (FNP nurses), NHS England. If we assume that on average women were recruited by 18 weeks gestation then the annual cost for the intervention is £1,762.22 per woman. The Apeteligen study<sup>204</sup> also reports the costs of the FNP programme in England. This study reports an average cost of £2,664 per case per annum for a team of eight Family Nurses (varying between £2,136 and £3,129). The cost increases to an average of £3,083 per case per annum (varying between £2,469 and £3,648) when based on a typical team of four Family Nurses, a full-time supervisor and a part-time administrator. The cost estimation we have conducted here includes exclusively staff costs related to the nurses providing the intervention (FNP nurses or supervisors); costs related to national FNP training are not included in our analysis either. The Apeteligen study considered both staff and non-staff related costs. Although staff costs accounted for approximately 73% of the total costs reported other non-staff costs (overhead charges, premises costs, IT charges and costs of equipment and office supplies) were also included in the Apeteligen cost estimations. Travel costs to attend national training were also considered.

Table 14.9 summarises the mean cost by item of resource use based on all available cases and according to allocated treatment. Costs differences were very small across groups. Costs associated with the delivery of the FNP intervention and the inpatient stays in hospital for babies were the major cost drivers for the cost-effectiveness analysis.

Table 14.8 Costs associated with all available cases: mean (standard deviation). Costs discounted from year 2 at 3.5% according to ITT. Mean incremental costs and 95% CI estimated using OLS regression

	Mean cost £ (SD)		Difference (FNP - Usual care)
	FNP	Usual care	(95% CI)
<b>GP surgery visits for mothers</b>	429.95 (17.49)	382.35 (16.20)	47.60 (0.82; 94.37)
<b>GP home visits for mothers</b>	25.82 (4.42)	24.92 (4.18)	0.89 (-11.96; 12.84)
<b>Nurse surgery visits for mothers</b>	21.17 (1.69)	22.63 (1.41)	-0.83 (-5.17; 3.50)
<b>Community Midwife visits</b>	15.51 (332.38)	15.29 (314.19)	-20.96 (-63.82; 21.89)
<b>Community Health visitor visits</b>	135.67 (11.34)	217.78 (10.25)	-82.10 (-112.42; -51.78)
<b>Community Counsellor visits</b>	16.86 (71.56)	19.08 (94.79)	-2.22 (-11.62; 7.20)
<b>Inpatient length of stay mothers</b>	6354.57 (8460.72)	6661.17 (9679.04)	-306.59 (-1193.20; 580.00)
<b>Day case admissions for mothers</b>	775.22 (1041.62)	781.72 (1216.929)	-6.50 (-116.98; 103.96)
<b>Outpatient visits for mothers</b>	889.49 (903.30)	875.63 (918.99)	13.85 (-75.01; 102.71)
<b>A&amp;E attendances for mothers</b>	167.06 (277.82)	172.79 (289.34)	-5.72 (-33.39; 21.93)
<b>GP surgery visits for babies</b>	367.74 (14.92)	342.37 (12.80)	25.36 (-13.13; 63.86)
<b>GP home visits for babies</b>	33.13 (6.64)	32.64 (8.38)	0.49 (-20.57; 21.56)
<b>Nurse surgery visits for babies</b>	8.96 (1.03)	9.21 (0.95)	-0.25 (-3.00; 2.50)
<b>Inpatient length of stay for babies</b>	3773.35 (25939.83)	4882.99 (50019.88)	-1109.64 (-5198.3; 2979.6)
<b>Day case admissions for babies</b>	142.02 (702.62)	145.17 (615.10)	-3.15 (-70.38; 64.08)
<b>Outpatient visits for babies</b>	290.96 (983.72)	272.92 (842.08)	-18.03 (-111.56; 75.49)
<b>A&amp;E attendances for babies</b>	293.12 (370.60)	254.93 (298.36)	38.16 (3.94; 72.38)
<b>FNP visit/encounters</b>	3845.32 (76.69)	47.27 (16.08)	3798.05 (3644.70; 3951.4)
<b>FNP calls</b>	33.27 (2.84)	0 (0)	33.27 (27.70; 38.83)

Inpatient costs for mothers include the costs associated with deliveries. However, mode of delivery costs were analysed separately. The average costs for all delivery episodes in the FNP group was £1961.30 vs £1923.47 for the usual care group. As shown in Table 14.10, mode of delivery costs were very similar for both groups.

Predictably, those costs are in line with the unit costs reported in the NHS Reference costs dataset for 2012/2013. National unit costs (averaged across all inpatient settings) for a normal delivery is £1680; £2488 for an assisted delivery and £3,607 for a caesarean section (including planned and emergencies ones).

Table 14.9 Mean cost for the different types of deliveries in the analysis

	FNP (£)					Usual care (£)				
	N	Mean	Median	Min; Max	Total	N	Mean	Median	Min; Max	Total
Normal Delivery	471	1792.25	1687.00	94.93; 15166.21	844147.90	477	1680.36	1687.00	94.93; 7325.84	801531.90
Assisted Delivery	127	1897.18	2179.19	326.78; 4249.94	240941.30	140	1923.10	2036.46	187.47; 4103.37	269234.20
C-Section	101	2558.40	2672.15	326.78; 11157.97	258398.90	96	2811.34	3080.80	326.78; 16191	269888.80

#### 14.3.4 Cost-effectiveness analysis and uncertainty

The base case analysis shows that the FNP intervention is associated with greater costs and a very small QALY gain when compared to Usual care. Table 14.11 shows the comparison of the mean costs and mean QALYs between the multiple imputation results and the complete case dataset. The FNP intervention costs on average £1,992.89 more per participant when compared with usual care (95% CI -2700.3; 5744.4). The incremental costs decrease very slightly when adjusted for the randomisation balancing factors. Incremental mean QALYs when adjusted for baseline utility are marginally higher for FNP (mean difference 0.0036, 95% CI -0.017; 0.025). This difference is even lower when adjusted for the rest of covariates (mean difference 0.0030, 95% CI -0.017; 0.027). The net monetary benefit (NMB) associated with the FNP intervention is negative (-1,750.57), indicating that this intervention is not cost-effective as the resources to be displaced would be greater than the benefit to be gained with the delivery of FNP intervention.

The differences in mean costs and QALYs are not statistically significant, indicating that there might be some uncertainty associated with this conclusion. In order to analyse this uncertainty non-parametric bootstrapping approach was used. Figure 14.2 shows the joint distribution of costs and effects for the 5,000 bootstrapped replicates on the cost-effectiveness plane. The location of the incremental cost pairs show that there is uncertainty regarding both costs and QALYs. This is consistent with the non-significant difference in costs and QALYs between the two groups.

The cost-effectiveness acceptability curve (CEAC) derived from the joint distribution of costs and effects is represented in Figure 14.3. The curve was constructed by plotting the proportion of incremental effect pairs that are cost-effective for a range of thresholds. The probability of the FNP intervention being cost-effective ranges between 0% and 100%. The horizontal interrupted line indicating a 50% probability of FNP representing a value for money option for the NHS. As shown in the graph the probability of FNP being cost effective is less than 20% (MIm dataset) given NICE currently willingness to pay £20,000 for an additional QALY. The probability is slightly higher for a threshold of £30,000 for an additional QALY, but still far from enough to be considered a cost-effective alternative for the NHS.

The complete case analysis indicates that the FNP intervention is a dominated option (more costly and less effective) and with 0% probability of being cost-effective at the current thresholds. Cost-effectiveness plane and CEAC for the Complete Case are included in Appendix 20.

Table 14.10 Cost-effectiveness analysis based on the Multiple Imputation approach. Using HES and GP CRF records. Self-report data used for Midwife and Health Visitor visits. Excluding mandatory withdrawals

	Difference (Intervention – Control)		Difference (Intervention – Control)		ICER	Probability CE £20,000/QALY	Probability CE £30,000/QALY
	<i>Adjusted for baseline utility</i>		<i>Adjusted for balancing factors</i>				
	Cost (£)	Effect (QALYs)	Cost (£)	Effect (QALYs)			
(BCA 95% CI)	(BCA 95% CI)	(BCA 95% CI)	(BCA 95% CI)	Adjusted balancing f			
<b>Multiple</b>	1992.89.	0.0036	1811.57	0.0030	593957.4	16.78%	16.94%
<b>Imputation</b>	(-2700.3; 5744.4)	(-0.017;0.025)	(-2814.7; 5547.7)	(-0.0171; 0.027)			
<b>Complete</b>	4599.72	-0.0119	4548.68	-0.0068	DOMINATED	0%	0%
<b>Case</b>	(3207.4; 5991,9)	(-0.05; 0.023)	(3174.8; 5922.5)	(-0.042; 0.0277)			

Figure 14.2 Cost-effectiveness plane (ITT analysis). It includes resource use from both mothers and babies (based on HES and GP CRF datasets)

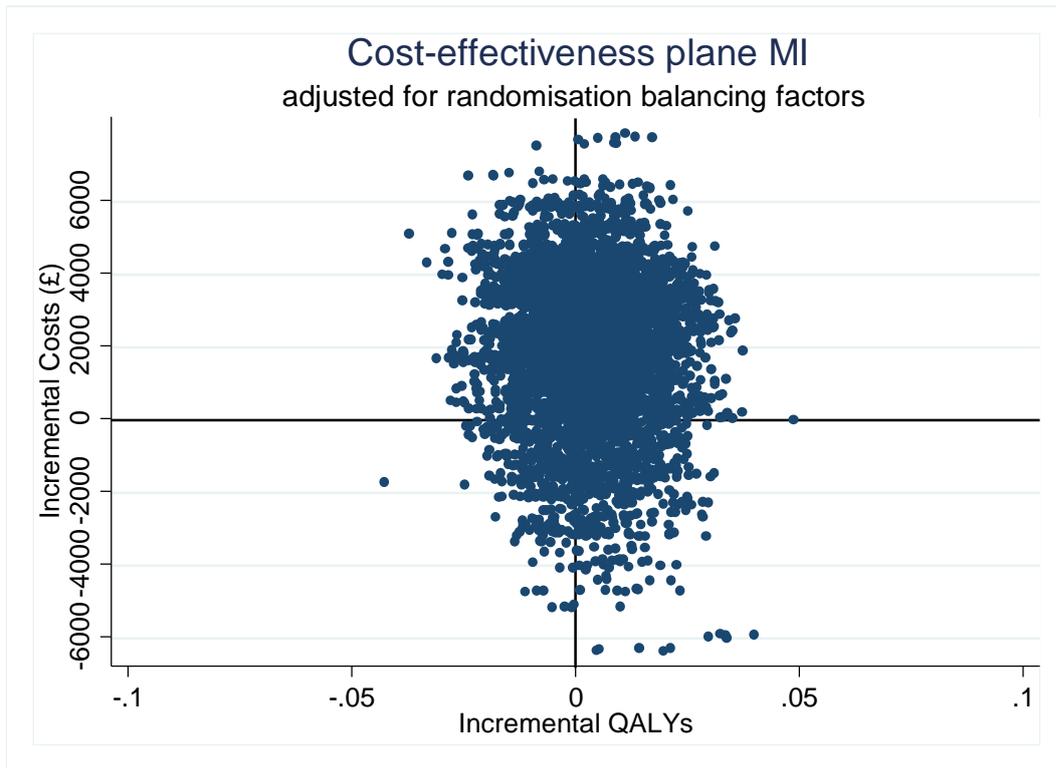
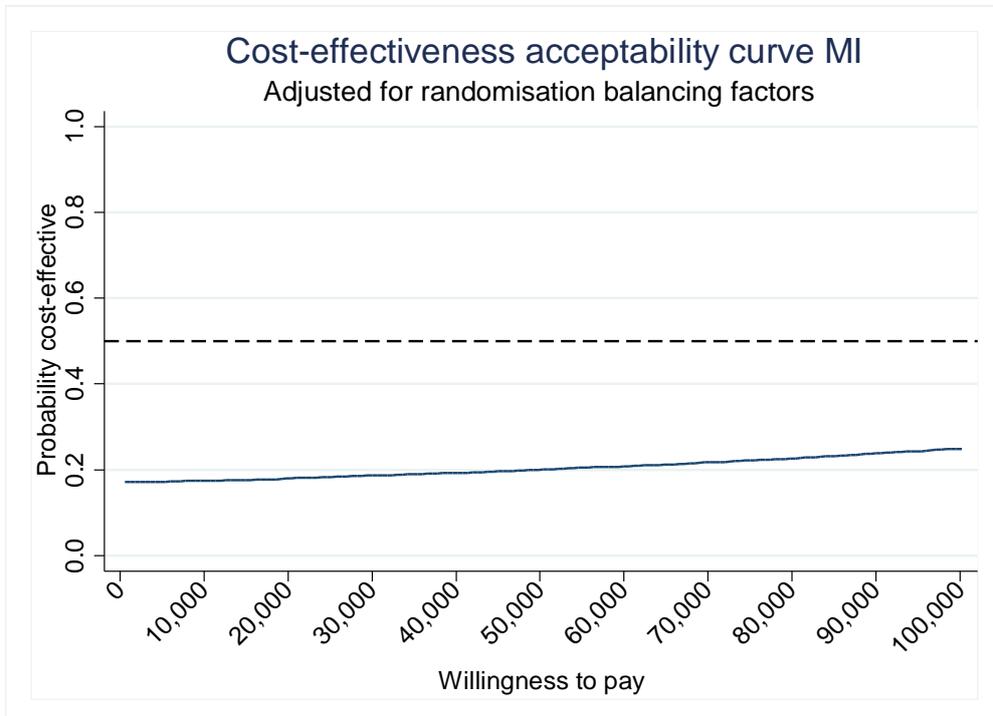


Figure 14.3 Cost-effectiveness acceptability curve (ITT analysis)



### 14.3.5 Sensitivity analysis

Besides the complete case described above, different scenario sensitivity analyses were conducted to test the robustness of the cost-effectiveness results for the base case. Cost-effectiveness planes and cost-effectiveness acceptability curves for each scenario are presented in Appendix 21. For scenario 1, midwife visits reported by mothers allocated to the FNP intervention were removed from the analysis to avoid double counting in case those visits were already included in the FNP IS dataset. The results are shown in Table 14.11. The results for both the MIm and the CC are consistent with the base case and therefore the same conclusions can be drawn.

Table 14.12 shows the results when including the available data for those mothers who drop out due to mandatory withdrawals. As expected this had no impact in the results either. If only mother's costs are taken into account (Table 14.13) then the difference in costs between both groups increases as expected. This is because inpatient hospital costs for the babies in the usual care group was much higher than for the babies in the FNP intervention; when this is eliminated from the analysis the differences between the groups are mainly driven by the cost of the delivery of the FNP intervention.

Because it was felt that the cost of the intervention is the main cost driver for the analysis, the cost of the FNP intervention was halved to assess the impact in the cost-effectiveness conclusions. Table 14.14 shows that the mean difference in costs per participant is reduced to £360.47 (95% CI -3680.5: 4351.8); the difference in mean total QALYs is still very marginal 0.0047 (95% CI -0.0130; 0.0221). The results continue to be uncertain and the probability of FNP intervention being cost-effective not greater than 50%.

Finally, Table 14.15 describes the cost-effectiveness results when both the CC and the MIm are conducted using the self-report data as the main source for the analysis. This scenario includes resource use exclusively for the mothers, therefore babies' resource use reported by mothers is not included in the estimations. The amount of missing data is now higher as there is also incomplete information related to hospital activity. The main alteration in the results is that now there is no uncertainty related to the mean incremental cost, indicating that providing the FNP intervention will always be more expensive than usual care.

Table 14.11 Sensitivity analysis for Scenario 1. Excluding midwife visits for the FNP group.

	<b>Difference (Intervention – Control)</b>		<b>Difference (Intervention – Control)</b>		<b>ICER</b>	<b>Probability CE</b>	<b>Probability CE</b>
	<i>Adjusted for baseline utility</i>		<i>Adjusted for balancing factors</i>				
	<b>Cost (£)</b>	<b>Effect (QALYs)</b>	<b>Cost (£)</b>	<b>Effect (QALYs)</b>			
<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>Adjusted balancing f</b>	<b>£20,000/QALY</b>	<b>£30,000/QALY</b>	
<b>Multiple</b>	2088.85	0.0044	1933.1	0.0046	420241,30	15.90%	16.07%
<b>Imputation</b>	(-2570.1; 5851.5)	(-0.017; 0.027)	(-2641.3; 5653.8)	(-0.0170; 0.027)			
<b>Complete</b>	4669.58	-0.0091	4618.76	-0.0036	DOMINATED	0%	0%
<b>Case</b>	(3321.7; 6017.3)	(-0.04; 0.026)	(3290.1; 5947.4)	(-0.039; 0.0314)			

Table 14.12 Sensitivity analysis for Scenario 2. Including mandatory withdrawals as part of the imputation process as well

	<b>Difference (Intervention – Control)</b>		<b>Difference (Intervention – Control)</b>		<b>ICER</b>	<b>Probability CE</b>	<b>Probability CE</b>
	<i>Adjusted for baseline utility</i>		<i>Adjusted for balancing factors</i>				
	<b>Cost (£)</b>	<b>Effect (QALYs)</b>	<b>Cost (£)</b>	<b>Effect (QALYs)</b>			
<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>Adjusted balancing f</b>	<b>£20,000/QALY</b>	<b>£30,000/QALY</b>	
<b>Multiple</b>	2061.53.	0.0055	2061.53	0.0055	368938,39	17.14%	17.29%
<b>Imputation</b>	(-1948.9; 6072.0)	(-0.014; 0.025)	(-1948.9; 6072.0)	(-0.0142; 0.025)			

Table 14.13 Sensitivity analysis for Scenario 3. Including only resource use related to mothers (excluding costs related to babies)

	Difference (Intervention – Control)		Difference (Intervention – Control)		ICER	Probability CE	Probability CE
	<i>Adjusted for baseline utility</i>		<i>Adjusted for balancing factors</i>				
	Cost (£)	Effect (QALYs)	Cost (£)	Effect (QALYs)			
(BCA 95% CI)	(BCA 95% CI)	(BCA 95% CI)	(BCA 95% CI)	Adjusted balancing f	£20,000/QALY	£30,000/QALY	
<b>Multiple</b>	3293.12	0.0035	3272.18	0.0036	908938.9	0 %	0%
<b>Imputation</b>	(2309.3; 4326)	(-0.017; 0.02)	(2287.7; 4294.8)	(-0.0177; 0.025)			
<b>Complete</b>	4646.7	-0.005	4596.18	-0.0014	DOMINATED	0%	0%
<b>Case</b>	(3288.2; 6005.2)	(-0.005; 0.01)	(3263.4; 5928.4)	(-0.036; 0.03)			

Table 14.14 Sensitivity analysis for Scenario 4. Providing a less intensive FNP intervention

	Difference (Intervention – Control) <i>Adjusted for</i>		ICER	Probability CE	Probability CE
	<i>balancing factors</i>				
	Cost (£)	Effect (QALYs)			
(BCA 95% CI)	(BCA 95% CI)	Adjusted balancing f	£20,000/QALY	£30,000/QALY	
<b>Multiple</b>	360.47	0.0047	73924.59	45.01%	45.04%
<b>Imputation</b>	(-3680.5; 4351.8)	(-0.0130; 0.0221)			
<b>Complete</b>	2248.45	-0.0068	DOMINATED	0%	0%
<b>Case</b>	(891.50; 3605,4)	(-0.0421; 0.0277)			

Table 14.15 Sensitivity analysis for Scenario 5. Using self-reported data (for mothers only) as main source for all resource use in the analysis.

	<b>Difference (Intervention – Control)</b>		<b>ICER</b>	<b>Probability CE</b>	<b>Probability CE</b>
	<b>Adjusted for balancing factors</b>				
	<b>Cost (£)</b>	<b>Effect (QALYs)</b>			
	<b>(BCA 95% CI)</b>	<b>(BCA 95% CI)</b>	<b>Adjusted balancing f</b>	<b>£20,000/QALY</b>	<b>£30,000/QALY</b>
<b>Multiple</b>	3708.12	0.0016	222498	0%	0%
<b>Imputation</b>	(2925.0; 4545)	(-0.0194; 0.0223)			
<b>Complete</b>	4590.36	0.0091	501893	0%	0%
<b>Case</b>	(3816.6; 5364.1)	(-0.020; 0.038)			

## 14.4 Conclusion

Participant-level data from the Building Blocks trial provides robust evidence of the cost-effectiveness of the FNP intervention in conjunction with usual care, when compared with usual care alone for young, first time parents who live in areas with a low social socio-economic profile. Apart from the delivery cost of the FNP intervention itself, which is the main cost driver in the analysis, overall there were no clear differences in resource use or QALYs associated with the FNP intervention. The base case analysis (MIm dataset) for the ITT approach suggests that FNP is expected to be more costly and provide only a marginal benefit compared with the current standard care that the NHS currently provide to those women. In that sense the cost-savings that might occur through the delivery of the FNP intervention in order to offset the additional cost of providing this service are not currently evident. Similarly the analysis of uncertainty confirmed that it is unlikely that FNP represents an efficient intervention for the NHS, as the probability of being cost-effective is 17% or below. Despite reducing considerably the cost of the intervention the probability of being cost-effective is below 50% at the current NICE's willingness to pay thresholds. The results were robust to all the sensitivity analysis conducted.

The FNP is currently provided in England to first-time pregnant teenagers, however from this analysis, it was not possible to conclude that providing FNP is more cost-effective than providing universal services alone. Disinvesting of existing non cost-effective interventions will give the opportunity to invest NHS resources elsewhere. In this particular case, displacing the resources currently used in the FNP and investing in other cost-effective interventions will result in health gains for this population of young, first time parents.

## 15 Secondary Economic Analysis

Analyses based solely on single trials are considered of limited usefulness for decision makers as they do not use all the relevant evidence and have a restricted time horizon (dictated by the follow-up of the trial).<sup>205</sup> The process of evidence synthesis and decision modelling is a central process of Health Technology Assessment (HTA) in general, and represents a crucial role in the NICE appraisal process.<sup>206</sup> Motivated by this fact, we aimed to conduct further economic analyses in the shape of an extrapolation exercise to explore the impact of the intervention over a longer, more appropriate, time horizon.

Our initial aim was for the two-year trial outcomes to be extrapolated to a longer time-frame. The purpose of this would be to provide decision makers with a more complete picture of the costs and outcomes of the intervention than the trial alone would do.

The extrapolation exercise was to consider the primary outcomes of the trial for the mother and baby, and aimed to link these with longer term outcomes in health, education, employment and criminality (inclusive of both serious crime and anti-social behaviour). The analysis focused on providing answers to the following interlinked questions:

- Can the outcomes of pregnancy, birth and early childhood (as covered by the primary outcomes of the trial) be predictors of outcomes in the later life of both the index baby and mother?
- Can some qualitative association between the outcomes of the trial and the longer terms outcomes be demonstrated based on the literature?
- Can this relationship be quantified?

Initially, an extrapolation study was to be undertaken in the following phases:

- i) Conducting a systematic review to capture information on studies that examine the association between the primary outcomes of the trial and longer term outcomes in health, education, employment and criminality. It was intended that these findings would be presented in a narrative form and in terms of a matrix similar to the one presented in Appendix 22. The cells of this matrix would be populated with the available information on that specific combination of outcomes, e.g. if the systematic review showed a link between the birth weight of the baby and educational achievement in childhood, then all the available studies have been summarised.
- ii) Use the combined results of the trial and the systematic review to draw up estimates of the potential long-term benefits associated with the primary trial outcomes which could be considered when assessing 'value for money' of the FNP intervention.

However, in order for an extrapolation analysis to be justified, significant and meaningful intervention effects should be present. As evidence of intervention effects in the Building Blocks trial were not found, alternative methods of economic analysis were explored to ensure a complete picture of the costs and consequences of the trial could be delivered to policy makers. This section thus describes and summarises the secondary economic analysis conducted for the Building Blocks trial. This comprises the following;

- i) A cost-consequence analysis to list all relevant health and non-health related resource use and costs associated with each of the trial arms as well as the consequences of the trial, namely, the primary outcomes.
- ii) Top down costing to draw comparisons to a previous estimate of the cost of delivering the FNP intervention.

The results of the systematic review and additional economic analyses are presented sequentially.

## **15.1 Systematic review**

The aim of this systematic review was to identify, evaluate and summarise all relevant existing studies set within a UK context that have explored the association between the primary outcomes of the Building Blocks trial and longer term effects for the children in terms of health, education, employment and criminality.

The specific objectives of the review were to:

- Identify relevant longitudinal studies relating to the long-term effects of maternal smoking during pregnancy on the child.
- Identify the long-term outcomes associated with infant low birth weight.
- Identify the effects of short-interval to subsequent pregnancy.
- Identify relevant longitudinal studies relating to childhood A&E attendances and inpatient admissions.

The review therefore aimed to inform our extrapolation study.

### **15.1.1 Methods**

#### **15.1.1.1 Search strategy**

The principal method of literature identification involved a search of online databases to identify longitudinal, epidemiological and observational studies. A range of electronic datasets were searched including MEDLINE and MEDLINE In Process & Other Non-Indexed Citations (Ovid), British Education Index (ProQuest), Criminal Justice Abstracts (EBSCO), ERIC (ProQuest), PsycINFO (Ovid), Social Policy and Practice (Ovid) and Social Science Citation Index (Web of Knowledge), covering literature published to 2012 (ingestions to 2013). The observational study design filter created by SIGN was used and adapted for these searches<sup>207</sup>. In addition to

searching these databases, reference checking and citation searching from identified papers was also carried out. The complete search strategy is presented in Appendix 23.

Potentially relevant articles were retrieved and saved in an EndNote library. As the primary intention of the systematic review is to inform the extrapolation study within a UK context, the search and subsequent inclusion of studies was restricted to UK based research only. All UK constituent countries (England, Scotland, Wales and Ireland) were included in the search strategy. These studies were then assessed for potential inclusion in the review by the primary reviewer (BCM) based on a strict set of inclusion and exclusion criteria.

### 15.1.2 Inclusion / exclusion criteria

A defined set of inclusion / exclusion criteria were applied to identify studies for inclusion in the review (Table 15.1). These sought to ensure that only studies examining an appropriate population through an appropriate design whilst measuring appropriate outcomes were included. Any study outcome relating to the primary trial outcomes (birth weight, prenatal tobacco use, emergency attendances and inpatient admissions, and second pregnancy within two years of first birth) were considered for inclusion. The review aimed to be sufficiently inclusive so that studies that looked at outcomes, such as termination in addition to second pregnancy, were included in the review to ensure that relevant data (reported in different ways) will be used to inform economic extrapolation. Study outcomes were not limited by time, i.e. studies could measure outcomes at later points in childhood, adolescence and adulthood.

Table 15.1 Eligibility criteria for retrieving studies in systematic review

	<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
Design	Longitudinal prospective / retrospective studies	Non-longitudinal studies, prevalence based studies
Population	Mothers and children (defined as under 18 years of age)	None
Location	UK only	Non-UK
Outcome	Health / well-being / criminality / education outcomes relating to Building Blocks trial outcomes	Risk factors associated with a Building Blocks trial outcome

#### 15.1.2.1 Selection methods

Study selection took a step-wise approach. Article titles and, where available, abstracts were screened by the primary reviewer to determine whether they fulfilled eligibility criteria. Articles not immediately meeting the inclusion criteria were rejected and the reasons for exclusion recorded. Papers meeting the full inclusion criteria were retrieved for detailed assessment. The first 10% of citations were screened independently by both the primary reviewer (BCM) and a secondary reviewer (SJR) to minimise the risk of bias or errors. Any disagreements were resolved via discussion between the two reviewers. The inclusion strategy was then

definitively established and the lead reviewer completed the remaining 90% of the papers. A flow chart showing the number of studies remaining at each stage was used to document this selection process (Figure 15.1).

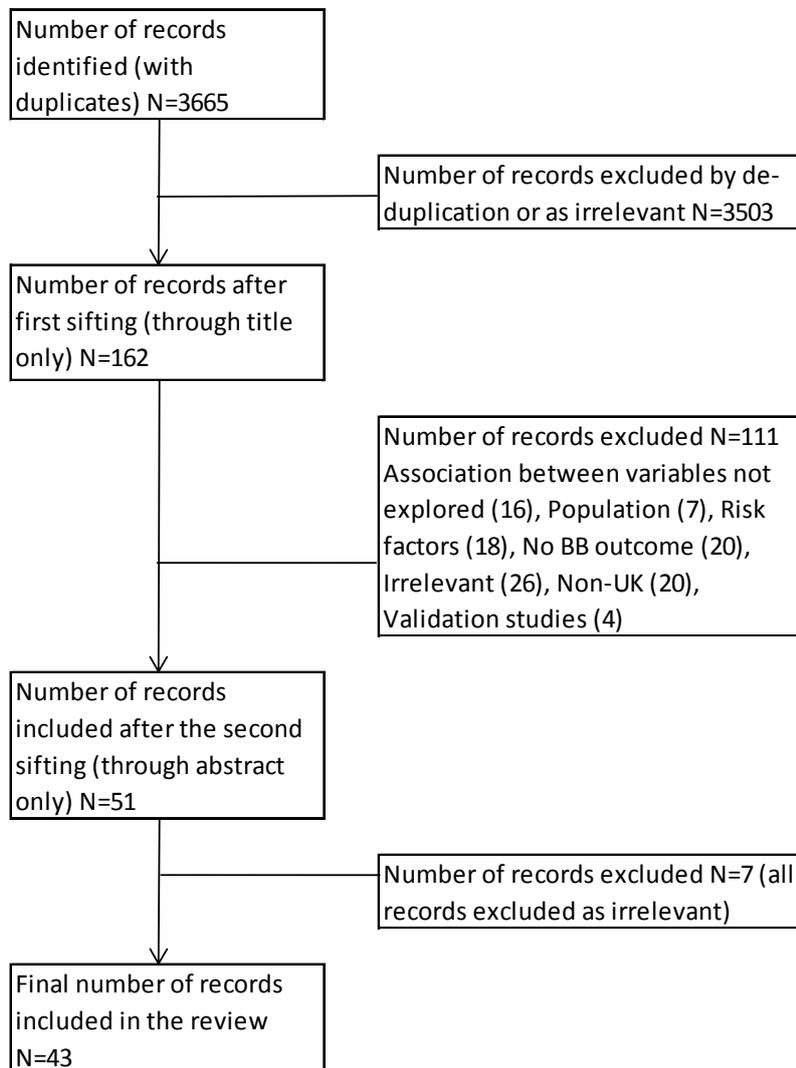


Figure 15.1 Flow chart showing the selection process for the systematic review

### 15.1.2.2 Assessment of methodological quality

Critical appraisal of identified studies was undertaken with the aid of a known checklist. Although several tools exist, no singular tool has been adopted universally to assess quality in non-randomised studies<sup>208</sup>. The existing tools have been systematically reviewed<sup>209</sup>, resulting in six tools being identified as useful for quality assessment, but all of which requiring a level of adjustment depending on the research questions. For the present review, relevant articles were evaluated using an adapted version of the Effective Public Health Practice Project (EPHPP) 'Quality Assessment Tool for Quantitative Studies'<sup>210</sup>, as identified as a useful tool in the systematic review. This tool considers the appropriateness of the study design to the research question, risk of bias, choice of outcome measure, analytical methods, quality of reporting, quality of the intervention and generalisability.

### **15.1.2.3 Data extraction**

Data extraction was conducted on all included studies and considered information on study and participant characteristics, outcomes, method of analysis and main findings. A data extraction form was designed according to the aim of this review and all extracted data were logged in an Excel spreadsheet for analysis.

A high degree of heterogeneity was identified between the studies meeting the inclusion criteria for the review. The results are discussed through means of a narrative synthesis, which highlights the potential long-term benefits that may arise from the outcomes of the Building Blocks trial.

## **15.1.3 Results**

The search identified 3,665 studies of which 3,503 were excluded on the basis of title and abstract leaving a total of 162 for retrieval and full study assessment. Of these, 43 records were deemed suitable, fulfilling the inclusion criteria for the review. For a list of all included studies see Appendix 24.

Of the 43 studies retrieved 29 concerned smoking related outcomes, 13 concerned outcomes associated with low birth weight and one discussed the outcomes associated with short inter-pregnancy interval.

### **15.1.3.1 Study characteristics**

As per the inclusion criteria, all studies were conducted within a UK context, though 1 study included comparative data from the Czech Republic<sup>183</sup>. Studies comprised of varying sample sizes and examined a vast range of outcomes. The majority of the studies were prospective longitudinal cohort studies (n=33) though 10 retrospective/ case-control studies also met the inclusion criteria.

The included studies were largely of moderate or high quality, though 2 studies did not meet the minimum criteria outlined in the quality checklist (Thomson, 1996) and thus were deemed low quality.

### **15.1.3.2 Data synthesis**

Results were summarised according to the key outcomes of the Building Blocks trial. The results pertaining to each of these outcomes of interest are discussed below.

### **15.1.3.3 Maternal smoking and child outcomes**

Data were extracted from 21 studies exploring the effects of maternal smoking during pregnancy on child outcomes. Maternal smoking was entirely assessed through self-report measures, with mothers generally asked to report on the number of cigarettes smoked per day thus all study results are likely to be affected by some level of bias. Maternal smoking was found to impact on a range of longitudinal outcomes.

#### **15.1.3.4 Health**

Maternal smoking during pregnancy was linked to a wide range of both childhood and adulthood health outcomes. Table 15.2 summarises the findings.

Table 15.2 Maternal smoking during pregnancy and child longitudinal health outcomes

Study	Aim	Methods	Outcome measure	Findings	Covariates	Quality assessment
Blair et al., 1996 <sup>188</sup>	To investigate the effect of exposure to tobacco smoke on the sudden infant death syndrome	Two year population based case-control study  Participants: 195 babies who died and 780 matched controls	SIDS	A dose response was associated with exposure to tobacco smoke. Maternal smoking during pregnancy was significantly related to SIDS (OR=2.10 [95% CI:1.24-3.54]) in the multivariate analysis. After adjustment, paternal smoking had an additional independent effect (OR=2.50 [95% CI: 1.48- 4.22])	Maternal age, household structure, high parity, multiple births, short gestation, low socioeconomic status, sleeping position, maternal alcohol consumption, parental use of illegal drugs, parental bed sharing, breastfeeding and birth weight.	Moderate
Fertig, 2010 <sup>194</sup>	To examine the importance of selection on the effect of prenatal smoking by using three British cohorts	Data from 3 UK birth cohort studies used providing a large data set of 45400 participants.	Birth weight	The effect of prenatal smoking in 2000 on low birth weight is over 50 percent greater than in 1958 and is approximately double with respect to the probability of a low birth weight birth conditional on gestation. Selection could explain as much as 50% of the current association between prenatal smoking and the probability of low birth weight birth.	Child gender, parental marital status, timing of the first prenatal doctor's visit, parity, maternal age, maternal education, parental social class.	Strong
Golding et al., 1990 <sup>196</sup>	Association between child cancer and factors during pregnancy, labour and delivery and other maternal aspects.	Case-control study of 132 children. Development of childhood cancer was recorded.	Child cancer	Childhood cancer was associated with antenatal smoking (OR=2.69 [95%CI:1.05-6.89]). Logistic regression showed independent relationship between childhood cancer and maternal smoking (OR=2.5 [95% CI:1.20-5.08])	Maternal age, parity, social class, marital status, and whether the birth was single or multiple.	Moderate

Hawkins et al., 2009 <sup>198</sup>	Association between risk factors (including birth weight and smoking during pregnancy) obesity.	Prospective cohort study using data from the Millennium Cohort Study (n=13188)	Childhood obesity	Early childhood obesity was associated with maternal smoking during pregnancy (1-9 cigarettes daily: OR=1.34 [1.17-1.54] fully adjusted; 10-19 cigarettes: OR=1.49 [1.26-1.75] fully adjusted).	Birth weight, child's ethnicity, breastfeeding duration, introduction of solid foods, TV viewing, household structure, smoking during pregnancy, parental weight, maternal pregnancy weight, access to a garden, country, and ward type.	Strong
Henderson et al., 2001 <sup>183</sup>	Association between smoking during pregnancy, environmental tobacco smoke (ETS) exposure and wheezing illness of infants of 6 months old	Longitudinal cohort studies from the UK and Czech Republic (n=14269).	Wheeze	In the UK, infant wheeze was significant associated with maternal smoking during pregnancy OR=1.30 [95% CI: 1.09-1.56] adjusted). In the Czech Republic, infant wheeze during the first 6 months after birth was significantly associated with ETS exposure (OR=1.66 [95% CI: 1.17-2.36] adjusted).	Child gender, maternal age, parity, gestational age, season of birth, duration of breastfeeding, maternal history of asthma, and overcrowding living condition.	Moderate
Koshy et al., 2011 <sup>211</sup>	Association between children's weight and height and cigarette smoke exposure during mothers' pregnancy	Use 2 UK cross-sectional surveys from 1998 and 2006 (n=3038)	Childhood obesity	Smoking during pregnancy was associated with an increase in the likelihood of obesity in children (OR= 1.61[95% CI: 1.19–2.18])	Socioeconomic status, low birth weight, child gender, survey year and current household smoking.	Moderate

Larsson & Montgomery (2011) <sup>212</sup>	To assess the association between smoking during pregnancy and poorer motor competence among offspring	Longitudinal study of 13207 families in GB followed up to age 11.	Hand control and coordination assessed using known measures.	After adjustment, heavy smoking during pregnancy was significantly associated with poorer performance in PUM (picking up matches) task for the non-dominant hand in both boys (Coeff=1.474 [95% CI: 0.47-2.48 p =.004] and girls (Coeff=1.203 [95% CI: 0.15-2.26 p =.026]). It also negatively affected boys' performance in CD (copying design test score) (Coeff=-0.185 [95% CI:-0.32 - -0.05 p =.006]).	Maternal smoking during pregnancy, child gender, birth weight, gestational age, breastfeeding, social class, parental education, maternal age, laterality and pubertal development.	Moderate
Little et al.. 2004 <sup>213</sup>	Association between smoking and orofacial clefts	Case-control study of 438 children from England and Scotland.	Orofacial clefts	Maternal smoking during pregnancy had a positive association with cleft lip with or without cleft palate (CL+/-P)(OR=1.9 [95% CI:1.1-3.1] adjusted), and cleft palate (CP) (OR=2.3 [95% CI:1.3-4.1] adjusted). A dose-response was observed for both CL+/-P (p value=0.012) and CP (p value=0.004). Passive smoking of mothers also had weak effect.	Child gender, season of birth, maternal education, children's ethnic group, material deprivation, total energy intake, folate intake, supplemental vitamin use, and alcohol consumption.	Moderate
Pang et al.. 2003 <sup>214</sup>	Association between parental preconceptional smoking and maternal smoking in pregnancy, and risk of developing cancer in childhood	UK based case control study using children diagnosed with malignancy or CNS tumour under 15 years (n=3838) and matched controls (n=7629).	Childhood cancer	Significant monotonic decreasing trends in risk were found in relation to the amount of cigarettes smoked by the mother during pregnancy for all child cancers, leukaemia, lymphoma, CNS tumours and other solid tumours (p<0.001, p=0.03, p=0.01 and P=0.03 respectively), with ORs statistically significantly below 1 among heavy smokers.  For primitive neuroectodermal tumours the OR was 0.55 (P=0.01).	Child's age at diagnosis, child gender, UKCCS region, parental ages, and household deprivation score.	Strong
Power et al.. 2010 <sup>215</sup>	Association between maternal smoking during	Prospective UK cohort study following members up to	Risk factors of CVD in adulthood	Maternal smoking during pregnancy was associated with an increased likelihood of obesity in adult offspring classified by BMI (OR = 1.40 [95% CI: 1.25–1.56]) and high waist circumference (OR =	Birth covariates: Maternal age, parity, education, social class, maternal and	Strong

	pregnancy and risk factors for CVD	age 45 years (n=8815).		1.32 [95% CI: 1.19–1.47])	<p>paternal height and weight, birth-weight, gestational age, breastfeeding</p> <p>Childhood covariates: teacher-rated behaviour at 7 years, and cognitive ability tested at 7 years,</p> <p>Adulthood covariates: qualifications by 42 years old, social class at 42 years old, frequency of exercise, television and personal computer use, consumption of healthy and unhealthy foods, smoking status and alcohol consumption.</p>	
Power et al.. 2003 <sup>216</sup>	To investigate growth trajectories and predictive factors for those with low birth weight and high adult BMI	<p>Birth cohort study followed up to age 33.</p> <p>Full data available for 7017 participants.</p>	Adulthood obesity	Maternal smoking during pregnancy was associated with an increased likelihood of obesity in adult offspring classified by BMI for both males (OR=1.79 [95% CI: 1.37-2.29] and females (OR=2.27 [95% CI: 1.79-2.86]).	Parental BMI, height, age, social class, maternal smoking during pregnancy, infant feeding method, and birth order.	Strong

Power and Jefferies 2002 <sup>217</sup>	Association between maternal smoking during pregnancy and obesity risk through childhood to age 33	Prospective GB cohort study of 5839 born in 1958.  Assessed obesity status (BMI) at age 33.	Adulthood obesity	Maternal smoking during pregnancy was associated with an increased likelihood of obesity in adult offspring classified by BMI for both males (OR=1.56 [95% CI: 1.22-2.00] and females (OR=1.41 [95% CI: 1.12-1.79]).	Parental body size, maternal age, infant feeding, parity, social class, own education level, smoking and diet.	Strong
Ramadas et al.. 2007 <sup>218</sup>	1. Association between the IL1RN gene polymorphisms with asthma; and 2. association between the gene (IL1RN) - environment (smoke exposure) interactions and asthma	UK based prospective cohort study.  Outcome measure: Asthma, airway obstruction and BHR	Asthma	The rs2234678 genotype GG was significantly associated with repeated measurements of asthma in children of mothers who smoked during pregnancy (ETS-2 group: OR 4.43, CI 1.62–12.1, p=0.0037) but not in children without maternal smoking exposure during pregnancy (ETS-0 or ETS-1). This suggests that exposure to maternal smoking may be more detrimental to some children than others.	Maternal smoking during pregnancy, post-natal ETS exposure, low birth weight (<2500g), male sex, and breastfeeding for at least the first 3 months of life.	Moderate

Sadeghnejad et al.. 2008 <sup>219</sup>	To investigate whether there is a combined effect of interleukin-13 gene polymorphisms and tobacco smoke on persistent	UK based cohort study followed up to age 10 (n=791)  Outcomes were wheezing and persistent childhood asthma	Wheezing and asthma	Maternal smoking during pregnancy was associated with early onset persistent wheeze (OR=2.93, p < 0.0001). However, the effect of maternal smoking during pregnancy was stronger in children with certain genetic features (OR= 5.58 and OR =1.29, respectively; p for interaction = 0.014). When analyzing asthma instead of wheezing, the interaction was statistically significant (p = 0.03) for persistent asthma. Children with a CCG/CCG haplotype pair had an	Gender, low birth weight (<2500g), breastfeeding, household cat present during pregnancy, and household dog present during pregnancy.	Moderate
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	childhood wheezing and asthma			OR of 5.57 (95% CI 2.13 to 14.63, p = 0.0005) for ETS-2 on persistent asthma. For subjects with haplotype pairs other than CCG/CCG, the OR was 1.32 (95% CI 0.57 to 3.04, p = 0.587).		
Severson et al.. 1993 <sup>220</sup>	Association between parental smoking and alcohol consumption and childhood AML.	Case control study in the US and Canada.	Childhood cancer (Acute Myeloid Leukemia (AML))	No statistically significant associations were found for maternal cigarette smoking when exposures were restricted to the month immediately preceding pregnancy; the first, second, or third trimester of pregnancy; or during the time the mother was nursing the index child.	Maternal age, maternal education, maternal drug use, child gender, and child ethnicity.	Moderate
Sorahan et al.. 1995 <sup>221</sup>	Association between childhood cancer and consumption of alcohol and tobacco.	Case-control study in England and Wales.	Childhood cancer	There was no association between maternal smoking and childhood cancer (P = 0.602).	Parental class, maternal age, and paternal age.	Moderate
Sorahan and Lancashire 2004 <sup>222</sup>	Relation between parental cigarette smoking and hepatoblastoma	Case-control study in UK.  43 cases of hepatoblastoma and 5777 controls	Childhood cancer	Positive associations were found between hepatoblastoma risks and both maternal and paternal smoking. The largest relative risk is shown in the fuller model for both parents being smokers (RR=2.69, P<0.05, 95% CI 1.18–6.13).	Gender, age at death or corresponding age for controls, year of death or corresponding year for controls, social class, maternal age, paternal age, and obstetric radiography.	Moderate
Strachan et al.. 1996 <sup>223</sup>	The relationship between incidence of wheezing illness from birth to age 33 and perinatal, medical, social,	Prospective longitudinal study across the UK. 18559 participants followed to age 33	Asthma and wheeze	Maternal smoking during pregnancy was associated with increased incidence of childhood wheezing (OR=1.72 [95% CI: 1.11-2.67]), when compared to cohort members whose mother never smoked.  Birth order, birth weight and birth weight for gestation were not significant independent risk	Child gender, maternal age, birth order, gestation, albuminuria, bleeding in pregnancy, pneumonia by age 7, whooping cough by age 11, tonsillectomy by age 16, hay fever, Eczema, abdominal pain, Vomiting,	Strong

	environmental, and lifestyle factors			factors.	migraine, father's social class at age 11, paternal smoking at age 16, maternal smoking, and cohort member's smoking.	
Thomas et al.. 2007 <sup>224</sup>	To explore how prenatal exposures known to be associated with low birth weight effect glucose metabolism in midlife.	UK cohort study of 7518 cohort members born in 1958.	Adult metabolism (diabetes)	No association was found between maternal smoking and rates of adulthood diabetes in offspring after accounting for birth weight for gestational age (BGA) and adult adiposity.	Gestational age, parity, preeclampsia, pre-pregnancy BMI, smoking during pregnancy, and socioeconomic position.	Strong
Toschke et al.. 2007 <sup>225</sup>	To look at the association between maternal smoking and type 2 diabetes.	GB prospective cohort study.  5214 cohort members from NCDS and 6069 from BCS70.	Diabetes	No association between diabetes and postnatal maternal smoking was observed.	Child gender, paternal smoking, maternal smoking in pregnancy, postnatal maternal smoking, number of siblings, maternal and paternal age and social class.	Moderate
Toschke et al.. 2003 <sup>226</sup>	Association between smoking in pregnancy and appetite control in offspring	GB prospective cohort study  10557 cohort members born 1958	Appetite control	An association was found between maternal smoking during pregnancy and offspring appetite control in adulthood (OR= 1.22 [95% CI: 1.01-1.48]).	Current smoking at age 42 years, social class during childhood, self-reported indigestion, depression, and BMI at age 42 years.	Moderate

Although five studies reported on the association between prenatal exposure to maternal smoking and incidence of childhood cancer, only one of the five studies reported significantly elevated odds of development,<sup>196</sup> with the remaining studies finding no significant association. This study was unique in the sense that it analysed the impact based on *all* types of childhood cancer, in contrast to the other four which focused on only specific types of cancer. Whilst this aspect of the design may be beneficial to assessing the relationship between smoking exposure and the broad spectrum of cancer diseases, the study was largely hindered by a very small case-control based sample size (n=132), matched on only a narrow range of potentially confounding variables. Given the limitations of this design and the high correlation between the other 4 studies identifies, there appears to be little evidence in a UK setting supporting a link between maternal smoking and subsequent incidence of childhood cancers.

One potential benefit that was largely evident in the literature is the potential to reduce the number of wheeze and asthma-related health problems. Of the four studies identified that measured this outcome<sup>183,218,219,223</sup>, all four noted a significantly increased likelihood of wheeze and asthma related problems in association with maternal smoking during pregnancy (OR 1.3-4.43), though one of these addressed a particular subset of the population with a specific genotype.<sup>218</sup> All four studies were deemed of moderate to high quality, employing large, generalizable samples and accounting for a good range of covariates in statistical models.

The most prominent health-related problem associated with maternal prenatal smoking was weight-related problems, which were noted not only in childhood but also throughout adulthood. Eight studies engaged this as an outcome measure, 2 of which looked at child outcomes<sup>198,211</sup> with the remaining six focusing on adult outcomes.<sup>215-217,224-226</sup> Children of prenatal smokers were between 1.23 and 1.49 times more likely than children of non-smokers to develop childhood obesity, according to the number of cigarettes mothers smoked per day.<sup>198,211</sup> The probability of developing obesity in adulthood was slightly more pronounced with similar increases in the likelihood being found across the three studies using this outcome (OR 1.4-2.27).<sup>215-217</sup> Additionally children of prenatal smokers were also more likely to experience poor appetite control in adulthood (likely to facilitate obesity),<sup>226</sup> and may be more likely to develop diabetes,<sup>224</sup> though this specific association is questionable and inconsistent across studies,<sup>225</sup> Given the vast health related costs associated with weight related problems, this finding presents a clear example of how a reduction in maternal prenatal smoking could be vastly beneficial and cost saving over time, assuming this relationship is causal.

Though these health outcomes appeared to be the most prominent and well researched, thus presenting the most likely potential sources of benefit from a reduction in maternal prenatal smoking, the results also suggested potential links with Sudden Infant Death Syndrome (SIDS),<sup>188</sup> orofacial abnormalities such as cleft palate,<sup>213</sup> and neurological functioning assessed through measures of motor control,<sup>212</sup> emphasising the breadth of potential health benefits that could be achieved.

#### **15.1.3.5 Cognitive development and educational attainment**

Table 15.3 presents the findings relating to maternal smoking and child cognitive and educational outcomes.

Table 15.3. Maternal smoking during pregnancy and child longitudinal cognitive/ educational outcomes

Study	Aim	Methods	Outcome measure	Findings	Covariates	Quality assessment
Brion et al., (2010) <sup>189</sup>	To assess the association between maternal prenatal smoking and child psychological problems.	Prospective cohort study in 3 health districts in England and Brazil. N= 6735 in England, 509 children in Brazil	Behavioural outcomes measured by SDQ (England) or CBCL (Brazil) around age 4	In the UK cohort maternal smoking was significantly associated with hyperactivity/attention problems (OR = 1.17 [95% CI 1.04-1.31]), and peer social problems (OR = 1.24 [95% CI 1.1-1.4]).  Smoking was also associated with conduct/externalizing problems in both cohorts (ALSPAC: OR=1.24 [95% CI:1.07-1.46]; Pelotas: OR=1.82 [95% CI: 1.19-2.78]),	UK: Socioeconomic status, social class, family income, parental psychopathology, maternal prenatal alcohol, paternal prenatal alcohol intake; Brazil: maternal psychiatric problems, birth weight, gestational age and breastfeeding	Strong
Collins et al., (2007) <sup>190</sup>	To assess the association between prenatal tobacco exposure and child academic achievement.	Longitudinal analysis of 6390 mother-child pairs across the UK.	Adolescent offspring academic achievement measured through pass/fail on O-level (GCSE equivalent) and A-level at ages 16 and 18 respectively.	Prenatal exposure had no significant effects on test failure in adolescence.	Maternal smoking before pregnancy, maternal age, parental socioeconomic classification, child gender, and adolescent smoking status	Moderate
Hutchinson et al., (2010) <sup>201</sup>	Associations between maternal smoking in pregnancy and child behaviour.	Prospective cohort study of 13778 families across the UK (MCS) followed from birth	Children's conduct and hyperactivity/inattention problems measured by the SDQ at age 3 years.	After adjustment, for boys, mothers' persistent smoking in pregnancy was significantly associated with conduct problems (OR=1.44 [95% CI: 1.01-2.06] for light smoker; OR=1.80 [95% CI: 1.28-2.54] for heavy smoker) and hyperactivity-inattention problem (OR=1.56 [95% CI: 1.12-2.15] for light smoker; OR=1.62 [95% CI: 1.13-2.33] for heavy smoker).	Socio-demographic factors, problematic relations, problematic parenting, poor adaptive functioning, and health related behaviours.	Strong
Maughan et al., (2004)	Explore association	Longitudinal study of 1116	Children's conduct problems at age 5 and 7	No significant association between maternal smoking and child behaviour.	Mothers' and fathers' prior history of	Moderate

227	between prenatal smoking and early childhood behaviour	families in England and Wales.	years were assessed using the CBCL measures.		antisocial behaviour, maternal postnatal depression, and family socioeconomic status disadvantage.	
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No association was identified between maternal prenatal smoking and children's academic attainment measured through test scores.<sup>190</sup> However, two studies did report a significant association with problematic behaviour in school aged children,<sup>189,201</sup> which may affect learning. Increases in the likelihood of children engaging in problematic behaviour ranged from 1.17 times more likely to 1.80 times more likely depending on the type of behaviour measured and the quantity of cigarettes the mother had smoked during pregnancy. However, both of these studies lacked a rigorous selection of potential confounders in the analysis. Additionally, the final study employing this outcome reported no significant association after covariates had been adjusted for.<sup>227</sup> The limited UK-based literature available suggests that the potential value of reducing prenatal smoking in mothers on children's educational outcomes is small, with a reduction unlikely to bring about any considerable benefits or cost savings over the long term. However, it is important to recognise that this finding is based on only a small number of studies conducted exclusively within a UK context.

#### **15.1.3.6 Criminal activity / anti-social activity**

Table 15.4 presents the findings relating to maternal smoking and criminal activity / anti-social activity.

Table 15.4 Maternal smoking during pregnancy and child criminal/anti-social activity in adolescence and adulthood

Study	Aim	Methods	Outcome measure	Findings	Covariates	Quality assessment
Hay et al., (2010) <sup>228</sup>	To examine the links between exposure to maternal depression in pregnancy and antisocial outcomes in children.	Longitudinal study of 120 families in Britain.  Families were followed until the child was around 16 years.	Incidence of arrests and DSM diagnoses.	Antenatal exposure to cigarette smoking did not predict antisocial outcomes for children.	Maternal social class, maternal education, cultural background, maternal age, marital status, household structure, mother's education, maternal smoking and drinking during pregnancy, mother's antisocial behaviour, and father's history of arrest	Moderate
Macleod et al., (2008) <sup>229</sup>	To estimate the prevalence of alcohol and tobacco use among children	Birth cohort study in England (n=6895, 3410 male)	Measured self-reported use of tobacco and alcohol at age 10.	After adjusting for potential covariates no significant association was found between maternal smoking and child tobacco and alcohol use.	Parental smoking, alcohol and cannabis, child gender, family adversity, parental social class, financial difficulties, and childhood problems (including low IQ, conduct problem, peer problems, depressed, victim, and bullying)	Moderate
Murray et al., (2010) <sup>230</sup>	To identify early predictors of conduct problems and crime	Large UK cohort study (n=16401) followed up to age 34 years	Child conduct problems at age 10 measured using parent-rated Rutter A2 scale.  Convictions were self-reported at ages	In fully adjusted models, maternal smoking during pregnancy was significantly associated with conduct problems at age 10 (partial OR=1.8 [95% CI: 1.3-2.5] for girls; Partial OR=1.7 [95% CI: 1.4-2.2] for boys) and convictions in adulthood (partial OR=1.8 [95% CI: 1.2-2.7] for girls; partial OR=1.4 [95% CI: 1.1-1.7] for boys).	Pregnancy-birth risk factors (maternal smoking in pregnancy and birth complications), Child risk factors (conduct problems at age 5, visual-motor skills,	Strong

			30 and 34 years.		and IQ), parent risk factors (parental loss, low cognitive stimulation, authoritarian parenting, and maternal depression), and socioeconomic risk factors (teenager and single mother at birth, large family size, family deprivation, and poor neighbourhood).	
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Three studies reporting on criminal activity or anti-social behaviour measures during late childhood through to adulthood met the criteria for inclusion. Although no significant association was found between maternal smoking and child smoking and alcohol use at age 10<sup>229</sup> and child antisocial behaviour at age 16,<sup>228</sup> children of prenatal smokers were found to be more likely to report convictions for criminal activity in adulthood (OR 1.4-1.8), with female children being more affected than male children.<sup>230</sup> Although these findings are drawn from only 1 study, this was deemed high quality research boasting a vast sample size (n=16,401), where a diverse range of covariates were included in statistical analyses, including maternal depression, a known risk factor for problematic behaviour and criminal activity in children.<sup>230-232</sup> A high cost is associated with criminal activity, particularly that associated with incarceration with the annual average cost for each prisoner in the UK exceeding £36,000.<sup>233</sup> Thus if maternal prenatal smoking is linked to children committing criminal offences in later life, this represents another opportunity for later cost savings associated with a reduction in smoking.

#### **15.1.3.7 Low infant birth weight and child outcomes**

##### *Health*

Table 15.5 presents the findings relating to low birth weight and health

Table 15.5 The effects of low birth weight on child long-term health outcomes

Study	Aim	Methods	Outcome measure	Results	Covariates	Quality assessment
Annesi-Maesano et al., 2001 <sup>185</sup>	To explore how in utero and perinatal factors and health outcomes affect the development and severity of asthma in childhood	Prospective cohort study.  4065 children and 2583 mothers.  Mean age among non-CM mothers was 31.0±3.3 years.	Childhood asthma	Low birth weight (<2.5kg) was associated with child asthma (OR= 1.57 [95% CI: 1.10-2.25])	Child age, child gender, prematurity, birth weight of <2.5 kg, and birth order of the child; maternal age at child's birth, parity, smoking during the 12 months before child was born, and asthma of mother.	Strong
Davies et al., 2004 <sup>192</sup>	Association between birth weight and adult total cholesterol concentration (TC)	Cross-sectional 1994-1996  18286 men and 7557 women. British Telecom employees  The mean age is 38.9 for men and 36 for women	Adult cholesterol	After adjustment, in men a -0.09 mmol/L reduction in TC was observed per 1 kg increase in birth weight (95% CI, -0.11 to -0.06 mmol/L; P<0.001); in women, a -0.006 mmol/L reduction in TC was observed per 1 kg increase in birth weight (95% CI, -0.04 to 0.03; P=0.8).	Age, BMI, socioeconomic position, alcohol intake, ethnicity, smoking, physical activity, and menopausal status.	Moderate
Gale and Martyn 2004 <sup>195</sup>	Association between birth weight and risk of psychological distress and depression	Prospective cohort study  5187 participants included for the 16-year follow-up; 8292 for the 26-year follow-up	Adult depression	Low birth weight ≤2.5 kg was associated with depression in women at age 26 (OR=1.3 [95% CI:0.9-1.8]) and men at age 26 years (OR=1.6 [95% CI:1.1-2.3]).	Gestational age, father's social class at birth, maternal age, parity, smoking during pregnancy, maternal depression at 5 years, separation from mother, tenure of family accommodation at 5 years, parental divorce/separation,	Strong

					and experience of care by local authority.	
Law et al.. 1993 <sup>234</sup>	Association between low birth weight and high blood pressure	Longitudinal study 1895 children (0-10 years) and 1231 men and women aged 59-71 years.	Childhood and adult blood pressure	Every kg of birth weight increase was associated with 2.8 mm Hg (95% CI: 1.4-4.1) decrease in blood pressure at the age of 4, 4.0 mm Hg (95 % CI: 1.5-6.5) decrease at the age of 64, and 5.2 mm Hg (95% CI: 1.8-8.6) decrease for the age of 64 to 71	Cuff size, age at examination, ambient temperature, and sex	Strong

Moore 2005 <sup>235</sup>	To identify the incidence and characteristics of preventable childhood deaths.	Retrospective survey 34 childhood preventable deaths. City of Wolverhampton, UK Mother's age <20 years (33%)	Childhood death	Preventable deaths were associated with low (2933 g) birth weight (p<0.001).	<u>Child gender, birth weight, ethnic origin, maternal age, area of residence, and adverse social factors.</u>	Weak
Orfei et al.. 2008 <sup>236</sup>	Association between adult lung function and birth weight, postnatal growth and early air-pollution exposure	Data drawn from 2 UK cohort studies (n=3262 and 9377).  Lung function (forced expiratory volume in 1 sec (FEV1), and forced vital capacity (FVC)). The 1946 cohort was assessed for lung function at age 43 years; the 1958 cohort was assessed at age 44-45 years.	Lung function	When the two cohorts were pooled and mutually adjusted, 1 SD increase in birth weight was associated with 30.4 ml increase in FEV1 (95% CI: 16.1-44.8) and 26.9 ml increase in FVC (95% CI: 8.0-46.0).	Child gender, height, adult smoking status, social class in childhood, air-pollution exposure in childhood, proportion of adult height represented by the trunk, and proportion of adult height reached by age 7.	Strong
Pearce et al.. 2012 <sup>237</sup>	Direct and indirect associations between foetal, infancy and adult risk factors and fibrinogen levels	Prospective study 394 singleton study members Newcastle upon Tyne, UK	Adult fibrinogen level (a risk factor for CVD)	No significant association was found between standardised birth weight and adult plasma fibrinogen levels (Beta-coefficient=-0.03, 95% CI: -0.01-0.001, p = 0.34, unadjusted)	Family history of cardiovascular disease, sex, standardised birth weight, gestational age, social class at birth, housing conditions at birth, duration of being breast fed, social class at age 49-51 years, cigarette smoking status at 49-51 years, alcohol consumption at age 49-51 years, physical activity at age 49-51 years, percent body fat at age 49-51	Moderate

					years, BMI at age 49-51 years, cigarette smoking history (pack-years), height and waist-hip ratio at 49-51 years.	
Riordan et al.. 2006 <sup>238</sup>	The association between perinatal circumstances and subsequent young adult suicide	Birth cohort study 1061830 participants birth between 1 Jan 1969 - 31 Dec 1986	Adult suicide	Individuals of low birth weight (<2500 g), when compared with the reference group (3250–3749 g) were at higher risk of suicide (HR=1.35, 95% CI 1.05–1.72) and at higher risk of death from other causes (HR=1.41, 95% CI 1.24–1.61).	Gender, maternal parity, maternal age, birth weight, gestational age, and parental occupation	Strong

Robertson and Harrild 2010 <sup>239</sup>	Association between maternal and neonatal risk factors and type 1 diabetes in children under 15 years old	361 case children and 1083 controls 1972-2005 Scottish Study	Childhood diabetes	The risk of development childhood type 1 diabetes was not associated with birth weight (OR 0.66 CI95% 0.34 to 1.28; p= 0.22 adjusted).	Maternal age, maternal BMI, previous abortions, maternal smoking, pre-eclampsia, amniocentesis, maternal deprivation, syntocinon, mode of delivery, APH, Rhesus isoimmunisation, ABO isoimmunisation, sex of baby, gestational age, birth order, birth weight, jaundice, phototherapy, breastfeeding, admitted to neonatal	Moderate
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					unit, apgar score at 1 min, and apgar score at 5 min.	
Smith et al., 2007 <sup>240</sup>	the relation between complications in a first livebirth (such as preeclampsia, preterm birth, or intrauterine growth restriction) and the risk of unexplained stillbirth.	retrospective cohort study 133,163 women having a second birth  Scotland	Subsequent pregnancy outcomes	Small for gestational age birth weight (smallest 10 percent for sex and gestation) shows an increase in the risk of stillbirth in the second pregnancy (HR 2.32 CI95% 1.82, 2.96 p<0.001)	socioeconomic deprivation, smoking, maternal age, maternal height, and marital status.	Strong

Data was extracted from nine studies exploring the effects of low birth weight on future health outcomes. Three of these were prospective trials representative of the entire British population,<sup>185,195,234</sup> four longitudinal<sup>237-240</sup> and two cross sectional<sup>192,235</sup> studies that addressed the association between birth weight and long-term health outcomes.

In childhood, having a low birth weight (<2.5kg) was associated with an increased likelihood of asthma and wheeze disorders (OR 1.57, 95% CI 1.1-2.25)<sup>185</sup> and moreover was identified as a factor that is often associated with preventable childhood death occurring before the age of five.<sup>235</sup>

Preventing low birth weight may be important for some factors affecting cardio vascular health in adulthood. For instance, for every additional kilogram in birth weight, a significant decrease was found in blood pressure, both in childhood (age 4) and throughout adulthood (to age 71).<sup>234</sup> Similarly increasing birth weight to a normal level was associated with lower cholesterol levels in adulthood<sup>192</sup> though no significant effects on fibrinogen levels in adulthood<sup>237</sup> or diabetes in childhood<sup>239</sup> were noted. Improving birth weight could thus potentially bring about a substantial potential benefit given the associations between high blood pressure and various health conditions such as hypertension and stroke.

Psychological health in adulthood may be affected by low birth weight, with both men and women being more likely to report a history of depression,<sup>195</sup> and being of greater risk of suicide.<sup>238</sup> Having a first child with a low birth weight was identified as a significant risk factor for complications in subsequent pregnancies, most notably stillbirth (HR 2.32, 95% CI 1.82-2.96,  $p < .001$ ).<sup>240</sup>

### **Cognitive development and educational attainment**

Table 15.6 presents the findings relating to low birth weight and social outcomes.

Table 15.6 The effects of low birth weight on child cognitive and educational outcomes

Study	Aim	Outcome measure	Methods	Results	Covariates	Quality assessment
Strauss 2000 <sup>241</sup>	To determine the long-term functional outcome of Small for Gestational Age (SGA) (2436 g) infants	Educational and employment attainment	Prospective cohort study 14189 full-term cohort infants	Teachers were less likely to rate SGA children in the top 15th percentile of the class at 16 years (13% vs 20%, $P < 0.01$ ) and more likely to recommend special education (4.9% vs 2.3%, $p < 0.01$ ).  Adults (26 years) born SGA were less likely to have professional or managerial jobs (8.7% vs 16.4%, $p < 0.01$ ) and reported significantly lower levels of weekly income.	Child gender, social class, region of birth, and neonatal distress.	Strong
Mackay et al., 2013 <sup>242</sup>	Association between gestation and birth weight and each cause of special educational need	Causes of special educational needs	Retrospective cohort study 407503 school children aged between 4 and 19 years	Low birth weight was associated with sensory (OR 2.85, 95% CI 2.04–3.99), physical or motor problems (OR 2.47, 95% CI 1.82–3.37), and intellectual impairments (OR 2.67, 95% CI 2.41–2.96).	Child gender, maternal age and height, marital status, parity, induction of labour, mode of delivery, year of delivery, previous spontaneous and therapeutic deliveries, and the 5-minute Apgar score.	Moderate
Bartley et al., 1994 <sup>186</sup>	Association between birth weight and socioeconomic disadvantage during childhood, adolescence, and early adulthood up	Socio-economic disadvantage	Longitudinal analysis 4321 participants have data on birth weight and financial problems; 3370 have data on birth weight, housing conditions and social class.	Birth weight under 2721 g (6 lb) experienced the combined disadvantage of lower social class and overcrowding in the household ( $P = 0.01$ , $0.01$ , and $0.13$ at ages 7, 11, and 16 years, respectively). Lower social class without household amenities or sharing them ( $P = 0.008$ ,	Statistical analyses were unadjusted	Moderate

	to 23 years old		1958-1981 (when cohort members were followed up at 23 years old)	0.002, and 0.18 at ages 7, 11, and 16 years, respectively). Strong association ( $P < 0.001$ ), with cohort members of low birth weight being more likely to experience housing inadequacy.		
O'Brien et al., 2004 <sup>243</sup>	To investigate the neurodevelopmental progress in a cohort of preterm (median 1282 g) survivors by comparing the results of detailed assessment at 8 and 14 years.	Disability and educational outcomes	Longitudinal  151 (out of 224 eligible infants) were available for the assessment at 14-15 years.	In preterm was an increase in the proportion of subjects with disability from 11% at 8 to 22% at 14–15 years of age.  Full scale IQ decreased from 104 to 95 from childhood to adolescence, and more adolescents (24%) were requiring extra educational provision than they had at the age of 8 years (15%).	Without control group, statistical analyses were unadjusted	Weak

Data were extracted from four studies examining the effects of low infant birth weight on cognitive development and well-being. Low birth weight may increase the likelihood of requiring special educational support in childhood with teachers being more likely to recommend specialist support at age 16 for children who had a low birth weight compared to children that fell within the normal range (4.9% vs 2.3%).<sup>241</sup> This study also showed that low birth weight children were less likely to be in the top performing 15th percentile of their class (13% vs 20%,  $p < 0.01$ ) possibly reflecting differences in cognitive abilities. Indeed, one large scale retrospective cohort study reported that children of low birth weight were almost 2.5 times more likely to experience intellectual impairments (OR 2.67 CI 2.41-2.96), sensory problems (OR 2.85, 95% CI 2.04–3.99) and motor problems (OR 2.47, 95% CI 1.82–3.37).<sup>242</sup>

In adulthood, low birth weight children were found to be less likely to have professional or managerial jobs at age 26 (8.7% vs 16.4%,  $p < 0.01$ ) and yield significantly lower levels of weekly income, earning on average £21 per week less than children of normal birth weight ( $p < 0.01$ ).<sup>241</sup>

#### **Short-duration to second pregnancy and child outcomes**

Table 15.7 presents the findings relating to a short interval to second pregnancy only one study of moderate quality was identified pertaining to the impact of a short duration to a second pregnancy.<sup>244</sup> This study employed a retrospective cohort of 89,194 families in Scotland, UK, and focused on the outcomes for the second child. A short inter-pregnancy interval of six months or less was identified as an independent risk factor for both extremely preterm birth occurring at 24-32 weeks (OR 2.2, 95% CI 1.4-3.6) and moderately preterm birth occurring at 33-36 weeks (OR 1.6, 95% CI 1.3-2.0). More severely, a short inter-pregnancy interval was also associated with an increased likelihood of neonatal death (unrelated to a congenital abnormality) (OR 3.6, 95% CI 1.2-10.7).

Table 15.7 The effects of having a short interval to subsequent pregnancy (<2 years)

Study	Aim	Methods	Outcome measure	Findings	Covariates	Quality assessment
Smith et al., (2003) <sup>244</sup>	To determine whether a short interval between pregnancies is an independent risk factor for adverse obstetric outcome.	Retrospective cohort study conducted in Scotland, UK. 89,194 women were included	Outcomes were measured for the second child:  Intrauterine growth restriction, extremely preterm birth, moderately preterm birth and perinatal death.	A short inter-pregnancy interval (< 6 months) was an independent risk factor for extremely preterm birth (adjusted odds ratio 2.2, 1.4 to 3.6), moderately preterm birth (1.6, 1.3 to 2.0), and neonatal death unrelated to congenital abnormality (3.6, 1.2 to 10.7).	Maternal age, marital status, height, socioeconomic deprivation category, smoking, previous birth weight, and previous caesarean section.	Moderate

## **15.1.4 Summary**

### **15.1.4.1 Principal findings**

The review aimed to identify, evaluate and summarise all relevant existing studies in a UK context that have explored the association between the primary outcomes of the Building Blocks trial and longer-term effects for the children in terms of health, education, employment and criminality. A broad search aimed to identify studies relating to maternal smoking during pregnancy, effects of low birth weight, effects of short interval to subsequent pregnancy (<2 years) and to identify relevant longitudinal studies relating to childhood A&E attendances and inpatient admissions.

After undertaking a rigorous search of the literature guided by predefined inclusion and exclusion criteria 43 studies were identified for inclusion in the review. The Building Blocks outcome measure most notably found in the literature was maternal smoking during pregnancy and the effects this has on children's health and general development. This accounted for 28 of the included studies. Studies centring on outcomes relating to low birth weight were the second most prevalent (14 studies), whereas studies relating to the final two trial outcomes were prominently absent with only one study discussing short interval to subsequent pregnancy and no studies addressing the long-term outcomes associated with early A&E attendance and outpatient attendances. This reflects a key gap in the literature within this subject area.

Of the trial outcomes addressed in the review maternal smoking during pregnancy was most consistently associated with negative child outcomes, particularly health. Weight related problems and child respiratory conditions such as asthma and wheeze were strongly associated with maternal smoking during pregnancy and several other child health outcomes were also highlighted as potential consequences. Low birth weight was also associated with a range of health outcomes such as cardiovascular, respiratory and psychological health. Some potential links with educational attainment were also visible in the literature.

### **15.1.4.2 Methodological quality of included studies**

The quality of research entered into a systematic review is directly related to the quality and validity of the results. All included studies were thus assessed for methodological quality using recognised screening criteria.<sup>210</sup> Of the 43 studies included in the review, 41 met the criteria to be considered high or moderate quality, having larger sample sizes, more robust assessment measures and more rigorously conducted statistical analyses controlling for a good range of important potential confounders. Only two studies did not meet these criteria. Given that 95% of included studies were considered good quality, we can assume validity in the review findings.

### **15.1.4.3 Strengths and limitations of the approach**

A systematic review was considered the best methodology to answer the current research question. A rigorous search strategy and distinct inclusion and exclusion criteria were employed which yielded a diverse range of relevant good quality studies. The search strategy itself was derived using expert guidance from a systematic

review specialist, thus we can be confident of its adequacy in addressing the question and retrieving the maximum number of results. Predefined inclusion and exclusion ensured a robust study selection procedure, further enhanced by the engagement of two reviewers in the selection process.

Although findings from non-UK countries were omitted from the search, thus reducing the global generalisability of the findings, the extrapolation study, which the review aimed to inform, required information for a UK context only. This restriction is thus viewed as both a strength and a limitation.

Examining outcomes pertaining to aspects beyond the realms of health care, such as educational attainment and criminal activity, is a particular strength of the study, providing a more complete picture of the potential long-term outcomes associated with the primary trial outcomes which allows for potential benefits not only to the health care system but also to other areas of society to be observed.

As no studies exploring the association between childhood A&E attendances and admissions were identified, this could highlight a potential limitation in the search strategy. The inclusion of literature examining the long-term outcomes associated with maltreatment were considered. However, it was deemed inappropriate to include maltreatment in the extrapolation model as the primary study outcome, A&E attendances and hospital admissions, can merely provide an indicator of potential maltreatment from which we cannot conclude that the FNP intervention delivered in the Building Blocks trial effects levels of maltreatment. Consequently, maltreatment was not included as an outcome measure in the present systematic review, though it has been reviewed elsewhere<sup>245</sup>. Instead, the search aimed to identify A&E attendances and hospital admission related studies. No studies exploring the association between this outcome measure and later health and development were found. This is not a surprising finding given that studies are more likely to report long-term outcomes based on the cause of A&E attendances/ hospital admissions, rather than focusing on the dichotomy of whether children experienced these attendances or not. It would be impossible to derive a search strategy that could encompass all causes of A&E attendances/ hospital admission and all the long-term consequences. This is thus a limitation of the present review.

#### **15.1.4.4 Implications for the extrapolation study**

This review highlights a number of areas where large potential benefits could be observed as a consequence of improvements made to the primary outcomes of the trial. For instance, a reduction in maternal smoking during pregnancy would likely result in a decrease in the proportion of health problems in their children, as well as bringing about gains in educational attainment and criminal activity. If an extrapolation study was indicated by the results of the trial, data from the studies included in this review could be used to estimate potential long-term outcomes associated with the trial outcomes.

#### **15.1.4.5 Conclusion**

Taken together, the findings of the systematic review show that if improvements could be made in terms of the primary trial outcomes, real benefits could be observed over the longer-term. The most promising gains lie in childhood and adult health, particularly for respiratory illness and weight management problems. Further potential benefits to educational attainment through improved behaviour and cognitive development were also identified.

Table 15.8 Overview of review findings by Building Blocks outcome measure with the health, education and criminal justice domains

		Trial Primary Outcomes			
		Short term			
		Pregnancy & birth domain		Child health & development domain	Maternal life & economic domain
		Birth weight	Tobacco use	Emergency attendances and admissions	Second pregnancy
Childhood long term outcomes	Health Domain	Stillbirth in subsequent pregnancy: <sup>240</sup> HR 2.32 CI95% 1.82, 2.96 p<0.001)	SIDS: <sup>188</sup> OR = 2.1 (95% CI: 1.24-3.54)		Pre-term birth in second pregnancy: <sup>244</sup> OR= 2.2,(95% CI 1.4 - 3.6) extremely OR= 1.6 (95% CI 1.3 - 2.0) moderately  Neonatal death in second pregnancy: <sup>244</sup> OR= 3.6 (95% CI 1.2 - 10.7)
		Blood pressure: <sup>234</sup> Every kg increase in BW = 2.8 mm Hg (95% CI: 1.4-4.1) decrease in blood pressure at the age of 4	Cancer: <sup>196</sup> OR = 2.69 (95% CI: 1.05-6.89) <sup>214,220-222</sup> NS		
		Wheeze and asthma: <sup>185</sup> OR= 1.57 (95% CI: 1.10-2.25)	Wheeze and asthma: <sup>183</sup> OR= 1.3 (95% CI: 1.09-1.56) <sup>219</sup> OR= 2.93 (p < 0.0001) <sup>223</sup> OR= 1.72 (95% CI: 1.11-2.67) <sup>218</sup> OR= 4.43 (95% CI: 1.62–12.1)		
		Diabetes: <sup>239</sup> NS	Orofacial clefts: <sup>213</sup> OR =1.9 (95% CI: 1.1-3.1) Cleft lip with or without cleft palate (CL+/-P) OR =2.3 (95% CI: 1.3-4.1) Cleft palate (CP)		
			Obesity: <sup>198</sup> (1-9 cigarettes per day) OR = 1.34 (95% CI: 1.17-1.54), (10-19 cigarettes per day) OR = 1.49 (95% CI: 1.26-1.75). <sup>211</sup> OR 1.61 (1.19-2.18)		

	<b>Education Domain</b>	<p>Special education:  <sup>241</sup> 4.9% vs 2.3% (p&lt;0.01) teacher rating</p>	<p>Behavioural problems:  <sup>227</sup> NS</p> <p>Hyperactivity/attention:  <sup>189</sup> OR= 1.17 (95% CI 1.04-1.31)  <sup>201</sup> OR=1.56 (95% CI: 1.12-2.15) for light smoker (boys)  OR=1.62 (95% CI: 1.13-2.33) for heavy smoker (boys)</p> <p>Peer/social:  <sup>189</sup> OR 1.24 (95% CI 1.1-1.4)</p> <p>Conduct:  <sup>189</sup> OR=1.24 (95% CI:1.07-1.46)  <sup>201</sup> OR=1.44 (95% CI: 1.01-2.06) for light smoker (boys)  OR=1.80 (95% CI: 1.28-2.54) for heavy smoker (boys)  <sup>230</sup> Partial OR=1.8 (95% CI: 1.3-2.5) for girls  Partial OR=1.7 (95% CI: 1.4-2.2) for boys</p>		
		<p>Intellectual impairments:  <sup>242</sup> OR= 2.67 (95% CI 2.41–2.96)</p>	<p><sup>212</sup> PUM (picking up matches) Coeff=1.474 [95% CI:0.47-2.48 p =.004] (boys)  Coeff=-1.203 [95% CI:0.15-2.26 p =.026] (girls).</p>		
	<b>Criminal Justice Domain</b>		<p>Antisocial outcomes:  <sup>228</sup> NS</p>		
<b>Adulthood long term outcomes</b>	<b>Health Domain</b>	<p>Mental health:  Depression:  <sup>195</sup> BW &lt;2.5kg  OR=1.3 (95% CI:0.9-1.8) female  OR= 1.6 (95% CI:1.1-2.3) male</p> <p>Suicide:  <sup>238</sup> HR=1.35, (95% CI 1.05–1.72)</p>	<p>Obesity:  <sup>216</sup> OR 1.79 (95% CI: 1.37-2.29) boys  OR 2.27 (95% CI: 1.79-2.86) girls  <sup>217</sup> OR=1.56 (95% CI: 1.22-2.00) boys  OR=1.41 (95% CI: 1.12-1.79) girls  <sup>215</sup> OR 1.4 (95% CI: 1.25-1.56)</p> <p>Appetite control:  <sup>226</sup> OR 1.22 (95% CI: 1.01-1.48)</p>		
		<p>Blood pressure:  <sup>234</sup> Every kg increase in BW = 4.0 mm Hg (95 % CI: 1.5-6.5) decrease at the age of 64, and 5.2 mm Hg (95% CI: 1.8-8.6) decrease for the age of 64 to 71</p>	<p>Diabetes:  <sup>224</sup> OR 1.33 (95% CI: 1.04-1.71)  <sup>225</sup> NS</p>		

	<b>Education Domain</b>		Test scores: <sup>190</sup> NS		
	<b>Employment Domain</b>	Skilled jobs: <sup>241</sup> 8.7% vs 16.4% (p<0.01) Professional/ managerial jobs  Earnings: <sup>241</sup> £21 less per week (p<.01)			
	<b>Criminal Justice Domain</b>		Convictions : <sup>230</sup> partial OR=1.8 (95% CI: 1.2-2.7) girls partial OR=1.4 (95% CI: 1.1-1.7) boys		
<b>Mothers long term outcomes</b>	<b>Health Domain</b>				
	<b>Education Domain</b>				
	<b>Employment Domain</b>				
	<b>Criminal Justice Domain</b>				

[Study citation]; NS: Non-significant

## 15.2 Cost-Consequence analysis

Despite the benefits of conducting technical forms of economic evaluation such as cost-effectiveness analyses, there is some concern that relying heavily on QALYs as a utility-based index of health benefit can present interpretation problems in a decision making context.<sup>246</sup> Consequently, more simplified approaches to summarising costs and outcomes have been advocated. Cost-consequence analysis can cover a wider range of outcome measures that can then be accounted for in decision making<sup>247</sup> and combines and summarises costs and outcomes (clinical and other) in an intuitive and informative manner.

The Building Blocks trial assesses a large number of primary and secondary outcomes. Hence, for a complete picture of the trial's results, the cost-consequence analysis aimed to present all costs and outcomes in a descriptive and disaggregated way. Such presentation can assist decision makers in making the appropriate judgement on the outcome of the interest without overlooking the wider effectiveness of the intervention<sup>248</sup>.

### 15.2.1 Methods

#### 15.2.1.1 Resource use

For the cost-consequences analysis, the mean value per woman of the non-health care items are presented for both groups for the duration of the trial in their respective units, e.g. average number of weeks in education, mean number of contacts with the Connexion personal advisor etc. The difference between the two groups for these items is also presented.

Whenever appropriate, the non-health care items have been translated into costs by applying the appropriate unit costs. There has been no attempt to produce a composite measure of costs or outcomes for this analysis. Rather, a tabular form of all costs and primary outcomes of the trial, including EQ-5D data and QALYs, is presented. Similarly, there has been no valuation of the production loss due to the disparate nature of this population, as a proportion of this group should join education rather than the workforce.

Resource use data collected include health care utilisation such as GP visits, hospital overnight stays, accident and emergency visits etc. and the non-health related such as social assistance, temporary accommodation, educational attendance, childcare and other services. The totals for each item (e.g. total number of GP visits) have been calculated for each participant in both groups over the duration of the trial (i.e. from baseline up to the 2-year interview).

Resource use is averaged across all women in each arm leading to small mean numbers for resource use. Median, minimum and maximum values are reported to highlight the highly skewed nature of resource use. Costs were largely associated with only a minority of women using each resource. Resource use and associated

costs are reported in terms of the mother only. All consequences of the trial, for both mother and child, are reported.

#### **15.2.1.2 Unit costs**

As in the within-trial analysis, unit costs applied to the resource usage were retrieved from several sources. Unit costs pertaining to health care resource use were sources from NHS reference costs<sup>249</sup> and PSSRU Unit Costs of Health and Social Care 2013.<sup>191</sup>

As no unified document currently exists to provide unit costs for the non-health related items, these were sourced from other relevant sources such as governmental websites, research documents and reports.

In one instance, nursery / crèche attendance within a school or college, a UK national average value could not be sourced. Consequently an average was derived using per hour values from a range of such establishments around the country. Very little variation was observed between the different establishments thus we can assume that the average value derived is adequately representative. Unit costs of other types of day care were derived through a similar methodology. Average national costs of the different types of childcare are represented in the literature as 'per 25 hours' thus the average totals were divided by 25 hours to get a per hour rate. This is also true for educational costs whereby annual costs were divided by 52 weeks to gain an estimate of the weekly cost of education.

Given that costs were taken from a range of sources the years of pricing vary for each item. These are all reported in Appendices 15-18. No attempt was made to discount / inflate these items to a consistent rate as appropriate inflation rates for this type of resource are not available. It is thus acknowledged that current figures per resource use may differ slightly from those documented.

Details on the unit cost estimates and their sources for non-health care related resource items are presented in tabulated format and displayed separately from estimates of resource use (Appendix 25).

#### **15.2.1.3 Assumptions**

Though it was possible to attribute a cost directly to the unit of resource use, several assumptions were made. Inpatient attendance costs were split in terms of overnight stays and day admittances in line with the within-trial analysis. For outpatient attendances costs are reported in terms of maternity versus non-maternity related attendances. Maternity-related attendances were considered to be those delivered by obstetric, midwife and gynaecology health professionals. The total number of hours used for each type of childcare was calculated using mother's responses to the number of times per week a child attends day care and the duration per attendance.

Women were not asked about the number of visits to alcohol / drug support units, only whether or not they attended. To ensure consistency within the non-health related items it was desirable to analyse resource use in terms of number of visits. Consequently, it was assumed that all women who reported that they had attended an alcohol / drug support unit made at least one visit, thus a figure of 1 was used for all women in the calculation of total resource use. It is acknowledged that this methodology will likely result in an underestimate of the total cost attributable to this resource, however, given the limited uptake of this resource by women in the Building Blocks trial this is likely to be only a small underestimate of the actual values.

#### **15.2.1.4 Missing data**

Where resource use was missing a value of zero was assumed. Consequently, resource use and costs may be an underestimate, though it is unlikely there would be large differences from reality. For the purpose of the cost-consequence analysis, multiple imputation analysis was considered unnecessary as the model serves only to highlight likely resource use and the average costs per resource. This decision was further vindicated by the small number of women reporting using each of the resources, which in some cases was less than five women. Such small numbers of affirmative responses would prevent imputations from running effectively and result in high error rates.

### **15.2.2 Results**

Resource use for all health and non-health related resources used by the mother only are presented in Table 15.9.

Table 15.9. Descriptive statistics of maternal health and non-health related resource use by trial arm.

	FNP					Usual care				
	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max
<b>Health related resource use</b>										
<i>Inpatient attendances</i>										
Overnight length of stay (N nights)	808	3.99	3	0	99	810	4.09	2	0	110
Day admittances	808	3.53	2	0	60	810	3.58	2	0	77
<i>Outpatient attendances</i>										
Maternity services	808	7.31	6	0	75	810	7.13	5	0	45
Other attendances	808	1.31	0	0	37	810	1.42	0	0	59
<i>Hospital-related resource use</i>										
A&E visit	808	4.54	1	0	36	810	1.58	1	0	29
<i>Community based resources use</i>										
Midwife	459	10.40	10	0	41	422	10.69	10	0	41
Health visitor	363	5.88	0	0	62	321	12.93	10	0	87
<i>GP visitation</i>										
Surgery visits	468	9.36	7	0	48	471	8.46	7	0	48
Home-based visits	469	0.21	0	0	9	471	0.21	0	0	8
<i>Nurse visitation</i>										
Surgery visits	468	2.07	1	0	36	471	2.20	1	0	20
<b>Non-health related resource use</b>										
<i>Education (Weeks)</i>										
Mainstream school or FE College	808	6.24	0	0	86	810	5.26	0	0	88
Learning support unit	808	0.26	0	0	72	810	0.19	0	0	48
Pupil referral unit	808	0.00	0	0	0	810	0.01	0	0	4
Teenage mums support unit	808	0.26	0	0	46	810	0.29	0	0	69
<i>Other supportive services (Number of contacts)</i>										
Connexions advisor	808	1.51	0	0	62	810	1.38	0	0	70
School nurse	808	0.04	0	0	6	810	0.04	0	0	9
Young people's service	808	0.16	0	0	13	810	0.23	0	0	21
Family information service	808	0.08	0	0	8	810	0.13	0	0	12
Children's Centre	808	2.31	1	0	38	810	1.96	0	0	29
Child development centre	808	0.02	0	0	5	810	0.10	0	0	24
Crèche/day nursery	808	0.48	0	0	25	810	0.49	0	0	20
Toddler group	808	0.93	0	0	31	810	0.83	0	0	23
Leaving care service	808	0.08	0	0	17	810	0.06	0	0	10
Fostering services	808	0.01	0	0	3	810	0.05	0	0	26
Youth offending team	808	0.05	0	0	16	810	0.01	0	0	1
Social worker	808	0.72	0	0	54	810	0.64	0	0	43
Alcohol/drug support unit	808	0.01	N/A	N/A	N/A	810	0.01	N/A	N/A	N/A

<i>Childcare (Days per week)</i>										
Crèche / Day nursery at school or college	808	1.35	0	0	38	810	1.10	0	0	49
Nursery group at Children's Centre	808	0.38	0	0	30	810	0.25	0	0	13
Child-minder	808	0.46	0	0	26	810	0.34	0	0	26
Any other childcare	808	0.88	0	0	24	810	0.77	0	0	31
Foster care mother (total number of weeks)	808	0.10	0	0	53	810	0.18	0	0	68
Foster care child (total number of weeks)	808	0.18	0	0	72	810	0.17	0	0	68
<i>Housing (Weeks)</i>										
B&B	808	0.22	0	0	24.00	810	0.26	0	0	76
Teenage parent accommodation	808	0.74	0	0	52.00	810	0.36	0	0	52
Supported accommodation	808	0.75	0	0	64.00	810	0.39	0	0	61
Mother & baby hostel/unit	808	1.07	0	0	64.00	810	0.89	0	0	92
Women's refuge/domestic violence refuge	808	0.04	0	0	20.00	810	0.11	0	0	34
Homeless hostel	808	0.34	0	0	36.00	810	0.36	0	0	40

The results of the cost-consequences analysis can be seen in Table 15.10, providing a clear descriptive summary for use by decision makers. For each cost item, the mean resource use per participant for both the FNP arm and the usual care arm are displayed, alongside the incremental resource use. The mean cost per participant is also shown for each item according to trial arm, as well as the incremental cost. In terms of the consequences, the primary outcomes of the Building Blocks trial are listed for both the FNP arm, usual care arm and the difference between the two.

A descriptive summary of the costs and consequences is provided below, whereby items are discussed in a disaggregated format for the broad range of costs and consequences (spanning health care and non-health care) included in the analysis. Costs are again presented for the mother only.

Table 15.10 Cost-consequence balance sheet for the family-nurse based intervention for young mothers

Costs (resource use)	Mean resource use per participant			Mean cost per participant		
	FNP	Usual care	Incremental (FNP-Usual care)	FNP	Usual care	Incremental (FNP-Usual care)
<b>Health related resource use</b>						
<i>Inpatient attendances (Length of stay/ number of day admittances)</i>						
Inpatient stay	3.99	4.09	-0.10	6354.58	6661.18	-306.60
Day admittances	3.53	3.58	-0.05	775.22	781.73	-6.51
<i>Outpatient attendances (Number of attendances)</i>						
Maternity services	7.31	7.13	0.17	733.13	716.18	16.95
Other attendances	1.31	1.42	-0.11	156.37	161.23	-4.86
<i>Hospital-related resource use (Number of attendances)</i>						
A&E visit	6.50	9.00	-2.50	167.07	172.79	-5.73
<i>Community based resources use (Number of clinic attendances/ home visits)</i>						
Midwife visits	10.40	10.69	-0.28	622.91	643.87	-20.97
Health visitor visits	5.88	12.93	-7.05	135.68	217.78	-82.10
<i>GP visitation (Number of visits)</i>						
Surgery visits	9.36	8.46	0.90	421.35	380.54	40.80
Home-based visits	0.21	0.21	0.00	24.31	24.45	-0.14
<i>Nurse visitation (Number of visits)</i>						
Surgery visits	2.07	2.20	-0.13	21.10	22.40	-1.30
<b>Non-health related resource use</b>						
<i>Education</i>						
Mainstream education	6.90	6.62	0.28	710.36	682.15	28.21
Learning support unit	0.26	0.19	0.07	10.40	7.75	2.65
Pupil referral unit	0.00	0.01	-0.01	0.00	2.88	-2.88
Teenage mother support unit	0.26	0.29	-0.03	67.63	79.15	-11.52
<i>Other supportive services (Number of contacts)</i>						
Connexions advisor	1.51	1.38	0.13	58.13	53.23	4.90
School nurse	0.04	0.04	0.00	3.41	4.10	-0.69
Youth services	0.16	0.23	-0.07	2.76	3.84	-1.08
Family information service	0.08	0.13	-0.05	2.65	4.45	-1.80
Children's Centre	2.31	1.96	0.35	148.30	125.64	22.66
Child development centre	0.02	0.10	-0.08	0.84	3.23	-2.39
Crèche/day nursery	0.48	0.49	-0.01	2.04	2.09	-0.05
Toddler group	0.93	0.83	0.10	4.63	4.17	0.46
Leaving care service	0.08	0.06	0.02	1.53	1.28	0.25
Fostering services	0.01	0.05	-0.04	0.52	1.89	-1.37
Youth offending team	0.05	0.01	0.04	1.51	0.18	1.33
Social worker	0.72	0.64	0.08	28.86	25.58	3.28
Addiction support unit	0.01	0.01	0.00	0.35	0.35	0.00

<i>Childcare (Days per week)</i>						
Crèche / Day nursery at school or college	1.35	1.10	0.25	5.79	4.71	1.08
Nursery group at Children's Centre	0.38	0.25	0.13	1.68	1.09	0.59
Child-minder	0.46	0.34	0.12	1.85	1.35	0.50
Any other childcare	0.88	0.77	0.11	3.38	2.96	0.42
<i>Foster care (Weeks)</i>						
Mother	0.10	0.18	-0.08	60.61	114.64	-54.03
Child	0.18	0.17	0.01	117.28	106.00	11.28
<i>Housing (Weeks)</i>						
B&B	0.22	0.26	-0.04	75.03	87.67	-12.64
Teenage parent accommodation	0.74	0.36	0.38	146.21	70.48	75.73
Supported accommodation	0.75	0.39	0.36	112.13	57.78	54.35
Mother & baby hostel/unit	1.07	0.89	0.18	246.51	204.44	42.07
Women's refuge	0.04	0.11	-0.07	15.12	46.27	-31.15
Homeless hostel	0.34	0.36	-0.02	36.57	38.34	-1.77
<b>Consequences</b>						
Smoking (smoking or non-smoking in late pregnancy)	OR: 0.9 [95% CI: 0.67 to 1.22] p = 0.51					
Birth weight (mean difference in grams)	Mean adjusted difference = 20.75g [95% CI: -39.13 to 80.64] p = 0.497					
Child A&E attendances and admissions (attendance/admission or no attendance/admission)	OR: 1.32 [95% CI: 1.02 to 1.70] p = 0.033					
Short duration to subsequent pregnancy (<2years) (pregnancy or no pregnancy)	OR: 1.01 [95% CI: 0.80 to 1.28] p = 0.920					

### 15.2.2.1 Costs

Little difference was observed in terms of average health care resource use across the majority of services though consistently small differences were found between trial arms in favour of FNP. The largest differences in terms of resource use were the average number of A&E attendances and the mean number of health visitor visits received, both of which were lower for women receiving the FNP intervention compared to women under usual care.

As only small differences in average resource use were observed, the average per woman spend on each resource reflected only slightly notable differences. Overall, average total health-related resource use costs were slightly lower for the FNP arm compared to usual care. Lower average costs were found in the FNP arm in relation to inpatient care, outpatient attendances not related to maternity services, A&E attendances, and midwife and health visitor visitations. The largest difference in average costs was found in relation to inpatient care requiring one or more nights in hospital. In this instance, the mean difference between arms was £307 in

favour of FNP. A difference was also found between the average cost per participant in terms of community based maternity services, specifically health visitor and midwife visitation. On average £82 less was spent per woman receiving the FNP intervention compared to usual care for health visitor visits (both home and clinic based) whilst £21 less was spent per woman on midwife visits (both home and clinic based) reflecting a mean reduction in spend of just over £100 per woman on these key maternity services. The number of health visitor visits received by women was lower in the FNP arm than the Usual care arm as visits from FNP nurses were received in place of standard health visits. Consequently, though the cost attributed to health visitor visits appears reduced, there is the additional cost of the FNP nurses. The cost of the health visitors provided in usual care would thus not be saved through the FNP intervention but would be spent instead on specific FNP trained nurses. Only minor differences were noted in terms of cost associated with inpatient day admittances not requiring an over-night stay (-£6.51), non-maternity based outpatient attendances (-£4.86), and A&E attendances (-£5.73), with all been in favour of FNP. In total an average of £8, 872 was spent on health care for women receiving the FNP intervention compared to a total average of £9,162 per women in the usual care arm, a small difference of £290 per woman between the two arms.

In addition to health care resource use, there was very little difference in the non-health care resource use between the two groups. The average cost of non-health related resource use for women receiving the FNP intervention was £1,866 compared to £1,738 for women under usual care, an average difference of only £128 per woman. In general, reported uptake of all non-health related resources was fairly low in both groups as can be seen through the mean and median values presented in Table 15.10. For the majority of resource items the median resource use for both groups is zero, confirming a low uptake. Mean values are thus influenced by only a minority of women.

Participation in education and training was also highly similar between groups for both mainstream schooling and dedicated support units with little difference in resource use or mean costs.

In terms of supportive services, Children's Centres, such as Sure Start centres, were the most widely used service by both groups, though this averaged at only 2 visits per woman in each of the trial arms. Mean costs of children's centre use was slightly higher in the FNP arm. This is likely a consequence of outlying values as the maximum number of visits was considerably higher in the FNP arm compared to usual care (38 and 29).

Resource use of childcare was found to be particularly low at all time points and overall mean resource use per woman, within both groups, was particularly low. Slightly higher costs were found in FNP women in line with the marginally higher rates of resource use. The most widely used type of childcare was crèche/day nursery within a school or college though the mean number of weeks used throughout the follow-up period was very low at only 1.35 weeks for FNP women and 1.10 weeks for usual care women. As resource use was low the total resource use was low resulting in a low average cost per woman of £5.79 per FNP woman and £4.71 per usual care woman though the cost for women actually using childcare would be much higher.

Resource use for foster care and temporary accommodation was also low in terms of the number of women reporting usage of these resources for both groups of women. Average costs are thus driven by a minority of women. Average costs for temporary accommodation were higher for FNP women than usual care women for teenage parent accommodation, supported accommodation and mother and baby units due to increased use of these by FNP women. The largest average difference between groups was for teenage parent accommodation, with FNP women costing on average £75.73 more than usual care women, again this was due to higher levels of resource use in the FNP group.

### **15.2.2.2 Consequences**

The primary trial analysis showed no significant differences in 3 of the primary trial outcomes. No between group differences were found in the likelihood of smoking during late pregnancy ( $p=0.510$ ), in infant birth weight ( $p = 0.497$ ), or in the likelihood of subsequent pregnancy within the 2 year follow-up period ( $p = 0.920$ ). However, a significant difference was noted when assessing child A&E attendances and admissions. Adjusted odds ratios showed that children of mothers receiving the FNP intervention were more likely to attend A&E or be admitted to hospital (OR = 1.32,  $p=0.033$ ).

This analysis shows limited differences between the resource uptake and associated costs between the two trial arms (FNP intervention and usual care). Overall, average total health-related resource use costs were slightly lower for the FNP arm compared to usual care though this does not account for the actual intervention costs. Conversely resource use and associated average per person costs were higher for non-health related items. This however is not necessarily a negative outcome as some of the items associated with greater costs were positive aspects such as mainstream education and attendance at children's centres. Despite these resources being considered positive outcomes it is important to remember that these are still additional costs which could be incurred as a result of the FNP intervention and should be considered in policy making.

Results from a cost-consequence analysis cannot usually be used to draw conclusions as to whether an intervention is worth funding as the judgement usually lies upon the gains that would likely be attained by recipients. However, given that the FNP intervention does not bring about any significant improvements to recipients compared to usual care, together with the high cost of delivering the intervention, these two factors would suggest that it is highly unlikely that the FNP intervention is worth funding.

It is worth noting that although there were more child A&E attendances and admissions associated with families receiving the intervention, this is unlikely to be a detrimental effect of the intervention but reflect more on increased awareness of mothers receiving the intervention, and the increased contact with a health professional could mean that health concerns are identified more readily causing mothers to seek more help.

A cost-consequence balance sheet was implemented to provide policy makers with a clear descriptive summary of the health and non-health related costs associated with the FNP intervention. This offers an advantage over more technical methods of economic analysis. As a methodology, cost-consequence analysis is

generally limited by its dependence on subjective decision making by policy holders, as it relies on individual judgement on what consequences are sufficiently beneficial. It also simply lists costs and consequences without making statistical comparisons. However, as a supplementary analysis to a full within-trial cost-utility analysis, the cost-consequence model is of value to provide a simplistic over view of costs associated with the intervention, particularly those that are not obvious such as youth offending services and family information services.

In all, the cost-consequence model summarises the minor between-group differences in resource use and costs, alongside the primary trial outcomes. As can be seen, there are a large number of potential factors that are likely to attract additional costs beyond the obvious implementation costs of the intervention. Given these costs and the way in which only small benefits were observed in the trial analysis when considering primary outcomes alone, the cost-consequence model provides further support that the FNP intervention is unlikely to be worth the substantial costs and policy makers may wish to consider other options for investment.

### **15.3 Top-down costing**

In addition to the bottom-up costing undertaken as part of the within trial analysis, top-down costing was also conducted to explore the cost implications to the Department of Health of the FNP intervention overall and to draw comparisons with a previous estimate of the total cost of delivering FNP <sup>204</sup>.

#### **15.3.1 Methods**

We estimated the total expenditure on the FNP for women who took part in the FNP intervention, taking into account the total number of women that were seen as part of the intervention. The top-down costing used two different sources: (i) a costing report by Apteligen <sup>204</sup> and (ii) the cost calculations generated as part of the within trial analysis.

#### **15.3.2 Results**

The top-down costing exercise is summarised in Table 15.11. Data from the recent Apteligen costing report were utilised to estimate the total expenditure on FNP, based on 74 FNP teams in England, 100 women per team and the annual cost per person of £3,083. The total number of women who have taken part in the FNP intervention (7,400) has then been multiplied by the estimated annual cost per person to generate a total annual expenditure of £22,815,902. This cost figure is highly comprehensive, accounting for a wide range of costs such as training fees, other staff-related costs (including travel), overhead charges, premises costs, IT charges and others.

Table 15.11: Top-down costing of the FNP intervention, based on Apteligen costing report

Cost item	Value	Notes
Total number of FNP teams in England	74 <sup>a</sup>	
Number of women who took part in FNP intervention, per FNP team	100 <sup>a</sup>	
Annual cost per FNP team	£308,323 <sup>a</sup>	This is the cost of a typical FNP team based on a sample of 44 (out of 74) FNP teams in England. Note: this is for an established team, i.e. from year 2 onwards and gives a cost of £3,083 per person. [Based on 2011/12 prices]
Total cost per person per year	£3,083 <sup>a</sup>	
Estimated total number of women who took part in FNP intervention	7,400	Total teams by no. of women per team
Total annual expenditure on FNP	£22,815,902	Total no. of women who took part in FNP X cost per woman.

<sup>a</sup> Source: Apteligen costing report <sup>204</sup>

In addition to this estimate, we have also explored the expenditure on FNP to the Department of Health based on the intervention cost estimate from the within trial analysis. This analysis found an average per woman cost of £4,270 over the 2.5 year intervention and follow-up period equating to £1,762 per year (Chapter 14). From this, a total annual expenditure value can be estimated by multiplying the annual intervention cost (£1,762) by the total number of women who are estimated to take part in the FNP intervention nationally (7,400), resulting in an estimated total intervention cost of £13,040,428. However, this figure is likely to be a vast underestimate of the actual total intervention cost as it incorporates the cost of only one nurse for the duration. The costs of a full team and other set-up/running costs are not incorporated, as they were in the prior cost calculation generated by the Apteligen costing report data.

To build on this estimate the difference in health and non-health related resource use costs for the Building Blocks trial were incorporated into the model as can be seen in Table 15.12.

Table 15.12. Top-down costing incorporating findings from the Building Blocks trial with the Apteligen report

Cost item	value	Notes
Total number of FNP teams in England	74	Apteligen report (2012)
Number of women who took part in FNP intervention, per FNP team	100	Apteligen report (2012)
Estimated total number of women who took part in FNP intervention	7400	Apteligen report (2012)
Annual cost per FNP team	£308,323	Apteligen report (2012)
Total annual expenditure on FNP	£22,815,902	Apteligen report (2012)
Mean per person difference in cost associated with health care resource use	-£116.01	FNP trial (2014) – less additional health resource use was identified in the FNP arm compared to usual care
Total cost of health care resource use for FNP women	-£858,438	FNP trial (2014)

Mean per person difference in cost associated with non-health care resource use	£51.35	FNP trial (2014) – more non-health related resource use in FNP arm compared to usual care
Total cost of non-health related resource use for FNP women	£379, 990	FNP trial (2014)
Total cost associated with FNP	£22,337,454	Total annual FNP expenditure + resource use
Total cost per person per year	£3,018.57	Total cost of FNP divided by total no. of women who used FNP.

Apteligen: Based on 2011/12 prices. This is the cost of a typical FNP team based on a sample of 44 (out of 74) FNP teams in England. Note: this is for an established team, i.e. from year 2 onwards (gives cost of £3083 per person). In year 1, the average cost rises to £3,275 per case due to additional set-up costs and slightly higher salary costs \*FNP costs were calculated over the whole study and divided by 2.5 years to provide an estimate of annual costs.

As can be seen in Table 15.12, accounting for the cost differences in health care and non-health care resource use between the two trial arms brings about only a small reduction in the estimated average cost of delivering FNP to an individual woman per year from the original Apteligen value.

In contrast to the Apteligen model, the present model accounts for non-health related outcomes, driving up the cost of delivery. However, the results of the Building Blocks trial suggest there are slightly lower costs associated with health care resource use thus driving a reduction in the overall delivery costs once this is accounted for.

Given that the FNP intervention is delivered at substantial costs for only minor benefits, which are highly unlikely to be considered cost-effective under usual willingness to pay thresholds, the cost estimates presented in this section for the total annual spending on FNP indicate how much funding is set aside for the intervention and the potential for spending elsewhere.

# 16 Valuation of Effects: Discrete Choice Experiment

The Building Blocks trial has evaluated the effectiveness as well as the cost-effectiveness of the FNP intervention compared to usual care provided by the NHS. The level of success of this intervention, as measured by the outcomes of this trial and the cost-effectiveness, will influence the decision to implement or not implement this intervention on a wider scale. However, given the disparate nature of the outcomes / domains, and the possibility that outcomes / domains might conceivably move in different directions, it is necessary to establish some relative value (or trade-off) between the outcomes/domains that could be influenced by the intervention as expressed by the general population.

We used a discrete choice experiment (DCE) to examine the preferences of the general population for the outcomes of the trial. The DCE approach is a well-established method to explore preferences in health services research<sup>250</sup>. The approach is based on asking respondents to state their preferred option between two or more hypothetical scenarios which describe a service or a set of outcomes. With a sufficient number of scenarios and respondents, it is possible to model the impact of specific descriptors within the scenarios on the choice of the respondents.

The aim of this study was to quantify the relative values that members of the general public place on the different outcomes / domains examined in the Building Blocks trial through use of a DCE. The outcomes of the trial together with the valuation of the outcomes in this exercise will provide decision makers with useful knowledge that may inform the judgment about whether the intervention should be adopted or extended on a larger scale.

## 16.1 Methods

### 16.1.1 Selection of outcomes / domains and their levels

The Building Blocks trial measured a large number of primary and secondary outcomes related to both the mother and the child. This study aimed to be as inclusive as possible of these outcomes. The choice of the outcomes would cover the three outcome domains that the Building Blocks trial focused on: pregnancy and birth, child health and development, maternal life course and self-efficacy. After interviewing the study team on what outcomes they considered most important from this trial, it was decided that the following outcomes would be included in the DCE:

Outcomes related to the mother or directly related to the mother's behaviour:

- Occurrence of second pregnancy within two years from the birth of the first child
- Smoking habits during pregnancy
- Prenatal attachment
- Breastfeeding attempts
- Maternal education
- Maternal employment
- Child-centredness

- Sense of mastery or self-efficacy of the mother
- Relationship with partner
- Health status of the mother

Outcomes related to the child:

- Birth weight
- Emergency attendances/admissions of the child
- Immunisations of the child
- Language development of the child

All the above outcomes, with the exception of mother's health, were described in a binary format defining whether one outcome was considered positive or negative. For example, for the prenatal maternal tobacco usage the description was: mother was smoking during pregnancy (negative outcome) or mother was not smoking during pregnancy (positive outcome). The choice of two levels for the majority of the attributes was made with the criteria to keep the task simple and manageable for the respondents while obtaining the necessary information for assessing the relative importance of these attributes and link it to the Building Blocks trial outcomes as expressed in a qualitative manner rather than their magnitude.

The health of the mother was described as a four level attribute as described by the EQ-5D. This is in line with the fact that in the trial the health of the mother is measured by EQ-5D state. The descriptions for the mother's health were the equivalent of the following health states as described by EQ-5D: 11111, 11112, 11211 and 11212. So, the focus was only on two of the five domains of the EQ-5D questionnaire: usual activities and anxiety & depression. These were considered the domains that are potentially affected by pregnancy in this group of an otherwise healthy population. Hence, the mother could be in perfect health (i.e. 11111), could be moderately anxious or depressed (i.e. 11112), could have some problems with performing usual activities (e.g. work, study, housework etc.)(i.e. 11211) or could be moderately anxious or depressed in addition to having some problems with performing usual activities (i.e. 11212). These values are equivalent to the following utility scores: 1, 0.848, 0.883 and 0.812 respectively, based on the UK tariff<sup>105</sup>.

A detailed description of these outcomes is provided in Table 16.1.

Table 16.1 Attributes by Building Blocks research domain, their descriptions and levels

	Attribute Name	Description	Levels
<b>Pregnancy &amp; Birth</b>			
1	Smoking	Prenatal smoking: smoking habits of the mother during pregnancy	Mother did not smoke during pregnancy = 0 Mother smoked during pregnancy=1
2	Birth weight	Whether the baby was born a healthy weight	Baby was born a healthy weight =0 Baby was not born a healthy weight=1
3	Attachment	Pre-natal attachment: the emotional bond between the mother and her unborn baby	Mother developed an emotional bond with her unborn baby=0 Mother did not develop an emotional bond with her unborn baby=1
<b>Child Health &amp; Development</b>			
4	A&E	Whether the child attended an accident and emergency department for an injury or swallowing something harmful before the age of two	Child did not need to attend an accident & emergency department before the age of two=0 Child needed to attend an accident & emergency department before the age of two=1
5	Breastfeeding	Whether or not the mother breastfed her baby	Mother breastfed her baby=0 Mother did not breastfeed her baby=1
6	Vaccines	Immunisation: whether the child has had all recommended vaccinations	Child has had all recommended vaccinations=0 Child has not had all recommended vaccinations=1
7	Child needs	Child-centeredness: consideration and provision of the mother towards her child's needs	Mother considered & provided for the child's needs=0 Mother did not consider & provide for the child's needs=1
8	Language	Whether the spoken language development of the child is appropriate to the child's age	Child has developed spoken language appropriate to his/her age=0 Child has not developed spoken language appropriate to his/her age=1
<b>Maternal life course</b>			
9	Pregnancy	Whether the mother had another pregnancy or not within two years of the birth of her first baby	Mother did not have another pregnancy within two years of the birth of the first child=0 Mother had another pregnancy within two years of the birth of the first child=1
10	Education	Whether the mother stayed in education during/after pregnancy	Mother stayed in education=0 Mother did not stay in education=1

11	Employment	Whether the mother is employed during and after pregnancy	Mother was employed during & after pregnancy=0 Mother was not employed during & after pregnancy =1
12	Relationship	The relationship of the mother with her partner	Mother had a good relationship with her partner=0 Mother did not have a good relationship with her partner=1
13	Health	General health status of the mother: whether the mother has problems with mobility, self-care, usual activities (e.g. work, study, housework, family or leisure activities), pain or discomfort and whether she is anxious or depressed	Mother has no problems with mobility, self-care, usual activities, has no pain or discomfort & is not anxious or depressed =0 (utility score of 1)  Mother has no problems with mobility, self-care, usual activities, has no pain or discomfort & is moderately anxious or depressed =1(utility score of 0.848)  Mother has no problems with mobility, self-care, has some problems with performing usual activities, has no pain or discomfort & is not anxious or depressed =2 (utility score of 0.883)  Mother has no problems with mobility, self-care, has some problems with performing usual activities, has no pain or discomfort & is moderately anxious or depressed =3 (utility score of 0.812)
14	Confidence	Self-efficacy of the mother: whether the mother was confident about achieving her goals and believed she could solve problems well	Mother was confident that she could achieve her goals & believed she could solve problems well=0 Mother was not confident that she could achieve her goals & believed she could solve problems well=1

### 16.1.2 Experimental design

During the first phase of the study (i.e. deciding on the attributes to be included in the experiment), it was not possible to restrict the attributes into a smaller number as it was desirable for the DCE to mirror the outcomes measured in the trial. This would provide the possibility of assessing the profile of outcomes as a whole based on the preferences gathered from the DCE. Including all the 14 attributes in one design would result in a complicated, or nearly impossible task, as respondents might not make trade-offs. The decisions might be based on heuristics or lexicographic decision rules<sup>251,252</sup>. Secondly, the large number of attributes would result in a very complicated design. The full factorial would have resulted in  $2^{13} \times 4 = 32,768$  possible profiles, an extraordinary starting number to create an optimal number of choice sets to be presented to the respondents.

Hence, for the experimental design of the study, a ‘blocked attribute’ approach was adopted.<sup>252-254</sup> This approach allows for a large number of attributes to be allocated across more than one DCE design, with overlap in some attributes which can be called the “common attributes”. The approach is based on the fundamental assumption that the respondents will have the same preferences over the whole set of attributes if they are presented together compared with if they are presented in blocks.<sup>252</sup> The data from the different designs can be pooled, hence the models will be based on the common utility scale.

The attributes were split across four designs (Figure 16.1). The allocation of attributes across the designs was made in such a way that the designs contained two common attributes: one primary outcome related to the mother and one primary outcome related to the child. The rest of the attributes were allocated by attempting to have a balanced representation of mother and child related outcomes in each design.

**Figure 16.1 Allocation of attributes across the four DCE designs**

Design A	Design B	Design C	Design D
<ul style="list-style-type: none"> <li>•2<sup>nd</sup> Pregnancy</li> <li>•Emergency admissions</li> <li>•Education</li> <li>•Smoking</li> <li>•Breastfeeding</li> </ul>	<ul style="list-style-type: none"> <li>•2<sup>nd</sup> Pregnancy</li> <li>•Emergency admissions</li> <li>•Employment</li> <li>•Prenatal attachment</li> <li>•Immunisation</li> </ul>	<ul style="list-style-type: none"> <li>•2<sup>nd</sup> Pregnancy</li> <li>•Emergency admissions</li> <li>•Self-efficacy</li> <li>•Birth weight</li> <li>•Child-centeredness</li> </ul>	<ul style="list-style-type: none"> <li>•2<sup>nd</sup> Pregnancy</li> <li>•Emergency admissions</li> <li>•Relationship with partner</li> <li>•Language development</li> <li>•Health status of the mother</li> </ul>

The designs were constructed in SAS software by using the D-efficiency criterion<sup>255</sup>. The advantage of this method over other methods, e.g. use of catalogues with orthogonal main effects designs, is that the latter might not exist for the chosen number of attributes / levels for our four designs. SAS provided the flexibility of creating and evaluating all four designs (with attributes of differing levels). The SAS programme estimates and provides the D-efficiency of the design which is presented as relative measures of efficiency compared with a hypothetical orthogonal design which has optimal choice set size. The D-efficiency based designs are the result of the trade-off between degrees of orthogonality and balance, where one or more parameters cannot be estimated when D-efficiency is 0 or the design is perfectly balanced and orthogonal when D-efficiency is 100.

Fifteen choice sets were constructed for the designs A-C and 16 choice sets for the design D (an example of this is shown in Appendix 26). These were fractional factorial designs and only the main effects were included. Interaction effects between the attributes were not included due to the size and complexity of the designs. The D-efficiency was 98.96% for designs A-C and 83.91% for design D. In other words, these numbers show that relative to what is probably the optimal design (where the determinant of the variance-covariance matrix is minimised), the designs A-D are nearly 99% and 84% D-efficient.

The variance-covariance matrix for the two designs is presented in Appendix 27. The correlations between the variables were deemed to be reasonably low.

### **16.1.3 Qualitative work**

The aim of this work was to simplify the first version of the DCE in order to make the attributes easier to read and understand. Two rounds of cognitive interviews were conducted to achieve these objectives.

#### **16.1.3.1 First Round**

A questionnaire was devised using a sample of scenarios from each questionnaire and an extra scenario that simplified the attribute about the mother's health. These questionnaires were tested on six participants (three males, three females). Participants were asked to read the instructions and explain their understanding of the task, then they were asked to look at each choice set and were asked questions about why they chose A or B and their understanding of each attribute. They were also encouraged to 'think aloud' whilst making their choices. The interviews were audio recorded and the most important quotes were transcribed and notes were taken of key issues raised. The purpose of the first round of cognitive interviews was to:

- determine if respondents understand the DCE task in the way that it is intended.
- identify any problems with any individual attributes
- identify any problems with making a choice
- identify problems with making a rating

#### **16.1.3.2 Second Round**

Four questionnaires were used (designs A, B, C and D). These questionnaires were tested on eight participants (two participants per questionnaire design, 3 males and 5 females). Participants were asked to read the instructions and explain their understanding of the task, then they were asked to look at each choice set and were asked questions about why they chose A or B and their understanding of each attribute. They were also encouraged to 'think aloud' whilst making their choices. At the end of the interview participants were asked 'how was the overall experience?' The interviews were audio recorded and fully transcribed. The objectives of the second round of cognitive interviews were to:

- check if there is adequate background information.
- determine if respondents understand the DCE task in the way that it is intended
- identify any problems with any individual attributes
- identify any problems with making a choice
- identify any problems rating each scenario
- identify any problems with the DCE structure
- check / observe any memory biases
- check / observe acquiescent responses
- check the length of time

In general, participants understood the task and did not need any extra background information about the intervention. There were some attributes that were not interpreted as intended. These were the emergency admissions attribute and the employment attribute. The EQ5D attribute was seen more as an indicator of post-natal depression and health problems after pregnancy. Two participants thought a lot about the potential relatedness of attributes in each scenario and created a narrative to help them make a choice. However, this appeared to happen when they were making a decision on whether to accept the A&E attribute. This may have been because the attribute was too vague or because it was serious and the participant wanted to provide what they considered to be a reasonable explanation of why they had accepted it. It is not known whether the level of reasoning may have taken place because participants were being interviewed and may have wanted to present themselves or their ideas in a particular way.

Overall, the task of completing the questionnaire needed some more explanation to encourage participants to read each scenario carefully, think about the attributes in order of preference and to make each choice independently.

As a result of this qualitative work some attributes were refined and further explanations were given. The accident and emergency attribute was reformed and additional information on injury and ingestions was included. Similarly, the employment attribute was changed to reflect the level of employment more precisely, indicating that the mother was employed at one point. Regarding health-related quality of life it was necessary to clarify that the exercise was referring to the mother's health before and after pregnancy; and to include further information on one of the domains of the EQ-5D (usual activities). Finally, it was necessary to instruct participants to: (i) consider the importance of each point in the scenario when making their choices (rather than thinking about how the attributes in one scenario may be related); (ii) view each of the 16 choice sets independently, and therefore avoiding thinking about their previous responses to scenarios within previous choice sets; (iii) remember to rate each of the two scenarios within an individual choice set either independently or in comparison to each other.

#### **16.1.4 The choice task**

All the designs used a forced-choice approach where the respondents were requested to make a choice between the two scenarios; the 'none' or 'do not know' options were not provided. An example of one choice set is shown below in Table 16.2.

Table 16.2 Example choice set

Scenario A	Scenario B
<ul style="list-style-type: none"> <li>• Mother did not have another pregnancy within two years of the birth of the first child</li> <li>• Child did not need to attend an accident and emergency department for an injury or swallowing something harmful before the age of two</li> <li>• Mother was confident that she could achieve her goals and believed she could solve problems well</li> <li>• The mother did not consider or provide for her child's needs</li> <li>• The baby was born a healthy weight</li> </ul>	<ul style="list-style-type: none"> <li>• Mother had another pregnancy within two years of the birth of the first child</li> <li>• Child needed to attend an accident and emergency department a number of times for an injury or swallowing something harmful before the age of two</li> <li>• Mother was not confident that she could achieve her goals and did not believe she could solve problems well</li> <li>• The mother considered and provided for her child's needs</li> <li>• The baby was born below a healthy weight</li> </ul>
My choice <input type="checkbox"/>	My choice <input type="checkbox"/>

An introductory page with information about the aim of the Building Blocks trial as well as the choice experiment were provided at the start of the survey. The respondents were asked to choose the most preferred scenario out of the two in each choice set. Each scenario described possible outcomes of the Building Blocks trial. Respondents could be reminded about the meaning of the attributes via a 'hover-over' function which provided the description of each attribute in the choice set.

There were five groups of respondents, randomly assigned to complete one of the tasks: four groups were asked to complete one of the four designs each and the fifth group was asked to complete all four designs. The designs for the first groups as well as the order of the designs for the latter group were randomly allocated. As it will be explained further down, the survey was an internet based one. There is evidence to suggest that the acceptable number of choice sets to respondents that would not significantly affect responses is around 16<sup>256</sup>. Given the magnitude of the task (for example the group who completed all four designs was asked to respond to 15\*3+16= 61 choice sets), the respondents were given the opportunity to log onto the survey as often as needed and complete it over a period of time. However, they did not have the possibility to change previously recorded responses.

### 16.1.5 Participant recruitment and data collection

The study was designed as a self-completion survey over the internet. This decision was made based on a number of factors: the alternative methods would be either postal questionnaires (which usually have a low response rate) or via face-to-face interview. The required sample for this survey would make the latter approach prohibitive both in terms of timelines and costs involved.

A market research company was employed to undertake the design of the survey website, translate the paper-based questionnaire to a web-based one, recruit the respondents, collect and handle the data. Participants were invited to

complete the online survey by the market research company and were reimbursed for their participation in the survey (£2.50 per participation). These invitations were sent out based on a stratified probabilistic sampling approach. The strata were defined by age, gender and socioeconomic status (SES), supplemented by a minimum quota approach in case the respondents were not responding to the invitation.

The quota approach, following the random probabilistic sampling from the existing panel of potential respondents, has the advantage that it ensures that the adequate number of respondents is achieved so that real differences in preferences are identified. However, given that not all the invited participants will respond to the questionnaire, there is a danger of having a biased final sample and not fully representative of the general population. The demographics of the sample for this exercise will be discussed in the results section.

Before the survey was open for the main study, a soft-launch of the survey was performed to ensure that the on-line questionnaire and the randomisation were working correctly. The quality of retrieved data, both during the “soft-launch” and the main study was assessed. The counts of respondents who had seen each question and should have responded to a question were checked. Also, responders who were classified as “speeders” i.e. completed the survey much faster than anticipated were removed from the dataset. The final sample comprised 207 respondents who completed all four DCE designs (A+B+C+D) plus 200 respondents who completed one of the A, C or D designs and 201 who completed design B.

### 16.1.6 Data analysis

The data from the DCE were analysed using a random effects probit model using Stata software. This is one of the conventional approaches for analysing discrete choice experiment data. A random effects probit model is suitable for panel data, like those produced from a DCE, where there is a correlation between the responses from the same respondents. It embodies two assumptions: that the individual effect has a normal distribution and that it is uncorrelated with the explanatory variables<sup>257,258</sup>. The model used for the analysis of the data from the four datasets (one for each separate DCE design) was the following:

$$\Delta Y = \alpha_0 + \alpha_1(d\_Attribute\_1) + \alpha_2(d\_Attribute\_2) + \alpha_3(d\_Attribute\_3) + \alpha_4(d\_Attribute\_4) + \alpha_5(d\_Attribute\_5) + v + \varepsilon$$

(1) where  $\Delta Y$  is the change in utility from choosing scenario A over B (left – right scenario), and  $d\_Attribute\_1$  to  $d\_Attribute\_5$  represent the difference in the levels of the five attributes between the option A and B in each choice scenario.  $\alpha_0, \alpha_1 - \alpha_5$  are the coefficients to be estimated,  $v$  are the random effects and  $\varepsilon$  are the independent and identically distributed error terms. The Choice variable was coded as 0 if scenario B (right) is chosen and 1 if scenario A (left) is chosen.

The data from the four designs were pooled based on the assumption that the individuals will have the same preferences over the attributes if they are presented together compared with if they are presented in blocks<sup>252</sup>. The same model as (1) was applied, in principle, to the pooled dataset where all the attributes from the four designs were

included (14 attributes in total). For this model, 'no difference' in attribute levels for the omitted attributes was assumed, and so the variables in the analysis were zeroed out. The attribute related to mother's health was transformed into a continuous variable by applying the utility scores corresponding to each EQ-5D description as previously applied in the literature.<sup>259</sup> Values are presented in row 13 of Table 16.1.

A number of separate regression models were estimated. The first included the main attributes only. A separate model was fitted to the pooled data by adding dummy variables for each design. Dummy variables for each design were included to account mainly for unobserved differences in the average probability of selecting scenario A or B in each design, and also to control for differences between designs and samples in terms of respondents' characteristics that were not taken account of in the random allocation of designs across respondents.<sup>252</sup> Linearity was assumed for the two-level attributes.<sup>260</sup> A separate model was fitted by including a dummy for the respondents who completed all four designs.

Other models examined how preferences varied according to respondents' demographic characteristics (i.e. age, gender and parenthood/guardianship status). These models included the fourteen attributes (pooled data from four designs) and interaction term variables. Dummy variable interaction terms were constructed by multiplying the variables related to the difference in attribute levels between the two options in each scenario and the respective demographic characteristic (e.g. dummy for pregnancy\*age and so on). The coding for the demographic characteristics was as follows: Gender=1 for "Female" and 0 for "Male"; Age group=1 for age <= 65 and 0 for age > 65. Guardianship status=1 for parents/guardians and 0 for non-parents or guardians.

The dummy variable interaction terms will capture how the preference for one event happening / not happening, e.g. second pregnancy happening within two years of birth of index child, depends on age, gender, guardianship status. From the models that are described above, the importance of the attributes, as indicated by the significance of their coefficients, was investigated. Also, the compensatory attitude of the respondents between the attributes (i.e. how they trade one unit change in one attribute for a unit change in another) was examined.

The total utility or benefit score was estimated for scenarios describing the success of FNP relative to the best case scenario (i.e. if the FNP outcomes were to be positive). The estimation was based on a linear prediction by using the coefficients from the model on the pooled data and the difference in attribute levels between the two scenarios. One scenario was based on comparing the best vs worse case results of the Building Blocks trial i.e. FNP achieves positive results in all the outcomes and FNP achieves no positive results in any of the outcomes. In the second scenario, the best case results are compared with FNP achieving positive outcomes only for the five top attributes (i.e. with the smallest coefficients, hence the biggest impact on whether the programme will be adopted by the general population). The examples are an illustration of how the results of the DCE can be utilised for policy making purposes.

To test the appropriateness of pooling the data from the four separate designs, a likelihood ratio (LR) test was conducted.<sup>257,261</sup> This establishes whether the coefficients are comparable across the designs and the pooled data due to difference in scale parameters. The test was conducted by using the *lrtest* function in Stata which uses the stored estimates from running the five models (one for each of the four separate designs and one for the pooled data). The

results of the test are presented in Table 16.3; m1-m4 are the estimates from the separate models / designs and m5 from the model fitted on the pooled data. The test indicates that the hypothesis of parameter homogeneity between the separate datasets and the pooled dataset cannot be retained once the difference in scale between the models was taken into account.

Table 16.3 Likelihood-ratio test

Model	Obs	ll(null)	ll(model)	df	AIC	BIC
m5	24842	.	-11607.9	16	23247.72	23377.64
m1	6105	.	-2888.98	7	5791.95	5838.968
m2	6120	.	-3068.31	7	6150.612	6197.647
m3	6105	.	-2654.7	7	5323.398	5370.416
m4	6512	.	-2996.17	7	6006.347	6053.817

Assumption: (m5) nested in (m1, m2, m3, m4)

LR chi2(12) = -0.59, Prob > chi2 = 1.0000

## 16.2 Results

The sample recruited for this exercise achieved a good representation of the general UK population for all four categories of the age variable, home ownership and marital status variable. The gender split was not fully representative of the general population, as this sample appeared to have an over-representation of female participants. The sample broadly mirrors the split by SES of the general population, although there is a slight under-representation of the C2 and D categories (i.e. skilled or semi-skilled manual workers) and over-representation of the E category. Table 16.4 depicts the full details of demographic characteristics of the sample.

Table 16.4 Sample demographic characteristics

	N	%	Gen.Pop. (UK)
<b>Total</b>	<b>1008</b>	<b>100</b>	<b>100</b>
<b>Gender</b> <sup>129</sup>			
Male	308	31	49
Female	700	69	51
<b>Age</b> * <sup>129</sup>			
18-24	131	13	12
25-44	373	37	35
45-64	325	32	33
65+	178	18	21
<b>Social grade (NRS 2012-13)</b> <sup>262</sup>			

A (Higher managerial / professional / administrative)	63	6	4
B (Intermediate managerial / professional / administrative )	277	27	22
C1 (Supervisory or clerical / junior managerial / professional/ administrative / student)	312	31	27
C2 (Skilled manual worker)	101	10	22
D (Semi or unskilled manual worker)	79	8	16
E (Casual worker – not in permanent employment /Housewife / Homemaker / Retired and living on state pension/ Unemployed or not working due to long-term sickness / Full-time carer of other household member)	176	17	9
<b>Guardian</b>			
Yes	256	25	
No	740	73	
N/A	12	1	
<b>Marital Status <sup>129</sup></b>			
Divorced / widowed	109	11	19
Married / living with partner	594	59	47
Single	293	29	35
N/A	12	1	-
<b>Education</b>			
5 grade C GCSEs (or equivalent) or less	185	18	
A levels / AS levels / Scottish Highers / NVQ	258	26	
More than 5 grade C GCSEs (or equivalent)	91	9	
Postgraduate Degree or equivalent	115	11	
Professional Qualification	108	11	
Undergraduate degree or equivalent	234	23	
N/A	17	2	
<b>Home status <sup>129</sup></b>			
Owned	692	69	66
Rented	295	29	33
N/A	21	2	1
<b>TOBACCO – Interest in tobacco products</b>			
Not interested	636	63	
Somewhat interested	94	9	
Very interested	76	8	
N/A	202	20	

\* Refers to the percentage of each group for the UK general population above 18 years old;

NRS: national readership survey.

Table 16.5 presents the results from the analysis of data from each design separately as well as the analysis of pooled data, with and without including the dummy variables for each design. The significant value of Rho (confidence intervals do not include 0) suggests that the responses from each individual were correlated; hence, the random effects model was appropriately used in this case. The design-specific dummy variables are not significant, suggesting that there were no unobserved differences between the samples that completed each design or between the designs. The differences in respondents' characteristics might have been accounted for by the random allocation of the designs across respondents.

The random effects probit model was run by including a dummy variable for the respondents who completed all four designs and demonstrated that the responses from this group of respondents were not different from those who filled out separate designs (the coefficient was insignificant at the value of 0.033, with confidence intervals CI: 0.022, 0.088).

The results of the model on the pooled data, without including the design dummies (as they are insignificant) are discussed here. Given the coding of the binary attributes, as presented in Table 16.1, the negative signs of the coefficients would suggest that respondents' utility decreases as the level of the attribute increases (0= positive outcome, 1=negative outcome). Positive signs would indicate the contrary i.e. respondents derive higher utility as the level of the attribute decreases (i.e. becomes a "positive outcome"). All the regression coefficients have the expected signs and are statistically significant, indicating that the respondents prefer improvements of the outcomes described in this exercise, e.g. mother returns to education, second pregnancy does not take place within two years of birth of index child and so on. The results are in line with the a priori expectation of the study that positive outcomes related to vulnerable, pregnant women and their children are preferable to negative outcomes.

Given the coding for each choice option (i.e. 0 if respondent chose the right-hand scenario (or scenario B) and 1 if respondent chose the left-hand scenario (or scenario A)), the positive constant sign suggests that there might be a general preference for scenario A, possibly linked with a "left" bias. The positive constant sign also reinforces the above hypothesis i.e. respondents will prefer a scenario which has positive outcomes (their coding is 0; hence the positive constant reflects the base category of the dummy variables).

The ranking of the coefficients from all the models is presented in Table 16.5. It is interesting to note that the attributes with the highest ranked coefficients for the separate designs are the five top highly ranked attributes in the model on the pooled data. The relative ranking of the two common attributes (second pregnancy and A&E attendances) is the same in all the models: A&E has a larger coefficient than occurrence of second pregnancy, i.e. it is always a more important outcome than the occurrence of a second pregnancy. In the pooled model, the largest coefficients are mainly related to outcomes that affect children directly: whether the mother fulfils the child's needs, whether there is a bond between mother and child, A&E attendances for the child and the language development. Although smoking and relationship between mother and her partner are not directly related to the child, they are considered to have an immediate impact on them. So, one could conclude that the outcomes related to the child are valued higher than the outcomes that are related to the mother (say her employment or education).

The results of the model that included the interaction effects between the attributes and demographic characteristics (gender, age and parenthood/guardianship) are presented in Table 16.6. The coefficients and the associated p-values demonstrate that preferences for the occurrence of the following: A&E attendance for the child, education and employment of the mother and whether the child's needs are met varied by gender (statistically significant coefficients for the interaction terms). The preferences between genders change in terms of their magnitude (i.e. whether females receive higher utility from one outcome) rather than the nature of the outcome; they still prefer the positive outcomes over the negative outcomes as it is indicated by the negative coefficients for the interaction terms with gender. The baseline for gender was the male group (coded as 0), hence females have higher disutility than men if the above attributes take the "negative outcome" value i.e. the child attends A&E, the mother does not return to education or employment and the child's needs are not met. The findings are intuitive as two out of the four significant differences relate to outcomes directly impacting on the mother (education and employment) and the hypothesis is that women would choose those levels that would increase their welfare.

Preferences varied by age group as well. Significant differences were observed for A&E attendances, smoking during pregnancy, employment of the mother, vaccination of the child and confidence of the mother. It is interesting to observe that for A&E attendances, vaccination of the child and the confidence of the mother, the respondents who were of "conventional working age" (i.e. age less than or equal to 65) derive higher utility from the negative outcomes taking place (i.e. children attend A&E during the first two years of their life, they do not have the recommended vaccinations and mother does not feel confident that she can achieve her goals) compared to the retired portion of the respondents (over 65 years old).

Preferences did not vary greatly by guardianship status. The coefficients for only two attributes were statistically different between the two groups: birth weight and language development of the child. Parents/guardians received higher utility if the birth weight of the baby was below a healthy range and the language development of the child was not according to its age. It is difficult to comment on the possible reason why the direction of preferences was such that they do not follow the intuitive expectations for both age and guardianship status.

The coefficients from the regression can be used to calculate the marginal rates of substitution between each attribute and provide a picture on the relative values that the respondents place on each attribute. For example, if second pregnancy happened within two years of the birth of the index child, that would need to be compensated by the equivalent of 0.15 units in maternal health related quality of life score  $(-0.124/0.817)$ .

Table 16.8 presents the utility or benefit scores calculated for two scenarios. In the case that FNP achieves no positive outcomes in any of the domains, the score is -6.1, while if the FNP achieves positive outcomes in the top five ranked attributes then the benefit score is -2.2. Hence, by improving five outcomes (i.e. child's needs, smoking, attachment, relationship with partner and A&E) there is a 2.7 fold higher chance  $(-6.1/-2.2)$  that the general public will "accept" the FNP programme.

Table 16.5 Results of random effects probit model on separate and pooled data from all the designs, including design dummies

	Design 1		Design 2		Design 3		Design 4		Pooled data		Design dummies	
	$\beta$	95% CI	$\beta$	95% CI	$\beta$	95% CI	B	95% CI	$\beta$	95% CI	$\beta$	95% CI
pregnancy	<b>-0.132<sup>c</sup></b>	-0.173,-0.092	<b>-0.101<sup>c</sup></b>	-0.139,-0.062	<b>-0.117<sup>c</sup></b>	-0.158,-0.076	<b>-0.153<sup>c</sup></b>	-0.191,-0.115	<b>-0.124<sup>c</sup></b>	-0.143,-0.105	<b>-0.126<sup>c</sup></b>	-0.146,-0.107
A&E	<b>-0.634<sup>c</sup></b>	-0.680,-0.587	<b>-0.569<sup>c</sup></b>	-0.613,-0.525	<b>-0.417<sup>c</sup></b>	-0.463,-0.371	<b>-0.681<sup>c</sup></b>	-0.721,-0.641	<b>-0.591<sup>c</sup></b>	-0.612,-0.570	<b>-0.588<sup>c</sup></b>	-0.610,-0.566
education	<b>-0.200<sup>c</sup></b>	-0.238,-0.162							<b>-0.197<sup>c</sup></b>	-0.234,-0.159	<b>-0.198<sup>c</sup></b>	-0.236,-0.160
smoking	<b>-0.864<sup>c</sup></b>	-0.912,-0.817							<b>-0.850<sup>c</sup></b>	-0.890,-0.810	<b>-0.845<sup>c</sup></b>	-0.886,-0.804
breastfeeding	<b>-0.235<sup>c</sup></b>	-0.275,-0.195							<b>-0.230<sup>c</sup></b>	-0.269,-0.192	<b>-0.226<sup>c</sup></b>	-0.265,-0.187
employment			<b>-0.130<sup>c</sup></b>	-0.167,-0.093					<b>-0.129<sup>c</sup></b>	-0.166,-0.093	<b>-0.132<sup>c</sup></b>	-0.169,-0.095
attachment			<b>-0.670<sup>c</sup></b>	-0.715,-0.625					<b>-0.687<sup>c</sup></b>	-0.726,-0.647	<b>-0.677<sup>c</sup></b>	-0.718,-0.636
vaccines			<b>-0.455<sup>c</sup></b>	-0.495,-0.416					<b>-0.466<sup>c</sup></b>	-0.504,-0.428	<b>-0.461<sup>c</sup></b>	-0.499,-0.423
confidence					<b>-0.210<sup>c</sup></b>	-0.249,-0.170			<b>-0.222<sup>c</sup></b>	-0.262,-0.181	<b>-0.220<sup>c</sup></b>	-0.260,-0.180
Child needs					<b>-1.028<sup>c</sup></b>	-1.076,-0.980			<b>-1.116<sup>c</sup></b>	-1.159,-1.073	<b>-1.121<sup>c</sup></b>	-1.165,-1.077
Birth weight					<b>-0.223<sup>c</sup></b>	-0.264,-0.181			<b>-0.253<sup>c</sup></b>	-0.294,-0.212	<b>-0.259<sup>c</sup></b>	-0.301,-0.217
relationship							<b>-0.641<sup>c</sup></b>	-0.681,-0.602	<b>-0.618<sup>c</sup></b>	-0.655,-0.581	<b>-0.616<sup>c</sup></b>	-0.653,-0.578
language							<b>-0.516<sup>c</sup></b>	-0.555,-0.477	<b>-0.499<sup>c</sup></b>	-0.535,-0.462	<b>-0.496<sup>c</sup></b>	-0.533,-0.459
health							<b>0.840<sup>c</sup></b>	0.524,1.157	<b>0.817<sup>c</sup></b>	0.509,1.125	<b>0.830<sup>c</sup></b>	0.521,1.139
Dummy for design 2											<b>0.013</b>	-0.047,0.073
Dummy for design 3											<b>-0.047</b>	-0.110,0.015
Dummy for design 4											<b>-0.037</b>	-0.098,0.024
Constant	<b>0.055<sup>a</sup></b>	0.004,0.107	<b>0.090<sup>c</sup></b>	0.038,0.143	<b>0.091<sup>c</sup></b>	0.038,0.144	<b>0.039</b>	-0.009,0.087	<b>0.050<sup>c</sup></b>	0.022,0.077	<b>0.068<sup>b</sup></b>	0.021,0.116
Insig2u Constant	<b>-3.032<sup>c</sup></b>	-3.589,-2.475	<b>-2.633<sup>c</sup></b>	-3.054,-2.212	<b>-2.874<sup>c</sup></b>	-3.379,-2.369	<b>-2.449<sup>c</sup></b>	-2.826,-2.072	<b>-2.662<sup>c</sup></b>	-2.885,-2.439	<b>-2.671<sup>c</sup></b>	-2.894,-2.448
Number of observations	6105		6120		6105		6512		24842		24842	
Number of Cases	407		408		407		407		1008		1008	
Wald chi2 (df)	1428.399(5)		1212.608(5)		1814.054(5)		2100.356(5)		6930.774(14)		6943.648(14)	
Log likelihood	-2888.975		-3068.306		-2654.699		-2996.174		-11607.859		-11605.334	
sigma_u	0.22	0.166,0.290	0.268	0.217,0.331	0.238	0.185,0.306	0.294	0.243, 0.355	0.264	0.236, 0.295	0.263	0.235,0.294
rho	0.046	0.027, 0.078	0.067	0.045, 0.099	0.053	0.033, 0.086	0.079	0.056, 0.111	0.065	0.053, 0.080	0.065	0.0523, 0.080

<sup>a</sup> p<0.05, <sup>b</sup> p<0.01, <sup>c</sup> p<0.001 Choice= 0 for right scenario; = 1 for left scenario

Table 16.6 Ranking of the coefficients from all the pooled data and all the designs

Pooled data		Design 1		Design 2		Design 3		Design 4	
<b>Child needs</b>	-1.116	<b>smoking</b>	-0.864	<b>attachment</b>	-0.67	<b>Child needs</b>	-1.028	<b>A&amp;E</b>	-0.681
<b>smoking</b>	-0.85	A&E	-0.634	A&E	-0.569	A&E	-0.417	<b>relationship</b>	-0.641
<b>attachment</b>	-0.687	breastfeeding	-0.235	vaccines	-0.455	Birth weight	-0.223	language	-0.516
<b>relationship</b>	-0.618	education	-0.2	employment	-0.13	confidence	-0.21	pregnancy	-0.153
<b>A&amp;E</b>	-0.591	pregnancy	-0.132	pregnancy	-0.101	pregnancy	-0.117	health	0.84
language	-0.499								
vaccines	-0.466								
Birth weight	-0.253								
breastfeeding	-0.23								
confidence	-0.222								
education	-0.197								
employment	-0.129								
pregnancy	-0.124								
health	0.817								

Table 16.7 Model with interaction effects for demographic characteristics: age, gender, guardianship

Choice= 0 for right scenario(B); = 1 for left scenario(A)	Gender		Age		Guardianship	
	$\beta$	se	$\beta$	se	$\beta$	se
pregnancy	-0.148***	0.017	-0.143***	0.026	-0.119***	0.011
A&E	-0.474***	0.018	-0.720***	0.029	-0.603***	0.013
education	-0.129***	0.035	-0.195***	0.049	-0.203***	0.022
smoking	-0.872***	0.037	-0.656***	0.051	-0.865***	0.024
breastfeeding	-0.241***	0.036	-0.319***	0.049	-0.225***	0.023
employment	-0.070*	0.033	-0.029	0.051	-0.135***	0.022
attachment	-0.690***	0.035	-0.768***	0.055	-0.688***	0.024
vaccines	-0.445***	0.034	-0.587***	0.053	-0.473***	0.023
confidence	-0.219***	0.034	-0.340***	0.053	-0.235***	0.024
Child needs	-0.859***	0.035	-1.147***	0.057	-1.099***	0.026
Birth weight	-0.223***	0.034	-0.281***	0.054	-0.277***	0.024
relationship	-0.608***	0.035	-0.681***	0.053	-0.627***	0.022
language	-0.497***	0.034	-0.574***	0.053	-0.538***	0.022
health	0.584*	0.285	1.192**	0.444	0.783***	0.185
pregnancy*demographic (gender or age or guardian)	0.036	0.021	0.022	0.028	-0.017	0.022
A&E*demographic	-0.177***	0.022	0.148***	0.031	0.02	0.024
education*demographic	-0.099*	0.042	-0.004	0.053	0.02	0.045
smoking*demographic	0.023	0.044	-0.232***	0.055	0.052	0.047
breastfeeding*demographic	0.013	0.043	0.103	0.054	0.01	0.045

employment*demographic	-0.088*	0.04	-0.116*	0.055	0.019	0.043
attachment*demographic	0.001	0.042	0.092	0.058	0.004	0.045
vaccines*demographic	-0.035	0.041	0.139*	0.057	0.037	0.044
confidence*demographic	-0.006	0.042	0.139*	0.057	0.048	0.048
Child needs*demographic	-0.405***	0.045	0.032	0.061	-0.089	0.05
Birth weight*demographic	-0.051	0.043	0.033	0.058	0.113*	0.048
relationship*demographic	-0.02	0.041	0.072	0.057	0.02	0.043
language*demographic	-0.007	0.041	0.086	0.056	0.142***	0.043
healthy*demographic	0.347	0.342	-0.428	0.474	0.132	0.36
Constant Insig2u	0.050***	0.014	0.049***	0.014	0.051***	0.014
Constant	-2.684***	0.115	-2.647***	0.113	-2.663***	0.115
Number of observations	24842		24842		24430	
Number of Cases	1008		1008		996	
Wald chi2(df)	6925.94(28)		6957.02(28)		6825.879(28)	
Log likelihood	-11536.55		-11569.896		-11376.712	
sigma_u	0.261		0.266		0.264	
rho	0.064		0.066		0.065	

\* p<0.05, \*\* p<0.01, \*\*\* p<0.001

Table 16.8 Success rate of accepting FNP programme

	Coefficients from the pooled data (A)	Best case scenario (B)	Worst case scenario (C)	Difference worst - best case (D)	Product of A x D	Success in five top attributes (F)	Difference five top attributes - best case (G)	Product of F x G
Child needs	-1.116	0	1	1	-1.116	0	0	0
smoking	-0.85	0	1	1	-0.85	0	0	0
attachment	-0.687	0	1	1	-0.687	0	0	0
relationship	-0.618	0	1	1	-0.618	0	0	0
A&E	-0.591	0	1	1	-0.591	0	0	0
language	-0.499	0	1	1	-0.499	1	1	-0.499
vaccines	-0.466	0	1	1	-0.466	1	1	-0.466
Birth weight	-0.253	0	1	1	-0.253	1	1	-0.253
breastfeeding	-0.23	0	1	1	-0.23	1	1	-0.23
confidence	-0.222	0	1	1	-0.222	1	1	-0.222
education	-0.197	0	1	1	-0.197	1	1	-0.197
employment	-0.129	0	1	1	-0.129	1	1	-0.129
pregnancy	-0.124	0	1	1	-0.124	1	1	-0.124
health	<b>0.817</b>	1	0.812	<b>-0.188</b>	<b>-0.1536</b>	0.812	<b>-0.188</b>	-0.1536
constant	<b>0.05</b>							
<b>Utility score</b>					<b>-6.1</b>			<b>-2.2</b>

## 16.3 Discussion

The purpose of this DCE was to establish the relative values for the outcomes measured within the FNP trial. Frequently, economic evaluations in the health sector employ the Quality Adjusted Life Year as a measure of Health Related Quality of Life, often reflecting the (predominantly) NHS perspective of the study. While HRQoL was an important outcome in this trial, it is not the only outcome and indeed health is not the only sector being considered. Thus to make the results as useful as possible for decision makers, it was necessary to assess the relative value or importance of these outcome measures. This DCE achieved over 1,000 responses from a sample of the UK general public that was broadly representative on key variables. The results demonstrated that individuals' responses were consistent with a priori expectations. As expected, decrements in mothers' health would be associated with lower utility scores as would factors that might adversely affect the child's health (maternal smoking, child not vaccinated and so on). The direction and magnitude of the coefficients around the attributes supports the assertion that the DCE was understood by respondents. The attributes that were associated with the most negative utility was "mother not provided for her child", followed by "Mother smoked during pregnancy" and "Mother not developed an emotional bond with baby". This suggests that respondents valued maternal outcomes mostly when these impacted on the health/well-being of the child. Outcomes that primarily affected the mother (mother has some problems with usual activities, mother not employed) tended to be ranked lower.

While preference varied between different subgroups, in most occasions, these differences were plausible and intuitive. For example, females placed a higher disutility on mothers not returning to work or employment when compared with males. However, there were occasions when the preferences across subgroups would be considered counter intuitive. For example, respondents who were over typical working age expressed a greater disutility associated with childhood A&E attendance than those of typical working age. This could be a result of many factors (such as a change in perception of A&E departments since GP out-of-hours services have been located there).

In general, the results of this experiment appear consistent and plausible and show that a broad range of outcomes, not just the health of the mother, are valued. However, there are a number of caveats. Firstly, while respondents were able to trade-off attributes, it is not clear whether there are interactions between attributes that have been omitted from the analysis. Omission of important interactions may lead to biased parameter estimates, in this case an under or over estimate of the relative value of an attribute. Second, in order to be consistent with decision-making bodies such as NICE, the DCE responders were members of the general public. However, there is also an argument for considering the preferences of individuals who have experience in the condition of interest. Brazier et al. (2005) call for greater debate on the subject of patients' valuation of health states<sup>263</sup>. DCEs based on, for example, recent teenage mothers may yield differing estimates of the relative

importance of attributes. Despite these limitations, the results should help interpret the results of the trial if the FNP intervention is effective in changing these outcome measures and / or if the direction of effect differs between variables.

# 17 Summary Discussion and Conclusions

Building Blocks was a pragmatic randomised controlled trial conducted to determine whether the Family Nurse Partnership (FNP) programme worked when implemented in a normal English healthcare setting.<sup>264</sup> Women invited to participate were intended to broadly represent the clients the programme would enrol in practice. It was expected that the intervention would be delivered in line with programme defined parameters. Trial outcomes by two years postpartum included those considered important by programme developers and providers. The results are therefore intended to inform policy-makers about the effectiveness of FNP as delivered in England.

## 17.1 Key trial findings

### 17.1.1 Primary outcomes

**Smoking** was measured using maternal self-report calibrated on the basis of baseline cotinine sample. There was no evidence of a reduction in either rate or quantity of smoking in late pregnancy attributable to the intervention. Planned sensitivity analyses supported the robustness of the findings. No differences were found when restricting the sample to women for whom calibrated self-report was available at both baseline and follow-up (for comparisons of either rate of smoking or number of cigarettes smoked) or when treating number of cigarettes as a categorical variable.

Children's **birth weight** data were retrieved from maternity records for all registered births. Babies in the Intervention arm were on average 21g heavier but there was no statistical evidence of difference between trial arms when assessing weight as either a continuous or categorical outcome.

Data on **attendance at accident and emergency departments and emergency inpatient admission** were retrieved for 1,500 children, with 1,478 available for inclusion in analysis and of whom 78.8% had experienced at least one event within two years of their birth. While a larger proportion of children in the Intervention arm experienced an event than in the Control arm (81.0% v 76.6%) this did not provide statistical evidence of a difference. Further modelling of the observed intervention effect (32% higher odds of an event in the Intervention arm compared to the control) showed that if a maximum of prescribed visits were received the odds of an event could be 51% higher in the Intervention arm.

**Subsequent pregnancies** were determined using evidence from routine data sources (hospital in-patient / out-patient, abortions statistics) and supplemented by maternal self-report and GP data. The overall rate of subsequent pregnancy within two years for the 1,289 women included in the primary

analysis was high (66.2%) and there was no difference in proportion between Intervention (66.3%) and Control arms (66.1%). Sensitivity analyses using single data sources only (hospital inpatient and outpatient records, maternal self-report, primary care records) also found no differences between trial arms.

For all four primary outcome analyses, there was no evidence of differential intervention effects due to age, deprivation, participation in education or training, or basic life skills.

### **17.1.2 Secondary outcomes**

**Pregnancy and birth:** Similar and high levels of engagement with antenatal care services were seen in both trial arms with a mean of 10 antenatal check-ups, matching the number recommended by NICE for nulliparous women.<sup>61</sup> There was no evidence for differences between trial arms for either maternal or parenting and child outcomes.

**Child health and development:** The effect of the intervention on infant feeding was limited to late pregnancy when a higher proportion of participants in the Intervention arm, compared to the Control arm, expressed an intention to breastfeed, (58.4% v 50.4%;  $p=0.036$ ). Following birth, similar patterns of infant feeding were seen across trial arms. Although a slightly higher proportion of participants in the Intervention arm initiated breastfeeding compared to the Control arm (57.6% v 54.9%) there was no statistical evidence for a difference. The median duration of breastfeeding was also short, seven days in the Intervention arm and 14 in the Control arm. The timing of weaning and quality of infant diets following weaning were similar across arms.

Language and general child development assessments primarily relied upon maternal report, either through the telephone interviews at 12 and 18 months and the home based assessment at 24 months. There was no difference between arms at 12 and at 18 months in terms of reported developmental concerns. However, at 24 months the proportions of children with a concern were 8.1% and 12.6% in the Intervention and Control arms respectively. The level of developmental language concern was lower in the Intervention arm compared to the Control arm at 12 (11.0% v 19.9%) and 18 months (17.1% v 24.2%). This difference was maintained at 24 months with children in the Intervention arm achieving higher mean scores on the Early Language Milestone scale indicating fewer developmental concerns.

A greater proportion of children in the Intervention arm compared to the Control arm attended an Emergency Department (ED) for an injury or ingestion by six months (4.1% v 2.8%) or 24 months of age (30.8% v 27.8%). Despite this, a smaller proportion of children in the Intervention arm were admitted as an emergency to hospital with an injury or ingestion compared to the Intervention arm

by six months of age (1.9% v 2.4%) or by 24 months (4.8% v 6.6%). However, there was no statistical evidence for these differences.

A larger proportion of participants in the Intervention arm (35.3%) reported at 24 months visiting a Children's centre than the Control arm (27.7%), but there was no overall difference across the follow-up period. Over the same time period, a greater proportion of children in the Intervention arm had a safeguarding event recorded in their GP record (n=64, 13.6%) compared to the Control group (n=38, 8.0%) an adjusted odds ratio of 1.85 (95% CI of 1.02 to 2.85) for the 945 children for whom data were available. Finally, whilst not assessed statistically due to small numbers, the number of participants and children needing foster care during the study period was nine in the Intervention arm and 18 in the Control arm.

**Parental life course:** Participant engagement with education, employment, and training was summarised in terms of NEET status. By 24 months postpartum, levels of non-engagement were higher in the Control arm (69.7% NEET) than in the Intervention arm (62.1%) but there was no overall difference between arms over the full follow-up period. At the same point in time, participants in the Intervention arm reported higher rates of being in paid employment (18.7%) than in the Control arm (15.7%) but there was no statistical evidence for a difference. Similarly, there was evidence of a difference in rates of reported access to Connexions personal advisors at six months between participants in the Intervention arm (32.9%) and the Control arm (27.9%) but no difference over the full follow-up period.

When participants reported their use of contraceptives across the study period we found no statistical evidence for an overall difference, although at 24 months postpartum rates of usage were 72.6% in the Intervention arm and 67.9% in the Control arm. Upon review of summary descriptives across each assessment point, participants in the Intervention arm report higher levels of longer-acting contraception use (injection, implant, coil) than women in the Control arm, who in turn seem to be using more frequently daily, short-term contraception. For example, rates of reported use of implant/coil for Intervention and Control arms are 39.2%:30.6%, 40.7%:38.3%, 47.7%:38.4% and 46.1%:41.8% at 6, 12, 18 and 24 months postpartum respectively. However, this has not been assessed formally and would require further verification.

At 18 months a higher proportion of participants in the Intervention arm (25.7%) reported maximum levels of social support compared to participants in the Control arm (20.3%). Mothers in the Intervention arm reported marginally higher levels of relationship quality and of generalized self-efficacy across the full follow-up period. These small effects are consistent with the creation of a more positive environment for both mother and child. Similarly, fewer participants in the Intervention

arm (30.4%) reported ever being homeless than in the Control arm (36.3%), although in this case there was no statistical evidence for a difference.

Finally, pregnancy is a known risk factor for the commencement or escalation of domestic violence with younger women at increased risk. Our trial found participants to be exposed to high risk of domestic abuse (39.4%), but abuse was not reduced by the intervention.

### **17.1.3 Economics**

The cost-effectiveness analysis used resource usage identified in primary and secondary health care records and maternal self-report and assessed against QALYs gained. The Intervention was associated with only marginal gains in maternal QALYs and cost an average £1,992.89 per participant more over the duration of the programme compared to usual care. The probability of the intervention being cost-effective remained low even when adopting a higher willingness-to-pay threshold. Sensitivity analyses, including halving the cost of FNP delivery, did not alter the conclusion that the intervention was not cost-effective.

A systematic review of UK-based studies found associations between outcomes chosen as short-term primary trial outcomes and longer-term gains for the child within health and education domains (in their later childhood) and within health, education, employment and criminal justice (in their adulthood). The review was undertaken to inform an extrapolation study which would assess the likely longer-term benefits given intervention effects observed in the trial. The subsequent trial results though indicated an alternate approach to economic analysis based on cost-consequences. Overall, average health resource costs were lower for women in the Intervention arm and non-health resources costs were slightly higher, resulting in an aggregate reduction before the cost of the intervention was considered. These savings were applied via top-down costing to the estimated costs of delivering FNP locally. This indicates the funding set aside for providing FNP and therefore the potential for spending elsewhere.

A discrete choice experiment identified the value placed upon key trial outcomes by a large sample of the UK general public. Respondents placed highest value upon child-related outcomes and maternal outcomes that directly impacted upon the child. Some variations in preferences were found to be associated with demographic characteristics of respondents, such as gender.

### **17.1.4 Process evaluation**

The Building Blocks trial integrated a set of process evaluation sub-studies. First, programme delivery against FNP core model elements and fidelity goals was assessed using supplied FNP monitoring data. Targets for early enrolment were not achieved as fully as specified by the programme. Quantity of expected visits by phase, levels of uptake, and attrition rates showed greater consistency with

programme targets. Content domain coverage was largely consistent with programme goals, although a comparison of self- and rater-assessed sessions showed how actual variation in domain coverage may be under-represented by self-reporting. A second sub-study found that Family Nurses were able to successfully integrate principles of Motivational Interviewing within their client visits, although found that some specific behaviours may be more challenging to achieve, perhaps due to the structure and informational intent of the programme.

Focus groups with Family Nurses, Midwives and Health Visitors from a sample of trial sites identified factors that may have hindered implementation of FNP either due to trial processes (e.g. the informed consent process, random allocation, data collection), perceived programme requirements (e.g. reticence about sharing materials and knowledge with non-FNP colleagues) or actions of and relationships with other local services (e.g. prioritisation in referral into FNP of high need clients). The commitment to maintaining programme fidelity was impressively present in the discourse of Family Nurses and challenges to this from a variety of sources frequently identified, as were attempts to manage this. Qualitative client interviews identified how visit content and processes were operating to support the three main programme goals (improving: pregnancy outcomes, child health and development, parental life course). Clients valued the personal bond with their nurse, the programme's strengths-based approach, a flexible approach to visit focus, and the informational content provided. Barriers to engagement identified included competing time commitments and adequacy of existing support, although leavers from FNP were not interviewed so further exploration of barriers was limited.

## **17.2 Interpretation of results**

When provided in addition to local routinely available supportive health and other services, FNP does not provide the benefits suggested by the US programme logic model. Each of the four primary trial outcomes are expected to be modified through programme participation by the child's second birthday – that is, they are short-term outcomes. Positive pregnancy outcomes, including increased birth weight for younger participants, would be expected to improve short-term child health outcomes, which in turn would contribute to benefits in the longer term. The small difference in rates of children being admitted for injuries and ingestions (lower for FNP) suggests that whilst FNP may reduce the incidence of more serious injuries requiring hospital admission, a lowering of maternal threshold for attendance may increase Emergency Department presentations. Such differences in rates of presentation and admission for injuries and ingestions are too small to provide statistical evidence and therefore, there is no current evidence in this trial of a protective effect due to FNP by two years.

However, there are some outcomes suggestive of benefit attributable to FNP, notably language development and developmental concern up to age two years which are important developmental outcomes. It will be important to determine whether this advantage is sustained over time, and that it may be verified by objective assessment and other indicators of successful development, for example, at school entry. The higher reported levels of social support and at two years greater use of Children's centres for FNP clients are consistent with the programme's goal to nurture the mother's supportive network and facilitate more sensitive and competent caregiving.

The overall proportion of participants reporting a referral for their child to Social Services was larger than the proportion of children for whom a safeguarding event was documented in their primary care record. Referrals to children's services that do not progress to a child protection investigation or case conference (at which point a general practitioner is likely to be notified) are not always documented in the primary care record. Documented safeguarding events are therefore likely to indicate a higher level of concern. The consistent direction of intervention effect (higher rate of referrals and higher rate of documented safeguarding event in the Intervention arm) supports the validity of these results.

Any bias resulting from loss to follow-up from primary care records could limit the safeguarding finding. As data were collected by Local Researchers or abstracted by practice staff, there is less scope for participant-level bias, although participants who failed to register with a GP or moved frequently may be harder to obtain data for and may represent a higher risk group. Practices less able to respond to requests for data access or abstraction may also bias the obtained sample, for example, if that reflected greater neighbourhood deprivation. Participants for whom their child's primary care data were collected were mostly similar at baseline to those for whom their child's data were not collected. Nevertheless, participants not having data returned for their child had marginally higher rates of not being in employment, education or training (51.2% v 45.8%) and higher rates of reporting difficulties with at least one basic skill (30.0% v 24.2%). Therefore, this analysis may marginally under-represent such participants but would not alter our conclusions.

Safeguarding is a positive intervention to protect children either at risk of or actually experiencing harm and is a function of underlying level of risk / harm, detection and thresholds for intervention. There is no obvious rationale for considering that FNP would increase underlying levels of risk or harm. It is more likely that the greater level of health professional contact (with Family Nurse) would lead to more children being identified with concerns. The personal relationship with the Family Nurse may also facilitate disclosure by the mother of concerns and further referral or help seeking behaviour. In both trial arms undetected risk or harms, or the long term emotional, behavioural and developmental effects on the child of early childhood maltreatment may arise subsequently, after the current follow-up period. Additional data for safeguarding events documented in primary care

records were limited. Further work would be required to establish their nature and determine the pattern of safeguarding interventions over a longer time period.

### **17.3 Factors influencing observed outcomes**

The study explored processes that may have influenced observed impacts of the intervention to determine its applicability to other settings and identify opportunities for optimisation. There were a number of quantitative and qualitative opportunities to do this, although the former were limited by the relative lack of effect observed.

First, we assessed differential intervention effects using planned sub-group analyses. Informed by the US trials of NFP where some effects were found for more vulnerable women (e.g. poor, unmarried, teenagers) the analyses examined variation associated with age, NEET status, having problems with basic skills, and area based deprivation. For each primary outcome no differential effect was found for any of the four baseline variables modelled. For the one primary outcome where there was an overall difference, emergency attendances and admissions, although the intervention effect was 77% higher for participants not in education, employment or training there was no statistical evidence for a difference. There is no evidence that the intervention is more effective within sub-groups of the sample defined by age, NEET status, problems with basic skills or deprivation.

Second, we explored whether outcomes varied by the practitioner delivering the programme or by the trial site using a three-level regression model for the primary comparative analysis for each primary outcome. Clustering by site would indicate that attributes that varied by trial site were responsible for differences in outcomes. Clustering by practitioner would indicate attributes of individual Family Nurses associated with differences in outcome. There was no evidence to demonstrate that any of the four primary outcomes differed between sites or the Family Nurse delivering the intervention. We have not assessed whether there was an interaction between site, and by nurse with the intervention. Some insight into the quality of engagement from FNP clients is available from FNP clinical encounter data. This addresses levels of nurse-perceived client involvement, conflict with materials and understanding of materials for each recorded visit. Although this does not represent direct response from the client, but rather a nurse assessment, there may be some value in exploring the relationship between engagement and observed outcomes. However, we do not have data on the client's perception of relationship quality with her Family Nurse, which would have provided an additional perspective on programme delivery (nurse as mediator of FNP effect).

Third, we assessed whether dosage of intervention received varied intervention effect using CACE analysis. This would show the potential for additional impact if programme clients received the full set of expected visits. For smoking, birth weight and second pregnancies CACE analysis made no

difference to our conclusions. For Emergency attendances and inpatient admissions, we found that exposure to the full amount of visits was associated with a 51% increase in rate of emergency attendances or admissions.

Fourth, as described above, we analysed descriptively intervention delivery against FNP programme targets, principally proportion of expected visits, attrition, content domain coverage, practitioner skilfulness in delivery (MI). Programme optimisation may be possible depending upon the extent to which actual number of visits fell short of those expected and the indication from CACE analysis for increased benefit from increased number of visits. The proportion of valid visits received to expected visits decreased by each phase. Whilst some decrease may be due to non-addressable reasons (for example, child being taken into care), there is scope to increase dosage to programme clients. Similarly, there may be some small adjustments possible to domain coverage towards greater alignment with programme targets, although in interview, nurses identified how such deviation may be consistent with meeting present client needs (e.g. regarding housing) and for Family Nurses to continue developing their micro-consultations skills in line with Motivational Interviewing.

Fifth, nearly 40% of women in our study reported intimate partner violence in the preceding 12 months when assessed by interview at 24 months. In long-term follow-up of Elmira study participants in the US, retrospective maternally reported domestic violence was reported to be a moderator of programme effect for maltreatment outcomes, although not for other maternal and child outcomes<sup>265</sup>. The potential for intimate partner violence to impact upon intervention effect can be further explored, particularly with data from our longer-term follow-up study.

Lastly, findings from the qualitative client interviews and practitioner focus groups identified factors that may serve to facilitate or hinder implementation. Relevant issues from the client interviews were client enrolment, the role and consultation style of the Family Nurse and interactions with other health professionals. Whilst trial recruitment processes limits what can be concluded about client enrolment it remains clear that referring midwives play a crucial role in ensuring optimal routing of potential clients to FNP. Enrolled clients placed a high value on the personal relationship with their Family Nurse and the nurses' flexible consultation style (including both meeting arrangements and agenda-matching) and sometimes in contrast to their pre-enrolment expectations. Whether the continuation of the relationship after the child's second birthday, which was evident for some former clients, is ultimately beneficial or indicative of over-reliance is unknown. There appears to be a contrast for clients in the interactional styles with Family Nurses and with other professionals and a more consistent autonomy supportive inter-disciplinary approach may support programme goals more effectively. The contrasting approaches to clients was echoed by both Family Nurses and Health visitors, and amongst the latter enthusiasm expressed for a more strengths-based approach. Overall, a well-briefed professional workforce able to communicate effectively with prospective clients and

with each other (for example, sharing notes, understanding enrolment criteria) seems essential to optimise programme implementation. Geography was a key factor for nurses in rural locations and delivery was formally and informally adjusted (for example, reducing caseload and out-of-hours working) to maintain adequate client contact. Whilst the need to rapidly consolidate skilful programme delivery was noted by some Family Nurses, trial sites contained a balance of established and more recently trained teams and the main comparative analysis described above provides no indication that sites varied in how effectively they delivered the programme.

## **17.4 Strengths and limitations**

### **17.4.1 Choice and validity of primary outcomes**

Three of the four primary outcomes (birth weight, emergency attendances and admissions, second pregnancy) were largely established on the basis of routinely collected data sourced either through the HSCIC or directly from maternity unit records. For a study period extending over two and a half years and with a sample who may be mobile and hard to reach this provided some reassurance that data retention rates could remain high for the most prominent outcomes being assessed. Linkage via NHS number and other identifiers permitted data to be retrieved from potentially several otherwise unconnected sites (e.g. Emergency Department attendances at different hospitals) and achieve matching rates that were higher than anticipated with a resultant data set less dependent upon participant self-report. Using routine data meant analysis was less susceptible to response bias and, with a fuller sample, less susceptible to bias associated with loss to follow-up.

The assessment of subsequent pregnancies drew upon multiple sources of information. An indication of a subsequent pregnancy from any source was considered definitive. Incorporating terminations data into a dataset anonymised for analysis meant that the accuracy of the outcome could be enhanced without compromising participant confidentiality. It is unlikely that the routine data sources (secondary or primary care visits associated with a pregnancy, notification of termination) would over-represent the incidence of pregnancies or be associated with biased reporting whilst self-report would be more likely to be associated with a bias. By using multiple sources we are likely to have arrived at a more accurate representation of pregnancies when they occurred. The importance of using several sources of data was borne out by the difference found between the primary comparison and the sensitivity analysis restricted solely to out-patient / inpatient records, maternal self-report and GP derived data. Cases not included due to missing GP data differed on key baseline demographic characteristics to those included (the former group had more difficulties with basic life skills, lived in more deprived areas and had a larger non-white ethnic population). Given that these data were collected from records rather than from individual participants it is worth considering why these difference might exist. The mothers may have been less likely to be currently registered with a

GP, we may have had more difficulty maintaining contemporary GP details for them if they moved, or practices in deprived areas may have been harder pressed to respond to the data request.

The fourth primary outcome, tobacco use in pregnancy, required self-report of a health-related behaviour likely to be subject to social desirability bias. By collecting cotinine samples at baseline to calibrate self-report at follow-up using a validated protocol we were able to address reporting behaviour at an individual level observed to deviate from objective assessment. The calibrated measure provides a more accurate estimate of fetal exposure over self-report or cotinine alone (the snapshot provided by the latter may not reflect exposure at all well if women's actual smoking fluctuates). Of course, the methods can also introduce some misclassification (in particular for those with no follow-up cotinine), but compared to the scale of misclassification based on self-report alone, or the amount of missing data available if we had only cotinine, we are making the best use of the available data. Finally, the complete case sensitivity analysis (i.e. using full self-report and cotinine at both baseline and follow-up) did not alter conclusions from the primary comparison supporting the robustness of the findings.

#### **17.4.2 Study power and retention rates**

The commissioning brief for the study stated the size of sample that could be achieved (n=2,400) given the number and size of potential sites and expected duration of recruitment. The research team indicated the effect sizes that may be expected given the predicted level of accrual. Subsequently, during the recruitment phase the sample size was re-estimated to enable us to detect small effects in each primary outcome. Therefore, the study aimed to recruit 1,600 women and to collect routine data on about 90% of the participants where there was a live birth. Recruitment exceeded this number and rate of linkage to birth data, for example, was 96%. For non-withdrawn children, only six cases could not be matched to secondary care records. We aimed for at least 1,418 cases for the analysis of emergency attendances / admissions and of subsequent pregnancies (at 90% power), and we actually included 1,478 and 1,289 respectively. The absence of any observed difference in pregnancy rates between Intervention (66.3%) and Control arms (66.1%) means that increasing the sample size is not likely to change the result. Overall incidence rates for both outcomes were higher than expected but are not considered to have made any difference to our conclusions.

The trial sample was large and geographically dispersed. Self-reported data collection had to balance resource and data protocol requirements whilst maximising rates of follow-up across the full follow-up phase. This was achieved by use of office-based researchers collecting outcome data via telephone interview for all interim self-reported assessments. The nature of the assessment required at 24 months necessitated face-to-face data collection with locally-based researchers completing these interviews. Additional effort to secure follow-up at 24 months was put in place, including alternate

modes of data capture (e.g. mailed paper questionnaire) leading to a higher rate of follow-up compared to earlier data collection phases. Of the 1,562 women randomised at baseline who were not subject to mandatory withdrawal,<sup>viii</sup> 73.8% were successfully followed up at 24 months. Comparable figures from the other contemporary trial of the programme in the Netherlands show a rate of follow-up at 24 months of 55.1% for all women recruited who were not subject to similar mandatory exclusions.<sup>95</sup> A second study of a related programme in Germany had attrition rates of 55% at 24 months.<sup>266</sup> However, these rates are all lower than reported in the US trials of NFP and emphasise the importance in the current trial placed upon routine data for the primary outcomes and the application of appropriate sensitivity analyses.

### 17.4.3 Sources of potential bias and imprecision

**Loss to follow-up:** For self-reported outcomes unsupported by additional routine sources, reliance upon interview data (telephone or in-person) could introduce bias through loss to follow-up. We assessed how the sample completing the 24 month data collection differed from those who did not. There were some small baseline differences in relationship status (e.g. non-completers reporting lower rates of being closely involved with or the girlfriend of their baby's father) but the largest difference relates to socio-economic status. Those lost to follow-up included a greater proportion of women not in education, employment or training (NEET). Whilst differences appeared small this could suggest that women with lower levels of engagement may be under-represented in these analyses. For the one primary outcome particularly reliant upon self-report, smoking, there was a similar difference according to NEET status with 45.5% of those not analysed assigned as NEET, compared to 39.5% of those who were analysed. Again the smoking results may therefore slightly under-represent this more vulnerable group of women.

Overall, there was differential follow-up at 24 months with rates<sup>ix</sup> of 72.3% and 68.0% respectively in the Intervention and Control arms. A similar disparity was observed in the Dutch VoorZorg trial with 58.3% and 51.9% follow-up at 24 months for the Intervention and Control arms.<sup>95</sup> Women in receipt of FNP would have had greater trial-related contact overall, may have felt more engaged as a consequence and would also have been easier to maintain on-going contact with (e.g. Family Nurses may have been able to identify new and alternative contact telephone numbers). From the process evaluation client interviews it was also clear that some clients failed to distinguish trial and FNP processes, which may also have served to enhance rates of follow-up.

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<sup>viii</sup> Mandatory withdrawals (where an outcome for the child such as miscarriage, necessitated removal from the study) accounted for 43% all withdrawals

<sup>ix</sup> Rate is number of completed assessments at 24 months as proportion of all allocated

**Recruitment process:** Our recruitment strategy involved locally employed researchers (mostly nurses or midwives) working with community midwives who would identify potentially eligible women. Delays in site set-up most often reflected challenges in appointing suitable staff, which in some cases was partially addressed by employing Contract Research Organisation (CRO) staff. Concerns were expressed by some Family Nurses in focus group interviews that consent and baseline data collection would lead to recruited women withdrawing. In fact, the rate of elective withdrawal by late pregnancy was 5%, but was imbalanced with a two-fold higher proportion in the Intervention arm discontinuing. We would have expected some withdrawals during this busy phase for young women adjusting to their first pregnancy, and often with other challenges to contend with. Consenting to trial and FNP enrolment may have added to this burden.

Identification and approach of potentially eligible women was primarily by community midwives or staff within maternity units. The presentation of equipoise by recruiting researchers ensured neutrality in approach but was uncomfortable for Family Nurses (perhaps particularly if they had previously enrolled clients directly themselves), as was the random allocation to the Control arm for women considered to be especially vulnerable. However, the local clinical teams generally embraced the experimental requirements, even in sites that had been previously delivering FNP. In just under half of the sites, implementing the trial required suspending a service that had been implemented area wide. In some cases there were benefits of this, for example, where referral systems had been established and adjoining clinical services such as midwifery were positively engaged. In contrast, this caused problems where newly established processes and clinical expectations had to be adjusted.

**Randomisation process:** Recruitment via locally based researchers independent of intervention delivery using remote randomisation reduced risks of selection bias. Randomisation sought to achieve a balance within each site of three variables: gestational age, smoking and preferred language of mother. Overall, balance for gestational age and smoking was achieved. With only six women in total who expressed a preference for a language other than English, balance on this variable was not relevant in practice. Within sites, balance was also evident for gestational age and smoking. Some small imbalances were found in sites where overall recruitment was relatively lower. By minimising we aimed to reduce bias that may have been introduced by having women allocated to trials arm who differed by potential for exposure to the intervention (gestational age) or by current health behavior (smoking). This goal was therefore achieved.

**Contamination:** Family Nurses interviewed in the focus group were mindful of the potential for contamination and may have led to some covertness about their work when interacting with non-FNP colleagues. Whilst a very small number of women allocated the control group were enrolled into FNP, otherwise the scope for meaningful contamination was probably low given the intensity, structure and licensing requirements of FNP.

**Blinding of assessment:** Participants were unable to be blinded to the intervention. The same is true for those delivering the intervention. Telephone interviewers were blinded to allocation (i.e. for self-reported outcomes measured after baseline and before 24 months). Three of the four primary outcomes used routinely collected data, for which we were therefore able to avoid response bias. Some assessments could be blinded at the point of rating (e.g. rating video recordings for maternal child interaction) but this would not have been the case for its collation (i.e. by field-based researchers). Data collection at the 24 month interview could have been subject to bias associated with unblinded data collection although the interview used a fully scripted computer-driven schedule to reduce interviewer effect and the researcher was independent of either intervention or usual care delivery.

#### **17.4.4 Comparison with usual care alone**

Pragmatic trials often compare new interventions with usual care to enhance applicability and feasibility but whilst important to describe usual care, this is often not done.<sup>267</sup> In the Building Blocks trial usual care was broadly represented by a combination of mainly health care services focused particularly on health visiting. We further explored the nature of usual care service provision and receipt in the trial through a process that detailed the range and variation in services available at each site, and is reflected by the range of health and non-health resources contributing to the cost consequences analysis. Services available to participants in both trial arms, represent the threshold above which FNP is aiming to provide an incremental advance. Collectively these services may represent a greater resource than that available to women in control groups in other trials of FNP.

#### **17.4.5 Allocated and not enrolled women**

89 women allocated to the Intervention arm did not enrol in FNP within the trial. Some of these women would have continued to participate in the trial by providing data through self-reported interview and consent to access routine data (i.e. they did not withdraw from the study). Thus, analysis of outcomes would have included in the Intervention arm women not exposed to FNP. In the Birkbeck FNP implementation evaluation 87% of eligible women were enrolled (similar to the rate in the Building Blocks trial, 89%). As an effectiveness trial we are asking the question about the benefit accrued when the intervention is offered to all eligible consenting study participants and not just those who experience the intervention in its entirety. An alternative analytic strategy, such as per protocol (or non-randomised observational comparison) would include only those participants who received the intervention as intended but compromises the randomisation and is associated with bias, particularly if used in isolation.<sup>267</sup> It is also the case that the intention to treat analysis would have included the ten Control arm participants who actually were exposed to FNP. Any real between group difference attributable to the intervention could therefore have been reduced by these

participants but as this represents only 0.6% of the overall sample at baseline the effect is likely to have been minimal.

#### **17.4.6 Fidelity to programme**

Barnes and colleagues established the feasibility and acceptability of delivering FNP in England. Notwithstanding Barnes' evaluation, we needed to determine how well programme delivery within the trial matched core model elements and fidelity goals and therefore establish how solid was the base for concluding intervention effectiveness. Access to the FNP IS allowed some of these attributes to be assessed and also a comparison with performance in non-trial sites delivering FNP. First, attributes of *enrolment, recruitment and engagement* were assessed. Individual level client characteristics (voluntariness, first-time mothers, high risk) were satisfied by virtue of the trial eligibility and consent process. However, it is interesting to note from the Family Nurse focus groups how such voluntariness could be potentially subverted by other services requiring women to enroll in FNP (e.g. as a condition of a child protection order). At trial sites, FNP clients in the trial and non-trial samples were of a similar mean age (17.4 vs 17.2 years) and gestational age at enrolment (17.9 vs 18.2 weeks). A marginally smaller proportion in the trial sample were enrolled by 16 weeks gestation compared to the non-trial sample (39.7% vs 41.6%), and in both cases this fell short of the goal of 60%. This difference between trial and non-trial samples is likely to reflect the delay introduced into the enrolment process associated with an initial additional stage of trial recruitment and consenting.

The proportion of eligible women offered the programme who enrolled exceeded the 75% target. However, nearly a third of enrolled clients saw more than one nurse during the course of their participation. The extent to which nurses accrued clients was not possible to determine, although the FNP workforce would have comprised nurses previously delivering FNP as well as those recruited following the second wave of site commissioning.

Our assessment of *Family Nurse* attributes focused on visit frequency, timing and coverage of content domain, the principal data available via the FNP IS under this component. Nearly a quarter of all available visit records were excluded from consideration due to the visit not being completed, an indication of the challenge of maintaining regular client contact. The visiting schedule includes 64 visits expected if women are enrolled sufficiently early in pregnancy. For participants enrolled to FNP, the mean number of observed visits received was lower than the target in each phase (Observed:Target – 9.71:14, 18.63:28, 13.22:22). Reported mean number of visits by phase in the Birkbeck implementation were 7.3, 12.8 and 7.4. The mean number (range) of completed visits in the first two US trials of NFP (Elmira, Memphis) were respectively 9 (0 to 16) and 7 (0 to 18) in the pregnancy phases, and 23 (0 to 59) and 26 (0 to 71) in the infancy and toddlerhood phases combined.<sup>268</sup> There was considerable variation between Building Blocks trial sites in the median number of visits received (for example, between 15 and 23 visits in infancy phase).

For only participants who completed the FNP programme, fidelity targets for expected valid visits completed were met by 62.5%, 60.1% and 50.9% of women for the pregnancy, infancy and toddlerhood phase respectively. Figures from the Birkbeck implementation study show rates of women reaching fidelity goals for proportion of expected visits by phase of 30%, 42% and 42%.<sup>107</sup> Overall therefore, actual number of visits delivered in the trial are similar or exceed by phase those observed in the first two US trials of the programme and levels of client engagement were greater compared to the implementation evaluation but still lower than that prescribed by the programme.

Fidelity goals are for programme attrition not to exceed 10%, 20% and 10% through each successive phase, with a cumulative rate of no more than 40% overall. In the Building Blocks trial only 21% of enrolled women failed to complete the programme (3.6% in pregnancy, 10.1% in infancy and 7.9% in toddlerhood). If a conservative approach to missing data is taken the overall reported attrition rate increases to 24%, compared to the overall rate of 41% in the implementation evaluation study.<sup>269</sup> Cumulative trial withdrawals in the Intervention arm during the pregnancy phase added up to 88 and therefore should be at the minimum reported leaving FNP during that phase (rather than the 26 reported via FNP). However, only 16 new trial withdrawals were recorded in infancy (compared to 70 reported as inactive or leavers by the FNP IS). It is reasonable to assume that there was a delay in formal trial withdrawals being reflected in corresponding FNP records.

Overall, completed visits were actually longer than the target minimum of 60 minutes by nearly 30%. Percentage delivery of domain specific content varied against programme targets, but mostly by a small degree. Environmental health received greater attention across all three phases than specified in the programme. A disadvantage of the FNP monitoring system for reporting domain coverage is that Family Nurses are reporting on their own behaviour when also aware of programme targets. Self-assessment of time use is likely to be task associated with other sources of error. Therefore, the trial process evaluation included an objective assessment of time usage. This supported the general pattern of Family Nurse self-reporting in terms of balance across domains but also suggests that there may be a tendency to report within a narrower range than the data would indicate and so underestimate variability in practice. A general note of caution should be flagged when assessing data derived from the FNP IS. The data are collected for programme delivery and monitoring purposes and lack the independence offered by other data reported here.

The Building Blocks trials provided further evidence about how specialist training to support behaviour change (Motivational Interviewing, MI) was implemented. Nurses demonstrated skillfulness in key aspects of MI delivery as measured by independently rated global scales. Importantly nurses avoided non-MI adherent behaviour and achieved high levels of MI adherent behaviour. Providing mothers with information is a core part of the programme and in this nurses

also practiced in a collaborative and MI consistent manner. Assessment of other MI competencies such as question asking and use of reflections revealed more modest levels of practice. This could indicate scope for further training in these aspects of practice, and demonstrates the challenge for integrating a structured information-provision rich intervention with skilfully delivered Motivational Interviewing.

In summary, programme delivery within the trial against the FNP targets generally matched or exceeded that reported in the implementation evaluation. This is understandable as many of these sites carried through to the trial and all sites would have benefited from the learning from that phase of programme development. Nevertheless, for some components this was still below the target levels. Other model elements were not possible to assess with the data available but would be site-level responsibilities under licensing conditions and monitored by the FNP national unit.

### **17.5 Generalisability of study findings and features of study setting that may influence results**

A large minority (37%) of the recruited sample were not living with either parent. For those aged 16 at the end of the previous academic year, there was a large proportion not in education, employment or training (47.9%). This compares with national (UK) rates of 4.4% (for women aged 16 to 17 years old) and 20.0% (for women aged 18 to 24 years).<sup>x</sup> Nearly a fifth of women reported being homeless at some point in their lives and the mean deprivation score was 38.2, compared to an English average of 21.67.<sup>142</sup> Over a third of women reported that they had been arrested by police, nearly half that they have ever been suspended or expelled from school and nearly three quarters that they had truanted from school. Women recruited to the Building Blocks trial therefore faced challenging circumstances, consistent with programme eligibility criteria.

At the time of the trial, women were also being enrolled to FNP at other locations in England and we assessed how our sample of women compared to women at these non-trial sites using FNP enrolment data. There are small differences between trial and non-trial samples respectively in ethnicity (85.5% vs 82.9% white background) and reported recent smoking behaviour at enrolment (40.8% vs 34.0%). The former may be associated with a study sites selected not being fully representative of all English sites currently providing FNP. It is also possible that women excluded due to an inability to converse without the support of an interpreter may have been associated with fewer women recruited from

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<sup>x</sup> Based on seasonally adjusted ONS figures for reporting period January to March 2013.

non-White backgrounds. Overall the trial sample seemed to represent well the population of women to whom FNP is currently being delivered in England.

Trial eligibility criteria aimed to reflect those of the intended client group and this appears to have been successfully achieved. Short-term intervention effects in the US trials were most evident in the most vulnerable women at enrolment, who were the focus of the Memphis and Denver trials. In the Dutch VoorZorg trial a two-stage selection process involving the intervention nurses and an expert committee selected women on the basis of additional risk factors<sup>94</sup>. This could have resulted in a Dutch trial sample with a greater concentration of those at highest risk, those thought more likely to be responsive, or most compliant compared to the Building Blocks sample. However, some of our trial eligibility criteria did relate to such factors, for example, women not leaving the study area for longer than three months (i.e. compliance with programme requirements) and being aged 19 or less (proxy for increased risk).

In England, young maternal age was chosen as a proxy for low income and the associated long term adverse child outcomes<sup>99</sup>. This principal programme and trial criterion may have resulted in greater heterogeneity and comparatively less disadvantage than the previous related studies. Although the absence of interaction effects addressing a priori markers of vulnerability does not suggest that broad FNP enrolment criteria masked intervention effects, differential effect by sub-group could be explored further.

FNP is being delivered across a large number of sites in England and the UK. Local partnerships applied to first deliver FNP, and further to do so in the context of a trial - in the process having to satisfy DH criteria. We would expect these sites to be representative of other sites that currently deliver FNP in England and to be amongst the most proactive and committed. As is clear from the programme's UK history, the implementation evaluation and from the Family Nurses interviewed in the trial's process evaluation, learning about how best to deliver FNP will continue to evolve. Given that the last trial participant would have graduated from FNP in early 2013, it is likely that programme delivery has moved on. Whilst an objective of pragmatic trials is often to assess deliverability and capacity for broader roll-out, the expansion of the programme already satisfies this objective.

The previous US trials of the intervention were single centre studies (one semirural, two urban), involved a small number of intervention nurses delivering the intervention (e.g. 10 in Denver study) and were led by the intervention developers. In contrast, our trial was led independently of the 131 Family Nurses working in locally managed teams delivering the intervention in ten government regions that included 18 trial sites across the breadth of England. Our trial represents a more pragmatic evaluation of the intervention compared to the previous US and Dutch trials.<sup>270</sup>



### 17.5.1 Risks of multiple analyses and relevance of selected outcomes

With a large number of measured outcomes it was key that the a priori statistical plan specified which were to be regarded as primary outcomes, and for these that a conservative alpha was applied. Secondary comparative analyses included assessments considered as potential intervention outcomes, as well as other measures of interest. In some cases within a single outcome domain we had several related measures which would not have been expected to be independent from each but which may have been easily retrievable (e.g. from maternity records) and which allowed a more detailed description of the experience of women and their children in this study. Only some outcomes would be considered to be potentially attributable to the intervention (according to the NFP logic model), or FNP programme goals in England. An example is the assessment of domestic abuse at 24 months, which although it has been found to be a moderator of longer term maltreatment outcomes<sup>265</sup> and has been found to be positively effected by the VoorZorg intervention in the Netherlands, is not specified in the programme logic model. Other potential programme impacts were not assessed in the trial, for example, promoting a stimulating home environment for the child (a finding from both the Elmira and Memphis trials). As such, we cannot comment on performance against some programme goals.

The total number of completed analyses was inflated by the additional pre-specified sub-group analyses, which were though restricted to a subset of variables selected to identify any differential benefit for more disadvantaged members of the study sample. Additional sensitivity analyses were run to challenge any assumptions that may have been made in the primary analyses. In most cases these served to support the conclusions from the primary analyses (e.g. smoking) or illustrate where caution in interpretation may be required.

The primary trial outcomes represented one early (pregnancy and childbirth) and one later (postpartum) outcome for both mother and child. Three of the four primary outcomes (smoking, second pregnancy and emergency attendances and admission) were selected on the basis of policy interest following nomination at commissioning. The fourth primary outcome (birth weight) was clinically important, was likely to have been retrieved reliably from routine sources and in the Elmira trial had been improved by exposure to NFP in younger women, particularly if recruited by 20 weeks gestation. All four outcomes are identified as short-term outcomes (i.e. by programme exit) in the theory of change logic model either for whole or sub-groups, and are supported by evidence from the US trials.

Although a large number of adverse events were reported to the trial team, none were judged to be intervention-related and most were events expected to occur in the course of a normal pregnancy. Some were more serious but again were not unexpected when considering a large number of first-time pregnancies in young women, some of whom lived in challenging personal circumstances.

### **17.5.2 Interpretation of the economic analysis**

Evaluating cost-effectiveness through the within-trial cost-utility analysis in isolation could be considered inappropriate due to its reliance on maternal QALYs only. Using EQ-5D to derive QALYs is a standard framework in cost-effectiveness analysis, used widely across Europe and in comparative work within a pregnant population.<sup>271</sup> In this trial it can only provide an evaluation of the cost-effectiveness from the mothers' perspective based on differences in her health utility. Utility was not anticipated to be largely improved by the intervention given that pregnancy and childbirth is not generally associated with health problems. Given that FNP aims to improve outcomes for both mother and child, this information cannot be accounted for through standard cost-utility analysis alone. Therefore, secondary economic analyses were undertaken to ensure a complete picture of the cost-effectiveness of the FNP intervention investigated in the trial could be provided to policy makers. The cost-consequence analysis and subsequent top-down costing exercise thus build on the cost-utility analysis to provide the complete picture accounting for both the primary outcomes relating to the child (birth weight and emergency attendances and admissions) and the wider costs implicated alongside the FNP intervention in other domains.

The cost-utility analysis centres on a single preference-based valuation of health states driven by estimated QALYs and applies rigorous statistical techniques compared to the simplistic descriptive approach taken in the cost-consequence analysis. Though fundamentally different in their approach, the findings of both approaches converge on the conclusion that the intervention does not offer sufficient benefits to the mother or the child by two years postpartum to justify the high costs of intervention delivery. Overall, the cost-utility analysis found no clear differences in resource use or QALYs associated with receiving the FNP intervention and the likelihood of the intervention being considered cost-effective at traditional willingness to pay thresholds was below 17%. Sensitivity analysis revealed that even if delivery costs could be cut in half, the probability of being cost-effective is below 50%.

These findings were echoed in the cost-consequence model which highlights only minor differences in resource use and associated costs of both health care and non-health care related items, together with only minimal gains for the primary outcomes. Taken together these analyses indicate that the FNP intervention is highly unlikely to deliver value for money with the high implementation costs stimulating only minor gains in the short-term.

## **17.6 Interpretation in the context of other studies**

Smoking cessation is an important short-term behavioural goal for the programme and evidence from two of the US trials (Elmira and Denver) and more recently the Dutch trial of VoorZorg (based on NFP)

has shown a treatment effect in late pregnancy. The latter study is not directly comparable as it included women up to age 25 years and used self-reported smoking only. The difference between self-reported smoking and cotinine verified rates in our study demonstrates the need for objective verification. While the Dutch VoorZorg trial examined difference in smoking rates, the two US trials assessed reduction in baseline smokers either verified using cotinine for a sub-sample (Elmira) or using cotinine alone (Denver). In our trial we have calibrated self-report for all women at baseline (rather than a sub-sample) to provide a validated measure of smoking. In our trial smoking rates remained high during pregnancy, and few participants in either trial arm reported accessing any supportive smoking cessation services.

Birth weight was not influenced by the FNP programme even within the younger women and those living in more deprived areas. This contrasts with the findings from the first US trial where positive effects were found amongst the youngest women studied. Findings from the Building Blocks trial are similar to the Dutch trial where no differences were found by either birth weight or gestational age. The rate of low or very low birth weight babies in the Building Blocks trial was higher than UK rates for women aged 15-24 (9.4% vs 7.1%) so there appears to be considerable scope for improving this clinical outcome.<sup>272</sup> The lack of programme effect on smoking would also be consistent with no impact on birth weight.

A reduction in rates of subsequent pregnancy was a consistent finding in the US trials of NFP although in the Elmira trial this was restricted to poor, unmarried women. In contrast, Rubin and colleagues undertook a retrospective analysis of women in receipt of NFP in Pennsylvania finding no programme effect in its first three years of delivery, but a benefit after a longer period of implementation, in particular for younger women living in rural settings<sup>273</sup>. Rubin also found evidence that the programme delayed rather than prevented second pregnancies in a second study of Latin American mothers, also in Pennsylvania.<sup>274</sup> Previously, Gray and colleagues undertook a secondary analysis of the Denver NFP trial assessing family and career planning and their association with repeat pregnancy.<sup>275</sup> They found that assistance with contraception or short-term goal planning was found in less than a third of visits, and others such as partners were rarely involved in visits. Given the structure of the programme delivered in England it is perhaps less likely that such a lack of focus may have contributed to the finding in our trial, but may be worthy of further investigation. In our focus groups, Family Nurses noted the challenges of competing socio-cultural norms and also of clients who receive good FNP support and therefore are more confident about having a second child. The aggregate observed rate of subsequent pregnancy remained high and a challenge for ongoing intervention.

In contrast to the Elmira and Memphis trials, secondary care encounters for injuries and ingestions were marginally higher for children in the Intervention arm. In Elmira there was a reduction in

emergency department visits in the second year after birth and in Memphis a decrease in outpatient visits across the two years following birth. The small decrease in admissions for injuries and ingestions we observed is consistent with the reduction in in-patient durations in the Memphis trial although our finding lacked statistical evidence.

In the Elmira trial, duration of employment to 22 months postpartum was two and a half times longer for poor, unmarried, older nurse visited participants.<sup>86</sup> In Denver nurse visited participants in the second year postpartum were employed for on average 1.14 months longer than participants in the Control arm.<sup>171</sup> Although rates of women not in employment, education or training were slightly lower at 24 months postpartum (and rates in education and in paid employment similarly slightly higher) there was no overall difference by arms. An emerging difference by 24 months postpartum for employment and education may suggest a longer-term benefit for nurse-visited participants. The high rates of second pregnancies observed equally for the two trial arms may however, limit this potential advantage. Longer-term follow-up to determine actual inter-birth interval and employment rates will be required to determine whether any suggestion of potential benefit at 2 years is either fulfilled or falls away.

Olds and colleagues found improvements in maternal child interaction. In Elmira in a sub-group analysis poor unmarried teenagers in receipt of nurse visiting punished and restricted their child less at 10 and at 22 months compared with their control group counterparts.<sup>83</sup> In Denver there was small overall difference found from videoed interactions (a single factor of responsive interaction) collected at each assessment point (100.31 vs 98.99 standard score points,  $p=0.05$ ) for the full available sample.<sup>171</sup> In contrast we assessed maternal child interaction at 24 months postpartum for all interviewed participants willing to be recorded and found no difference between trial arms. The analysable sample achieved was broadly representative of recruited participants, although those lost to follow-up reported at baseline marginally higher rates of problems with adaptive functioning and not being in education, employment or training. The instrument used to assess interaction has proven sensitivity but adding in a distress condition during assessment could potentially enhance its ability to detect differences where they are present.

Olds and colleagues noted the importance of the wider social context and how different levels of community services affect both process and outcome.<sup>51</sup> Specifically, the programme may function even better in settings where existing services are themselves even better (i.e. where there are existing supportive services to which nurses can refer clients). Our exploration of locally available services emphasises the extent of support that is potentially available and reportedly accessed by participants in our study. In contrast to the US trial settings, it is possible that the range of services routinely available may actually limit the potential for FNP to show additional benefits, although it is clear that important outcomes remained poor for all participants in this trial.

More broadly, individual evaluations of home visiting interventions frequently report many outcomes and without correction for chance findings<sup>70</sup>. Therefore, there is a risk of drawing positive conclusions on the basis of single or a few findings. While we pre-specified primary outcomes and adjusted for multiple comparisons we would still be wary about over-interpretation of small effect sizes found for any of the secondary outcomes.

As a theory-based intervention, FNP should be more likely to provide benefit than other non-theory based programmes<sup>71</sup>. Segal and colleagues' meta-review of home-visiting looked at both the link between theory and programme components and the match between theory and target population. Short-term intervention effects in the US NFP trials were most evident in the most vulnerable women at enrolment, who were the focus of the Memphis and Denver trials. In the Dutch VoorZorg trial a two-stage selection process included women with multiple risk factors<sup>94</sup>. In England, young maternal age was chosen as a proxy for low income and the associated long term adverse child outcomes.<sup>99</sup> The programme being delivered in England and therefore associated trial criterion may have resulted in greater heterogeneity and comparatively less disadvantage than the previous related studies. Although the absence of interaction effects addressing a priori markers of vulnerability does not suggest that broad FNP enrolment criteria masked intervention effects, differential effect by subgroup could be explored further. In summary, our trial represents a more pragmatic evaluation of the intervention compared to the previous US and Dutch trials which had a greater emphasis upon efficacy and the match between programme theory and target population may be different from that in the original US trials.<sup>270</sup>

Sweet and Appelbaum's meta-analytic review of 60 home visiting programmes found an inconclusive relationship between population served (targeted versus universal enrolment) and impact.<sup>67</sup> For example, programmes targeting low-income families had higher average parenting behaviour effect sizes but lower average 'potential child abuse' benefits (e.g. ER attendances, injuries and ingestions) than those not targeting such families. Compared to universal enrolment, programmes targeting teenage mothers were no more likely to positively impact child cognition, potential child abuse and parenting behaviour outcomes but were more likely to positively impact maternal education outcomes.

## **17.7 Major changes from published protocol**

There were no major changes from the published study protocol. Three moderate changes were that (i) process evaluation data collection by telephone interviews with local stakeholders was instead

incorporated in stakeholder focus groups, (ii) immunisation data were collected centrally from primary care trusts in addition to directly from general practices and (iii) the primary comparative analyses of prenatal smoking included rate in addition to number of cigarettes smoked.

## **17.8 Implications for practice and policy**

FNP is not likely to deliver improvements within two years postpartum in important programme goals of prenatal smoking cessation, delayed subsequent pregnancies and reduction in child injuries and ingestions when provided for first-time pregnant teenagers in addition to supportive care already available in England. It is not likely to improve birth weight for the first child of FNP clients, another potential programme benefit in younger mothers. FNP is likely to deliver small improvements within two years postpartum in terms of some aspects of child health and development (reduced developmental and language concern) and parental life course (social support, relationship quality, generalized self-efficacy). FNP is associated with increased rates of safeguarding events documented in primary care, which may result from increased contact with a health professional (Family Nurse). The value of these potential benefits will need to be considered against the costs of the delivering the programme in addition to existing locally available maternal and child services.

In summary, our trial found there was no evidence of benefit to adding FNP to existing health service provision in England on the primary outcomes, but there was some evidence of advantage on a small number of secondary outcomes measured for both mother and child by their second birthday. In the absence of improved maternal utility, and with the additional cost of the programme, FNP cannot be recommended as a cost-effective addition to normally provided services in England when considering the mother's perspective. Further expansion of the programme is not supported by our findings and the small benefit seen at two years does not in itself justify continuation of the programme.

Benefits attributable to FNP would be expected to arise at different stages of the maternal and child life course. However, by two years, short-term policy and FNP goals remained mostly unmet in our trial. We recommend on the basis of current findings but note that any evidence of effect on child development outcomes may become more apparent in children only after the age of two. This is the rationale for our current follow-on work assessing key outcomes up to age six years and due to be reported in 2018. Such outcomes include maltreatment, child safety (injuries and ingestions) and early educational attendance and assessments (e.g. Key stage 1).

Our follow-on study will determine whether the indication of child development and language benefit at age two is maintained. It will clarify if our interpretation of safeguarding results is warranted. Policy re-appraisal of FNP would be required at that time to consider such findings.

FNP has already been expanded beyond trial sites in advance of our results becoming available making the context for policy recommendations from research findings atypical. Policy makers now need to consider existing investment, disinvestment and the cost of re-instatement if supported by further evidence. Finally, our findings do highlight the extreme vulnerability of these families, the limited impact of usual care on policy priority outcomes and levels of remaining unmet need. Investment in evidence-based interventions remains a priority. Should standards of usual care observed in the trial diminish in the future then a re-evaluation of the relative effectiveness of candidate interventions, including FNP, would be warranted.

## **17.9 Implications for further research**

Existing US evidence for programme effectiveness has most strongly been observed in the longer term. For example, in a sub-group analysis of 54 women considered most at risk (poor unmarried teens) in the Elmira efficacy trial, by age 2 the difference between control group and NFP in proportion (95% confidence interval) of verified abuse / neglect was 0.15 (-0.01 to 0.31), a potential effect but providing less substantial statistical evidence.<sup>83</sup> In the same trial cohort 15 years after birth, mothers as perpetrators of abuse were less common in the NFP / Infancy group compared to the Control arm (0.29 vs 0.54;  $p < 0.001$ ), an effect even greater for the most vulnerable sub-group (low socio-economic status, unmarried; 0.11).<sup>276</sup>

Work is underway to determine the longer -term impact of FNP within the trial cohort using pseudonymised linkage to routinely collected data from health and educational domains. The aim of the research funded through the UK NIHR Public Health Research Programme will explore the clinical and cost-effectiveness of FNP in reducing maltreatment and related outcomes for children by aged six years old. The innovative linkage approach planned means that detailed information for outcomes such as Child in Need status, child protection referrals and 'looked after' status could be assessed for the entire period from birth to the child's sixth birthday. The potential to augment this research database with outcomes in other domains (e.g. education, criminal justice) and over the longer -term means that the initial investment in the trial can be built upon with relatively little additional cost.

## **17.10 Conclusions**

When delivered in an English NHS context, the Family Nurse Partnership did not impact upon any of the four primary short-term outcomes that it may have been expected to on the basis of existing trial evidence and the programme's theory of change logic model. Rate of smoking in pregnancy and rate of having a second pregnancy by two years postpartum were not reduced. Birth weight was not

affected. Whilst there was a slightly higher rate of emergency secondary care contact for children in the FNP group by their second birthday, this was not accounted for by a difference in injuries and ingestions and there was no statistical evidence of a difference. It is possible that care by nurse visited mothers led to closer monitoring of their child and more rapid engagement with supportive healthcare but not necessarily lower rates of events indicative of maltreatment. Some secondary outcomes provide evidence of small positive programme impacts. These are intention to breast feed, child cognitive and language development, and within maternal life course, levels of social support, relationship quality and generalised self-efficacy. Rates of safeguarding concerns documented in primary care records are higher for FNP clients, which may be due to higher levels of contact with a health professional (Family Nurse). Maternal life course outcomes are expected to benefit the child in the medium term (four to six years) and in the longer term. For other outcomes there is little to distinguish those who received the intervention, and those who did not. Despite some relative delay in enrolling allocated clients, FNP appears to have been delivered well to clients, and in line with how it may be expected to be delivered in routine practice. As such the trial provides a suitable basis for concluding effectiveness. Despite some reduction in other health costs for recipients of FNP, with only minimal gains in maternal QALY and the additional cost associated with the intervention it would not be regarded as cost-effective from the perspective of the mother's health. The study provides evidence of limited programme effectiveness within the domain of child health and development, and within the domain of parental life course and some suggestion that mothers may be more responsive in accessing supportive healthcare for their child, and that nurse visiting increases detection of safeguarding concerns. The value of these benefits would need to be set against the cost of providing the programme in the context of existing supportive maternal and child services.

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# 19 Acknowledgements

## Lead researcher/Chief Investigator

**Dr Mike Robling** Reader and Co-Director, South East Wales Trials Unit, Cardiff University. Trial methodologist and psychologist, overall lead for study design, funding, implementation, data analysis and reporting. Overall guarantor for study.

## Co-Investigators

**Professor Christopher C Butler**, Professor of Primary Care, University of Oxford, Nuffield Department of Primary Care Health Sciences and Cardiff University, Institute of Primary Care and Public Health. Chair Management Group, contributed to study design, implementation, interpretation and writing the report.

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**Professor David Torgerson**, Director of the York Trials Unit, Department of Health Sciences, University of York. Health Economics. Responsible for overseeing the economic analysis, and writing the report.

## Core Project Team members

**Katy Addison**, Trial Administrator, South East Wales Trials Unit, MITI coding.

**Dr Marie-Jet Bekkers**, Researcher, South East Wales Trials Unit. Contributed to all components of the Process Evaluation, and writing the report.

**Kerry Bell**, Research Fellow, Department of Health Sciences, University of York, Health Economics. Responsible for the within trial analysis, all aspects of the secondary trial analysis and writing the final report.

**Dr Kristina Bennert**, Researcher, University of Bristol, Contributed to the Process Evaluation, and writing the report.

**Dr Rebecca Cannings-John**, Senior Statistician, South East Wales Trials Unit Cardiff University. Trial Statistician and writing the report.

**Belen Corbacho Martin**, Research Fellow, Department of Health Sciences, University of York, Health Economics. Within trial economic analysis and extrapolation work, including the systematic review, and writing the report.

**Dr Sue Channon**, Consultant Clinical Psychologist, Cardiff and Vale University Health Board. Clinical Psychology, Process Evaluation lead including Parent-Child Interaction, and writing the report.

**Professor John W Gregory**, Professor in Paediatric Endocrinology and Honorary Consultant Paediatrician, Cardiff University. Contributed to study design, interpretation of results (birth weight data and other paediatric outcomes) and writing the report.

**Professor Kerry Hood**, Co-Director, South East Wales Trials Unit, Cardiff University. Senior trial management and writing the report.

**Professor Lesley Lowes**, Florence Nightingale Foundation Chair of Clinical Nursing Practice Research, School of Healthcare Sciences, Cardiff University. Member stakeholder involvement work package.

**Gwenllian Moody**, Data Manager, South East Wales Trials Unit, Cardiff University, Trial data manager and writing the report.

**Dr Eleri Owen-Jones**, Trial Manager, South East Wales Trials Unit Cardiff University. Trial manager and writing the report.

**Dr Gerry Richardson**, Senior Research Fellow, Centre for Health Economics, University of York, Health Economics. Responsible for the design of the economic analysis/questionnaires, overseeing all aspects of the economic analysis, and writing the report.

**Dr Zoë E S Roberts**, Lecturer in Medical Statistics, Cardiff University. Trial statistician, and writing the report.

**Sarah Ronaldson**, Research Fellow, Department of Health Sciences, University of York, Health Economics. Responsible for the within trial economic analysis, extrapolation work, and writing the report.

**Dr Julia Sanders**, Senior Clinical Research Fellow and Consultant Midwife, South East Wales Trials Unit, Cardiff University. Study implementation, management, interpretation and writing the report.

**Eugena Stamuli**, Research Fellow, Department of Health Sciences, University of York. Responsible for the discrete choice experiment, and all aspects of the economic analysis and writing the report.

**Jackie Swain**, Trial Administrator, South East Wales Trials Unit Cardiff University.

## Collaborators

**Lily Bidmead**, Involving People, Lay member stakeholder involvement work package

**Dr Kamila Hawthorne**, Member stakeholder involvement work package

**Professor Alastair Hay**, Primary care advice and input

**Roiyah Saltus**, Lay member stakeholder involvement work package

**Dr Lesley Wye**, Member Process Evaluation work package

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**Process evaluation assistance:** Michelle Edwards, Cathy Lises, Dr Sarah Morgan-Trimmer, Dr Claire O'Neill, Ria Poole, Hayley Prout.

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**Maternal child interaction coding:** Eugenia Baibazarova (trainer), Kali Barawi, Laura Dewar, Azmat Iqbal, Alice Spiby.

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## Trial Steering Committee Independent Members

Professor Ann Louise Kinmonth, Professor of Primary Care, Cambridge University (Chair); Dr Silvia van den Heijkant, Youth Healthcare Physician, EMGO+ Institute for Health and Care Research, VU University Medical Center, Department of Public and Occupational Health, Amsterdam; Pamela Park, Parenting UK; Professor Stavros Petrou, Professor of Health Economics University of Warwick; Rachel Tonkin, Parenting UK.

## Data Monitoring Committee Independent Members

Dr Gordon Taylor, University of Bath (Chair); Lucy Akhtar, Children in Wales; Dr Sara Kenyon, Senior Lecturer in Public Health, Epidemiology and Biostatistics, University of Birmingham. We would like to pay a special tribute to Professor Paul Wainwright (Kingston University and St George's, University of London) who was the initial Chair of the Data Monitoring Committee and who tragically died in 2010. Paul was an early and important friend to the research team. His personable and supportive leadership of the DMC was hugely appreciated and

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### **Local Researchers**

**Barnsley:** Jacqui Ford, Debbie Hardy; **Berkshire East:** Wendy Bishop-Suitters, Carrie Grainger, Barbara Williams; **Cornwall:** Kim Arnell, Anna Fouracres, Lynne Graves, Mary Kirkpatrick, Sue Mackay; **Coventry:** Angela Bradley, Sue Buswell, Joanne Duffy, Kate Field, Karen Hotchkiss, Deborah Kirkan; **Cumbria:** Margaret Brunton, Julie Butler, Nicci Kelsall, Jackie Purcell, Gillian Pilkington; **Derby:** Pauline Darbyshire, Jill Smith; **Hull:** Helen Bexhell, Teresa Doto, Sarah Ford; **Lambeth and Southwark:** Nellie Daura, Yvonne Evans; **Leeds:** Jane Hayes; **Liverpool:** Kathryn Cobain, Kate Franks, Emma McCurry, Sue Thompson, Lorna Wood; **Manchester:** Nicola Bamford, Alex Hodges, Jane Roach, Cara Taylor, Kathy Unsworth; **Northampton:** Justine Hill, Anbar Nazir, Joanne Woodward; **South Birmingham:** Pauline Darbyshire, Chloe O'Hara; Sarah Hooper; **South East Essex:** Vicky Goater, Victoria Katsande, Teresa Smith; **Sunderland:** Dawn Edmundson, Trish Wake; **Tower Hamlets:** Tracy Lavelle, Clare Wilson; **Walsall:** Nona Giurici, Diane Mellers.

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## 20 Appendices

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# Appendix 1 – Details requested in FNP site selection bids to Department of Health

## FAMILY NURSE PARTNERSHIP, 2008-09 RECRUITMENT OF SECOND WAVE OF SITES, BIDDING PROCESS AND CRITERIA (Summary)

### Information:

1. Number of first time births in area including numbers of mothers under the age of 20, and aged 20 - 24 years.
2. Any additional information on population characteristics, needs and outcomes of young parents and their children.
3. Geographical area to be covered by the FNP.

### Evidence of:

1. Involvement of local Public Health Department.
2. A track record of integrated services and partnership working for children and families. Examples of partnership working across interventions, particularly those supporting the most vulnerable and aiming to reach the marginalized, as well joint service planning.
3. The planned integration between children's health services and Children's Centres, as well as plans for delivering the FNP through Children's Centres.
4. History of innovation and successful service redesign. Information on changes introduced to the Child Health Promotion Programme, health visiting and midwifery.
5. How the FNP would fit within strategic plans for children and families and how it would be embedded within universal services, especially the Child Health Promotion Programme.
6. How FNP would be integrated with other initiatives for young parents, such as teenage pregnancy midwifery, targeted youth support, Connexions, Family Intervention Projects.
7. How feedback from local parents would be sought and plans for engagement of the client group in developing the FNP locally.
8. Plans for recruiting the Family Nurses and Supervisor and delivering the FNP whilst maintaining universal service provision.
9. Demonstration of support by Chief Executive of the PCT and Director of Children's Services in LA with joint LA and PCT governance arrangements.
10. Involvement of midwifery services and referral mechanisms.
11. Agreement to keep the fidelity of the programme and contribute to evaluation and research.



<<Local Trust logo to be added>>

## Appendix 2 - Participant Information Sheet

### Part 1 of the information sheet

#### Study title: Building Blocks - A trial of home visits for first time mothers

The study is called 'Building Blocks'. It is a study of the effectiveness of a new programme called the 'Family Nurse Partnership', which we describe below.

We would like to invite you to take part in a research study. Before you decide if you would like to take part, you need to understand what the research is about and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish, for example, members of your family or friends.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about how the study will be organised.

Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

#### What is the purpose of this study?

The purpose of this study is to see if providing young first time mothers with extra support before and after the birth is helpful for both mother and child. We are specifically interested in whether the programme makes a difference to you and your baby's health and behaviour:

- during pregnancy and at birth (such as cutting down or stopping smoking, and the weight of your newborn baby)
- in the first two years after birth (such as how often your child might have to attend hospital, whether you have any more children, and whether you breast feed your child)

The study will follow two groups of first time mothers. One group will receive usual care from NHS maternity and child health services. This means they will receive exactly the same care as they would if they were not taking part in the study. The other group of women will also receive usual care from NHS maternity and child health services but will have additional home visits from specially trained nurses. These visits will take place throughout pregnancy and afterwards until the baby is 2 years old. We aim to recruit 2400 first time mothers in this study.

The results of this research will help the government in England to decide the best way to support young mothers during their pregnancy and in the early years of their new baby's life.

#### Why have I been chosen?

You have been invited to take part in this study because you are aged 19 or under, are expecting your first child and are less than 24 weeks pregnant. If you wish to be in the study, it is also important that you feel able to talk with the Family Nurse in English. If you would prefer to use an interpreter for the interviews described in the "What will I have to do?" section we can arrange this for you. You must though have conversational English to enter the study.

#### Do I have to take part?



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It is up to you whether or not you take part in this study. This information sheet is yours to keep. If you agree to take part, we will ask you to sign a consent form to show you have agreed to this. We hope that women who join the study will continue to take part until their baby is two years old. But if you want to leave the study, you can at any time. You do not have to give a reason to leave the study.

Should you decide not to join the study, or join and later leave, the usual NHS care you and your baby receive will not be affected. Your usual NHS care will not be affected at any time.

### **What will happen to me if I take part?**

If you decide to take part, the research nurse will tell you which group you will be in. You are not able to choose which group you are in as this is decided at random (like flipping a coin). The research nurse will tell you whether you have been chosen to have **either**:

(1) Services that are routinely available to all mothers and their babies/children in your area

**or**

(2) Routine midwifery services **plus** a structured programme of home visits called Family Nurse Partnership (FNP). This is described below in more detail.

We will not take any blood as part of this study but we will collect two urine samples. The first sample will be taken now and the second just before you are due to give birth. This will measure any nicotine in your body. This gives us an indication of your smoking status and is one of the measures we are looking at. This urine sample will only be tested for nicotine and not for anything else. There are no other tests for this study.

Your consent will allow the study researchers to access your medical notes and to look at the results of tests or check-ups in relation to your pregnancy and baby (this will include clinical information about you and your baby's experience at child birth, such as your baby's weight and other measures of his / her health). This may include contact with your GP out-of-hours, Accident and Emergency and hospital notes as well as GP notes. We are interested to find out whether you and your baby have attended your GP or hospital and for what reason. This information will be used to find out how women and babies in the two study groups compare in terms of their on-going health and development. We will treat this information in strict confidence and we will not share this information with other health professionals or others outside of the research team.

### **Expenses and payments**

We cannot pay you to take part in this study. However, as a token of our thanks, we will send your child a retail voucher on his/her first and second birthday, and we will also send you a £10 phone top-up card upon entry to the study and at other important data collection time-points. You should not incur any travel expenses by being in the study.

### **What will I have to do?**

Regardless of which group you are in, we will need to take up some of your time to ask certain questions at specific times during the study. These questions may be asked to you face to face by a research nurse (who is different from the Family Nurse Partnership nurse), or by a trained interviewer over the telephone at a pre-arranged time convenient to you. There will be six occasions when we will need to ask you some questions. These will be:



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- (1) When you give consent and are randomised to this study (a face to face interview);
- (2) 34-36 weeks into your pregnancy (a telephone interview);
- (3) 6 months after the birth of your child (a telephone interview);
- (4) 1 year after the birth of your child (a telephone interview);
- (5) 18 months after the birth of your child (a telephone interview);
- (6) 2 years after the birth of your child (a face to face interview).

If you would prefer to use an interpreter for these interviews, we can arrange this for you.

During these research interviews you will be asked questions about yourself and your own family background (for example, about school, college and work); your health; your views, thoughts and experiences about being a mother (for example, how you play with your child); your own lifestyle (such as eating, drinking and smoking); your family and your social life; your experiences of getting support from health and other services. Similar questions will be asked at each interview, although there will be fewer questions in the telephone interviews.

This information is only being collected for the research and will not affect the care that you receive from your doctor, midwife or other health professional. All your answers will be kept confidential and not shared with your doctor or midwife. If you do not want answer any individual question you do not have to do so – that is your choice.

If you are randomised to receive the Family Nurse Partnership (FNP) programme, you will also be asked to spare some of your time to the programme as mentioned below.

### **What is the programme that is being tested?**

If you are selected to join the group that receives the Family Nurse Partnership (FNP) programme, you will receive visits from a specially trained 'Family Nurse', who has experience of working with families in the community. The Family Nurse would normally come to your home, but can see you somewhere else if you prefer. The Family Nurse will visit you every week for the first month after you join the study, and then every other week until your baby is born. The Family Nurse will then visit you weekly until your baby is six weeks old and then once every two weeks until your child is 20 months old. The last four visits are monthly until your child is 2 years old.

It is hoped that your Family Nurse will be the same person throughout the study, starting now in early pregnancy and continuing until your child is 2 years old. The involvement of your baby's father and other family members is encouraged, but you can decide if you want this.

The Family Nurse Partnership is a new way of working with new mothers. The aim is to help young mothers by offering frequent home visiting. Each visit will last about an hour and aims to help you with:

- 1) your own health and lifestyle
- 2) providing a safe and happy home for your baby
- 3) planning for your own future
- 4) preparing to look after your baby
- 5) involving your family and friends
- 6) getting support for you and your baby.



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### **What are the alternatives for treatment?**

If you choose not to take part in the study, or are selected to be in the group that **does not** receive the Family Nurse Partnership (FNP) programme, you will continue to receive routinely available maternity and child health services.

### **What are the possible disadvantages and risks of taking part?**

If you decide to take part, and are selected to be in the group that receives the Family Nurse Programme, you will need to meet your Family Nurse regularly. Mothers in both groups will be asked to spare some time for interviews, as described above, to see how you are getting on.

### **What are the possible benefits of taking part?**

There may be no benefits to anyone taking part in this study. The study is being undertaken to find out whether or not the Family Nurse Partnership helps young mothers and their babies. Even if you do not see a Family Nurse you will be helping to answer this question, which may benefit other young mothers in the future.

### **What if there is a problem?**

Any complaint about the way you have been dealt with during the study or possible harm you might suffer will be addressed. More information about this is given in Part 2.

### **Will my taking part in this study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

As is usual, if during any of your meetings with anyone involved with this study (with any of the nurses or whilst you are talking with the telephone interviewer) somebody is concerned that you, your unborn baby or a child may be at risk, we will contact the relevant authorities.

### **This completes Part 1.**

**If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.**



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## Part 2 of the information sheet

### What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, without giving a reason. If you withdraw at any time, or decide not to take part, it will not affect the standard of care you or your child receives now or in the future.

If you do decide to withdraw from the study, we will use the data collected up to that point but we will collect no more data. If you decide you do not want to continue having visits from your Family Nurse, we would still like to interview you to see how you have been getting on.

If the study is stopped for any other reason, we will tell you and the care of you and your child will continue as usual.

### What if there is a problem?

#### *Complaints*

If you have a concern about any aspect of this study, you can speak to the researchers at Cardiff University who will do their best to answer your questions (contact details below).

#### *Contact for further information about the study:*

Eleri Owen-Jones  
South East Wales Trials Unit  
Department of Primary Care and Public Health  
Cardiff University  
Neuadd Meirionnydd  
Heath Park  
Cardiff  
Wales  
CF14 4YS  
Tel: 029 2068 7601

If you remain unhappy and wish to complain formally, you can do this through the Research and Commercial Division of Cardiff University (details below).

#### *Contact for formal complaints procedure at Cardiff University:*

Mr Chris Shaw  
Research Governance Officer  
Cardiff University  
Research and Commercial Division  
30-36 Newport Road  
Cardiff  
CF24 0DE  
Tel: 029 2087 9130 or 029 2087 9277

#### *Harm*

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.



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### **Will my taking part in this study be kept confidential?**

Yes. All information which is collected about you and your child during the course of the research will be kept strictly confidential (kept a secret). Study data stored at the University will be kept separate from personal information (names and addresses). Only members of the research team will have access to view identifiable data. However, in some instances, official people from regulatory authorities may need to access data for checking the quality of the research. All members of the research team and regulatory bodies are trained in data protection issues and bound by the terms of the Data Protection Act 1998.

As is usual, if during any of your meetings with anyone involved with this study (with any of the nurses or whilst you are talking with the telephone interviewer) somebody is concerned that you, your unborn baby or a child may be at risk, we will contact the relevant authorities.

Once the study is complete and it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information. Records will be kept securely for up to 30 years in line with Cardiff University's policies.

### **Involvement of the Family Doctor**

As your Family Doctor is involved in your care during your pregnancy and afterwards, if you decide to join the study he or she will be informed with your permission. We will also inform your midwife and health visitor that you are taking part in the study, again with your permission.

### **What will happen to any samples I give?**

Once the nicotine tests are completed, the urine samples will be destroyed.

### **Will any genetic tests be done?**

No. We will not be doing any genetic tests.

### **What will happen to the results of the research study?**

A report of the research results will be completed and sent to the Department of Health who are paying for the study. Results will be published in scientific journals and presented at scientific meetings. You or your child will not be identified in any report, publication or presentation.

Once the research study is completed, if you would like a report of the research findings this will be available by contacting Dr Owen-Jones (see below).

### **Who is organising and funding the research?**

This study is being organised by the South East Wales Trials Unit, Cardiff University. The research is being paid for by the Department of Health.

### **Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Research Ethics Committee for Wales.

### **Contact for Further Information**

Dr Eleri Owen-Jones (Trial Manager) / Katy Addison (Trial Administrator)  
South East Wales Trials Unit, Department of Primary Care and Public Health, Cardiff University, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS.  
Tel: 029 2068 7601 / 7617

**THANK YOU FOR CONSIDERING TAKING PART IN THIS STUDY.**



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## Appendix 3 - Building Blocks Consent Form

**Study Title: Building Blocks – A trial of home visits for first time mothers**

**Name of Researcher:** \_\_\_\_\_

- |    |  | Please<br>initial box    |
|----|--|--------------------------|
| 1. | I confirm that I have read and understood the Participant Information Sheet dated 13 <sup>th</sup> October 2009 (Version 1.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered to my satisfaction.   | <input type="checkbox"/> |
| 2. | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my (or my child's) medical care or legal rights being affected.   | <input type="checkbox"/> |
| 3. | I understand that information about me and my child needed for the study (including personally identifiable information) may be collected from us and from our medical records and looked at by the research team from Cardiff University during the trial. It may also be looked at by regulatory authorities supervising the trial, and the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records. | <input type="checkbox"/> |
| 4. | I understand that my urine will be tested for nicotine by the laboratory.  | <input type="checkbox"/> |
| 5. | I give permission for my GP, midwife and health visitor to be informed of my participation in this study.  | <input type="checkbox"/> |
| 6. | I agree to take part in the above trial.   | <input type="checkbox"/> |

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

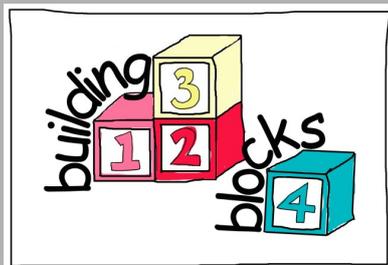
\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Researcher

When completed please place the top copy in the site file, place 1 copy in the participant's medical notes and give 1 copy to the participant.



# Building Blocks Newsletter

September 2011

Welcome to the Building Blocks Local Researcher Newsletter!

We are looking forward to seeing you at the 2 year training days in October and November 2011!

## Researcher two-year interview training, October and November 2011

As you know we are currently planning the two-year training sessions. One of these training sessions will be held in Manchester on Monday the 10th October, and the other will be in Birmingham on Monday the 7th November.

We hope that these training sessions will be as successful as the previous sessions and the annual event in April. Please have a think about any queries you would like to be answered on the day, or email Gwen with these in advance. Obviously if anything is urgent then contact the team at any time.

We are looking forward to seeing you all!

## 6 Month Interview

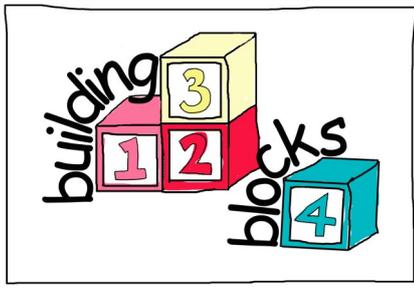
We have now finished collecting data for the 6 month telephone interview and are very happy to announce that the follow-up rate has been 65%! We would like to thank you for all your hard work in obtaining new phone numbers for us. As you know the 12 and 18 month telephone interview are ongoing so please keep up the good work!

## IT Equipment

As the 2 year interviews will be starting soon you will need to re-familiarise yourself with your Building Blocks IT equipment (laptop and BlackBerry) once again, especially those of you who completed collecting Birth CRFs a while ago, and those who weren't in post for the recruitment phase. Please check all your equipment is working, and that you are not missing anything e.g. that your BlackBerry still has its charger and data transfer (USB) cable. Please let Gwen know if you are missing any equipment or if any of it is not working.

## Annual Leave

We know most of you already do so but please remember to let us know if you have booked any annual leave. We will also endeavour to let you know when one of the staff you have contacts with (e.g. Gwen) is away on leave.



# Building Blocks Newsletter

Continued.....

## Retention Table

The table below shows the progress of each site with regards to follow-up. This table includes some aspects of follow-up directly affected by Researcher work at sites (e.g. birth CRF). The table also includes telephone interview follow-up rates, these are indirectly related to Researcher work as they are dependent on the collection of updated phone numbers for participants.

Site ID	Total Recruited	Count of completed Birth CRFs		Count of participants who have completed 6 month Interview		Count of participants who have completed 12 month Interview		Count of participants who have completed 18 month Interview	
		Count of completed Birth CRFs	Percentage of completed Birth CRFs from overall recruited not including withdrawals	Count of participants who have completed 6 month Interview	Percentage of participants who have completed 6 month Interview from overall recruited not including withdrawals	Count of participants who have completed 12 month Interview	Percentage of participants who have completed 12 month Interview from overall recruited not including withdrawals	Count of participants who have completed 18 month Interview	Percentage of participants who have completed 18 month Interview from overall recruited not including withdrawals
1	43	40	100	28	68	27	73	9	75
2	50	45	98	25	54	21	51	2	40
4	143	121	95	75	58	50	56	9	53
5	39	37	95	22	56	18	75	5	100
7	56	53	100	38	66	33	66	14	67
8	40	34	94	28	72	20	69	2	40
9	50	40	100	27	66	27	79	8	89
10	113	91	94	62	63	36	55	9	47
21	69	98	95	56	54	37	46	10	50
22	115	63	98	55	86	37	84	2	100
23	100	91	94	74	77	53	75	9	64
24	95	83	100	65	76	33	62	6	100
25	150	131	96	99	69	59	80	12	71
26	36	28	97	19	66	13	54	8	80
27	144	136	100	78	55	42	56	10	59
28	141	123	98	83	65	51	61	9	53
29	127	110	98	73	63	32	49	4	33
30	134	116	96	74	61	41	61	10	63
<b>Total</b>	<b>1645</b>	<b>1440</b>	<b>97</b>	<b>981</b>	<b>65</b>	<b>630</b>	<b>63</b>	<b>138</b>	<b>62</b>

## Appendix 5 - Measure modification and scoring details

### Measure Modification for Maternal outcomes

#### Relationship Status

The first question in the Relationship status only was taken from Millennium Cohort Study [65,66], the text was also modified slightly to be suitable for use with teenage responders.

*I'd like to ask you about your relationship with your baby's father. Which of these best describes your relationship?*

- 1) *married*
- 2) *separated*
- 3) *divorced*
- 4) *closely involved/boyfriend*
- 5) *just friends*
- 6) *or, not in any relationship?*

The following questions were newly derived by the trial team:

*If answer is anything other than married, ask:*

*And are you in a relationship with someone other than your baby's father?*

- 1) *Yes..... and which of these best describes that relationship?*
  - 1) *married*
  - 2) *separated*
  - 3) *divorced*
  - 4) *closely involved/boyfriend*
  - 5) *just friends*
  - 6) *or, not in any relationship?*
- 2) *No*

#### Family background and social class

The Family background and social class variables included questions relating to time living away from parents from the Millennium Cohort Study [65,66] that were adapted:

*Have you spent any time living away from both of your parents?*

- 1) *Yes*
- 2) *No*

*Where did you mainly live?*

- 1) *Children's home*

- 2) *Foster parents*
- 3) *Boarding school*
- 4) *Living with relatives or friends*
- 5) *Living with boyfriend, partner, or husband*
- 6) *Prison/Young Offenders Institute/Borstal*
- 7) *Some other place*\_\_\_\_\_

The following newly derived items about parental education and job were also included (repeated for father):

*Did/Does your mother have any of the following qualifications? Tell me the first one I read out that she had/has:*

- 1) *A higher degree, like a master's degree, or a PhD*
- 2) *A first degree, like a BA or BSc*
- 3) *A certificate or diploma in higher education*
- 4) *A or AS or S levels*
- 5) *O levels or GCSE grades A-C*
- 6) *GCSE grades D-G*
- 7) *Overseas qualifications*
- 8) *Other qualifications.....please write in*
- 9) *None of these qualifications*

*And what was/is your mother's usual job?*

## **Home**

For the Home variables, questions from the Millennium Cohort Study [65,66] were re-ordered and adapted to be made suitable for teenagers, and a subset of questions were used. The following questions were adapted:

*How many bedrooms do you and the other people in your household have?*

*And is this place owned or rented or do you have some other arrangement?*

- 1) *Owned by parents or family members*
- 2) *Owned by self and/or boyfriend, partner, husband*
- 3) *Rented by parents or family members*
- 4) *Rented by self and/or boyfriend, partner, husband*
- 5) *Live rent free*
- 6) *Squatting*

7) Other \_\_\_\_\_

The following newly derived items were also included:

*Since the birth of the baby(ies), have you been housed in any of the following types of accommodation? (yes/no answers to each item, if participants answered 'yes' they were asked about the number of weeks spent at the accommodation)*

- 1) B&B
- 2) Teenage parent accommodation
- 3) Supported accommodation
- 4) Mother and baby hostel/unit
- 5) Women's refuge/domestic violence refuge
- 6) Homeless hostel

*Did anyone from outside your friends or family help you find housing for you and your baby(ies)?*

- 1) Yes
- 2) No

*Did any of the following people or organisations help you with your housing?*

*(yes/no answers to each item)*

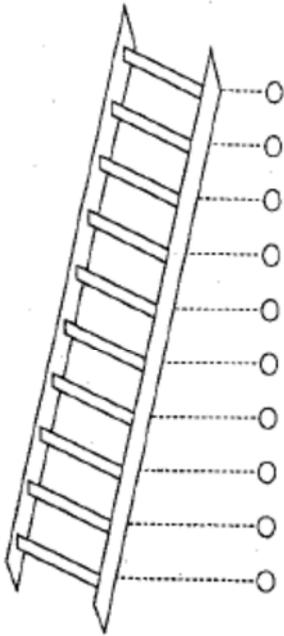
- 1) Midwife
- 2) Health visitor
- 3) Family Nurse
- 4) Social Worker
- 5) Local Authority Housing Department
- 6) Charity
- 7) *Was there anybody else who helped you? (if yes, participant was asked 'who?')*

Some women, on occasions, need to make contact with a refuge especially for women who need time away from a partner. Have you needed to make contact with such a refuge since your baby(ies) was born?

- 1) *Yes, if yes ask what led to the need to make contact details of duration of stay or type of contact* \_\_\_\_\_
- 2) No

## Subjective social status

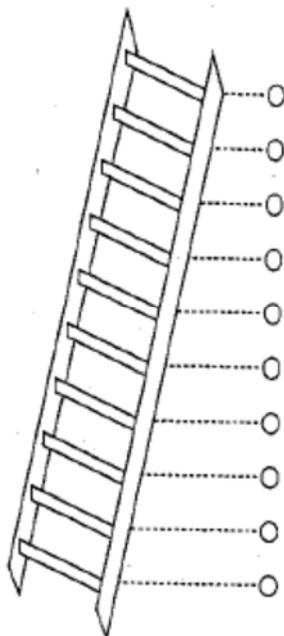
In the Subjective social status [90] items text was modified from being more suitable for use with an American audience, to being more suitable for a UK setting.



*Imagine that this ladder pictures how British society is set up.*

- *At the top of the ladder are the people who are the best off – they have the most money, the most schooling, and the jobs that bring the most respect*
- *At the bottom are people who are worst off – they have the least money, little or no education, no job or jobs that no one wants or respects.*

*Now think about your family. Please think where your family would be on this ladder. **Fill in the circle that best represents where your family would be on this ladder.***



*Now imagine that this ladder is a way of picturing your school or college or workplace, or your group of friends.*

- *At the top of the ladder are the people with the most respect, the most popular, the ones with the highest standing*
  - *At the bottom are people who no one respects, no one wants to hang out with*
- Where would you place yourself on this ladder. **Fill in the circle that best represents where you would be on this ladder.***

### **Antisocial behaviour**

In original measure [88,89], antisocial behaviour items asked of females and males were different. Both were asked about fighting, stealing, and involvement with police. In the Building Blocks study the participants (female) were asked both male and female questions combined. These included questions about expulsion/suspension from school, and skipping school and running away overnight.

### **Adaptive Functioning**

The adaptive functioning scale selected items were drawn from the Community Life Skills (*italicised*) and Difficult Life Circumstances scales [13,14]. The following items were used:

- *Do you eat at least one meal a day at home with family or friends?*
- *Do you have a diary or a calendar for keeping track of appointments or home visits or obligations?*
- *Do you have a phone, either a mobile or a landline?*
- *Do you have a bank account?*
- *Do you plan your spending money or make a budget for yourself?*
- Do you have to care for anybody with a long-term illness or a problem with alcohol or drugs?
- Do you feel you have enough privacy?
- Do you have people living with you that you wish weren't there?

The following questions were drawn from the Millennium Cohort Study [65,66].

*As you may know, many people have problems with reading. Can I just check, could you read aloud to a child from a children's storybook?*

*IF YES: Can you usually read this easily or with difficulty?*

- 1) *Yes, easily*
- 2) *Yes, with difficulty*
- 3) *No*

*Can you usually read and fill out forms you might have to deal with?*

*IF YES: Can you usually read this easily or with difficulty?*

- 1) *Yes, easily*
- 2) *Yes, with difficulty*
- 3) *No*

*When you buy things in shops with a five or ten pound note, can you usually tell if you have the right change?*

*PROBE IF YES: Can you usually do this easily or with difficulty?*

- 1) *Yes, easily*
- 2) *Yes, with difficulty*
- 3) *No*

*IF have difficulty with reading aloud, filling in forms, checking change in shops:*

*Do problems with reading, writing or maths make it difficult to manage day to day activities, like paying bills, writing letters and so on?*

- 1) *Yes*
- 2) *No*

Using the above items three subdomains for Adaptive Functioning were created;

- **Difficulty in at least one basic skill.** Binary variable created where;
  - 1=difficulty in at least one of reading, writing or maths
  - 0=no difficulty in reading, writing and maths
- **At least one life burden.** Binary variable created where;
  - 1=answered yes to at least one difficult life circumstance
  - 0=no difficult life circumstance
- **Three or less life skills.** Binary variable created where;
  - 1=answered yes to 3 or less questions in the community life skills questions.
  - 0=answered yes to 4 or 5 questions in the community life skills questions.

### **Measure modification for Parenting and child outcomes**

#### **Prenatal Attachment Inventory**

The prenatal Attachment Inventory [23] was reduced from 21 items to 8 items , the following items were retained:

Responses to all items were:

- 1) Almost Always
- 2) Often
- 3) Sometimes
- 4) Almost Never

- *Can you please tell me how often you wonder what the baby looks like now?*

- *And how often do you enjoy feeling the baby move?*
- *How often do you plan the things you will do with your baby?*
- *How often do you buy or make things for your baby?*
- *How often do you feel love for your baby?*
- *How often do you try to imagine what your baby is doing in there?*
- *How often do you stroke your baby through your tummy?*
- *How often do you get very excited when you think about your baby?*

### **Feeding and Development**

For the Feeding and development domain a reduced set of questions was used from the Schedule of Growing Skills [25] when measuring both Cognitive development and Language Development.

#### Cognitive development

The table below shows the items used at each timepoint to measure cognitive development. If a child did not score positively on some items they were scored as being developmentally delayed.

<b>Item</b>	<b>12 month interview</b>	<b>18 month interview</b>	<b>24 month interview</b>
<i>Is your baby sitting independently, that is without help, on their own?</i>	✓ (delay grossmotor)	✓ (delay grossmotor)	
<i>Is your baby crawling or bottom shuffling?</i>	✓	✓ (delay grossmotor)	
<i>Is your baby walking around furniture?</i>	✓	✓ (delay grossmotor)	✓ (delay grossmotor)
<i>Is your baby walking with one hand held?</i>	✓	✓ (delay grossmotor)	✓ (delay grossmotor)
<i>Is your baby walking independently, that is without help, on their own?</i>	✓	✓ (delay grossmotor)	✓ (delay grossmotor)
<i>Can your baby clap their hands?</i>	✓ (delay finemotor)		
<i>Can your baby throw toys?</i>	✓		
<i>Can your baby pick up small objects like raisins or small sweets?</i>	✓ (delay finemotor)	✓ (delay finemotor)	
<i>Does your baby drink from a beaker?</i>	✓		

<i>Does your baby wave bye-bye?</i>	✓ (delay social)		
<i>Does your baby show an interest in books?</i>	✓		
<i>Can your baby use a spoon to feed him/herself?</i>		✓	✓ (delay finemotor)
<i>Does your baby throw toys deliberately?</i>		✓ (delay finemotor)	
<i>Can your child run confidently stopping and starting without bumping into objects?</i>			✓ (delay grossmotor)
<i>Can your child pick up an object from floor when standing without falling over?</i>			✓ (delay grossmotor)
<i>Can child walk and turn corners and stop suddenly?</i>			✓ (delay grossmotor)
<i>Can your child turn pages of a book 1 at a time?</i>			✓ (delay finemotor)
<i>Can your child turn pages of a book several at a time?</i>			✓ (delay finemotor)
<i>How many bricks can your child build in a tower?</i>			✓
<i>Can your child do to and fro scribbling?</i>			✓
<i>Can your child do circular scribbling?</i>			✓
<i>Can your child copy straight lines?</i>			✓

### Language development

The table below shows the items used at each timepoint to measure language development.

<b>Item</b>	<b>12 month interview</b>	<b>18 month interview</b>
<i>Is your baby chewing food yet?</i>	✓	✓
<i>Is your baby making recognised sounds like ma ma, ba ba, dada?</i>	✓	✓
<i>Does your baby have two or three recognised words with meaning?</i>	✓	✓
<i>Does your baby put two words together?</i>		✓

<i>Does your baby name objects?</i>		✓
<i>Does your baby repeat words?</i>		✓

### **Child Safety**

A reduced set of questions was also used for the Child Safety items, only some items from section B ‘Injuries and Injury Prevention’ of the California Health Interview Survey [27] were used:

- *Put up or used baby gates for stairs or doors, window guards or other barriers?*
- *Put up or used locks or safety latches on cabinets where things like cleaning supplies are kept?*
- *Put up or used padding around sharp edges such as coffee tables or fireplaces?*
- *Covered electrical outlets so your child could not insert {his/her} fingers or other things?*
- *Turned down the temperature of the hot water heater?*

A participant was coded as having a “safe home” if they used all five of the above safety measures. If a participant had at least one missing value then they were unable to be coded. If a participant responded that a question was “not applicable” then this question was excluded and all remaining safety features had to be present for the participant to be coded as having a safe home.

### **Baby diet**

In the absence of a standardised measure of infant feeding considered to be applicable to this sample, we developed a new measure reflecting healthy and less healthy food choices which reflected FNP guidance for mothers.

- *How often does your toddler eat food you have cooked, rather than just using jars or heating frozen food in the oven?*
- *How often does your toddler drink fizzy pop, sweetened tea, or squash*
- *How often does your toddler eat fruit or veg? (including frozen or tinned)*
- *How often does your toddler eat cake, biscuits, or sweets?*
- *How often does your toddler eat fast food?*

### **Early Language Milestone Scale**

This was scored in the following way:

Global Score (totalled by Research Nurse): This is the total global score provided by the RN on the score sheet.

Global Score (on form): This is the global score based on actual items ticked on the score sheet and added up by a Trial Team member according to strict ELM criteria;

A new score called 'Global Score (Building Blocks)' was created as the 'Global Score (totalled by Research Nurse)' was frequently incorrect or missing, and 'Global Score (on form)' ignored scale items that were not ticked but have obviously formed part of the test or could be seen to be self-evident given the age of the child or the overall pattern of scoring. The 'Global Score (Building Blocks)' is the global score based on actual items ticked on the score sheet as well as assumptions based on the Research Nurses' scoring system and the child's performance in the test overall.

### **Maternal child interaction**

For the Maternal-child interaction recordings, three minutes of recording were used for each parent-child interaction as opposed to the 5 minutes used by Fish and Stifter 86.

## Appendix 6 - Fields requested from HSCIC

### Inpatient data

Field type	Field	Description
PATIENT	endage startage dob_cfl extract_hesid	Age at end of episode Age at start of episode Date of birth check flag Patient-identifier HES generated
ADMISSIONS	admidate adm_cfl admimeth admisorc	Date of admission Admission date check flag Method of admission Source of admission
DISCHARGES	disdate dis_cfl disdest dismeth	Date of discharge Discharge date check flag Destination on discharge Method of discharge
EPISODES AND SPELLS	bedyear spelbgin epiend epistart speldur spelend epidur epiorder epie_cfl epis_cfl epistat epitype provspno wardstrt	Bed days within the year Beginning of spell Date episode ended Date episode started Duration of spell End of spell Episode duration Episode order Episode end date check flag Episode start date check flag Episode status Episode type Hospital provider spell number Ward type at start of episode
CLINICAL	diag_nn diag4 cause oper_nn oper3 opdte_nn mainspef tretspef	All Diagnosis codes Primary diagnosis – 4 characters External cause of injury or poisoning All operative procedure codes Main operative procedure Date of operation Main speciality Treatment speciality
HEALTH CARE RESOURCE GROUPS	domproc hrg_3.5 hrgnhs hrgnhsvn	Dominant procedure Healthcare resource group:v 3.5 NHS generated HRG code NHS generated HRG code version number
ORGANISATION	procode protype	Provider code – 5 character Provider type
MATERNITY	antedur dobbaby birweit delchang delmeth delplac (actual) gestat birstat postdur	Antenatal days of stay Birth date Birth weight Change of delivery place Delivery method Delivery place Length of gestation Live or still birth Postnatal stay
SYSTEM	neocare opcs43	Neonatal level of care OPCS 3.4 used flag

	epikey	Record identifier
<b>Outpatient Data</b>		
Field type	Field	Description
PATIENT	apptage extract_hesid	Age at day of appointment Patient ID – HES generated
APPOINTMENT	apptdate attendid atentype attended outcome	Appointment date Attendance identifier Attendance type Attended or Did Not Attend Outcome of Attendance
CLINICAL	diag_nn diag4 oper_nn opertn_01 oper3 mainspef tretspef	All diagnosis codes Primary diagnosis – 4 character All operation codes Main operation Main operation – 3 characters Main speciality Treatment speciality
HEALTH CARE RESOURCE GROUPS	hrgnhs hrgnhsvn	NHS generated HRG code NHS generated HRG code version number
MATERNITY	babyage	Age of neonate baby
SYSTEM	attendkey	Record identifier

#### Accident and Emergency Data

Field type	Field	Description
PATIENT	apptage extract_hesid	Age at day of appointment Patient ID – HES generated
ATTENDANCES	aearrivalmode aeattenddisp aedepttype aeincloctype aepatgroup aerefsorce arrvaldate arrivaltime deptime	Arrival mode Attendance disposal Department type Incident location type Patient group Source of referral Arrival date Arrival time Departure time
CLINICAL DIAGNOSIS	diag n diag2 n D diaga n D	A&E diagnosis A&E diagnosis – 2 Char A&E diagnosis – Anatomical area
CLINICAL INVESTIGATION	invest n invest n D	A&E Investigation A&E Investigation – 2 Char
CLINICAL TREATMENT	treat n treat2 n D	A&E Treatment A&E Treatment – 2 Char
HEALTH CARE RESOURCE GROUPS	domproc hrgnhs hrgnhsvn	Dominant procedure NHS generated HRG code NHS generated HRG code version number
SYSTEM DATA	aekey	Record identifier

## Appendix 7 - Procedure of calibrating the self-reported numbers of cigarettes with the participant's cotinine level

Step One - calculate the self-reported weighted number of cigarettes ( $N_{self}$ ) based on the participant's last 3-day self-reports.

We adopted scenario 2 presented in the Dukic paper<sup>1</sup>. We assumed that the urine samples were taken at the interview venue during the interview. We also assumed that each woman voids in the morning at 7 a.m. and 12 noon on the day of interview. Furthermore, we assume no voiding between 7 a.m. and the time of interview if the interview was before noon, and one voiding at noon if the interview was in the afternoon. In this scenario, we calculate the weight of each cigarette as the difference between the fraction of the cotinine from the cigarette that would be in the urine sample had the woman not voided at all prior to the interview, and the fraction that was actually in her urine whenever she last voided prior to the interview (at 7 a.m. or at noon). Formulae (A.7) to (A.9) in the appendix of the Dukic paper are used<sup>1</sup>. Moreover, if the participant has provided the smoking time of the last cigarette on the interview day, we will implement this information to adjust smoking time interval on the day of interview.

Step Two - calculate the weighted numbers of cigarettes ( $N_{cot}$ ) based on the participant's cotinine level. Here we use 150 ng/ml per weighted cigarette as the standard which was recommended as giving the best and most balanced results in the Dukic paper<sup>1</sup>. So that all cotinine measurements could be used, those participants whose cotinine measurement was recorded as <100 ng/ml were assigned a cotinine value of zero and those whose cotinine measurement was recorded as >2000 were assigned a cotinine value of 2000.

Step Three - classify the participants into 4 reporting groups: over-reporter, accurate reporter, under-reporter and extreme under-reporter, by comparing their  $N_{cot}$  and  $N_{self}$  values.

Classify the woman as an over-reporter if

$$\sqrt{\frac{N_{cot}}{N_{self}}} - 1 < -0.15 \quad , \text{ i.e., } \sqrt{\frac{N_{cot}}{N_{self}}} < 0.85 \quad , \quad \frac{N_{cot}}{N_{self}} < 0.7225;$$

Classify the woman as an accurate reporter if

$$\left| \sqrt{\frac{N_{cot}}{N_{self}}} - 1 \right| < 0.15 \quad , \text{ i.e., } 0.85 < \sqrt{\frac{N_{cot}}{N_{self}}} < 1.15 \quad , \quad 0.7225 < \frac{N_{cot}}{N_{self}} < 1.3225;$$

Classify the woman as an under-reporter if

$$0.15 < \sqrt{\frac{N_{cot}}{N_{self}}} - 1 < 0.35 \quad , \text{ i.e., } \quad 1.15 < \sqrt{\frac{N_{cot}}{N_{self}}} < 1.35 \quad , \quad \frac{N_{cot}}{N_{self}} < 1.8225;$$

Classify the woman as an extreme under-reporter if

$$\sqrt{\frac{N_{cot}}{N_{self}}} - 1 > 0.35 \quad , \text{ i.e., } \quad \sqrt{\frac{N_{cot}}{N_{self}}} > 1.35 \quad , \quad \frac{N_{cot}}{N_{self}} > 1.8225.$$

If the participant reports zero cigarettes, i.e.,  $N_{self}$  is zero, we used an alternative rule to make the classification. We classified these participants according to their cotinine level: if their cotinine level  $N_{cot}$  is  $\leq 100\text{ng/ml}$ , they are classified as an accurate reporter; if their cotinine level  $N_{cot}$  is  $> 100\text{ng/ml}$  and  $< 1000\text{ng/ml}$ , they are an under reporter; and if their cotinine level  $N_{cot}$  is  $\geq 1000\text{ng/ml}$ , they are an extreme under reporter.

Step four – calculate the weighted difference between the self-report and cotinine level for each reporting group. With  $N_{cot}$  and  $N_{self}$  in 4 reporting groups, we calculated the difference between the average weighted self-report number of cigarettes and weighted cotinine number of cigarettes for each group.

Step five – for each participant use the weighted difference of their reporting group to calibrate their mean number of cigarettes. With the formulae (A.7) to (A.9) in the Dukic paper <sup>1</sup>, we can transform the weighted difference back to the actual number of the cigarettes. Also in line with the participant's last-3-day self-report pattern, we would spread the actual number of the cigarettes into the self-report numbers. Finally, we can work out the calibrated mean numbers of cigarettes.

## Testing the assumption that urine samples were collected at the same time as interview

One of the assumptions when calculating the calibrated number of cigarettes is that the urine sample is taken at the time of interview. At follow-up this was not possible as interview was by telephone and hence we explored whether consistency of reporting behaviour (ie, over-reporter, accurate reporter, under-reporter and extreme under-reporter) was affected by time lapse between interview date and sample date. This was carried out for 870 participants who had complete self-reported smoking and urine sample at both time points. The results in Table: x show little variation in consistency of reporting behaviour between the time lapse groups. Therefore the timing of the sample is not considered an important factor in pattern of reporting behaviour change so all follow-up data will be used.

**Table: Reporting consistencies between baseline and late pregnancy by time lapse between interview and sample date (time lapse applies to both time points)**

	1: Interview & sample on same day	2: Interview & sample within 2 weeks (exc. 1)	Interview & sample within 4 weeks (exc. 1&2)	Interview & sample >4 weeks apart	All
	n, % (95% CI)				
Consistent reporting	29, 59.2% (45.2%, 71.8%)	388, 62.6% (58.7%, 66.3%)	83, 56.8% (48.7 %, 64.6%)	35, 63.6% (50.4%, 75.1%)	535, 61.5% (58.2%, 64.7%)
Less under reporting at follow-up	10, 20.4% (11.5%, 33.6%)	101, 16.3% (13.6%, 19.4%)	30, 20.5% (14.8%, 27.8%)	12, 21.8% (12.9%, 34.4%)	153, 17.6% (15.2%, 20.3%)
More under reporting at follow-up	10, 20.4% (11.5%, 33.6%)	131, 21.1% (18.1%, 24.5%)	33, 22.6% (16.6%, 30.0%)	8, 14.5% (7.6%, 26.2%)	182, 20.9% (18.3%, 23.7%)

1. Dukic VM, Niessner M, Benowitz N, Hans S, Wakschlag L. Modeling the relationship of cotinine and self-reported measures of maternal smoking during pregnancy: A deterministic approach. *Nicotine & Tobacco Research* 2007; **9**(4): 453-65.

## Appendix 8 - Diagnoses codes

The following codes were used to select events from HSCIC data sources for certain outcomes.

Table a) A&E attendances for injuries and ingestions in children

Table b) Hospital admissions for injuries and ingestions in children

Table c) Pregnancy related hospital admissions

### a) Injuries and ingestion codes in A&E data

A&E Code	Description
01	Laceration
021	Contusion
022	Abrasion
03	Soft tissue inflammation
041	Concussion
042	Other head injury
051	Dislocation
052	Open fracture
053	Closed fracture
054	Joint injury
055	Amputation
06	Sprain/ligament injury
07	Muscle/tendon injury
08	Nerve injury
09	Vascular injury
101	Burns and scalds - electric
102	Burns and scalds - thermal
103	Burns and scalds - chemical
104	Burns and scalds - radiation
11	Electric shock
12	Foreign body
13	Bites/stings
141	Poisoning (inc overdose) - prescriptive drugs
142	Poisoning (inc overdose) - proprietary drugs
143	Poisoning (inc overdose) - controlled drugs
144	Poisoning (inc overdose) - other, inc alcohol
15	Near drowning
16	Visceral injury

**b) Injuries and ingestions codes in Inpatients data (hospital admissions)**

<b>ICD10 code</b>	<b>Description</b>
S00-S09	Injuries to the head (includes open wounds, fractures, crushing and dislocation)
S10-S19	Injuries to the neck
S20-S29	Injuries to the thorax
S30-S39	Injuries to the abdomen, lower back, lumbar spine and pelvis
S40-S49	Injuries to the shoulder and upper arm
S50-S59	Injuries to the elbow and forearm
S60-S69	Injuries to the wrist and hand
S70-S79	Injuries to the hip and thigh
S80-S89	Injuries to the knee and lower leg
S90-S99	Injuries to the ankle and foot
T00-T07	Injuries involving multiple body regions
T08-T14	Injuries to unspecified part of trunk, limb or body region
T15-T19	Effects of foreign body entering through natural orifice
T20-T32	Burns and corrosions
T33-T35	Frostbite
T36-T50	Poisoning by drugs, medicaments and biological substances
T51-T65	Toxic effects of substances chiefly nonmedicinal as to source (sting, alcohol, solvents etc).
T66-T78	Other and unspecified effects of external causes (effects of radiation, heat and light, hypothermia, electric shock, asphyxiation, food deprivation)
X40-X49	Accidental poisoning by and exposure to noxious substances

**c) Pregnancy related episodes in Inpatients data (hospital admissions)**

<b>ICD10 code</b>	<b>Description</b>
O00-O08	Pregnancy with abortive outcome
O10-O16	Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium
O20-O29	Other maternal disorders predominantly related to pregnancy
O30-O48	Maternal care related to the fetus and amniotic cavity and possible delivery problems
O60-O75	Complications of labour and delivery
O80-O84	Delivery
O85-O92	Complications predominantly related to the puerperium
O94-O99	Other obstetric conditions, not elsewhere classified
Z321	Pregnancy confirmed
Z33	Pregnant state, incidental
Z34	Supervision of normal pregnancy
Z35	Supervision of high-risk pregnancy
Z36	Antenatal screening
Z37	Outcome of delivery
Z38	Liveborn infants according to place of birth
Z39	Postpartum care and examination

## Appendix 9 – Retention Strategy

### 1) Project team management of participant information

**Collation of data:** Follow-up rates were collated to show overall progress for each wave of data collection and performance by site. Although follow-up was centrally organised, the role of the local researchers in maintaining contact and contact details was considered key in the success of interviews.

**Use of collated data:** Follow-up data was reviewed at weekly project team meetings, and at monthly management team meetings. Site outliers were monitored to explore local problems and successes. On-going low levels of follow-up at sites were further investigated with local research staff. High levels of follow-up were explored to identify good practice. Overall patterns of follow-up across waves of data collection was monitored.

The follow-up data was communicated to sites in a monthly newsletter. An example of this is shown in appendix 2.5. This was distributed to local researchers and to site PIs.

### 2) Management of field-based research nurse staff

Local research staff had a key role to play in maintaining participant engagement with the study. Not only were they vital for obtaining updates on participant contact details but they were the professional face of the study for participants. Every contact between participant and researcher was an opportunity to raise awareness and promote the study. Regular contact therefore enabled: the updating of participant contact details; monitoring for adverse events; and promotion of the value / progress of the Building Blocks trial. The role of the core team was to provide structure, share good practice and support these activities.

**Site support visits:** Some of the local researchers worked in relative isolation so site visits to support and monitor them were conducted. The core research team were primarily responsible for conducting such visits with additional support from some of the key collaborators. Visit content incorporated training of newly arising procedures, monitoring progress, problem-solving, management support and feedback of overall trial progress. Visit agendas were responsive to individual site needs and were also an opportunity to connect with the local FNP team.

***Proactive notification management:*** This related primarily to reporting of births, and involved the core team systematically contacting the local research with lists of women who were expected to have given birth, but also for checking contact details. A member of the core team (usually the data manager) emailed the local researchers monthly with a list of all of the trial participants at their site that were due to have given birth, or were due an interview the following month. Following this email, we expected the local researcher to confirm contact details prior to the waves of data collection, or to fax a birth notification form to the trial team. The principle was to prompt local research staff for information rather than solely to rely on them to develop and maintain their own system.

***Local problem-solving:*** The core project team shared information on follow-up rates with local research staff to facilitate attempts to solve problems locally. Summary reports were used to monitor follow-up and this was disseminated to sites using a monthly newsletter which was prepared by the data manager. An example of a newsletter is presented in appendix XX

***Engagement of local professionals:*** To maintain a high study profile at each site the local researcher continued to engage with other relevant health professionals, especially and increasingly health visitors and FNP teams. Although health visitor details were collected at the six month interview, this information was not available for non-responders. Both FNP teams and health visitors helped to provide contact information, report SAEs, and maintain awareness of the trial.

***Engaging participants:*** Local researchers were in regular contact with participants, which was an opportunity to capture contact details, identify adverse events, provide information about study progress and be generally supportive. The core project team monitored this activity and provided guidance.

### **3) Enhancing participant motivation**

***Use of incentives:*** To maintain engagement with trial participants, initial incentives approved by the ethics committee included the following: vouchers for telephone airtime, a first year birthday gift was sent with a birthday card to the trial participant, and a second year birthday gift was given on completion of the twenty four months interview. Both these gifts were age-appropriate books. Prior notification of all telephone interviews was via SMS messages to participants. Christmas (Holiday) cards were sent.

Based on suggestions from local stakeholders including young mothers, the following incentives were approved at subsequent timepoints by the ethics committee: High Street vouchers to the value of £25, £25 and £40 were given after completion of the 12, 18 and 24-month interviews respectively to acknowledge their time commitment to data collection.

A participant website was developed with the help of the stakeholder group, and this was used to encourage engagement of participants. The website contained current news items that were relevant to the trial population, information about the trial, and an interactive timeline for the trial participant and baby, regular competitions, games, activities for mother and baby, and links to other sites of interest. There was a need to register on the website for full access to it. This part of the website was for the trial participants to inform us via the site to any change in contact detail or any other issue. There was a restricted access part to the website which needed a log-in, using this the trial participants could inform the trial team of any changes in contact detail, circumstance or other issue. The restricted part also had a monitored forum (monitored by the qualitative researcher) where trial participants could post comments.

***Providing feedback to participants:*** The Stakeholder work package were tasked with providing feedback to the trial participants after the end of the trial.

***Interview notification:*** Prior notification of interviews was intended to increase response. SMS messages were sent to participants prior to contact by telephone by the PRC staff.

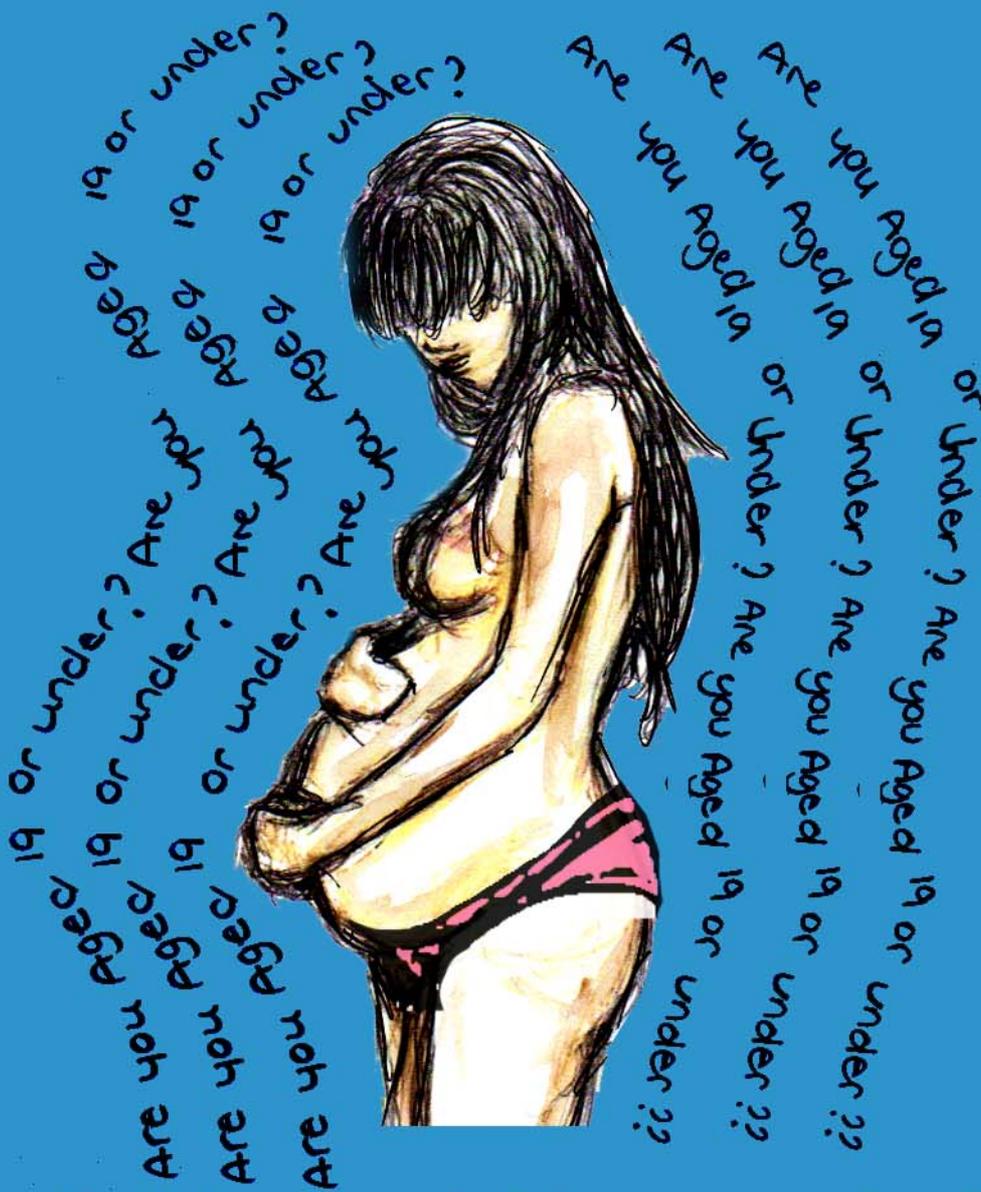
## Appendix 10 - Table of Substantial Amendments

Substantial Amendment number	Brief description of amendment	Date submitted to ethics for approval	Date approved by ethics
1	Updated participant information sheet with reply slip; GP, midwife and health visitor letters; updated consent form; participant information sheet; poster	24/02/2009 and 24/03/2009	06/04/2009
2	Use of phonecards	13/10/2009	23/10/2009
3	Trial poster	13/10/2009	23/10/2009
4	Trial arm allocation letter	13/10/2009	23/10/2009
5	Letter of withdrawal	13/10/2009	14/04/2010
6	Gift to midwives	13/10/2009	23/10/2009
7	Birth of baby card	13/10/2009	23/10/2009
8	Permission for PCT employees to approach potential trial participants	13/10/2009	23/10/2009
9	Audio recording consultations	18/01/2010	03/02/2010
10	Audio recording Part 2 and Client Interviews	18/03/2010	14/04/2010
11	Notification of additional sites	11/08/2010	06/09/2010
12	Sample size calculation, and focus group work	01/09/2010	05/10/2010
13	Notification of additional sites	12/11/2010	15/12/2010
14	Notification of additional sites	13/12/2010	15/12/2010
15	Use of vouchers	01/02/2011	25/02/2011
16	Two year interview schedule and participant website	23/08/2011	31/08/2011
17	Permission to place competition on website	23/08/2011	08/09/2011
18	Certificate of completion for trial participants	30/11/2011	20/12/2011
19	Use of voucher for process evaluation interviews	30/11/2011	20/12/2011
20	Short version of the two year interview, and form for permission to contact trial participants at a later date	09/02/2012	29/02/2012
21	Permission to accept ticks instead of initials in consent form boxes	12/12/2012	13/12/2012

# Are you Pregnant?

Do you feel left in the dark?

ARE YOU EXPECTING YOUR FIRST CHILD?



ARE YOU AGED 19 OR UNDER?

**'Building Blocks' - A trial of home visits for first time mothers.**

Building Blocks is a project that aims to find out whether first time mothers, and their babies, benefit from the Family Nurse Partnership Programme.

FREE Phone: 0800 0 276 113



## Appendix 12 - Coding smoking status

A key variable in the baseline interview is the participant's current smoking status. This information is used in the subsequent randomisation process (it is one of the stratifying variables). As the researcher conducting the interview you need to make a decision about how to code smoking status – based upon the responses the participant has given you. This section tells you how to do this.

The available codes for smoking status are:

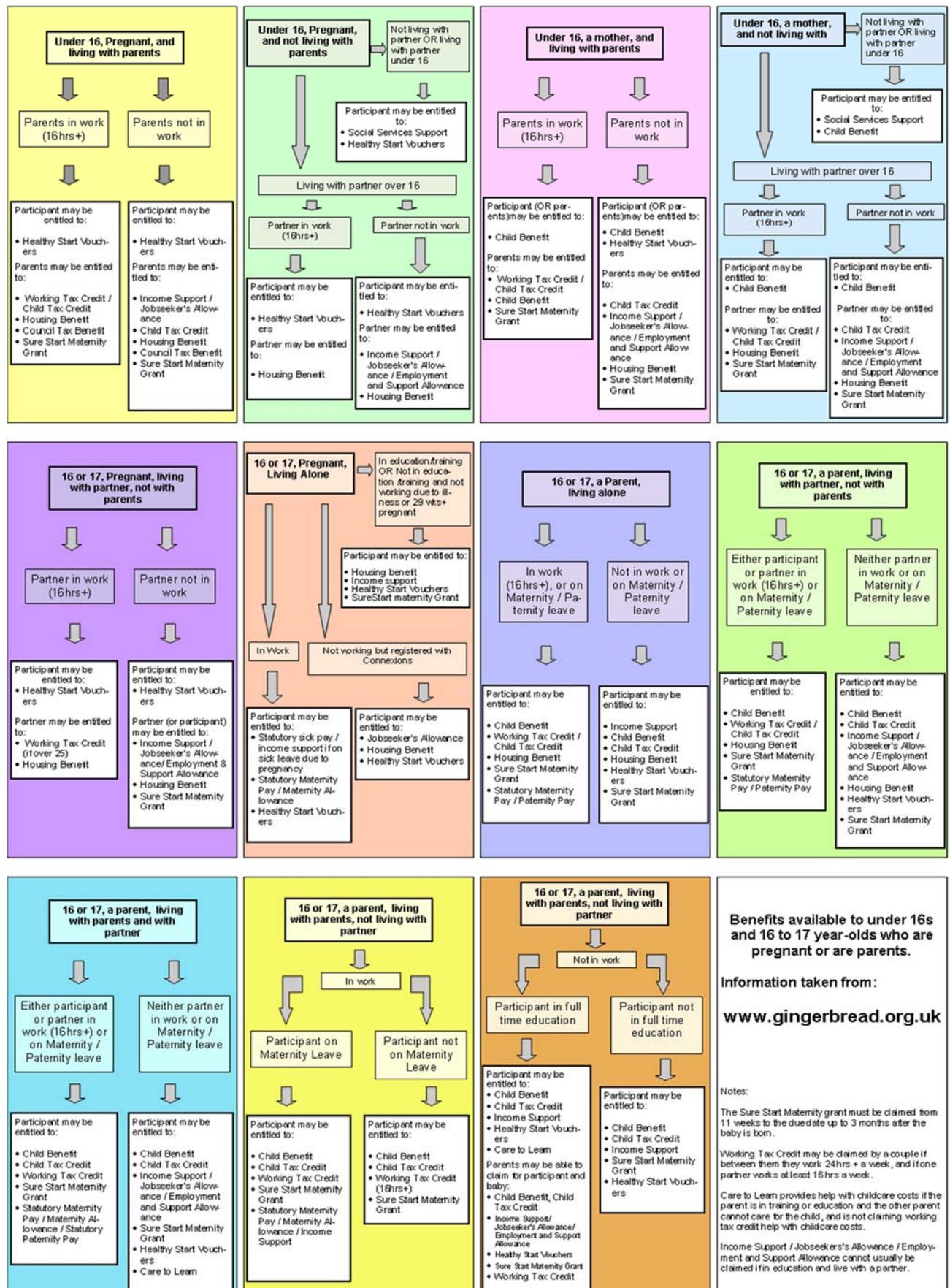
- 0 Never smoked
- 1 Current smoker
- 2 Quit more than 1 year before pregnancy
- 3 Quit immediately prior to pregnancy
- 4 Quit during pregnancy

To choose the right code:

Relevant item	Response	Assign code
<ul style="list-style-type: none"> <li>• Have you ever smoked cigarettes? (Yes / No)</li> </ul>	If not ever smoked	'Never smoked'
<ul style="list-style-type: none"> <li>• How about now, about how many cigarettes do you smoke on a typical week day?.....write in number of cigarettes per day (1pack=20)</li> <li>• And, how about on the weekends, how many cigarettes do you smoke a day?.....write in number of cigarettes per day (1pack=20)</li> </ul>	If smoking <b>any</b> cigarettes now (during week or weekend)	'Current smoker'
	From above, if <b>not</b> current smoker...	
<ul style="list-style-type: none"> <li>• Have your smoking habits changed at all during your pregnancy? ... Can you tell me more about this?</li> <li>• Could you describe how your smoking habits have changed? ...write in</li> </ul>	Use free-text response which follows a positive response to the item to determine whether:	'Quit more than 1 year before pregnancy' 'Quit immediately prior to pregnancy' 'Quit during pregnancy'

You will not be able to go back through the computerised interview to double check these responses, so make a note of which code to use as you go along. Ideally you would not have to check back with the participant when coding this variable. However, if you forget to do so, and you need to double-check with the participant do so (e.g. 'so, can I just summarise then that you have never smoked' or 'can I just summarise then that you stopped smoking after you became pregnant').

## Appendix 13 - Financial benefits possibly available to 16 to 17 year old trial participants



## Appendix 14 - Data collected for the economic analysis

Items	34-36 weeks	6 months	12 months	18 months	24 months
<b>Health Outcomes</b>					
EQ-5D for mother	✓	✓	✓	✓	✓
<b>Health related resource usage</b>					
Overnight stay in hospital (number of times, duration, reason and ward type)	M	M&Bs	M&Bs	M&Bs	M&Bs
Maternity unit	M	✗	✗	✗	✗
Visits to antenatal clinic	M	✗	✗	✗	✗
Visits to A&E	M	M&Bs	M&Bs	M&Bs	M&Bs
Outpatient attendances	M	M&Bs			M&Bs
<b>Contact (and venue) with healthcare professionals</b>					
Community midwife	M	M	✗	✗	✗
GP	M	M&Bs	M&Bs	M&Bs	M&Bs
Practice nurse	M	✗	✗	✗	✗
Other (e.g. district nurse, counsellor, physiotherapist, psychologist )	M	M&Bs	M&Bs	M&Bs	M&Bs
Health visitor	M	M	M	M	M
Use of ambulance (number of times and reason)	✗	✗	✗	M&Bs	✗
<b>Non-health related resource usage</b>					
Contacts with Connexions personal advisor	✗	M	M	M	✗
Employment status	✗	M	M	M	M
<b>Education – number of weeks &amp; hours per week attended</b>					
Mainstream school or FE College	✗	M	M	M	M

<i>Learning support unit</i>	<b>x</b>	M	M	M	M
<i>Pupil referral unit</i>	<b>x</b>	M	M	M	M
<i>Teenage mums support unit</i>	<b>x</b>	M	M	M	M
<b>Other supportive services (frequency per week and duration of contacts)</b>					
<i>School nurse</i>	<b>x</b>	M	M	M	M
<i>Young people centre/youth service</i>	<b>x</b>	M	M	M	M
<i>Family information service</i>	<b>x</b>	M	M	M	M
<i>Children's Centre (e.g., Sure Start group)</i>	<b>x</b>	M	M	M	M
<i>Child development centre</i>	<b>x</b>	M	M	M	M
<i>Crèche/day nursery</i>	<b>x</b>	M	M	M	M
<i>Toddler group</i>	<b>x</b>	M	M	M	M
<i>Leaving care service ( for young women leaving care)</i>	<b>x</b>	M	M	M	M
<i>Fostering services</i>	<b>x</b>	M	M	M	M
<i>Youth offending team</i>	<b>x</b>	M	M	M	M
<i>Social worker</i>	<b>x</b>	M	M	M	M
<i>Alcohol/drug support unit</i>	<b>x</b>	M	M	M	M
<b>Child care</b>					
<i>Crèche / Day nursery at school or college</i>	<b>x</b>	M	M	M	M
<i>Nursery group at Children's Centre</i>	<b>x</b>	M	M	M	M
<i>Child-minder</i>	<b>x</b>	M	M	M	M
<i>Any other childcare</i>	<b>x</b>	M	M	M	M
<i>Foster care (total number of weeks)</i>	<b>x</b>	M&Bs	M&Bs	M&Bs	M&Bs
<b>Housing (weeks)</b>					
<i>B&amp;B</i>	<b>x</b>	M	M	M	M

<i>Teenage parent accommodation</i>	✘	M	M	M	M
<i>Supported accommodation</i>	✘	M	M	M	M
<i>Mother &amp; baby hostel/unit</i>	✘	M	M	M	M
<i>Women's refuge/domestic violence refuge</i>	✘	M	M	M	M
<i>Homeless hostel</i>	✘	M	M	M	M
<i>Social services contact</i>	✘	✘	✘	✘	Bs

*Note: M refers to the data that are being collected for the mother only and M&Bs to the data that are being collected for both mother and baby (or babies, for multiple births).*

**Appendix 15 - Unit cost of hospital based activity  
(outpatient clinics, emergency and elective admissions)  
used for the cost-effectiveness analysis based on patients  
questionnaires if information on reason for attending  
hospital and type of ward/service was not available**

<b>Item</b>	<b>Unit</b>	<b>Cost</b>	<b>Reference</b>	<b>Notes</b>
<p><b><i>Outpatient activity</i></b></p> <p>Total outpatient attendances Midwife episode Obstetrics</p>	Unit of activity	£108 £73 £112	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Outpatient Attendances Data
<p><b><i>Inpatient admissions</i></b></p>	Unit of activity	£1612	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	<p>HRG codes for the analysis were derived from information provided by mothers (reason and type of ward)</p> <p>When the above information was missing, the unit cost was derived as a weighted average across all inpatient settings (elective, non-elective and day cases)</p>
<p><b><i>Emergency admissions</i></b></p>	Event	£101	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	<p>Accident and Emergency Services: <b>Leading to Non Admitted</b></p> <p>The unit cost was derived as a weighted average of all the activities.</p>

## Appendix 16 - Other unit costs used for the for the cost-effectiveness analysis based on patients questionnaires

Item	Unit	Cost	Reference	Notes
Podiatrist	Unit of activity	£42	NHS reference costs 2009/2010 NHS Trusts and PCTs combined	Community Health Services - Allied Health Professionals
Gynaecology	Unit of activity	£130	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Paediatric services	Unit of activity	£173	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data  The unit cost was derived as a weighted average of all the paediatric services
Cardiology	Unit of activity	£131	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Anaesthetics	Unit of activity	£92	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Family Planning Clinic	Unit of activity	£77	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Obstetrics	Unit of activity	£122	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Dermatology	Unit of activity	£98	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Clinical Genetic	Unit of activity	£372	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Diabetic Medicine	Unit of activity	£136	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Total Outpatient attendances data
Community Dentist	Unit of activity	£115	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Community Health Services - Medical and Dental
Drug and Alcohol Services	Unit of activity	£104	NHS reference costs 2012/2013 (NHS trusts and NHS foundation trusts)	Mental Health and other Services

## Appendix 17 - Outpatient attendance unit cost (main specialty)

	Unit costs (£)			
	2009/2010	2010/2011	2011/2012	2012/2013
Accident and emergency (A&E)	113	107	119	117
Adult mental illness	169	169	173	221
Anaesthetics	100	84	69	92
Audiological medicine	85	91	72	64
Audiology	137	104	56	70
Cardiology	124	134	130	131
Cardiothoracic surgery	194	211	233	275
Chemical pathology	73	67	61	64
Child and adolescent psychiatry	331	331	342	301
Clinical genetics	587	666	459	372
Clinical haematology	128	152	160	151
Clinical immunology and allergy	161	161	175	215
Clinical neuro-physiology	163	170	167	166
Clinical oncology	107	126	115	122
Clinical psychology	191	141	141	191
Community medicine	62	64	61	65
Critical care medicine	117	139	226	1063
Dental medicine specialties	100	101	105	116
Dermatology	92	94	93	98
Diagnostic imaging	27	29	33	37
Dietetics	52	56	60	64
Endocrinology	136	139	129	152
ENT	85	92	93	94
Gastroenterology	124	124	128	137
General medicine	138	149	150	153
General surgery	112	119	121	128
Geriatric medicine	198	203	196	204
Gynaecology	112	117	125	130
Haematology	128	152	277	151
Infectious diseases	214	241	251	142
Learning disability	169	169	173	221
Medical oncology	136	123	126	138
Medical ophthalmology	116	89	85	93

Midwifery	62	64	61	65
Nephrology	156	164	164	158
Neurology	166	169	169	176
Neurosurgery	162	157	159	174
Nursing	62	64	61	65
Obstetrics	108	112	116	174
Occupational medicine	62	56	61	63
Occupational therapy	87	80	61	63
Ophthalmology	80	83	85	86
Oral and maxilla-facial surgery	102	109	100	110
Oral surgery	111	110	109	111
Orthodontics	109	112	107	111
Orthoptics	51	51	53	53
Paediatric cardiology	243	210	184	178
Paediatric dentistry	106	85	108	119
Paediatric neurology	337	318	313	376
Paediatric surgery	87	165	149	179
Paediatrics	176	185	184	187
Paediatric ophthalmology	118	121	109	122
Paediatric urology	150	134	127	141
Periodontics	104	114	114	117
Physiotherapy	39	39	41	42
Plastic surgery	87	89	86	88
Podiatry	40	41	41	42
Prosthodontics	104	114	114	117
Radiology	148	148	153	264
Rehabilitation	119	126	85	163
Respiratory	144	147	143	150
Restorative dentistry	104	114	114	117
Rheumatology	135	137	136	140
Speech and language therapy	82	77	79	78
Trauma and orthopaedics	96	98	105	110
Urology	99	102	103	101

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## Appendix 18 - A&E attendance unit cost

	Unit costs (£)			
	2009/2010	2010/2011	2011/2012	2012/2013
A&E Service: Leading to Admitted	134.19	140.95	157.22	114.56
A&E Service: Not Leading to Admitted	103.20	107.96	108.22	114.56
Minor Injury Service: Leading to Admitted	47.61	64.31	73.64	114.56
Minor Injury Service: Not Leading to Admitted	53.89	60.52	60.48	114.56
Walk In Centres: Leading to Admitted	47.70	31.30	42.13	114.56
Walk In Centres: Not Leading to Admitted	40.04	40.13	41.61	114.56
Non-24 hour A&E/Casualty: Leading to Admitted	54.48	89.73	100.02	114.56
Non-24 hour A&E/Casualty: Not Leading to Admitted	74.51	88.14	100.02	114.56

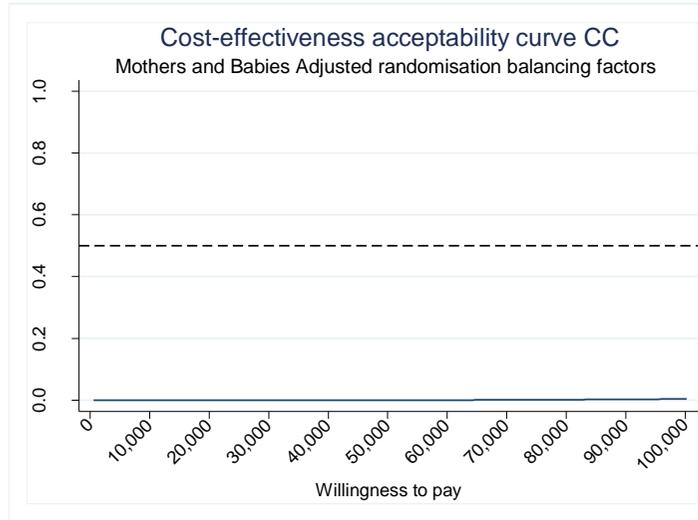
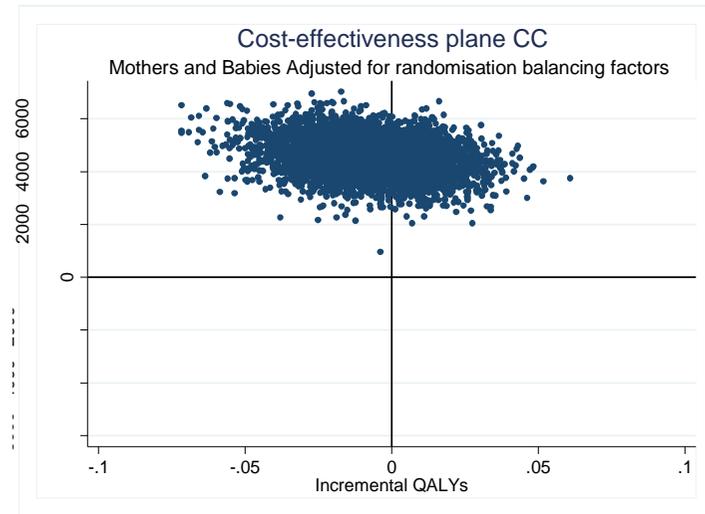
## Appendix 19 - Proportion of levels 1, 2 and 3 by dimension and treatment arm over the trial follow up

		Baseline		34-36 weeks		6 months		12 months		18 months		24 months	
		FNP	Usual Care	FNP	Usual Care	FNP	Usual Care	FNP	Usual Care	FNP	Usual Care	FNP	Usual Care
<b>MOBILITY</b>	<b>Level 1</b>	94.8	95.3	80.0	75.3	96.4	95.9	96.7	94.2	96.0	96.3	96.1	96.1
	<b>Level 2</b>	5.2	4.6	19.2	24.4	3.6	4.1	3.3	5.8	4.0	3.7	3.9	4.1
	<b>Level 3</b>	0.0	0.0	0.8	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>SELF-CARE</b>	<b>Level 1</b>	99.6	99.1	95.3	95.1	99.2	98.9	99.0	98.8	99.0	98.1	98.8	98.9
	<b>Level 2</b>	0.4	0.7	4.6	4.9	0.8	1.1	1.0	1.0	1.0	1.9	1.2	1.3
	<b>Level 3</b>	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0
<b>USUAL ACTIVITIES</b>	<b>Level 1</b>	92.6	92.0	84.7	82.5	97.6	94.0	97.3	96.0	97.2	96.6	96.7	95.4
	<b>Level 2</b>	6.8	7.8	14.0	16.7	2.0	5.5	2.7	4.0	2.8	3.4	3.3	4.6
	<b>Level 3</b>	0.5	0.0	1.3	0.8	0.4	0.4	0.0	0.0	0.0	0.0	0.0	0.0
<b>PAIN/ DISCOMFORT</b>	<b>Level 1</b>	76.2	77.3	52.2	49.8	86.0	86.8	88.8	87.7	89.4	89.7	87.0	88.8
	<b>Level 2</b>	23.4	22.2	45.2	47.7	13.0	12.4	9.8	11.7	9.4	10.1	12.8	11.2
	<b>Level 3</b>	0.4	0.4	2.6	2.4	1.0	0.9	1.4	0.6	1.2	0.2	0.2	0.2
<b>ANXIETY/ DEPRESSION</b>	<b>Level 1</b>	80.4	79.5	86.3	88.5	84.2	85.5	85.7	86.9	88.0	86.7	81.0	81.2
	<b>Level 2</b>	17.0	18.8	11.9	10.7	14.2	13.2	12.2	11.3	10.0	11.4	15.4	16.9
	<b>Level 3</b>	2.6	1.4	1.6	08	1.6	1.3	2.2	1.9	1.8	1.9	3.4	1.9

Levels: 1 – No problems; 2 – Some problems; 3 – Severe problems.

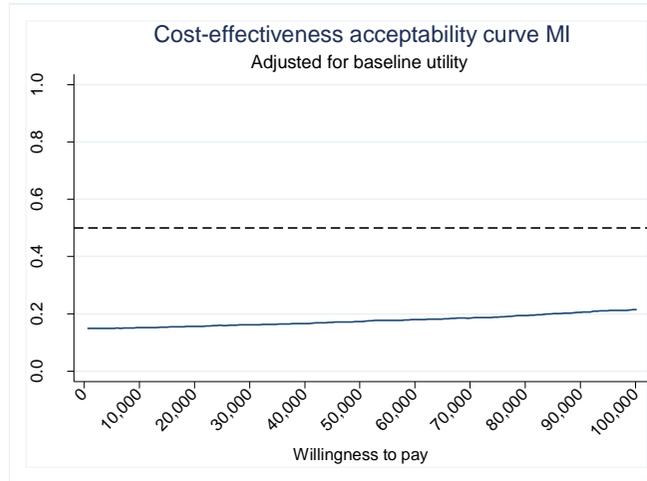
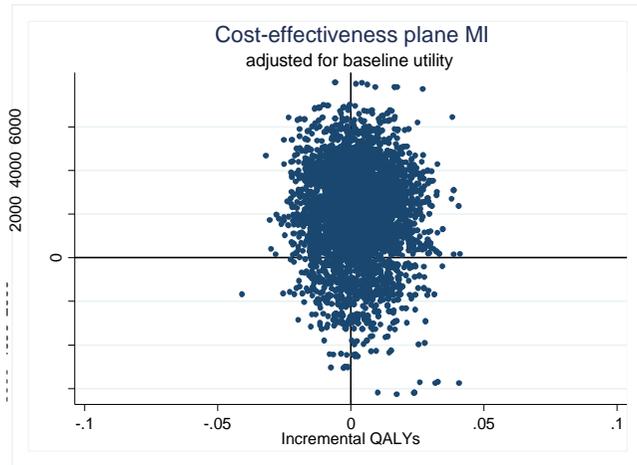
# Appendix 20 - Base-case: Complete case

*Cost-effectiveness plane and CEAC for the Complete Case (ITT)*

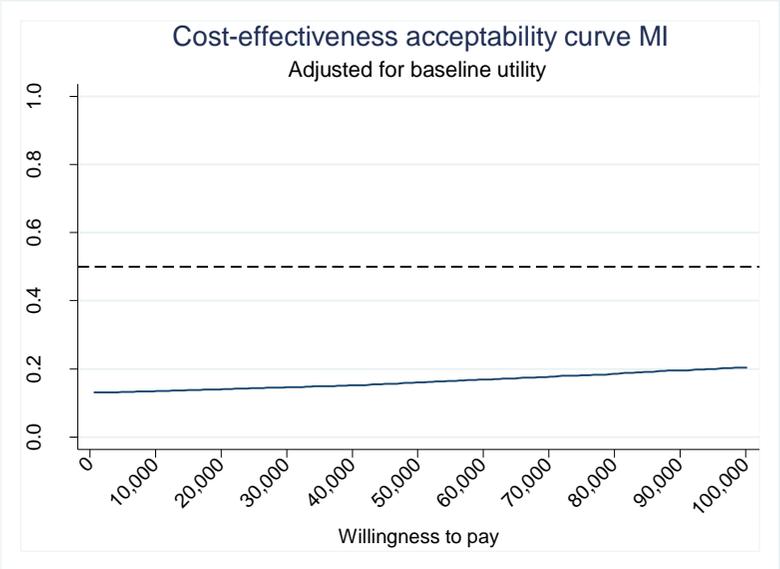
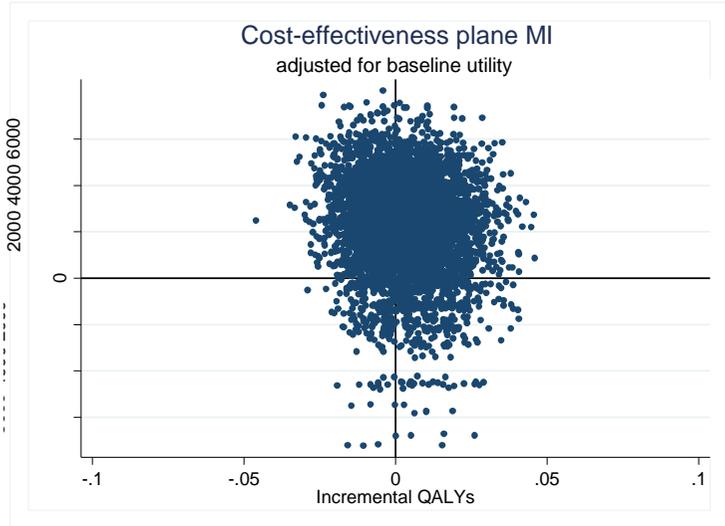


## Appendix 21 - Sensitivity analysis (MI analysis)

### Scenario 1 Excluding midwife visits for the FNP group

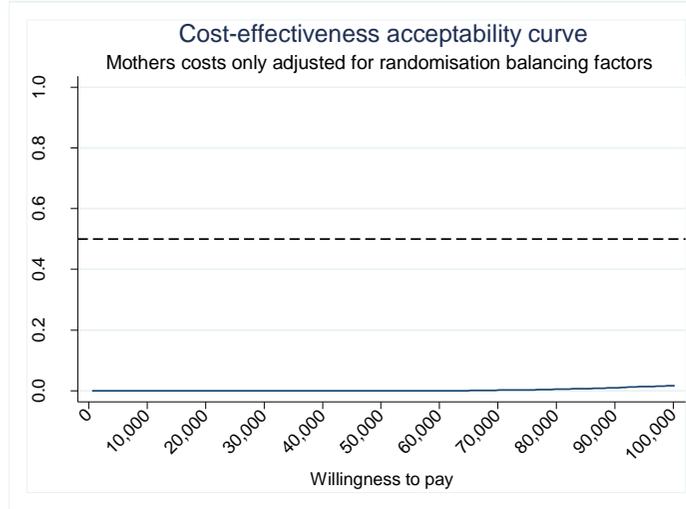
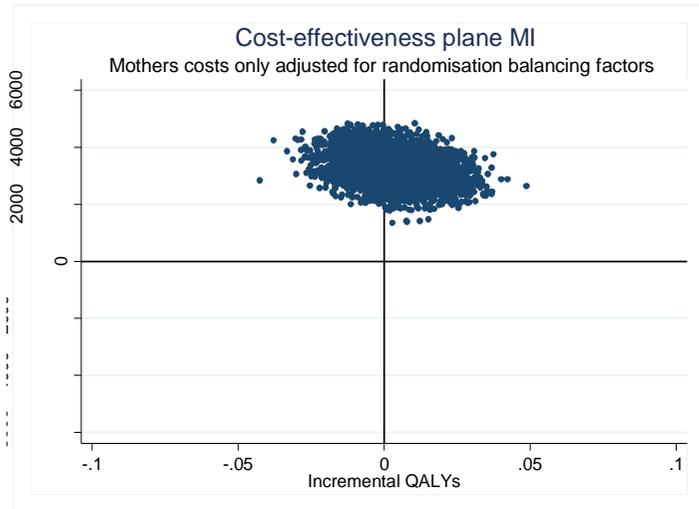


# Scenario 2 Including mandatory withdrawals as part of the imputation process as well



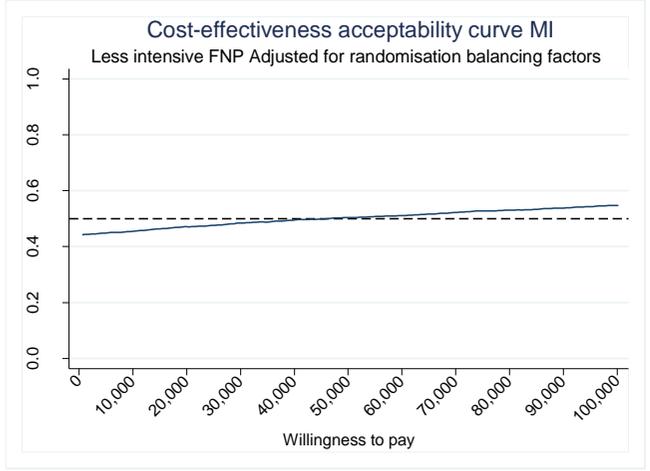
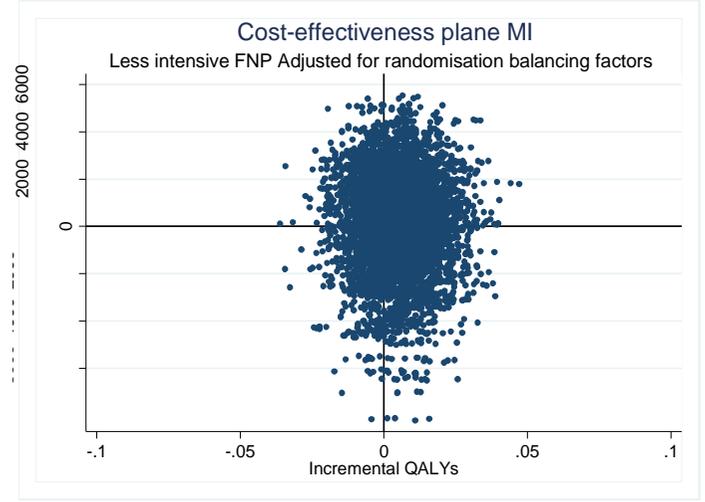
# Scenario 3 Including only resource use related to mothers (excluding costs related to babies)

*Including only resource use related to mothers (excluding costs related to babies)*



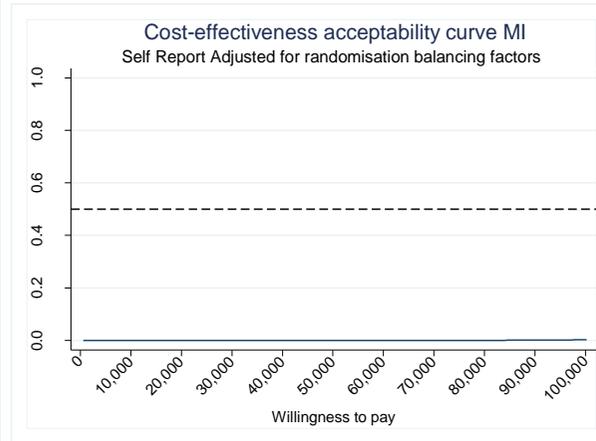
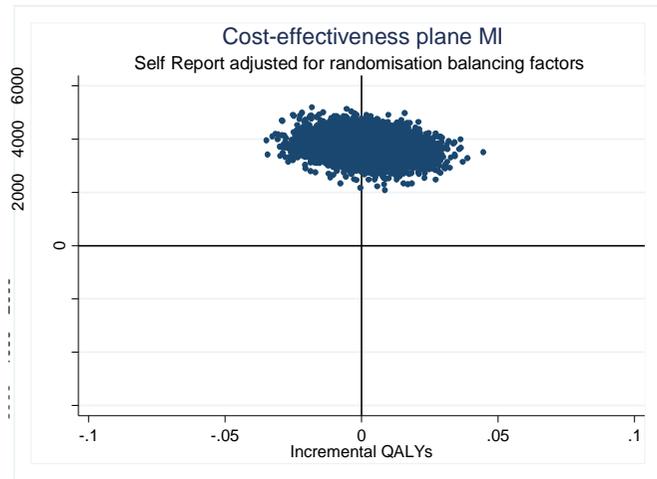
# Scenario 4 Providing a less intensive FNP intervention

## Providing a less intensive FNP intervention



# Scenario 5 Including only resource use related to mothers (excluding costs related to babies)

Using self reported-data (ONLY FOR MOTHERS) as main source for all resource use in the analysis.



## Appendix 22 - Presentation of findings of the literature review for the extrapolation exercise

			Trial Primary Outcomes			
			Pregnancy & birth domain		Child health & development domain	Maternal life & economic domain
			Birth weight	Tobacco use	Emergency attendances	Second pregnancy
<b>Childhood long term outcomes</b>	<b>Health Domain</b>	a				
		b				
		c				
	<b>Education Domain</b>	d				
		e				
		f				
	<b>Criminal Justice Domain</b>	g				
		h				
		i				
<b>Adulthood long term outcomes</b>	<b>Health Domain</b>	j				
		k				
		l				
	<b>Education Domain</b>	m				
		n				
		o				
	<b>Criminal Justice Domain</b>	p				
		q				
		r				
<b>Mothers long term outcomes</b>	<b>Health Domain</b>	s				
		t				
		u				
	<b>Education Domain</b>	v				
		w				
		x				

	<b>Criminal</b>	y				
	<b>Justice</b>	z				
	<b>Domain</b>	a				

# Appendix 23 - Systematic review search strategy

## LONGITUDINAL STUDIES

The aim of these searches was to identify longitudinal, cohort, epidemiological and observational studies

<b>Total number of records found (after deduplication): 3665</b>
--

## Databases

The following databases were searched:

- British Education Index (ProQuest)
- Criminal Justice Abstracts (EBSCO)
- ERIC (ProQuest)
- MEDLINE and MEDLINE In Process & Other Non-Indexed Citations (Ovid)
- PsycINFO (Ovid)
- Social Policy and Practice (Ovid)
- Social Science Citation Index (Web of Knowledge)

## Limits

- English language only
- Human studies only
- The observational study design filter created by SIGN was used and adapted for these searches <http://www.sign.ac.uk/methodology/filters.html#obs>

## Search strategies

<b>British Education Index (1975 - date)</b>
--

<b>Date searched: 25/02/13</b>
--------------------------------

<b>Records found: 1</b>
-------------------------

<b>ERIC</b>
-------------

<b>Date searched: 25/02/13 (1966 - date)</b>
--

<b>Records found: 19</b>
--------------------------

Set#: S1 Searched for: ti,ab("low birth weight" or "small for gestational age")
---

Results: 498

Set#: S2 Searched for: ti,ab(smok\* NEAR/2 pregnan\*)

Results: 96

Set#: S3 Searched for: ti,ab(tobacco NEAR/2 pregnan\*)

Results: 9

Set#: S4 Searched for: ti,ab(pregnan\* NEAR/2 second)

Results: 28

Set#: S5 Searched for: ti,ab(pregnan\* NEAR/2 subsequent)

Results: 26

Set#: S6 Searched for: ti,ab("second baby" or "second child")

Results: 52

Set#: S7 Searched for: ti,ab("pregnant again")

Results: 5

Set#: S8 Searched for: ti,ab("conceive\* again")

Results: 0

Set#: S9 Searched for: ti,ab("emergency room")

Results: 149

Set#: S10 Searched for: ti,ab(accident NEAR/2 emergency)

Results: 70

Set#: S11 Searched for: ti,ab(emergency NEAR/1 attend\*)

Results: 13

Set#: S12 Searched for: ti,ab("emergency department\*")

Results: 178

Set#: S13 Searched for: S9 OR S20 OR S11 OR S12

Results: 343

Set#: S14 Searched for: ti,ab(child or children or baby or babies or infant or infants or newborn)

Results: 259472

Set#: S15 Searched for: S13 AND 14

Results: 62

Set#: S16 Searched for: S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S15

Results: 752

Set#: S17 Searched for: ti,ab("long\* term outcome\*" or "long\* term effect\*")

Results: 1761

Set#: S18 Searched for: ti,ab(behavio\*r\* NEAR/1 (outcome\* or effect\*))

Results: 2531

Set#: S19 Searched for: ti,ab("health status" or "health outcome\*")

Results: 1809

Set#: S20 Searched for: ti,ab("quality of life")

Results: 3686

Set#: S21 Searched for: ti,ab("academic grade\*" or "grade point average\*")

Results: 5356

Set#: S22 Searched for: ti,ab((education\* or academic) NEAR/1 (effect\* or outcome\* or attainment or achievement or status))

Results: 32398

Set#: S23 Searched for: ti,ab("academic performance")

Results: 6812

Set#: S24 Searched for: ti,ab("criminal record\*" or "criminal conviction\*")

Results: 135

Set#: S25 Searched for: ti,ab(prison or borstal)

Results: 2487

Set#: S26 Searched for: ti,ab("young offender\*")

Results: 223

Set#: S27 Searched for: ti,ab("court case\*" or (court NEAR/1 appearance\*))

Results: 1922

Set#: S28 Searched for: ti,ab(employment or employed or unemployment or unemployed)

Results: 63506

Set#: S29 Searched for: ti,ab(occupation\* or vocation\* or career or job or jobs)

Results: 147583

Set#: S30 Searched for: S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29

Results: 231009

Set#: S31 Searched for: S16 AND S30

Results: 176

Set#: S32 Searched for: "Case control"

Results: 147

Set#: S33 Searched for: cohort NEAR/1 (study or studies)

Results: 791

Set#: S34 Searched for: "cohort analy\*"

Results: 1660

Set#: S35 Searched for: "Follow up" NEAR/1 (study or studies)  
Results: 3177

Set#: S36 Searched for: observational NEAR/1 (study or studies)  
Results: 713

Set#: S37 Searched for: Longitudinal  
Results: 28461

Set#: S38 Searched for: Retrospective  
Results: 2921

Set#: S39 Searched for: "Cross sectional"  
Results: 3549

Set#: S40 Searched for: S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39  
Results: 39010

Set#: S41 Searched for: S31 AND S40  
Results: 20

**Criminal Justice Abstracts (1968 - date)**

**Date searched: 25/02/13**

**Records found: 5**

S1 "low birth weight" or "small for gestational age"

S2 smok\* W2 pregnan\*

S3 tobacco W2 pregnan\*

S4 pregnan\* W2 second

S5 pregnan\* W2 subsequent

S6 "second baby" or "second child"

S7 "pregnant again"

S8 "conceive\* again"

S9 "emergency room"

S10 accident W2 emergency

S11 emergency W1 attend\*

S12 "emergency department\*"

S13 S9 OR S10 OR S11 OR S12

S14 child or children or baby or babies or infant or infants or newborn

S15 S13 AND S14

S16 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S15

S17 "long\* term outcome\*" or "long\* term effect\*"

S18 behavio#r\* W1 (outcome\* or effect\*)

S19 "health status" or "health outcome\*"

S20 "quality of life"

S21 "academic grade\*" or "grade point average\*"

S22 (education\* or academic) W1 (effect\* or outcome\* or attainment or achievement or status)

S23 "academic performance"  
 S24 "criminal record\*" or "criminal conviction\*"  
 S25 prison or borstal  
 S26 "young offender\*"  
 S27 "court case\*" or (court W1 appearance\*)  
 S28 employment or employed or unemployment or unemployed  
 S29 occupation\* or vocation\* or career or job or jobs  
 S30 S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29  
 S31 S16 AND S30  
 S32 "Case control"  
 S33 cohort W1 (study or studies)  
 S34 "cohort analy\*"  
 S35 "Follow up" W1 (study or studies)  
 S36 observational W1 (study or studies)  
 S37 Longitudinal  
 S38 Retrospective  
 S39 "Cross sectional"  
 S40 S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39  
 S41 S31 AND S40

**MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations 1946 to February Week 2 2013**

**Date searched: 25/02/13**

**Records found: 3463**

- 1 infant, low birth weight/ or infant, small for gestational age/ or infant, very low birth weight/ or infant, extremely low birth weight/ (24324)
- 2 (low birth weight or small for gestational age).ti,ab. (21982)
- 3 1 or 2 (33653)
- 4 Smoking/ or "Tobacco Use Disorder"/ (114322)
- 5 4 and exp Pregnancy/ (8082)
- 6 (smok\$ adj2 pregnan\$).ti,ab. (4013)
- 7 (tobacco adj2 pregnan\$).ti,ab. (121)
- 8 5 or 6 or 7 (9553)
- 9 (pregnan\$ adj2 second).ti,ab. (1939)
- 10 (pregnan\$ adj2 subsequent).ti,ab. (3637)
- 11 (second baby or second child).ti,ab. (822)
- 12 pregnant again.ti,ab. (199)
- 13 conceive\$ again.ti,ab. (62)
- 14 9 or 10 or 11 or 12 or 13 (6397)
- 15 emergency service, hospital/ or trauma centers/ (44211)
- 16 Emergency Medical Services/ (29613)
- 17 emergency room.ti,ab. (10384)
- 18 (accident adj2 emergency).ti,ab. (3797)
- 19 (emergency adj1 attend\$).ti,ab. (287)
- 20 emergency department\$.ti,ab. (41341)
- 21 15 or 16 or 17 or 18 or 19 or 20 (100072)
- 22 exp child/ or child, preschool/ or infant/ or infant, newborn/ (1902719)

23 (child or children or baby or babies or infant or infants or newborn).ti,ab. (1068658)  
24 22 or 23 (2151113)  
25 21 and 24 (18951)  
26 3 or 8 or 14 or 25 (67010)  
27 causality/ or precipitating factors/ or "confounding factors (epidemiology)"/ (19992)  
28 (long\$ term outcome\$ or long\$ term effect\$).ti,ab. (50445)  
29 27 or 28 (70319)  
30 Child Behavior Disorders/ (17511)  
31 (behavior?r\$ adj1 (outcome\$ or effect\$)).ti,ab. (14881)  
32 health status/ or health status disparities/ (59213)  
33 (health status or health outcome\$).ti,ab. (49475)  
34 "Quality of Life"/ (104610)  
35 quality of life.ti,ab. (128037)  
36 Prenatal Exposure Delayed Effects/ (18075)  
37 30 or 31 or 32 or 33 or 34 or 35 or 36 (293959)  
38 Educational Status/ (36302)  
39 (academic grade\$ or grade point average\$).ti,ab. (1137)  
40 ((education\$ or academic) adj1 (effect\$ or outcome\$ or attainment or achievement or status)).ti,ab. (12454)  
41 academic performance.ti,ab. (2369)  
42 38 or 39 or 40 or 41 (47795)  
43 exp Crime/ (98831)  
44 Criminals/ (633)  
45 juvenile delinquency/ or social behavior disorders/ (10855)  
46 (criminal record\$ or criminal conviction\$).ti,ab. (449)  
47 (prison or borstal).ti,ab. (5606)  
48 young offender\$.ti,ab. (301)  
49 (court case\$ or (court adj1 appearance\$)).ti,ab. (622)  
50 43 or 44 or 45 or 46 or 47 or 48 or 49 (113026)  
51 employment/ or unemployment/ (38178)  
52 (employment or employed or unemployment or unemployed).ti,ab. (226862)  
53 (occupation\$ or vocation\$ or career or job or jobs).ti,ab. (157797)  
54 51 or 52 or 53 (389892)  
55 29 or 37 or 42 or 50 or 54 (865711)  
56 26 and 55 (8163)  
57 exp animals/ not humans/ (3764020)  
58 56 not 57 (7983)  
59 Epidemiologic studies/ (5556)  
60 exp case control studies/ (584068)  
61 exp cohort studies/ (1224836)  
62 Case control.tw. (67216)  
63 (cohort adj (study or studies)).tw. (70281)  
64 Cohort analy\$.tw. (3093)  
65 (Follow up adj (study or studies)).tw. (34861)  
66 (observational adj (study or studies)).tw. (36654)  
67 Longitudinal.tw. (123410)  
68 Retrospective.tw. (239426)  
69 Cross sectional.tw. (142453)  
70 Cross-sectional studies/ (150856)  
71 or/59-70 (1689185)  
72 58 and 71 (3673)

**PsycINFO 1806 to February Week 3 2013**

**Date searched: 25/02/13**

**Records found: 144**

- 1 (low birth weight or small for gestational age).ti,ab. (2027)
- 2 (smok\$ adj2 pregnan\$).ti,ab. (953)
- 3 (tobacco adj2 pregnan\$).ti,ab. (41)
- 4 (pregnan\$ adj2 second).ti,ab. (88)
- 5 (pregnan\$ adj2 subsequent).ti,ab. (277)
- 6 (second baby or second child).ti,ab. (170)
- 7 pregnant again.ti,ab. (38)
- 8 conceive\$ again.ti,ab. (7)
- 9 emergency room.ti,ab. (2222)
- 10 (accident adj2 emergency).ti,ab. (388)
- 11 (emergency adj1 attend\$).ti,ab. (30)
- 12 emergency department\$.ti,ab. (3624)
- 13 or/9-12 (5904)
- 14 (child or children or baby or babies or infant or infants or newborn).ti,ab. (465226)
- 15 13 and 14 (875)
- 16 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 15 (4322)
- 17 (long\$ term outcome\$ or long\$ term effect\$).ti,ab. (9884)
- 18 (behavio?r\$ adj1 (outcome\$ or effect\$)).ti,ab. (12496)
- 19 (health status or health outcome\$).ti,ab. (19692)
- 20 quality of life.ti,ab. (34214)
- 21 (academic grade\$ or grade point average\$).ti,ab. (3565)
- 22 ((education\$ or academic) adj1 (effect\$ or outcome\$ or attainment or achievement or status)).ti,ab. (24113)
- 23 academic performance.ti,ab. (7779)
- 24 (criminal record\$ or criminal conviction\$).ti,ab. (816)
- 25 (prison or borstal).ti,ab. (10112)
- 26 young offender\$.ti,ab. (957)
- 27 (court case\$ or (court adj1 appearance\$)).ti,ab. (1192)
- 28 (employment or employed or unemployment or unemployed).ti,ab. (95516)
- 29 (occupation\$ or vocation\$ or career or job or jobs).ti,ab. (141611)
- 30 or/17-29 (325433)
- 31 16 and 30 (579)
- 32 Case control.tw. (5560)
- 33 (cohort adj (study or studies)).tw. (8196)
- 34 Cohort analy\$.tw. (481)
- 35 (Follow up adj (study or studies)).tw. (9602)
- 36 (observational adj (study or studies)).tw. (4515)
- 37 Longitudinal.tw. (63407)
- 38 Retrospective.tw. (19815)
- 39 Cross sectional.tw. (33243)
- 40 or/32-39 (131602)
- 41 31 and 40 (147)
- 42 limit 41 to english language (144)

**Social Policy and Practice All years - 201301**

**Date searched: 25/02/13**

**Records found: 11**

- 1 (low birth weight or small for gestational age).ti,ab. (123)
- 2 (smok\$ adj2 pregnan\$).ti,ab. (76)
- 3 (tobacco adj2 pregnan\$).ti,ab. (2)
- 4 (pregnan\$ adj2 second).ti,ab. (7)
- 5 (pregnan\$ adj2 subsequent).ti,ab. (18)
- 6 (second baby or second child).ti,ab. (14)
- 7 pregnant again.ti,ab. (2)
- 8 conceive\$ again.ti,ab. (0)
- 9 emergency room.ti,ab. (49)
- 10 (accident adj2 emergency).ti,ab. (225)
- 11 (emergency adj1 attend\$).ti,ab. (10)
- 12 emergency department\$.ti,ab. (295)
- 13 or/9-12 (441)
- 14 (child or children or baby or babies or infant or infants or newborn).ti,ab. (95275)
- 15 13 and 14 (103)
- 16 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 15 (341)
- 17 (long\$ term outcome\$ or long\$ term effect\$).ti,ab. (771)
- 18 (behavio?r\$ adj1 (outcome\$ or effect\$)).ti,ab. (249)
- 19 (health status or health outcome\$).ti,ab. (2348)
- 20 quality of life.ti,ab. (5433)
- 21 (academic grade\$ or grade point average\$).ti,ab. (28)
- 22 ((education\$ or academic) adj1 (effect\$ or outcome\$ or attainment or achievement or status)).ti,ab. (2422)
- 23 academic performance.ti,ab. (212)
- 24 (criminal record\$ or criminal conviction\$).ti,ab. (301)
- 25 (prison or borstal).ti,ab. (2431)
- 26 young offender\$.ti,ab. (1729)
- 27 (court case\$ or (court adj1 appearance\$)).ti,ab. (230)
- 28 (employment or employed or unemployment or unemployed).ti,ab. (20092)
- 29 (occupation\$ or vocation\$ or career or job or jobs).ti,ab. (13502)
- 30 or/17-29 (43812)
- 31 16 and 30 (52)
- 32 Case control.tw. (289)
- 33 (cohort adj (study or studies)).tw. (956)
- 34 Cohort analy\$.tw. (18)
- 35 (Follow up adj (study or studies)).tw. (466)
- 36 (observational adj (study or studies)).tw. (227)
- 37 Longitudinal.tw. (4610)
- 38 Retrospective.tw. (875)
- 39 Cross sectional.tw. (1889)
- 40 or/32-39 (8632)
- 41 31 and 40 (11)

**Social Science Citation Index (1856 - date)**

**Date searched: 26/02/13**

**Records found: 436**

# 1 5,027 Topic=("low birth weight" or "small for gestational age")  
# 2 1,673 Topic=(smok\* NEAR/2 pregnan\*)  
# 3 172 Topic=(tobacco NEAR/2 pregnan\*)  
# 4 262 Topic=(pregnan\* NEAR/2 second)  
# 5 382 Topic=(pregnan\* NEAR/2 subsequent)  
# 6 119 Topic=("second baby" or "second child")  
# 7 30 Topic=("pregnant again")  
# 8 13 Topic=("conceive\* again")  
# 9 2,160 Topic=("emergency room")  
# 10 726 Topic=(accident NEAR/2 emergency)  
# 11 237 Topic=(emergency NEAR/1 attend\*)  
# 12 7,060 Topic=("emergency department\*")  
# 13 9,414 #12 OR #11 OR #10 OR #9  
# 14 367,509 Topic=(child or children or baby or babies or infant or infants or newborn)  
# 15 1,685 #14 AND #13  
# 16 8,846 #15 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1  
# 17 7,161 Topic=("long\* term outcome\*" or "long\* term effect\*")  
# 18 1,525 Topic=(behavio\$\*r\* NEAR/1 (outcome\* or effect\*))  
# 19 28,318 Topic=("health status" or "health outcome\*")  
# 20 56,599 Topic=("quality of life")  
# 21 1,504 Topic=("academic grade\*" or "grade point average\*")  
# 22 23,261 Topic=((education\* or academic) NEAR/1 (effect\* or outcome\* or attainment or achievement or status))  
# 23 4,699 Topic=("academic performance")  
# 24 647 Topic=("criminal record\*" or "criminal conviction\*")  
# 25 10,971 Topic=(prison or borstal)  
# 26 850 Topic=("young offender\*")  
# 27 933 Topic=("court case\*" or (court NEAR/1 appearance\*))  
# 28 133,282 Topic=(employment or employed or unemployment or unemployed)  
# 29 135,360 Topic=(occupation\* or vocation\* or career or job or jobs)  
# 30 359,651 #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17  
# 31 1,589 #30 AND #16  
# 32 5,928 Topic=("Case control")  
# 33 14,887 Topic=(cohort NEAR/1 (study or studies))  
# 34 836 Topic=("cohort analy\*")  
# 35 8,163 Topic=("Follow up" NEAR/1 (study or studies))  
# 36 5,859 Topic=(observational NEAR/1 (study or studies))  
# 37 58,971 Topic=(Longitudinal)  
# 38 20,303 Topic=(Retrospective)  
# 39 46,335 Topic=("Cross sectional")  
# 40 144,063 #39 OR #38 OR #37 OR #36 OR #35 OR #34 OR #33 OR #32  
# 41 448 #40 AND #31  
# 42 436 #40 AND #31 Refined by: Languages=( ENGLISH )

## Appendix 24 - Systematic Review Reference List

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## Appendix 25 - Unit costs for non-health related resource use items for the cost-consequence analysis

Item	Unit	Cost	Reference	Notes
<b>Non-health related resource use</b>				
<b><i>Education and employment</i></b>				
Mainstream school or FE college	Per week of education	£77	The Centre for Social Justice (Press release, 2011)	Cost of mainstream education cited at £4000 per child per year. This was divided by 52 to give an estimate of weekly rate
Learning support unit (LSU)	Per week of education	£40 (+£77)	North Lincolnshire Learning Support Unit, 2012 ( <a href="http://shareit.yhgfl.net/nlincs/cpd/?page_id=2159">http://shareit.yhgfl.net/nlincs/cpd/?page_id=2159</a> )	Cost per session of 1 centre. Assumed mothers would have at least 1 session per week in addition to regular schooling
Pupil referral unit (PRU)	Per week of education	£346.15	The Centre for Social Justice (Press release, 2011)	Cost of PRU education cited at £18,000 per child per year. This was divided by 52 to give an estimate of weekly rate
Teenage mums support unit (TMSU)	Per week of education	£167.50 (+£77)	Government published information published online May, 2014 ( <a href="https://www.gov.uk/16-to-19-education-financial-support-for-students">https://www.gov.uk/16-to-19-education-financial-support-for-students</a> )	Education charged at the same rate as mainstream schooling. Mothers in a TMSU are eligible for 'Care to Learn' funding which provides a bursary of £160-£175 per week (average £167.50)
<b><i>Other supportive services</i></b>				
Connexions advisor	Cost per hour	£38.50	Unit Costs of Health and Social Care 2013	Page 217 £847 per 22 hours of a connexions advisors time gives an hourly rate of £38.50 per hour
School nurse	Unit of activity	£27	Unit Costs of Health and Social Care 2013	Average UK unit cost of school based children's health

				services
Young people centre/youth service	Unit of activity	£17	The cost of providing street based youth work in deprived communities	Cost per contact of youth services project
Children's centre	Unit cost per hour	£64.25	Cost Effectiveness in Sure Start Local Programmes: A Synthesis of Local Evaluation Findings, 2005	Unit cost of Sure Start children's centres
Child development centre	Unit cost per hour	£34	Unit Costs of Health and Social Care 2013	Unit cost for key worker
Crèche/ day nursery	Cost per hour	£4.28	<a href="http://www.truro-penwith.ac.uk/nurseries/truro-college-nursery/">http://www.truro-penwith.ac.uk/nurseries/truro-college-nursery/</a> <a href="http://www.bracknell.ac.uk/our_facilities/college_nursery.aspx">http://www.bracknell.ac.uk/our_facilities/college_nursery.aspx</a> <a href="http://www.hlcollege.ac.uk/college/nursery_fees.html">http://www.hlcollege.ac.uk/college/nursery_fees.html</a> <a href="http://www.york.ac.uk/univ/nrsr/y/finances.html">http://www.york.ac.uk/univ/nrsr/y/finances.html</a>	Average cost across a range of crèche/ day nursery facilities
Toddler group	Unit cost per hour	£5	Unit Costs of Health and Social Care, 2005	Page 26, Unit cost of toddler group
Leaving care services	Cost per hour	£20	Young People Leaving Care: A Study of Costs and Outcomes, 2006	Page 175, Leaving care worker/ personal adviser (per hour of client related activity)
Fostering services	Unit cost per hour	£38.20	Unit Costs of Health and Social Care 2013	Page 98, Cost per hour
Youth offending team	Unit cost per hour	£29	Unit Costs in Criminal Justice (UCCJ), 2013	Page 65, Cost of Youth Offending Team (YOT) practitioner
Social worker	Unit cost per hour	£57	Unit Costs of Health and Social Care 2013	Page 197, Unit cost per hour of social worker
<b>Child care</b>				
Creche/ day nursery at school or college	Cost per hour	£4.28	As above	Average cost across a range of crèche/ day nursery facilities
Nursery group at children's centre	Cost per hour	£4.40	Childcare Costs Survey, 2014	Page 4, Average UK cost of 25 hours per week £109.89 which equates to £4.40 per hour

Child-minder	Cost per hour	£3.99	Childcare Costs Survey, 2014	Page 4, Average UK cost of 25 hours per week £99.77 which equates to £3.99 per hour
Any other childcare	Cost per hour	£3.82	Childcare Costs Survey, 2014	Page 4, Mean cost of all types of childcare
Foster care mother	Unit cost per week	£636	Unit Costs of Health and Social Care, 2013	Page 88, Unit cost per week of foster care inclusive of admin and social services
Foster care child	Unit cost per week	£636	Unit Costs of Health and Social Care, 2013	Page 88, Unit cost per week of foster care inclusive of admin and social services
<b>Temporary accommodation</b>				
B&B	Cost per week	£334.95	Immediate costs to government through loss of home, 2012	Page 4, Average cost per week, UK
Teenage parent accommodation	Cost per week	£151.78	(1) Young people and teenage parent accommodation based services and floating support services, 2010  (2) Supported Housing Commissioning Strategy - 2005-2010, 2005 services and floating support services, 2010	Average of 2 sites taken:  (1) Page 4, Average cost per week (Brent, London)  (2) Page 29, Average cost per week (Sheffield)
Supported accommodation	Cost per week	£150	Supported lodgings as a housing option for young people report, 2008	Page 32, Average cost per week, UK
Mother and baby hostel/unit	Cost per week	£230	<a href="http://www.familyspacecroydon.co.uk/Contacts/details/christian-family-concern-mother-baby-unit/">Christian Family Concern Mother &amp; Baby Unit, 2014</a>	Actual cost per week at 1 site in London
Women's refuge	Cost per week	£421.15	The Cost of Domestic Violence, 2004	Page 76, Average of UK women's refuges
Homeless hostel	Cost per week	£107.45	Immediate costs to government of loss of home, 2012	Page 4, Average cost per week, UK

## Appendix 26 - Example choice set for the DCE survey

Scenario A	Scenario B
<ul style="list-style-type: none"> <li>• Mother did not have another pregnancy within two years of the birth of the first child</li> <li>• Child did not need to attend an accident and emergency department for an injury or swallowing something harmful before the age of two</li> <li>• Mother was confident that she could achieve her goals and believed she could solve problems well</li> <li>• The mother did not consider or provide for her child's needs</li> <li>• The baby was born a healthy weight</li> </ul>	<ul style="list-style-type: none"> <li>• Mother had another pregnancy within two years of the birth of the first child</li> <li>• Child needed to attend an accident and emergency department a number of times for an injury or swallowing something harmful before the age of two</li> <li>• Mother was not confident that she could achieve her goals and did not believe she could solve problems well</li> <li>• The mother considered and provided for her child's needs</li> <li>• The baby was born below a healthy weight</li> </ul>
My choice <input type="checkbox"/>	My choice <input type="checkbox"/>

## Appendix 27 - Characteristics for each design for the DCE survey

<b>Designs A-C</b>																																																
<p>It is also good to compare the number of parameters in the model with the maximum number of parameters that could be estimated with the number of choice sets and alternatives in this experiment. These are shown in this table. In this case, the maximum number is 15 and we have 5 parameters (design not saturated). Unless you have an optimal design, you will usually not want the number of parameters to be close to the maximum. The maximum value is the number of choice sets times the number of alternatives minus one: <math>15(2 - 1) = 15</math>.</p>	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 60%;">Choice Sets</td><td style="text-align: right;">15</td></tr> <tr><td>Alternatives</td><td style="text-align: right;">2</td></tr> <tr><td>Parameters</td><td style="text-align: right;">5</td></tr> <tr><td>Maximum Parameters</td><td style="text-align: right;">15</td></tr> <tr><td>D-Efficiency</td><td style="text-align: right;">14.8448</td></tr> <tr><td><b>Relative D-Eff</b></td><td style="text-align: right;"><b>98.9654</b></td></tr> <tr><td>D-Error</td><td style="text-align: right;">0.0674</td></tr> <tr><td>1 / Choice Sets</td><td style="text-align: right;">0.0667</td></tr> </table>						Choice Sets	15	Alternatives	2	Parameters	5	Maximum Parameters	15	D-Efficiency	14.8448	<b>Relative D-Eff</b>	<b>98.9654</b>	D-Error	0.0674	1 / Choice Sets	0.0667																										
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<p>We used standardised orthogonal contrast coding to evaluate the design and see how large the variances are relative to the optimal value.</p> <p>The designs look reasonable because the variances are not too far removed from one over the number of choice sets (1/ Choice Sets =0.0667)</p> <p>The variances are the diagonal values from the variance-covariance matrix, and the standard errors, which are the square roots of the variances.</p>	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 5%;">n</th> <th style="width: 15%;">Variable Name</th> <th style="width: 15%;">Label</th> <th style="width: 15%;">Variance</th> <th style="width: 5%;">DF</th> <th style="width: 15%;">Standard Error</th> </tr> </thead> <tbody> <tr><td>1</td><td>Var11</td><td>Var1 1</td><td>0.068182</td><td>1</td><td>0.26112</td></tr> <tr><td>2</td><td>Var21</td><td>Var2 1</td><td>0.068182</td><td>1</td><td>0.26112</td></tr> <tr><td>3</td><td>Var31</td><td>Var3 1</td><td>0.068182</td><td>1</td><td>0.26112</td></tr> <tr><td>4</td><td>Var41</td><td>Var4 1</td><td>0.068182</td><td>1</td><td>0.26112</td></tr> <tr><td>5</td><td>Var51</td><td>Var5 1</td><td>0.068182</td><td>1</td><td>0.26112</td></tr> <tr><td colspan="4"></td><td>5</td><td></td></tr> </tbody> </table>						n	Variable Name	Label	Variance	DF	Standard Error	1	Var11	Var1 1	0.068182	1	0.26112	2	Var21	Var2 1	0.068182	1	0.26112	3	Var31	Var3 1	0.068182	1	0.26112	4	Var41	Var4 1	0.068182	1	0.26112	5	Var51	Var5 1	0.068182	1	0.26112					5	
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	<b>Var1 1</b>	0.07	0.01	0.01	0.01	0.01
	<b>Var2 1</b>	0.01	0.07	0.01	0.01	0.01
	<b>Var3 1</b>	0.01	0.01	0.07	0.01	0.01
	<b>Var4 1</b>	0.01	0.01	0.01	0.07	0.01
	<b>Var5 1</b>	0.01	0.01	0.01	0.01	0.07

Checked whether the design is balanced and orthogonal

Frequencies:

<b>Var1</b>	15	15	<b>Design is balanced</b>
<b>Var2</b>	15	15	
<b>Var3</b>	15	15	
<b>Var4</b>	15	15	
<b>Var5</b>	15	15	

<b>Var1 Var2</b>	7	8	8	7	<b>Design not perfectly orthogonal as there are unequal frequencies</b>
<b>Var1 Var3</b>	7	8	8	7	
<b>Var1 Var4</b>	7	8	8	7	
<b>Var1 Var5</b>	7	8	8	7	
<b>Var2 Var3</b>	7	8	8	7	
<b>Var2 Var4</b>	7	8	8	7	
<b>Var2 Var5</b>	7	8	8	7	
<b>Var3 Var4</b>	7	8	8	7	
<b>Var3 Var5</b>	7	8	8	7	
<b>Var4 Var5</b>	7	8	8	7	

Checked whether there are duplicate profiles

**N-** 1  
**Way** 1 1 1 1 1 1 1 **No duplicate profiles**

**Design D**

	<table> <tr><td>Choice Sets</td><td>16</td></tr> <tr><td>Alternatives</td><td>2</td></tr> <tr><td>Parameters</td><td>7</td></tr> <tr><td>Maximum Parameters</td><td>16</td></tr> <tr><td>D-Efficiency</td><td>13.4262</td></tr> <tr><td><b>Relative D-Eff</b></td><td><b>83.9135</b></td></tr> <tr><td>D-Error</td><td>0.0745</td></tr> <tr><td>1 / Choice Sets</td><td>0.0625</td></tr> </table>	Choice Sets	16	Alternatives	2	Parameters	7	Maximum Parameters	16	D-Efficiency	13.4262	<b>Relative D-Eff</b>	<b>83.9135</b>	D-Error	0.0745	1 / Choice Sets	0.0625																																																
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	<b>Var5</b>	3	0	0	0	0	-0.01	0	0.09
Checked whether the design is balanced and orthogonal	Frequencies:								
	<b>Var1</b>	16	16	<b>Design not perfectly balanced</b>					
	<b>Var2</b>	16	16						
	<b>Var3</b>	16	16						
	<b>Var4</b>	16	16						
	<b>Var5</b>	8	8	8	8				
Checked whether there are duplicate profiles	<b>Var1 Var2</b>	8	8	8	8	<b>Design not perfectly balanced</b>			
	<b>Var1 Var3</b>	8	8	8	8				
	<b>Var1 Var4</b>	8	8	8	8				
	<b>Var1 Var5</b>	4	4	4	4	4	4	4	4
	<b>Var2 Var3</b>	8	8	8	8				
	<b>Var2 Var4</b>	8	8	8	8				
	<b>Var2 Var5</b>	4	4	4	4	4	4	4	4
	<b>Var3 Var4</b>	8	8	8	8				
	<b>Var3 Var5</b>	4	4	4	4	4	4	4	4
	<b>Var4 Var5</b>	4	4	4	4	4	4	4	4
<b>N-</b>	1	1	1	1	1	1	1	1	1
<b>Way</b>	1	1	1	1	1	1	<b>No duplicate profiles</b>		

## Appendix 28 - CONSORT 2010 checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist item	Reported in chapter and page
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Executive summary
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	Chap. 1, pg.52
	2b	Specific objectives or hypotheses	Chap. 1, pg.53
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Chap. 2, pg. 55
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	Chap. 2, pg. 57
	4b	Settings and locations where the data were collected	Chap. 2, pg. 64
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Chap. 2, pg. 57
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Chap. 2, pg. 74
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No
Sample size	7a	How sample size was determined	Chap. 2, pg. 72
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Chap. 2, pg. 73
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Chap. 2, pg. 73
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Chap. 2, pg. 73

Section/Topic	Item No	Checklist item	Reported in chapter and page
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Chap. 2, pg. 73
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Chap. 2, pg. 74
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Chap. 2, pg. 74
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Chap. 3, pg. 86
	13b	For each group, losses and exclusions after randomisation, together with reasons	Chap. 3, pg. 86
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Chap. 3, pg. 84
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Chap. 3, pg. 95-104
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Chap. 3, pg. 95-104
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Chap. 4 (all), Chap. 5 (all), Chap. 6 (all)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Chap. 4 (all), Chap. 5 (all), Chap. 6 (all)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Chap. 4 (all), Chap. 5 (all), Chap. 6 (all)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Chap. 17, pg. 452
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Chap. 17, pg. 459

Section/Topic	Item No	Checklist item	Reported in chapter and page
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Chap. 17, pg. 462
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	Title page
Protocol	24	Where the full trial protocol can be accessed, if available	References
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Executive summary

# Appendix 29 - Building Blocks Dissemination Strategy

## **Scope:**

This document describes the strategy for disseminating findings from the Building Blocks Trial by the investigator team. It considers dissemination and further engagement activity at the end of the trial.

This document does not address further dissemination of study findings by the sponsor following submission of the final study report. That remains the prerogative of the funder and it is expected that relevant stakeholders for the sponsors may be somewhat different than for the investigator team. Requirements for review of materials prior to dissemination remain as contractually stated, and therefore are not otherwise addressed in this document.

## **Aims:**

The document:

- Clarifies relevant stakeholders who may be targeted recipients of output from the trial
- Summarises dissemination activities

## **Who are our stakeholders?**

The following may be considered key stakeholders in relation to the dissemination of study outputs:

- 1) *Funders:* Of current trial (DH PRP), follow-on study (NIHR PHR) and other potential funders of linked research (work using existing BB data or infrastructure / data set)
- 2) *Policy partners:* Family Nurse Partnership NU; Management consortium for FNP (led by Tavistock), Local FNP partnerships, Department of Health (England)
- 3) *Study participants:* women and children participants; professional participants (e.g. midwifery, health visiting, Family Nurse Partnership teams). The latter are stakeholders by virtue of either direct involvement with the study (as subject's of observational assessment, contributors to process evaluation) or as representatives of professional groups with immediate interest in the trial
- 4) *Academic & research professional community:* current and prospective academic collaborators (the broad Building Blocks team and also follow-on study team), including international colleagues (e.g. Holland, Germany, Canada, Australia); researchers who have been involved in delivery of the trial (e.g. CLRN and NHS research nurses); broader academic dissemination
- 5) *Professional stakeholders:* (primarily) health and social care service providers (including managers) with role in delivering statutory and voluntary sector services to young first-time mothers in England. This will include professional bodies representative of such stakeholders (e.g. RCPCH, BACCH, RCGP, RCN, RCM).
- 6) *US Nurse Family Partnership team:* This includes David Olds (who could also be considered under several of headers above such as consultant to FNP NU / DH and as academic community stakeholder) and others aligned to David's team (including Kate Billingham)
- 7) *Policy leads:* Those with policy responsibility for delivering services to young first-time mothers in the UK. This could include in Wales (for example) the Chief Nursing Officer as well as Nursing Officer's for responsibility for Maternity & Early Years, and for Safeguarding.

## **Dissemination activities**

- Academic publications (international journals, general and specific)

*See separate current publication plan (available on request and not included in report)*

- Written trial summaries

*Summaries based on report to funders: primarily lay summary, (need for professional / technical summary – to be made available after relevant journal publication?). Available electronically (via SEWTU web) and in hard copy.*

- Building Blocks stakeholder meeting(s)

*A single stakeholder event is budgeted for. Attendees would be drawn from across the stakeholder spectrum (see summary below). Currently this is planned as primarily a dissemination exercise (rather than an attempt to validate, get further feedback / insight into study findings). Detailed plans for this event are maintained separately to this document, and should be referenced as required.*

- Targeted meeting with key stakeholders

*The aim would be to (i) provide an opportunity for gathering expert opinion prior to submission for publication, and (ii) targeted feedback and discussion about broad and specific aspects of study findings.*

- Mass media and other dissemination options

*Other formats for dissemination (including new media) can be considered if there is an important argument for doing so. In particular, we should consult with lay stakeholder group about other options.*

## Summary of dissemination options by stakeholder groupings<sup>1</sup>

Stakeholder group		(a) Report	(b) Scientific / professional meetings	(c) Academic publications	(d) Trial summaries	(e) BB Stakeholder Meeting	(f) Targeted stakeholder meeting	Notes
(i) Funders	DH PRP	✓						
	NIHR PHR	✓						
(ii) Policy partners	FNP NU, Management Consortium				✓	✓	✓	
	Local FNP partnerships (trial / non-trial sites)				✓	✓		
(iii) Study participants	Lay participants				✓	✓		Aim to do (e) – at least for a sample. We could look at ways of capturing content of day in visual format for broadcasting on web (as an alternative).
	Professional participants				✓	✓		Aim to do (e) – at least for a sample. (see comments above about alternative options)
(iv) Academic & research professional community	Current / prospective collaborators		✓	✓	✓	✓		See trial publication plan
	CLRN and NHS researchers		✓	✓	✓	✓		
	Broader academic community		✓	✓	✓			See trial publication plan
(v) Professional stakeholders				✓	✓	✓	✓	
(vi) US NFP Team				✓	✓		✓	
(vii) Policy leads				✓	✓	✓		

<sup>1</sup> This is a working document. Presence or absence of ✓ should not be taken as an indicator of final dissemination approach. It is expected that this framework will guide rather than dictate dissemination and will also evolve over time / as results become known