The Centre for Trials Research at Cardiff University is a UK Clinical Research Collaboration (UKCRC) registered clinical trials unit.
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**Images on front cover:**

1. Dr David Gillespie engaging the public with interactive games as part of the antibiotic resistance Superbugs event at Techniquest in Cardiff Bay.
2. Professor Kerry Hood presenting a TED-style talk at the Health and Care Research Wales Annual Conference 2018.
3. DNA double helix model from the Superbugs event for the public at Techniquest.
4. Person-centred care event organised by Linc Cymru and Victoria Shepherd.
5. Joanna Briggs Institute European Symposium in the Haydn Ellis Building at Cardiff University.
6. HRH the Duchess of Cambridge visiting MIST in Torfaen in her role as patron for charity Action for Children. Action for Children funded the MIST report carried out by qualitative researchers from the Centre for Trials Research (see page 17).
Foreword

Mission and strategic aims
The Centre for Trials Research is a UKCRC registered clinical trials unit that is dedicated to tackling the big diseases and health concerns of our time. We work with investigators to produce research evidence for policy leaders, service commissioners and practitioners about treatments and services that may improve the health and well-being of the public.

Key programme partners and beneficiaries
The Centre receives infrastructure funding from Health and Care Research Wales and Cancer Research UK. Cancer Research UK specifically funds work in our Cancer Division, whilst Health and Care Research Wales funds our three other Divisions. Both funders also support cross-cutting teams that work across the whole Centre. This funding allows us to invest in core activities that are inherent requirements for the design and oversight of high-quality studies and to win external funding to allow their conduct, analyses and publication. The majority of our work involves external investigators undertaking primary research in health or social care. The potential beneficiaries are broad, reflecting the range of studies and investigators we work in partnership with. These include: patients, members of the public, health and social care service providers and policy makers. These beneficiaries are in Wales, the rest of the UK and internationally.

Who's who
The Centre for Trials Research Director (and Director of Division of Infections, Inflammation and Immunity) is Professor Kerenza Hood. She is supported by a senior management team including Professor Michael Robling (Population Health Division), Professor Monica Busse (Mind, Brain and Neuroscience Division), Professor Richard Adams (Cancer Division), Professor Adrian Mander (Statistics) and Dr Sue Channon (Research Design and Conduct Service).

How we work
Our 151 researchers and professional staff work across our four divisions and within cross-cutting teams (information systems and database development (including technology solutions), quality assurance, regulatory affairs and professional services). Our current research portfolio includes evaluations of drugs and complex healthcare interventions, studies of mechanisms of disease and treatments, cohort studies and trials informing health and social care policy and practice. Public Involvement and Engagement, Social Care Aspects, Commercial / Industry Engagement and Collaboration, NHS Service Professional Engagement and Collaboration, Engagement with Welsh Government funded research infrastructure as well as Communications, Publicity, and Knowledge Transfer activities are all embedded within these areas of work.

Our work plan
We place continued emphasis on the development of working practices and expert staff to make sure we meet high standards for research across our portfolio. We design new studies and win the funding to make them happen in collaboration with researchers from other organisations across Wales and beyond. All our funded studies are conducted with the highest quality standards that produce outputs that will make a difference to the public and we strive to develop new ways to answer important clinical questions whilst sustaining a dynamic and professional workforce. Alongside this we support staff in the NHS and social care in Wales to develop their own research to address the important questions in the care of patients and the public. Here we showcase our work over the last year across all our divisions within the Centre for Trials Research.
Centre for Trials Research Directors

Professor Kerry Hood, Director Centre for Trials Research and Infections, Inflammation and Immunity Division

Dr Sue Channon, Director Research Design and Conduct Service (RDCS) SE Wales

Professor Mike Robling, Director Population Health Division

Professor Monica Busse, Director Mind, Brain and Neuroscience Division

Professor Richard Adams, Director Cancer Division

Professor Adrian Mander, Director Medical Statistics

Centre for Trials Research Divisions

- Infections, inflammation and immunity
- Mind, brain and neuroscience
- Cancer
- Population health
Work packages

Health and Care Research Wales support three of our divisions, whilst Cancer Research UK support the Cancer Division; both funders provide core funding to cross-cutting teams that work across all divisions. To report to Health and Care Research Wales, we organise our work across six work packages (WP) in the following way. Throughout this report, these graphics identify and introduce you to each section:

- **Work package 1:** Managing our work
- **Work package 2:** Working with other groups
- **Work package 3:** Developing new studies
- **Work package 4:** Overseeing funded studies
- **Work package 5:** Ensuring methodological and professional development
- **Work package 6:** Supporting innovation from NHS and social care practice

Cross-cutting themes

At the start of each work package throughout the report, you will see icons that represent our six cross-cutting themes below. This is to identify the ways in which our work has wider impact across the NHS, industry, social care, within Welsh Government and for the public. We hope you will find this a simple and easy way to navigate this report.

- Public involvement and engagement
- Social care
- NHS engagement and collaboration
- Commercial / industry engagement and collaboration
- Engagement with Welsh Government funded research infrastructure
- Communications, publicity and knowledge transfer
Over the last year (April 2018 - March 2019) we have maintained our international reputation in the design and conduct of trials across our areas of thematic interest.

Our now established divisional structure sees our innovative methods applied across trials and other well-designed studies in the fields of Cancer, Infections, Inflammation and Immunity, Mind, Brain and Neuroscience and Population Health.

We have continued to ensure that public involvement is appropriately embedded in all our research and have continued to build successful partnerships with other parts of the Health and Care Research Wales funded and the Cancer Research UK funded infrastructure, the NHS and social care across SE Wales and beyond.

We have developed specific expertise to support the use of routine data in trials and have developed the processes and systems to ensure that data and samples collected through prospective studies are made available for future research. Alongside this we have continued to support innovation from the NHS through our Research Design and Conduct Service, which supported 144 research ideas and 25 NHS and social care grant submissions in Wales.

Our policy and strategic development across all Centre for Trials Research activities has continued this year. We have continued to see great success with collaborative grant awards working with investigators in the NHS, social care, Health and Care Research Wales infrastructure and industry across Wales, the rest of the UK and internationally.

Infrastructure funding has facilitated our ability to ensure all staff are appropriately trained to deliver research to Good Clinical Practice (GCP) standards and have equal opportunities for development and training. Our effective resource management and success in retaining and developing our 151 skilled research and professional staff has helped us to secure almost £20.3M in funding from national and international funders (a total of 43 major awards in the Health and Care Research Wales and Cancer Research UK strategic thematic areas over the current period of funding). Note that the infographic on page 6 summarises only the figures from Health and Care Research Wales funded research, while we highlight here in the Executive Summary the total combined grant value and number of awards achieved as a result of having two core funders.

Our high-quality research is reflected by 87 peer reviewed publications over the past year, including high impact papers in the Lancet, British Medical Journal, and New England Journal of Medicine. Our programme of research has been underpinned by the inclusion of the public in the design, conduct and dissemination of research (14 engagement events and 154 public involvement opportunities in this period award).
We are a registered clinical trials unit and the largest group of academic clinical trials staff in Wales.

Increasing research capacity in Wales

The Centre for Trials Research is publicly-funded by Welsh Government through Health and Care Research Wales and Cancer Research UK to enable applied research that informs policy in health and social care, and is currently running studies across Wales, the UK and internationally.

Over the past year, we have continued to support and grow research capacity, particularly in Wales.

Here we highlight some of our achievements and impact during the past 12 months.

Lay summary: our year in numbers

- **151** Centre for Trials Research staff
- **62** papers published
- **1636** event attendees
- **37** new grant awards
- **154** public involvement opportunities
- **14** engagement and dissemination activities
- **£9,233,788** Total funding awarded
Work package 1: Managing our work

Recruiting and supporting staff and developing working practices to make sure we meet high standards for research

Staff

This year has seen further growth in staff numbers and we currently employ 151 staff working across our 4 divisions and associated cross-cutting teams. We have achieved these staffing levels through the efficient use of core infrastructure funding alongside project funding. Our cost recovery model and ongoing resource planning is critical to maintenance of these staffing levels.

A key recent appointment is Professor Adrian Mander who joined us from the University of Cambridge as our new Director of Medical Statistics on 1st May 2019. Professor Mander has been working in academic clinical trials for the past 20 years apart from 3 years spent at GlaxoSmithKline in their clinical pharmacology department. He has spent the last 10 years building up a research team in the area of adaptive clinical trial designs and has published many papers in trials methodology. Alongside the method development, he has been involved in some large scale trials such as weight-loss interventions and hypertension crossover trials. His move to the Centre for Trials Research provides us all with an opportunity to translate these new trial designs into practice as part of our methodological innovation strategy.

Professor Adrian Mander
Director Medical Statistics
In 2018 we created a new Public Involvement and Engagement (PI&E) Hub within the Centre. Its immediate focus was to:

- Embed public involvement and engagement into our Centre management structures more formally
- Establish engagement as a core part of studies
- Use the new national standards for public involvement as the defining core of our approach

To support this initiative, two lay research partner roles have been created. We are delighted that Susan Campbell and Sarah Peddle, have been appointed to this role. They have joined both the Hub and also the Centre’s main oversight board. The latter is the Centre’s highest level oversight committee, is convened by the College of Biomedical and Life Sciences at Cardiff University and meets annually to review Centre strategy and performance against key targets.

The Hub now meets regularly to support best practice in public involvement and engagement across the full range of Centre studies. Its terms of reference was developed with input from our new lay research partners. The Hub’s membership includes the Directorial lead for public involvement (Mike Robling), the Centre’s Senior Communications Officer (Richard Haggerty), researchers from across the Centre’s Divisions (Julia Townson, Claire Nollett, Julie Latchem-Hastings, Martina Svobodova), and dedicated administration support from Sarah Nash.
Assuring regulatory compliance
A key element of assuring regulatory compliance was the work of a task and finish group preparing for General Data Protection Regulation (GDPR), which came into force on 25th May 2018. Staff received mandatory training on our new policy and we audited all current studies for their readiness for the new regulations. We amended all relevant Centre Standard Operating Procedures (SOPs) and policies. We have also reviewed with sponsors issues such as sole and joint data controller status and how that affects data management and patient communications.

Earlier this year we completed the new Data Protection and Security Toolkit. This replaced the Information Governance Toolkit and provides assurance to NHS Digital, the data centre who provide confidential routinely collected clinical data to several studies in the Centre.

Open Research
As part of our commitment to support greater transparency about prospective research and greater sharing of datasets from completed studies, we now have in place our new policy for data sharing. This also extends the original process to cover requests for biological samples from patients and the public. For more information about accessing Centre for Trials Research data please visit our website www.cardiff.ac.uk/centre-for-trials-research

Routine data
The Centre has continued to develop a leading role as a trials unit with a methodological interest in using data routinely captured for service provision. Using routine data for research purposes offers many benefits to researchers, including resource-efficiency, objectivity, and reduction in patient and staff burden. In 2018 we provided a written submission to the House of Commons Science and Technology Committee’s inquiry on Digital Government and Dr Fiona Lugg-Widger provided evidence at a select panel meeting in December.

The Centre has now developed its own local policies and procedures for working with routine data. In 2018 we hosted a visit from NHS Digital. This visit was an opportunity to showcase our approach, consult with the data provider on specific studies and discuss future developments and collaboration. Maximising the use of routine data is a Wales Government policy priority and much of our focus has been on how we do so within the context of trials.
Professor Mike Robling continues to form part of the Department for Education funded What Works Centre Research Partnership for Children’s Social Care. The funding for the partnership’s work has recently been augmented by an additional £2M to support local authorities contributing as partners in Centre studies. The Research Partnership led by Professor Forrester in the Children’s Social Care Research and Development Centre (CASCADE) and working with the Centre for Trials Research (including most recently Dr Rebecca Playle) has drawn together a large group of social care researchers adding significant strength to this sector in Wales. Professor Robling also contributes as part of the Wales Government’s Social Care Research Strategy group.

Centre staff are actively collaborating with the Wales BRAIN unit in the set-up (Monica Busse is Principal Investigator) of a multi-site prospective longitudinal study measuring CSF mutant Huntington protein in patients with Huntington’s disease. Cardiff is one of only 5 UK sites (11 international sites) in this pivotal biomarker (including digital biomarkers) study. The study is part of the ROCHE long-term strategy of bringing their anti-oligosenside therapeutic to market as a disease-modifying drug for Huntington’s Disease. Centre for Trials Research and BRAIN unit staff collaborated on the development of the “TRIDENT Cup”, which won the award for best interactive stand at the Health and Care Research Wales annual conference. The purpose of the TRIDENT Cup was to communicate the basis of the trial and illustrate the barriers to successful delivery of the research. TRIDENT is funded by the Research for Public and Patient Benefit (RfPPB) funding scheme.
Highlights

• Delivered a methodology workshop at the Wales Centre for Primary and Emergency Care Research (PRIME Centre Wales) annual meeting on medication adherence, jointly with the Centre for Health Economics and Medicine Evaluation in Bangor University.

• Collaboration with Birmingham Clinical Trials Unit (BCTU) and the Cancer Research Clinical Trials Unit (CRCTU) to conduct a training needs analysis that will inform the development of 4 Massive Open Online Courses (MOOCs). This will focus on specific trial-related tasks and will be targeted at specific roles within clinical trials units (CTUs).

• Developed a new Investigator Guide, which describes what working with the Centre means for a new investigator. This will be made available on our website later in 2019.
Work package 3: Developing new studies

Designing new studies and winning the funding to make them happen

Mind, Brain and Neuroscience Division

DOMINO-HD

Chief Investigator: Professor Monica Busse

Professor Monica Busse led the successful submission of a full application (only 18 out of 72 applications were invited from outline to full application) to the value of €2,049,523 to the recent EU Joint Programme – Neurodegenerative Disease Research (JPND) multinational research projects on Health and Social Care for Neurodegenerative Diseases.

The DOMINO-HD study will integrate prospective, sensor-derived physical activity, and sleep data in a daily life context with nutrition assessments and commonly used clinical Huntington’s disease (HD) severity outcomes and quality of life measures to explore the interplay between multi-domain environmental factors and HD outcomes. Genetic risk factors will also be considered, and emerging information will inform development of personalised multi-modal environmental interventions.

People with HD, their families and carers will be fully involved as research partners. Their input will allow us to understand individual and family needs, abilities and preferences in the context of their disease. The general view that HD, as a single gene disorder, is a paradigm for more common neurodegenerative disorders with heterogeneous causes (including Alzheimer’s and Parkinson’s disease) significantly broadens the scope and potential public health impact of this work.
LEAP-MS

Chief Investigator: Professor Monica Busse
Study Manager: Dr Julie Latchem-Hastings

LEAP-MS (funded by the Multiple Sclerosis Society) aims to develop and evaluate an individualised supported self-management approach for physical activity with a specific focus on people with progressive Multiple Sclerosis (PwPMS) and severe disability. In the first year of this 3-year project, our researchers have spent a lot of time speaking with people with progressive MS about their physical activity. They have also spoken to physiotherapists about how they can support people with MS who need to use a stick, frame or wheelchair to be as physically active as possible.

The team are now using the information gathered from these discussions to develop a new web-based lifestyle programme called LEAP-MS, in collaboration with people with MS and health care professionals. It is expected that the initial intervention will be ready for testing in selected regions in Wales by the middle of 2019.
FRANK Friends

**Chief Investigator:** Dr James White

FRANK Friends has been funded by the National Institute of Health Research (NIHR) Public Health Research Board (£1.45M) and will be the largest school-based drug prevention randomised control trial (RCT) ever conducted in the UK. The estimated number of participants will be 5,600 pupils from 48 schools. This interdisciplinary collaboration led by Dr James White (Deputy Director of Population Health Trials, Centre for Trials Research) involves members of the Health and Care Research Wales National Centre of Health and Wellbeing Research, as well as partners in other universities and Public Health Wales.

Using publicly funded research data

**Chief Investigator:** Dr Gabriella Conti

An example of new work funded in the reporting period are two studies with a combined value of approximately £2M involving collaboration with a Chief Investigator based at UCL. Dr Gabriella Conti is an economist who has linked up with Professor Mike Robling to undertake further analysis of datasets generated from his evaluation of a specialist home visiting intervention. The new studies are funded by the EU Horizon 2020 programme and by the Nuffield Foundation. They will include data from linked European-based trials of the same home visiting intervention to explore how elements of the intervention come together to produce observable benefit to families. This is a prime example of how publicly funded research data are being used to answer new study questions. This maximises the value of the original research funding investment. Both studies will take advantage of the research database and data linkage model innovated by the Cardiff team.

PATHOS

**Chief Investigators:** Professor Mererid Evans and Professor Terry Jones

The aim of the PATHOS study is to reduce the long-term effects of head and neck cancer treatment. Current treatments can result in severe side-effects for some patients; for example, losing the ability to swallow. This study explores how treatment severity might be reduced; maintaining effectiveness, whilst reducing these lifelong consequences.

PATHOS has been chosen to be supported by the Stand Up To Cancer campaign for Cancer Research UK. The study received a £2.15 million grant in 2019 from Cancer Research UK to help fund the discovery of treatments for head and neck cancer patients that could improve quality of life.

AML18 and AML19

**Chief Investigator:** Professor Nigel Russell

Acute myeloid leukaemia is a blood cancer that affects more than 3,000 patients per year in the UK. These two international trials recruit the majority of patients diagnosed with this disease in the UK, as well as from Denmark and New Zealand. Whilst AML18 recruits older frailer patients AML19 recruits younger and fitter patients.

As well as the evaluation of new drug treatments aiming to improve survival rates, these trials use sophisticated laboratory techniques to monitor disease response and control. Patients with a laboratory-evaluated marker are randomised to be monitored or not, with the aim of seeing if monitoring can improve survival as well as quality of life. These studies are funded by Cancer Research UK.
Infections, Inflammation and Immunity Division

THESEUS

Chief Investigator: Dr John Ingram

THESEUS is funded by the NIHR Health Technology Assessment (HTA) Programme (value £660K) and is an observational study led by Dr John Ingram, Cardiff and Vale University Health Board. The study is fully coordinated by the Centre and aims to better understand what are the best management options for hidradenitis suppurativa (HS) when first line treatments fail. HS is a relatively common, often painful chronic skin disease characterised by recurrent boils in flexural sites. Many second-line therapies are used, including medical, surgical and laser, with a limited evidence base.

Previously, there was considerable variation in outcome measure instruments used in HS studies. This study will inform the design of future HS trials and help to understand how HS treatments are currently used. John Ingram was previously supported by a postdoctoral fellowship awarded by Health and Care Research Wales and then received Research for Public and Patient Benefit (RfPPB) project funding for the INDUCE Study. He is now the Chief Investigator (CI) of a large HTA study.
Work package 4: Overseeing funded studies

Running studies to a high quality and producing outputs that will make a difference to the public

Population Health Division

POOL

Chief Investigator: Dr Julia Sanders

The NIHR HTA funded POOL Study has successfully completed all major set-up milestones. The study will determine the safety of water birth deliveries in UK maternity services, a procedure used by around 60,000 mothers each year. The study involves collaboration with a software company who support maternity information systems at sites eligible to take part.

The POOL Study was quoted in Assembly Report Petition P-04-682 Routine Screening for Type 1 Diabetes in Children and Young People.

From the Report:

“The Children and Young People’s Wales Diabetes Network’s letter to the Health, Social Care and Sport Committee highlighted Cardiff University’s recent Early Detection of Type 1 Diabetes in Youth (EDDY) study. The EDDY study looked at the feasibility of delivering a community educational intervention, aimed at raising awareness of the symptoms of type 1 diabetes among parents, teachers, and primary care health professionals.”
MIST

Chief Investigator: Dr Sue Channon

A major report, the MIST study, funded by Action for Children, was published. The study evaluated the Multi-disciplinary Intervention Service Torfaen (MIST), which provides a therapeutic wrap-around service working with children and young people aged 5 to 21 years. MIST provides a unique community and family-based alternative to residential care for children and young people with complex mental health needs.

With little research in the area partly because of the complexity of young people’s experiences, there was also a lack of cohesive social care and mental health research evidence to inform and guide services. The exploratory research within MIST therefore enabled researchers to identify key components of a model and way of working with children and young people within this sector.

“Working in partnership with researchers from the Centre for Trials Research to discover more about why MIST works has been an exciting joint venture for us. Collaborative projects between academics, service providers and commissioners provide valuable opportunities for learning and benefit us all.”

Action for Children

The qualitative research team from the Centre had specialised experience of engaging with vulnerable participants in research: using informal and flexible approaches to gain access to participants; using play activities and crafts as a way of establishing rapport and engagement with children, so that they felt comfortable in conversation with the researcher. This allowed a chance to explore in greater depth the delivery of a very complex intervention in a social care setting.
Infections, Inflammation and Immunity Division

BATHE

Chief Investigator: Dr Miriam Santer

The BATHE study asked whether pouring emollient additives into a bath adds any benefit over the standard management practices of eczema. In the largest trial of emollient bath additives to date, 482 children were randomly allocated to two groups: one group was asked to use bath additives for a whole year and the other was asked not to use them. Families completed short questionnaires weekly for the first 16 weeks, then every 4 weeks from 16 to 52 weeks. The study found clear evidence that the emollients provided no additional benefit over standard care.

OSTRICH

Chief Investigators: Professor Chris Butler and Professor Nick Francis

Centre for Trials Research fully coordinated OSTRICH, a clinical and cost-effectiveness trial funded by the National Institute for Health Research (NIHR) and represents a partnership with the PRIME Centre Wales. As a fully coordinated study, the Centre for Trials Research took responsibility for all critical functions to deliver this trial including trial management, data management, statistics and research nursing. This has been possible due to the long-standing commitment to developing specialist methodologist expertise in infections trials led by Professor Hood and supported by funding from the Wales Government. The study results have now been published in The Lancet.

FLIGHT

Chief Investigator: Dr Charlotte Bradbury

The FLIGHT study successfully completed recruitment. FLIGHT is a study of two treatment pathways for patients with newly diagnosed Immune thrombocytopenia (ITP), which causes bruising and bleeding due to a low platelet count. It compares standard steroid treatment versus combined steroid and mycophenolate (MMF).

Patients are first given high-dose steroids but most suffer side effects. In addition, the majority of patients become ill again when the steroids are stopped: about 20% stay well long-term. First-line treatment for ITP is unsatisfactory, but has been unchallenged for decades.

ITP is non-cancerous and the rare impact on survival of ITP has historically prevented it from being a research funding priority. This underestimates the profound adverse impact an ITP diagnosis and its treatment has on patients - many of whom are young. The study was funded by the NIHR Research for Patient Benefit Programme (RfPB).
Cancer Division

FAKTION

**Chief Investigator:** Dr Robert Jones and Dr Sacha Howell

Millions of patients with incurable breast cancer could benefit from Welsh-led research of the FAKTION study.

The research shows that, by combining investigational therapy with a standard treatment, patients may expect that their cancer will be controlled for twice as long.

Involving 140 patients from 19 hospitals across the UK, the cancer trial called FAKTION is sponsored by Velindre University NHS Trust. It is jointly led by Dr Rob Jones from the Velindre Cancer Centre and Cardiff University and Dr Sacha Howell from the Christie NHS Foundation Trust and University of Manchester.

The 140 patients had all been diagnosed with incurable breast cancer amenable to hormone treatment, known as oestrogen receptor positive cancer.

One of the patients, retired doctor Susan Cunningham from Cardiff was first diagnosed with breast cancer in 2005. She joined the trial in 2017 after she discovered her cancer had spread and was incurable.

“Being on a trial has given me great hope for the future. It’s meant that I have been relatively well for the past two years. Initially I thought I wasn’t going to see my grandchildren but now I have hope that I am going to survive an awful lot longer and see my family grow.”

Mind, Brain and Neuroscience Division

SenITA

**Chief Investigator:** Sue Delport and Dr Rachel McNamara

SenITA is a pragmatic randomised controlled trial of sensory integration therapy versus usual care for sensory processing difficulties in autism spectrum disorder in children, and its impact on behavioural difficulties, adaptive skills and socialisation.

Rachel McNamara and her trial team ensured that the SenITA trial of sensory integration therapy for autism received formal approval to continue with recruitment having met major internal pilot milestones. This was particularly challenging for the Centre for Trials Research team due to extensive delays in negotiating excess treatment costs in England.

SenITA opened in 2016, runs to 2020 and is funded by the NIHR Health Technology Assessment Programme with a grant worth £1,193,553.
SenITA patient representative
CASE STUDY

Name: Gemma Warren

Which study have you been involved in?
I have been involved in the SenITA study since March 2017.

Why did you decide to be involved in a study?
I decided to take part in the study because my daughter (who has Autism Spectrum Disorder (ASD)) had benefitted from having Sensory Integration Therapy.

How did you find out about the study?
I learned of the study through her Occupational Therapist that she had been seeing.

What was your experience like of being involved in a study?
Having never been involved in any trial/study before, I was a little apprehensive of what was expected of me and what my thoughts could bring to the study. At first, I felt a little intimidated by the vast knowledge and experience of the team carrying out the study but gradually realised that I could bring my own experience of parenting a child with Autism Spectrum Disorder.

What was most unusual about being involved in the trial?
One of the more unusual experiences for me was taking part in a video showing some of my own experiences of raising a child with ASD.

Would you recommend being a Patient and Public Involvement (PPI) Representative in future to members of the public?
I would encourage members of the public to support studies as their input is invaluable, and they have a different outlook on the subject that is being researched. These trials are important. I hope in the future that studies like this could enable children to get early intervention therapy and for parents to have a better understanding about the difficulties their children face.
Work package 5: Ensuring methodological and professional development

Statistics

Coinciding with the new leadership from Professor Adrian Mander, the statistics group are refreshing their methodological strategy given their research interests that span efficient designs, Studies Within a Trial (SWATs), Trials within Cohorts (TwICs), novel designs, the use of routine data in trials, methods to handle missing data, data sharing, individual participant data meta-analysis, adherence within trials, propensity scoring, interrupted time series, multi-arm multi-stage trials, model-based dose escalation, platform trials and adaptive designs utilising methods to improve the ways trials are run. The initial activities were started with an away day focussing on joint working and areas of strengths. It will be followed over the next 6 months with the development of a strategy for developing methods research.

Intervention mapping

The Centre for Trials Research, Research Design and Conduct Service (RDCS) South East Wales and PRIME Centre Wales jointly hosted a workshop for 24 researchers from a range of backgrounds on intervention mapping, a protocol for developing effective behaviour change interventions, in November 2018. The workshop was led by Professor Gerjo Kok and Dr Gill Ten Hoor from Maastricht University. The workshop considered behavioural determinants, theories to underpin the development of behaviour change interventions and methods to ensure effective implementation. This was a refreshing opportunity to reflect on our current practice and further extend the methodologies that we routinely utilise in developing and evaluating complex interventions.
Qualitative group

In February 2019, the qualitative researchers group in the Centre ran an away-day to review their progress in developing a cohesive and integrated methodological group as part of the trials unit. The aim of the away day was to formally map out the model of qualitative research in the Centre, to show how it functions alongside other methodologies and study designs, the opportunities and challenges it faces being based within a trials unit and areas for future development. The review will lead to a publication that will inform other trials units and research centres of the groups’ experience which remains relatively novel in a UK context.

“Following on from this week we have plans for lots of future collaborations, I have a number of new friends and we already have papers planned. I leave inspired by a strong female leader who creates an environment that encourages people to grow and develop and hope to put this into practice back in Antwerp.”

Dr Sybil Anthierens, a primary care sociologist from Antwerp, reflecting on her visit to Cardiff University and the Centre for Trials Research

Foundations in Research for NHS staff

During October 2018 members of the Centre for Trials Research team contributed to the Health and Care Research Wales ‘Foundations in Research’ Course for NHS staff working in a research role. The course provides them with comprehensive information on the statistical methods and monitoring aspects of clinical trials research. We had Centre representatives from quality assurance, trial management and statistics at this event.
Routine data specialist researcher

As the Centre’s routine data specialist researcher, Dr Fiona Lugg-Widger has continued to lead a number of initiatives, in conjunction with the Directorial lead, Professor Mike Robling. These have included setting up a network of interested researchers in Cardiff University, developing a research strategy with the Centre on routine data and winning and delivering several funded studies with a significant or sole focus on routine data, both within healthcare and in other sectors. Fiona has worked with UK data providers such as NHS Digital to improve access and use of routine data for individual studies, recently hosted a meeting from their team and provided written and oral evidence to the House of Commons Select Committee’s inquiry on Digital Government.

“My supervisors were Professor Debbie Cohen and Professor Mike Robling in the Centre for Trials Research. Between them they had such a wealth of experience to draw on, I felt very lucky to have such knowledgeable and thoughtful supervisors providing me with support and guidance throughout the sometimes arduous PhD journey!”

Sarah Rees, who gained her PhD with support from the Centre for Trials Research

Staff Highlights

• Carolyn Blake, Administration and Development Officer, is studying a Level 5 Learning and Development Diploma with the Chartered Institute of Personnel Development (CIPD)

• Angharad Jones, Research Manager, is studying the Association of University Administrators (AUA) Postgraduate Certificate in Higher Education Administration, Management and Leadership

• Dr David Gillespie won a competitive postdoctoral fellowship to study adherence for PrEP medication

• Dr Magdalena Meissner was successful in gaining a Cancer Research UK clinical trial fellowship in association with the Centre for Trials Research

• Dr Rebecca Milton won Outstanding Contribution to International Work, Medic Star Award 2019, Cardiff University

• Sarah Rees passed her viva and gained her PhD: The development of an intervention to support doctors and medical students in their decision whether to disclose their mental ill health - with support from Professor Debbie Cohen, School of Medicine, and Professor Mike Robling from the Centre for Trials Research. The Centre supports a number of PhD students

• Mike Robling received his 25 years’ service to Cardiff University award

Professor Julia Sanders, who started her research in the Centre, pictured centre right holding her award certificate for BMJ UK Research Paper of the Year for BUMPES.

Vicky Shepherd had the award-winning poster at Health and Care Research Wales annual conference 2018.
L’Oréal Fellowship

A Cardiff University MSc and PhD graduate, Dr Hanan Khalil, won a prestigious L’Oréal-UNESCO For Women in Science Fellowship for her work on the association between magnesium levels and mental and body well-being. Her PhD supervisor was Professor Monica Busse, now Director for Mind, Brain and Neuroscience in the Centre for Trials Research.

“My mentors are the people who influenced me the most in my career. In fact, my PhD mentor was a very strong woman from whom I learned, not only science and research, but a lot of other skills that are important to a successful researcher.”

Dr Hanan Khalil

Dr Hanan Khalil won a L’Oréal-UNESCO For Women in Science Fellowship.

Centre for Trials Research contributes to successful Athena Swan Award

The School of Medicine has received an Athena SWAN Bronze Award in recognition of its commitment to tackling gender inequality.

The Athena SWAN Charter is a recognition scheme for UK universities who are working to advance gender equality and the representation of women in academia. It was originally set up to recognise equality in science, technology, engineering, medicine and mathematics fields but has now expanded to also recognise work undertaken in arts, humanities, social sciences, business and law, as well as in professional and support roles, and for trans staff and students.
In 2018, the Research Design and Conduct Service (RDCS) South East Wales (SEW) team worked with the Health and Care Research Wales Public Involvement Community to form a Research Review Ready Group (RRRG).

This is a group of ten members of the public prepared to review funding applications and provide feedback from a patient, carer, family member, service user or public perspective. The group’s first task was providing feedback on applications submitted in December, including Health and Care Research Wales Research for Public and Patient Benefit funding scheme (RfPPB).

Overall, the RDCS SEW supported 11 NHS practitioners from 4 Health Boards to develop applications to RfPPB this year. Eight applications were submitted and the other three chief investigators decided their projects were not deliverable within the budget available and so the team has been working with them to submit applications to different funders.

The team supported six pathway to portfolio applications from practitioners in four health boards and a further three applications to this scheme were made based on support the team had previously provided.

The team delivered their three regular open events for health and social care practitioners:

- The “early ideas” event in April started the cycle, introducing practitioners to the process of taking an idea from practice and developing a research proposal
- The second event “Developing a funding application” in September looked at the application process in more detail
- A subsequent two-day non-residential writing retreat in November gave delegates the chance to focus on writing applications, supported by the team and other research-active consultants

The RDCS SEW worked with partners in four different specialties to deliver bespoke events to building capacity. The RDCS SEW held an event with physiotherapists working in Musculoskeletal Services in Cwm Taf. The overall aim of the day was to develop their 5-year strategic plan and as part of the day RDCS SEW ran a research workshop supporting the physiotherapists in the development of their research ideas. 17 physiotherapists submitted research ideas for discussion.
In the Cardiothoracic research interest group, the RDCS SEW presented an overview of its service and the group are now working on specific proposals. They held a joint day workshop with the Sexual and Reproductive Health Forum in December, led by Professor Julia Sanders, Health and Care Research Wales specialty lead. This was attended by 15 NHS practitioners from four Health Boards and six clinical academics with a focus on building research funding applications. There is currently one funding application discussed on that day that is being actively developed and a further session to explore one of the other topics is planned for June 2019. They have recently met with the Pharmacy Research Strategy leads to consider the best way to build on the study day held in 2018.

In January 2019, a member of the RDCS SEW attended the Policy Forum for Wales Keynote Seminar: Putting A Healthier Wales into practice - integrating the health and social care system in Wales. The pathway for social care research support remains challenging but they have provided support to practitioners in three social care organisations. This pathway is under consideration by the All Wales RDCS committee and the South East Wales team are establishing links with the new local representative of Wales School for Social Care Research.

The RDCS SEW is waiting to hear about the applications that have made it to the final stage of the Health and Care Research Wales RfPPB schemes but in the year from April 2018 to March 2019, at least six applications were successful, totalling £570,894.
The Research Design and Conduct Service (RDCS) South East Wales supports staff working within the National Health Service and social care to develop high-quality research funding proposals.

Service provided by RDCS consultants from the Centre for Trials Research, the largest group of academic clinical trials staff in Wales.

144 requests for RDCS consultant support
25 individuals submit research funding applications

144 requests for RDCS consultant support

Clients from 4 Health Boards in Wales

Successful funding applications total £570,894
6 successful applications

Engagement

Health Board Research and Development conferences
Health and Care Research Wales annual conference
Policy Forum for Wales Keynote Seminar: Putting A Healthier Wales into Practice
Cardiothoracic research interest group

Supporting Research Capacity Building

✓ Group research consultation for physiotherapists working in Musculoskeletal Services in Cwm Taf UHB
✓ Joint research workshop with the Sexual and Reproductive Health Forum
Conclusion

The Centre for Trials Research exists to improve the health and well-being of the public through excellence in research. It achieves this by attracting, training, supporting and advancing the wide range of high-calibre staff necessary to deliver cutting-edge research. The research questions we answer are driven by the experience of clinicians, the insights from patients, the needs of policy and the broad socio-economic context within which our public services are set. In the last four years the substantial growth of the Centre has been achieved by historical mergers of existing trials units in Cardiff University, essential and effective collaboration with a wide range of investigators across Wales and the UK more generally, and the commitment and expertise of its own staff.

To have scaled up in this way has required an enduring focus on quality management and regulatory compliance across the diverse range of study types we support. These include adaptive clinical trials, observational studies using routine data, large-scale ethnographic studies, smaller scale feasibility studies in a range of settings and many more besides. Our core support from Health and Care Research Wales and from Cancer Research UK is essential in sustaining such excellence. Our Centre performance in this last year with 43 new studies, £20.3M of competitive funding awarded, 154 public involvement opportunities and 87 papers published indicates the difference that the Centre is continuing to make in building evidence to change practice and improve the health of the public in Wales.
Looking forward

In this, the final year of the current Health and Care Research Wales funding period, we are developing new risk proportionate, and green initiatives to align with our goal of efficiency in research.

We will be expanding our focus on public and patient involvement in research working with our newly formed PI&E Hub whilst continuing with our core business of bringing together teams to win grant funding. Alongside this and delivery of high-quality trials and studies, we are working to manage the uncertainty of Brexit: we have planned as best as we can for the supply of medicines for trials and have arrangements in place thanks to the Medical Research Council (MRC). We are also implementing a Centre-wide reorganisation of space with our increasing staff and student numbers.

We are currently undergoing a recommissioning process, alongside new and continued collaborations and further bids to Health and Care Research Wales.

Our PI&E Hub will continue to become embedded across the Centre and be involved in more activities including reviewing the engagement plan on new studies.

We will be organising a public-facing inaugural lecture for Professor Adrian Mander.

Prospect of new major studies (based on new submissions) and exciting new ones that are getting off the ground including FRANK Friends and CENTRIC.

Major studies including Building Blocks 2 and Confidence in Care will be reporting results.

We continue to increase the numbers of postgraduate research students and fellows working alongside our trials and studies.

We are also working towards becoming a greener clinical trials unit and have plans to address workload and risk proportionate approaches to studies to create an even more harmonious working environment.
Thank you

The Centre for Trials Research wishes to thank all the members of the public and study participants who give their time to take part in our studies, freely and with great generosity to help improve health outcomes for future generations. It is our vision to produce a more evidence-based culture, so we know what works and what does not. This is impossible without their contribution and support.

Thank you to all our “lay reps” who give their time to take part in study management groups, steering committees, and are both involved in and participating in research. You inform research questions, study design, planning, management and reporting, ensure study materials are helpful for the public – and ultimately help all our studies to progress to successful completion and publication.

Thank you to Seth Oliver / www.fizzievents.com / @relationalsoup for kind permission to use photos from the LEAP-MS co-production event.

In preparing this report we thank our Public Involvement and Engagement (PI&E) Hub representatives Sue Campbell and Sarah Peddle.

Contact us

The Centre for Trials Research is willing to consider any well-designed study or trial idea, even those outside its current areas of research. For more information about collaborating with our research team or to keep up to date with news and events:

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