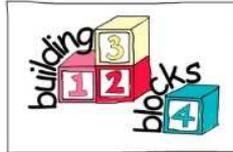




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# The Building Blocks Trial Executive Summary

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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# 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 NFP. 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.

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**The full trial report and link to the open access paper can be found at <https://bit.ly/buildingblockstrial>**