



Centre for
Trials Research

Canolfan
Ymchwil Treialon



Annual Report

2020/21



The Centre for Trials Research (CTR) at Cardiff University is a UK Clinical Research Collaboration (UKCRC) registered clinical trials unit.



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Glossary

CI	Chief Investigator
COPD	Chronic Obstructive Pulmonary Disease
CTR	Centre for Trials Research
CTU	Clinical trials unit
CU	Cardiff University
DCW	Domiciliary care worker
HTA	Health Technology Assessment
NIHR	National Institute for Health Research
PHR	Public Health Research
PI&E	Public Involvement and Engagement
RCT	Randomised Controlled Trial
RDCS	Research Design and Conduct Service
UKRI	UK Research and Innovation



Executive summary

Last year was the first of the new three-year funding period commissioned by Welsh Government through Health and Care Research Wales and the second year of the Cancer Research UK five-year funding period.

The year has seen major innovation efforts across all our activities to allow us to respond to the many challenges we have faced mid-pandemic. A highlight of our year was the online Centre for Trials Research (CTR) event introduced by Vaughan Gething AM, Minister for Health and Social Services, attended by 158 of our partners from Wales and across the UK.

As part of our continued efforts to achieve broad reach across Welsh funded infrastructure, we have prioritised urgent public health research including supporting vaccine studies. At the same time, we have worked to ensure that existing funded studies (for example TRUFFLE and LEAP-MS) were able to open given the constraints introduced by the pandemic. You can read about some of our collaborative, world-leading and relevant Covid-19 research (namely Pan-Covid and CABS-Covid) that is already contributing to the global pandemic response.

Our engagement with our Cancer Research UK funders has focused on our regular directorial and operational meetings, sharing best practice and supporting cancer clinical trials through the pandemic. We have taken part in a series of webinars addressing a range of subjects of common interest and leading a series of “bite size” methodology webinars for radiotherapy related research. Separately, we have supported Cancer Research UK in a significant piece of work looking at set up times for clinical trials and are now supporting in the leadership of an industry engagement strategy for cancer clinical trials, which will fit with work in the CTR.

Our high-quality research is reflected by 88 peer reviewed publications over the past year. Our programme of research has been underpinned by the inclusion of the public in the design, conduct and dissemination of research and further enabled by our Public Involvement and Engagement (PI&E) Hub which is now fully established and embedded in all the work that we do. You can read more about the work of the PI&E Hub and about our focus on inclusivity in research through the Talking Trials project.

We have seen great success with collaborative grant winning with investigators working in the NHS, social care, Health and Care Research Wales infrastructure and industry across Wales, the rest of the UK and internationally. Our effective resource management and success in retaining and developing our 161 skilled research and professional staff has helped us to secure £22,703,050 in funding from national and international funders (a total of 39 major awards in the Health and Care Research Wales and Cancer Research UK strategic thematic areas over the current period of funding).

We have collaborated with other UKCRC registered clinical trials units around UK to inform emerging strategies to enable remote trial set up and delivery. Over the past year, the Research Design and Conduct Service (RDCCS) South East Wales have offered methodological support to our NHS and social care partners, helping practitioners to develop evaluations of their service responses to the pandemic alongside supporting 70 support requests and 16 NHS and Social Care grant submissions in Wales.

In collaboration with the Wales Cancer Research Centre, we have sought out information on barriers to staff within the NHS becoming leaders in cancer clinical research and are moving forward in partnership with the NHS on a number of initiatives to engage and support individuals to develop and lead on future study ideas.

We are very proud of our focus on developing researchers both within CTR and more broadly within the NHS and social care in Wales. CTR staff have achieved promotion and regrading, two were awarded PhD by published works and one achieved success with a National Institute for Health Research (NIHR) advanced fellowship award. External to CTR, we provide academic mentorship to four of the recently awarded Health and Care Research Wales NHS Research Time Awards. We also host a full time Cancer Research UK Clinical Trials Fellow and provide clinical trials oversight for NIHR Senior Clinical Fellowship.

Thank you for taking the time to read about our work. We have taken the liberty of using some pre-pandemic photos in this report to remind us all what CTR activity used to look like. We would like to acknowledge our funders, research partners, staff and, above all, the participants in our research studies without whom none of this work would be possible.

Professor Monica Busse

Director, Mind, Brain and Neuroscience Division

Professor Mike Robling

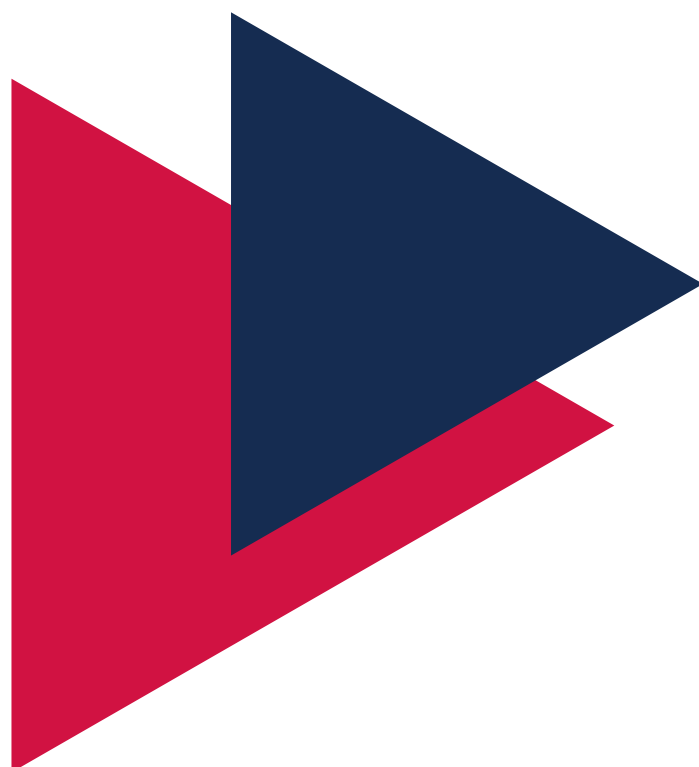
Director, Population Health Division

Professor Kerry Hood

Director, Infections, Inflammation and Immunity Division

Professor Richard Adams

Director, Cancer Division



Foreword

Mission and strategic aims

The Centre for Trials Research is a UKCRC registered clinical trials unit based in Cardiff University, Wales. The Centre 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, as well as from our host institution, Cardiff University. 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. Most of our work involves external investigators undertaking primary research in health or social care (or both). The range of potential beneficiaries is broad, reflecting the diversity of studies and investigators we work in partnership with. These will include patients, social care service users, members of the public, health and social care service providers, health and social care policy makers. These beneficiaries will be in Wales, the rest of the UK and in other countries outside of the UK. The Centre has a long-established record in promoting inclusive research and in producing evidence to support the care of traditionally underserved groups.

Who's who

The CTR Director (and Director of Division of Infections, Inflammation and Immunity) is Professor Kerry Hood. She is supported by a senior management team including Professor Mike Robling (Population Health Division), Professor Monica Busse (Mind, Brain,

Neuroscience Division), Professor Richard Adams (Cancer Division), Professor Adrian Mander (Statistics) and Dr Sue Channon (Research Design and Conduct Service).

How we work

Our researchers and professional staff work across our four divisions and within cross-cutting teams (including Information Services, Quality Assurance and Regulatory Affairs and Professional Services). Our current research portfolio includes evaluations of drugs and complex health and social care interventions, studies of mechanisms of disease and treatments, cohort studies and trials informing health and social care policy and practice. Activities embedded across these areas of work are public involvement and engagement, social care aspects, commercial / industry engagement and collaboration, NHS professional engagement and collaboration, engagement with Welsh Government funded research infrastructure and communications, publicity and knowledge transfer.

Our work plan

We place continued emphasis on the development of working practices and expert staff to ensure 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 high 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 and sustain 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
(RDSCS) 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 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.


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

Throughout this report, these graphics identify and introduce you to each section:

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
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This report features examples of key Covid-19 research we have been supporting. To make it easy to identify throughout the report, a Covid identifier indicates that activity.

Core Metrics

Reporting period: 2020/2021

**Health and Care
Research Wales
Infrastructure
award to
the group**

Direct funding
awarded
£823,571



Jobs created
through direct
funding



Grants won during reporting period

Grants won	Led by group	Group collaborating
Number	18	21
Value	£4,604,838	£18,098,212
Funding to Wales	£3,897,616	£12,915,619
Funding to group	£3,363,407	£1,718,791
Additional jobs created for Wales	38.78	148.58
Additional jobs created for group	38.78	19.06



Number of publications



Number of public
engagement events



Number of public
involvement opportunities

Clinical Trials Unit metrics



39

Number of
studies awarded



29

Number of studies
led by Welsh Chief
Investigators



18,129

Total number
of participants
recruited



14.25

% participants
from Wales

WORK PACKAGE 1:

Managing our work

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



Centre for Trials Research Virtual Stakeholder Event

The Centre for Trials Research Virtual Stakeholder Event in September 2020 was organised as both a celebration of recommissioning and of the Centre being 5 years old.

The day consisted of a series of presentations and panel discussions around 4 core themes: inclusion in trials, novel designs; efficiency in trial design and delivery; and existing and routine data. The day was launched by Professor Karen Holford, Deputy Vice Chancellor of Cardiff University, and Vaughan Gething AM, Minister for Health and Social Services.

Delegates included members of the public, lay representatives, funders, Welsh Government, patients and carers, researchers from outside the Centre, health professionals, methodologists and Cardiff University members of staff from outside the Centre.

Feedback was universally positive from delegates, including a wide variety of stakeholders and the public who reported finding it interesting and informative.



[Watch all the sessions here.](#)



Frank Atherton, Chief Medical Officer for Wales

Feedback from Hywel Dda University Health Board:

“Really enjoyed the session on inclusivity, I’m an EDI professional and do not work within the Trials sector but very interesting to hear of the challenges. I picked up useful knowledge that I can use when completing Equality Impact Assessments.”

Select comments from delegates:

“I’d just like to say many thanks to all the speakers, especially Kerry Hood, for such an informative and interesting day.”

“I think all the sessions were interesting and offered different information and aspects of research and enabled me to understand the different roles and research undertaken in the CTR.”

“Inclusivity. Lots of ideas to think about, both for inclusivity of participants and also of PPI involved in trials.”

“Novel design. I feel I understand this concept a lot better now.”

“The Inclusivity session was very enjoyable and interesting with a lot of take-home messages to use in future research. I particularly enjoyed the talk on the POOL study also - sounds very interesting and I’d be interested in the outcomes.”



Vaughan Gething AM, Minister for Health and Social Services



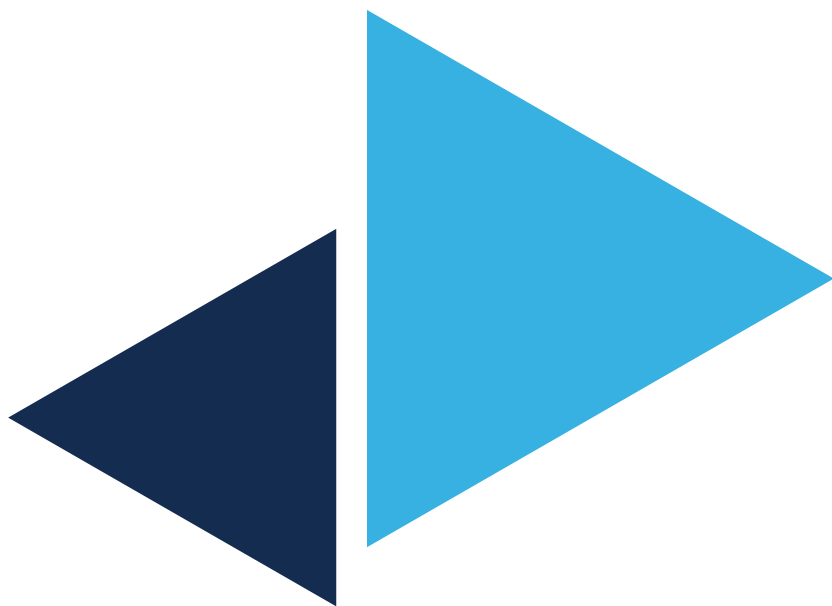
Public Involvement and Engagement Hub

The Centre for Trials Research Public Involvement and Engagement Hub is a group of Research Partners (members of the public) and Centre Staff who meet every two months. The Hub provides a central focus and oversight of the Centre's commitment to involve members of the public in research. It allows us to take a Centre wide approach to working with the public, to raise its profile, to share great ideas and to support innovation. We work closely with the public involvement and engagement team at Health and Care Research Wales and the School of Medicine Public Involvement and Engagement Champions.

Our vision is to build and support a community of Research Partners working with the Centre for Trials Research either on individual studies or across broader organisational activities. Centre policies and practice will enhance opportunities for attracting new and existing partners, for providing support and development in their role and for making them feel part of a broad community across the Centre. In this last year we have focused on producing an introductory guide for partners joining the Centre. The aim is to ensure a consistent approach to induction by providing information on payments, training and possible roles available.

We are also keen to encourage the dissemination of all study results as clearly, widely and transparently as possible. One aspect of this is how we feedback the study results to participants.

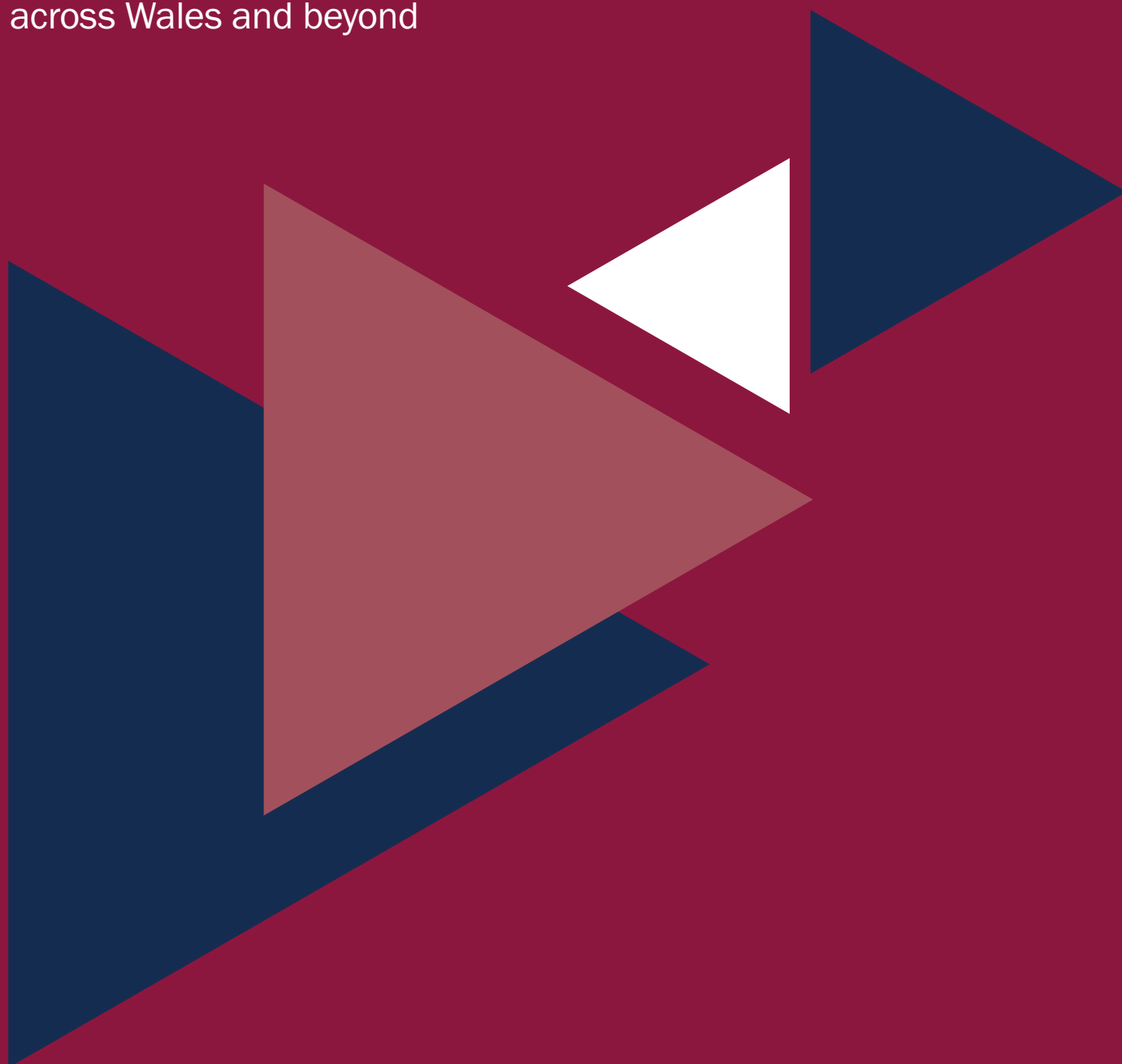
To provide a public perspective on broader CTR activities, two of our research partners contribute to the Centre Executive Committee meetings, Study Adoption Group and the Centre's Strategic Advisory Group.



WORK PACKAGE 2:

Working with other groups

Working in collaboration with researchers from other organisations across Wales and beyond



Routine Data

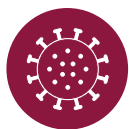
A key theme across many of our studies is the use of routinely collected administrative data. Whereas a few years ago using such data in trials was rare its use has become more common. For many studies we run, using existing data may offer a good return on investment for the funder. In observational studies as well as in some trials, the size of routine datasets also means we can achieve a precision that enables us to answer questions that are unlikely to have been possible using other methods. Two CTR studies in the Division of Population Health provide good examples of how we use such data - the OSCAR study and the Social Workers in Schools Study.

OSCAR

Establishing the impact of COVID-19 on the health of domiciliary care workers in Wales: developing a model for UK service planning and carer support.

Chief Investigators: Professor Mike Robling and Dr Rebecca Cannings-John, Centre for Trials Research

Funder: Economic and Social Research Council, part of UK Research and Innovation, as part of its call for research to examine the impact of COVID-19



OSCAR is quantifying the impact of Covid-19 on domiciliary care workers (DCW). In 2020 early indications of the impact of Covid-19 on social care workers, including DCWs suggested an increased risk of more serious outcomes but the picture remains unclear. In Wales, all DCWs are registered with the regulatory body, Social Care Wales. Anonymised registration data linked to data from labs, general practice, hospitals, and NHS 111 and held at the SAIL Databank will enable rates of Covid-19 infection, consultations and hospital admissions, to be precisely quantified. This will include comparisons before and after the onset of the pandemic. The results from the study will be critical to informing the Welsh and UK Governments' pandemic response and longer-term support for DCWs. The study is being run in partnership with colleagues at SAIL, Swansea University and Public Health Wales.

Social Workers in Schools Study

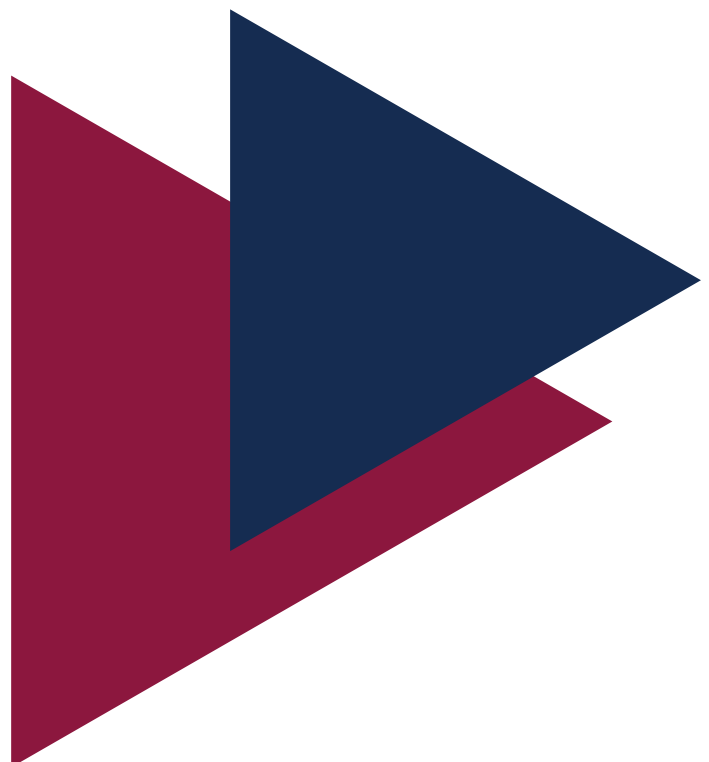
Chief Investigator: David Westlake, Research Fellow, CASCADE

Funder: What Works for Children's Social Care

For another study led by David Westlake at CASCADE, the Social Workers in Schools study (SWIS), it is arguable that this study would never be possible without routine data. This study is evaluating the effectiveness and cost effectiveness of placing social workers in schools in child protection enquiries. The study uses routinely collected data from local authorities. Secondary outcomes include the number of days in care and educational achievement (assessed through additional linkages to the National Pupil Database). The CTR team have already randomised 280 schools to receive a social worker or not and established data sharing agreements with local authorities.

Developing Allied Health and Nursing Researchers

We recognise the value of a professionally diverse workforce and encourage professional development and progression into clinical research through alternative routes. Here we have highlighted some of the successes achieved by our staff and some of collaborators over the past year.



Dr Julie Latchem-Hastings

Julie, started in CTR as a research physiotherapist three years ago. Having completed her PhD in Sociology in Cardiff University's School of Social Science in 2017, Julie combined her background as a practicing neurological physiotherapist with sociology and social science research methods expertise to set up the LEAP-MS study. This 3-year study funded by the Multiple Sclerosis Society UK resulted in the development and testing of a physiotherapy-led blended intervention to support people with progressive multiple sclerosis to be as physically active as possible.

Working on LEAP-MS enabled Julie to build on her expertise in designing research with and for under researched populations. Tackling research gaps discovered during her



doctoral work, Julie was successful in securing a Health and Care Research Wales Social Care Post-doctoral Fellowship in 2019. Her fellowship study 'FEAST' explores the role of food in the care and rehabilitation of younger adults with neurological conditions in long term care.

In 2020, Julie was also successful in securing a Wellcome Trust Engagement award for the 'Get CreActive project' which she has been running over the last year. Through this ISSF funding, using her interests in creative methods and public engagement, Julie has brought together a group of 20 women who, through facilitated discussions and engagement in a series of creative activities have explored the realities of living with hip dysplasia and identified key research priorities for the future. The project concludes this summer with plans to leave behind digital resources charting the group's experience, aimed at supporting others with hip dysplasia.

In this last year Julie was successful in her application for regrading to Grade 7 Research physiotherapist.

Dr Victoria Shepherd

Victoria joined as a research nurse 8 years ago to support a clinical trial being conducted in care homes where there can be ethical and practical challenges when recruiting frail older people, many of whom

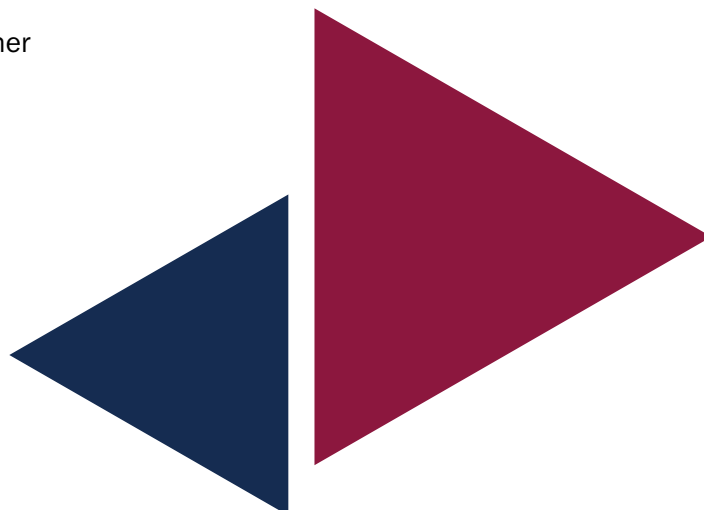


have impaired capacity. In 2016, she was awarded an NIHR Doctoral Research Fellowship funded by Health and Care Research Wales to develop a complex intervention to support the inclusion of adults who lack capacity in research (DECISION Study). The intervention is a decision support tool for families making decisions about research on behalf of someone unable to consent.

Following the completion of her PhD in January 2020, she was awarded a Wellcome Trust ISSF Consolidator Award to continue her research through the DECISION 2 Study. This enabled her to improve the decision tool, through interviewing family members of people with conditions such as dementia and develop ways of evaluating this type of intervention (CONSiDER).

The ISSF funding gave her the opportunity and skills to continue this area of research and time to develop follow-on research and publish results from her PhD. She has disseminated the key messages from this research and curated a research page for Social Care Wales.

ISSF funding and CTR support led to her being awarded a 4-year NIHR Advanced Fellowship, funded by Health and Care Research Wales, at the end of 2020.



Sue Delport

Sue is co-Chief Investigator with Dr Rachel McNamara on SenITA.

She established an Occupational Therapy clinic in 2013 at Cardiff University, creating the opportunity to research the effectiveness of intervention for children with developmental and sensory processing difficulties. Multi-school research was facilitated by Prof Monica Busse with a successful Wellcome Trust-ISSF cross disciplinary award for a pilot study. This small intervention study set her up for the next step in research.

A seminar run by the CTR offering support and inviting collaboration with practice, facilitated exploration of a research idea with partners in Aneurin Bevan University Health Board investigating the effectiveness of usual care for sensory processing difficulties. Simultaneously the National Institute for Health Research Health Technology Assessment (HTA) Programme commissioned call to investigate the evidence for sensory integration therapy for children with autism was launched. Having worked with Prof Busse on the Wellcome Trust pilot study, CTR were approached for support with the application.

The Centre for Trials Research agreed to adopt the study and work in partnership and using a co-CI model (with Dr Rachel McNamara). This partnership brought together clinical and research expertise, and the team were awarded HTA funding (£1.2 million) to conduct a pragmatic RCT of Sensory Integration Therapy versus usual care for sensory processing difficulties in Autism Spectrum Disorder in children: impact on behavioural difficulties, adaptive skills and socialisation (SenITA). This study started in 2017 and has now been successfully delivered as a result of this collaboration. The final report is due for submission in May 2021 and collaborations established here will now inform ongoing studies.



Talking Trials

Talking trials is an exploration of perceptions about clinical trials amongst those from a minority ethnic backgrounds.

Chief Investigators: Sarah Bridges and Martina Svobodova, Centre for Trials Research

Funder: Wellcome Trust Institutional Strategic Support Fund (ISSF) Public Engagement Proof of Concept Award

Research shows that clinical trials often lack the ethnic diversity typically seen in real patients and that minority ethnic patients have worse experiences when accessing treatment and poorer survival in general. In partnership with the South Riverside Community Development Centre, this project is working with a group of residents from Riverside (Cardiff), using focus groups and creative materials to produce an exhibition exploring perceptions of research, along with discussing the ways we can ensure that our research is more inclusive and better reflects the diversity in society.

The focus groups have, for example, discussed participant information sheets given out to anyone considering taking part in a clinical trial. As these sheets are often very complex and use difficult language, the group considered alternative ways of presenting this information.

Working with participants from diverse ethnic backgrounds has offered a unique insight into the public's reading and interpretation of trial participant materials and awareness of clinical trials in general. Informal arts engagements during the workshops have been providing the opportunity to complement the verbo-centric aspect of this research and helped gather holistic data and perspectives.



Academic Mentorship

We are providing the academic mentorship to four of the recently awarded Health and Care Research Wales NHS Research Time Awards:

- Drs Sadie Jones (clinical research fellow) and Sarah Gwynne (consultant clinical oncologist, South West Wales Cancer Centre, Swansea Bay University Health Board) - academic mentor Prof Richard Adams
- Dr Rachel Abbott (consultant dermatologist, Cardiff and Vale University Health Board) - academic mentor Dr Emma Thomas-Jones
- Dr Jane Nichols (consultant in sexual health, Cardiff and Vale University Health Board) - academic mentor Dr Dave Gillespie

Clinical Fellowship

Dr Magda Meissner obtained a Cancer Research UK clinical trials fellowship to work part time with the Centre for Trials Research in 2019. As a part of the success of her position we have secured funding in collaboration with the Wales Cancer Research Centre, which has seen her transfer from her clinical post in Bristol to adopt a full time clinical fellowship in Cardiff working between Cardiff University and Velindre NHS Trust. This will offer an enhanced ability for her to look for a longer term academic clinical trials researcher and honorary consultant medical oncologist position as we move in to 2022.

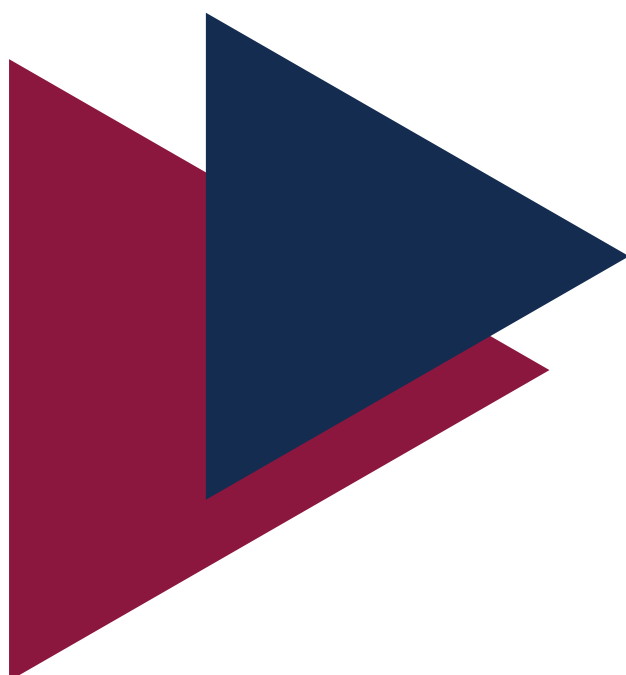
Working with Cancer Research UK and other Clinical Trials Units

We continue to have strong and positive relations with many CTUs across the UK, working collaboratively and as leaders. As an example, Claire Johnson leads both the CTR Quality assurance and regulatory affairs (internal) and the national UKCRC CTU Quality Assurance group (as chair) and is on the Executive group for UKCRC CTUs.

Much of our research is dependent upon charitable funding, which in turn is dependent upon donations from the public. The team have been acutely aware of the impact upon charities from the pandemic, including our largest funder Cancer Research UK. With this in mind we were instrumental in the establishment of the first “baton4cancer” initiative in Wales during the first wave of Covid and undertook a team virtual event in which we cycled around the coast of Wales, raising funds for Cancer Research UK. This was followed shortly after by participating in the Cycle 300 initiative, which was picked up by local media. We are now leading an initiative in collaboration with Cancer Research UK and the 7 other sister UK core funded Cancer Research UK clinical trials units, building upon our 2019 Bikeathon cycle to Wiltshire.

Adapting to support the NHS through the pandemic

Members of the CTR have been pro-actively supporting where they could during the pandemic and have engaged using their skills. This included assisting in the setting up and opening of Covid vaccine studies across Wales, taking work away from trial nurses diverted to clinical care. Meanwhile, our clinically trained staff returned to support the NHS by switching into full time NHS workload, returning to CTR work in the early autumn.



WORK PACKAGE 3:

Developing new studies

Designing new studies and winning the funding to make them happen





Cancer Division

NHS Survey

In October and November 2020, we undertook a survey across the NHS in Wales, led by Professor Richard Adams and in collaboration with Wales Cancer Research Centre and our Research Design and Conduct Service team.

In the questionnaire, we were seeking information on barriers to staff within the NHS becoming leaders in cancer clinical research. The questionnaire was distributed to all multi-disciplinary cancer teams across Wales. We evaluated the responses from 80 cancer healthcare practitioners including oncologists, surgeons, nurses, physiotherapists, radiographers, psychologists and clinical scientists.

The results of this survey show that there are barriers perceived and experienced at an individual and professional group level. While there is support available, through the RDCS and where needed through clinical trials units in Wales, this needs better signposting, workloads need to be reviewed and time needs to be allocated within job plans for the development of this important work and to ensure succession planning for our future leaders.

The survey has provided valuable information and areas for focus going forward and we are very grateful to all those who completed it.

Using information gained in the survey we are moving forward in partnership with the NHS on a number of initiatives to engage and support individuals to develop and lead on future study ideas and hope to report positively on this in next year's report.





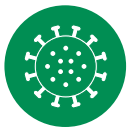
Infections, Inflammation and Immunity Division

PEACH

The Procalcitonin: Evaluation of Antibiotic use in Covid-19 Hospitalised Patients (PEACH) study is a collaboration between Cardiff, the University of Leeds and the University of Liverpool.

Chief Investigator: Dr Jonathan Sandoe, University of Leeds School of Medicine

Funder: National Institute of Health Research



To evaluate whether a simple blood test for bacterial infection could help to reduce the use of antibiotics in patients with Covid-19.

A procalcitonin blood test (PCT) is used in hospitals to distinguish between bacterial and viral infections and guide antibiotic treatment. This study will investigate whether the test is effective in Covid-19 patients by looking at data from the first wave of the pandemic in UK hospitals.

We aim to find out if use of the test in Covid-19 patients reduced antibiotics and/or improved patient outcomes, such as time in hospital or in intensive care, death rates, and infections with superbugs, and will also assess its cost effectiveness.

We will produce guidelines for doctors on how best to use the test in patients with Covid-19, so that antibiotics are started early if needed and stopped promptly if unnecessary, thus reducing side effects, antibiotic resistance and infections with superbugs.



“Covid-19 is caused by the SARS-CoV-2 virus, therefore antibacterial agents – antibiotics – have no direct effect. On top of this, published data indicates that rates of secondary bacterial infection are low in Covid-19 patients, so antibiotic use early in the course of the disease may be unnecessary. Despite this many patients are being prescribed antibiotics empirically because of concerns that they may have secondary bacterial infections.”

**Dr Emma Thomas-Jones,
Senior Research Fellow and Deputy
Director Infections Inflammation and
Immunity Division**





Mind, Brain and Neuroscience Division

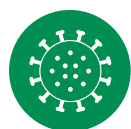
Our focus over the last year has been on adapting studies for delivery in the Covid environment alongside working with a range of investigators to submit new funding applications. Here we highlight one of our studies (LEAP-MS) which was modified for entirely remote delivery.

Study: LEAP-MS

Lifestyle, Exercise and Activity Package for People living with Progressive Multiple Sclerosis

Chief Investigator: Professor Monica Busse

Funder: Multiple Sclerosis Society



The LEAP-MS study evaluated a remotely delivered complex intervention with a multi-user web-based online resource, up to six physiotherapy coaching sessions and a training package for physiotherapists. This was initially intended to be delivered in a blended mode but was moved completely online due to Covid-19.

Physiotherapy consultations were conducted using video conferencing software or telephone. A training package focussing on intervention and study delivery procedures was implemented, and the process and fidelity evaluations were conducted remotely.

The NIHR Remote Trial Working Group has published their preliminary guidance for conducting trials remotely and features LEAP-MS as an example of remote intervention delivery that was achieved when lock down measures were restricting non-Covid research.

LEAP-MS has also been selected as one of the five case studies for the learning from Covid adaptations project Sheffield are running.



The guidance and examples can be found here.

SCHEMA

Secure Care Hospital Evaluation of Manualised (interpersonal) Art-Psychotherapy: A Randomised Controlled Trial

Chief Investigator: Simon Hackett

Funder: NIHR Senior Clinical Fellowship

The research team is made up of art psychotherapists and researchers. People with learning disabilities have spoken to us about this research and helped us to design it, plan how to do it, and how we tell people about it when it is finished.

In the past people who have a learning disability were often excluded from taking part in research. This means that knowing what works well for them is not always clear. Lots of psychotherapies available to help people with mental health difficulties are based on talking, which might not always be the best approach for people with learning disabilities. Doing artwork or creative things within art psychotherapy can be a helpful way for people to communicate about themselves. Interpersonal art psychotherapy has been designed to help people with learning disabilities in secure care. The art psychotherapist encourages people to use creative ways to express the things they are frustrated, angry, or distressed about.

We want to find out if interpersonal art psychotherapy is helpful and value for money for people with learning disabilities who are in secure care. We will be testing if interpersonal art psychotherapy works better than the standard care that is being provided. To do this we will need to recruit 240 people and put them into groups by chance, with half having interpersonal art psychotherapy and half on a waiting list for it. Everyone in the study will get a chance to have interpersonal art psychotherapy.

We will find out if interpersonal art psychotherapy can help people who are in secure care to improve their mood, become less distressed, and not hurt themselves or others. We think that this research will give people with a learning disability more choice about accessing psychotherapy in secure care.



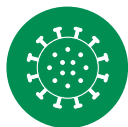
Population Health Division

In a period of time during which society has been dominated by the Covid-19 pandemic it is both essential and unsurprising that this has heavily influenced new work. Two examples from the Division of Population Health demonstrate this.

PAN-Covid online database

Chief Investigators: Professor Christoph Lees and Dr Ed Mullins, Imperial College London

Funder: Part of a £24.6m rapid research response funded by UKRI, and by the Department of Health and Social Care through the National Institute for Health Research



Centre researchers led by Dr Julia Townson have been collaborating with a team from Imperial College London to establish a global registry

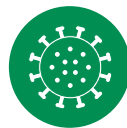
of those affected by Covid-19 in pregnancy. The PAN-Covid online database hosted by the Centre will collate data on women with suspected and confirmed Covid-19 from early pregnancy to after the birth of their baby. The research will help gain a better understanding of how Covid-19 affects early pregnancy, foetal growth, prematurity and virus transmission to the baby. The study has already shown that Covid-19 infection in pregnancy is not associated with stillbirth or early neonatal death. Based on records from the PAN-Covid and a second US database, the study has also shown that a positive test does lead to a higher rate of premature birth.

Moving On

People experiencing homelessness and offered accommodation since Covid-19 will be interviewed as part of research assessing the support they have received.

Chief Investigators: Dr Peter Mackie, Cardiff University School of Geography and Planning and Dr Rebecca Cannings-John, Centre for Trials Research

Funder: UKRI Economic and Social Research Council



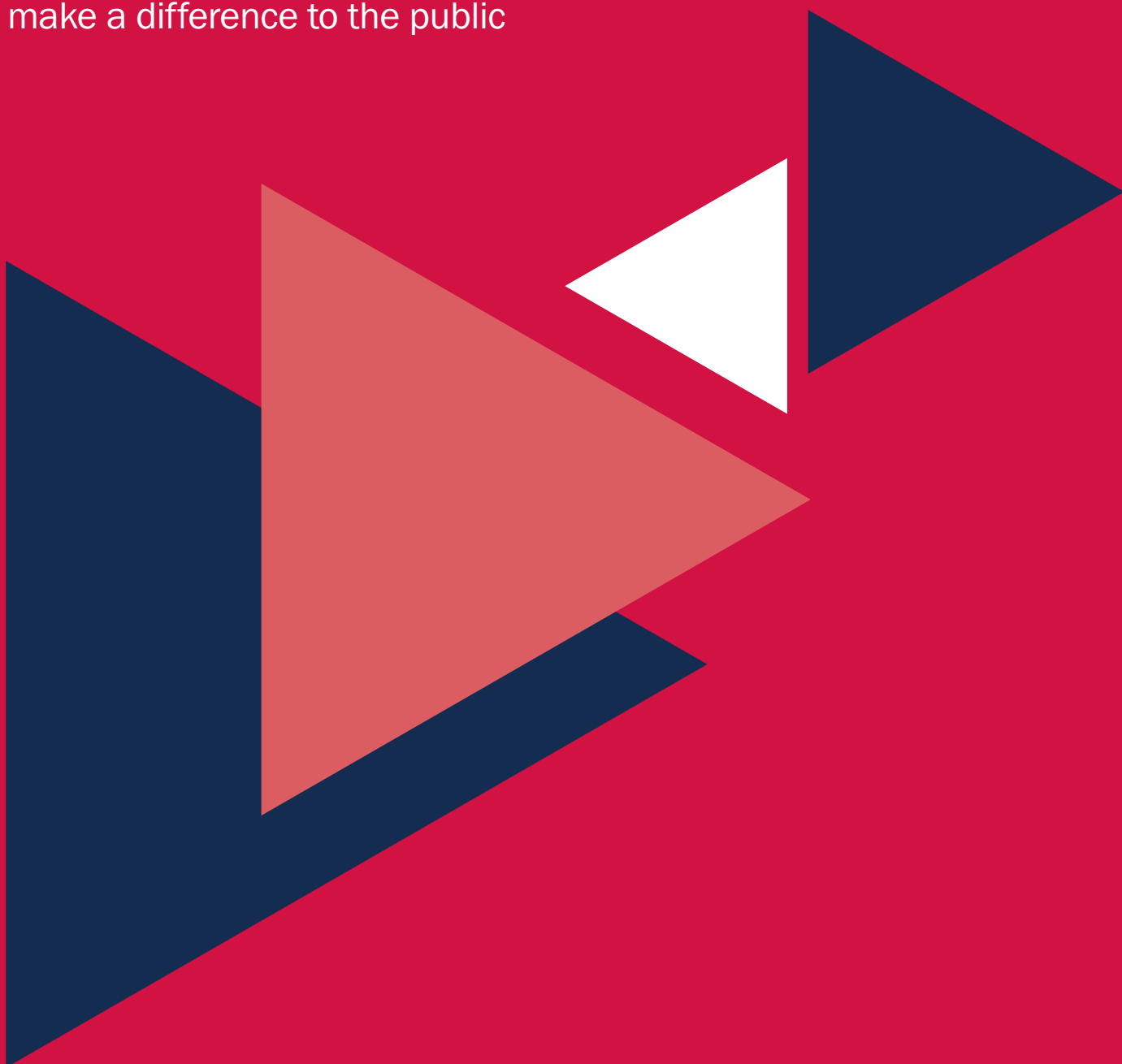
The study focuses upon people who are experiencing homelessness.

At the beginning of the Covid-19 lockdown, many people experiencing street homelessness were offered emergency accommodation to facilitate safe self-isolation. The study's primary objective is to investigate whether Settled Accommodation prevents Covid-19 infection and reduces housing instability compared to Temporary Accommodation. Dr Rebecca Cannings-John said "Moving On is the first trial to be conducted in the UK with people experiencing homelessness and we are delighted to work with the School of Geography and Planning and the Centre for Homelessness Impact to enable it to happen." The study is being delivered as a collaboration between the Centre for Homelessness Impact, Cardiff University, Alma Economics, and a group of partner local authorities.

WORK PACKAGE 4:

Overseeing funded studies

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





Cancer Division

We have been very busy expanding our international engagement over the last year, despite the evident challenges.

We have seen key trials open in the USA, Australia and France (PATHOS) and with constructive negotiations with the European Organisation for Research and Trials Coordination (EORTC) we aim to open more sites in four more European countries. The CORINTH trial opened in Norway and recruited its first patient there in February 2021. EWALL opened and recruited its first patient in France and is set to open over the next few months in Germany, Czech Republic, Sweden and even the UK.

At the start of the pandemic UK healthcare resources were channelled towards delivering NHS care and thus we stopped recruitment to the majority of our trials in order to reduce pressures on NHS staff, whilst still looking after the large numbers of patients who were already enrolled in our studies. However, shortly after the first wave we were being asked by many sites to re-commence recruitment as the studies were seen as key for optimal care especially for our cancer trials portfolio. We adopted a centralised risk review process to ensure that trials could be opened appropriately, strategically and safely and have seen the vast majority of our trials up and running over the last six months.

TIC-TOC

Chief Investigators: Professor Kate Brain and Dr Grace McCutchan, Cardiff University

Funder: Cancer Research Wales

Cancer Research Wales has prioritised cancer inequalities as a key area for research. Cancer incidence and mortality for some cancers is up to 25% greater in deprived areas compared to more affluent areas. The charity has funded 'TIC-TOC', a 'Targeted Intensive Community-based Campaign to Optimise Cancer Awareness' to address the limited success and transient nature of conventional awareness campaigns which often miss the targeted group. Led by Cardiff University, this research will create networks consisting of community cancer champions, primary care leads and strategically positioned Rapid Diagnostic Centres to dismantle barriers and improve health seeking behaviours that lead to cancer inequalities in Wales. The outcomes of this research will be applicable to other health conditions.

ROCS *Radiotherapy after Oesophageal Cancer Stenting*

Chief Investigators: Dr Douglas Adamson and Dr Anthony Byrne

Funder: NIHR Health Technology Assessment Programme

The ROCS study showed reduced bleeding in tumours treated with radiotherapy.

The ROCS study became the first prospective trial to show reduced bleeding in tumours treated with radiotherapy in patients with advanced disease. The study has also shown that combining radiotherapy with stent placement in this vulnerable population doesn't improve swallowing further and the treatment is burdensome and as such it is best avoided for the majority of patients in this context.

Dr Dougal Adamson said, "Palliative radiotherapy did reduce the risk of bleeding and this is the first prospective study that we know of that has shown robust evidence of the impact of radiotherapy on tumour bleeding risk. This should however be reserved for the minority at highest risk of bleeding to minimize burden and optimize benefits."

Dr Anthony Byrne said, "Our study shows how important it is to include patients in the palliative phase of their illness - with advanced disease - in clinical trials: they are rarely the focus of large scale studies despite the importance of such results to their care and quality of life."



Infections, Inflammation and Immunity Division

PACE study into antibiotic use wins research paper of the year

A study into antibiotic use in collaboration with the University of Oxford and King's College London won research paper of the year. C-reactive Protein guided antibiotic prescribing for COPD exacerbations was published in the New England Journal of Medicine and won the overall prize for clinical research from the Royal College of General Practitioners.

The study, by researchers from Cardiff University's School of Medicine and Centre for Trials Research, found a simple finger-prick blood test could help to prevent unnecessary prescription of antibiotics in patients with chronic obstructive pulmonary disease (COPD).



More information and video here.



Professor Chris Butler said: "This rigorous clinical trial speaks directly to the pressing issues of preserving the usefulness of our existing antibiotics; the potential of stratified, personalised care; the importance of contextually-appropriate evidence about point-of-care testing in reducing unnecessary antibiotic use and enhancing the quality of care for people with the common condition of chronic obstructive pulmonary disease."



Professor Nick Francis said: "Governments, commissioners, clinicians, and patients living with COPD around the world are urgently seeking tools to help them know when it is safe to withhold antibiotics and focus on treating flare-ups with other treatments.

"This is a patient population that are often considered to be at high risk from not receiving antibiotics, but we were able to achieve a reduction in antibiotic use that is about twice the magnitude of that achieved by most other antimicrobial stewardship interventions, and demonstrate that this approach was safe."



SenITA

A randomised controlled trial of Sensory Integration Therapy versus usual care for sensory processing difficulties in children with autism.

Chief Investigators: Dr Rachel McNamara and Sue Delpont

Funder: NIHR Health Technology Assessment Programme

Autism is a common lifelong condition affecting 1 in 100 people and can affect how a person relates to others and the world around them. Difficulty responding to sensory information (noise, touch, movement, taste, sight) is common. These 'sensory processing difficulties' are associated with behaviour and socialisation problems, and affect education, relationships, and participation in daily life. Sensory Integration Therapy is an intensive, therapist delivered play-based occupational therapy intervention, and Occupational Therapists also work with families providing advice on strategies that can be implemented at home. Research suggests this type of therapy might be helpful for some children with autism.

We recruited 138 children (69 allocated at random i.e. by chance, to receive therapy and 69 to continue with their usual care) and assessed behaviour, daily functioning, socialisation, and parent/carer stress at 6 and 12 months using questionnaires.

We organised discussion groups for therapists and carers before approaching people to take part, so that we could map out what people normally receive as 'usual care'. We were also interested in carers' views of their experience in the study and of their child's sensory problems, and interviewed a sample of carers. We also interviewed therapists to get a sense of what intervention was actually provided to people in the study. We have assessed the cost of providing this type of treatment, compared to usual care. Parents and carers of children with autism and sensory processing difficulties were involved in planning and managing this research.

We have now completed data collection for this study, and are preparing the final report to the funder.

STUDY PROTOCOL

Open Access

The Early Positive Approaches to Support (E-PAtS) study: study protocol for a feasibility cluster randomised controlled trial of a group programme (E-PAtS) for family caregivers of young children with intellectual disability



Elinor Coulman¹, Richard Hastings^{2*}, Nick Gore^{3*}, David Gillespie¹, Rachel McNamara¹, Stavros Petrou⁴, Jeremy Segrott⁵, Jill Bradshaw³, Kerry Hood¹, Andrew Jahoda⁶, Geoff Lindsay², Fiona Lugg-Widger¹, Michael Robling¹, Jacqui Shurlock² and Vaso Totsika⁸

E-PAtS

Early Positive Approaches to Support for families of young children with intellectual disability.

Chief Investigators: Professor Richard Hastings, University of Warwick and Dr Nick Gore, Tizard Centre, University of Kent

Funder: NIHR Health Technology Assessment Programme

We developed a parenting programme for parents of young children (one and a half to five years of age) with an intellectual disability called Early Positive Approaches to Support (E-PAtS). In E-PAtS, groups of parents are given practical strategies over an 8 week period. These strategies help them to look after themselves and support them with their child's development. Following training, a parent of a child with disabilities and a professional co-deliver E-PAtS.

We recruited 74 parent carers of young children with intellectual disability to take part. They were assigned, by chance, to attend an E-PAtS group or to receive only their usual supports. All parents, whether they attended the E-PAtS group or not, were asked to complete some measures of things that might change during E-PAtS. The most important measure was changes in parents' psychological well-being.

This study was a feasibility study – we were checking whether the research worked well so that a much bigger study could be planned in future. Amongst other things we found out that parents were willing to take part in the research, attended most of the E-PAtS sessions, completed the research measures, and organisations who delivered parenting courses expressed an interest in taking part in a larger study.

We also interviewed parents, the facilitators (people delivering E-PAtS), and people from the organisations who delivered E-PAtS. People enjoyed being part of E-PAtS groups, and were positive about taking part. We are now ready to conduct a wider study.



You can read the study here.



Population Health Division

Two examples of population health research in the last 12 months show the latest output from one long-standing research programme and first outputs from a new study which is itself part of a longer collaboration between Professor Kate Brain (Cardiff University, Division of Population Medicine) and the Centre.

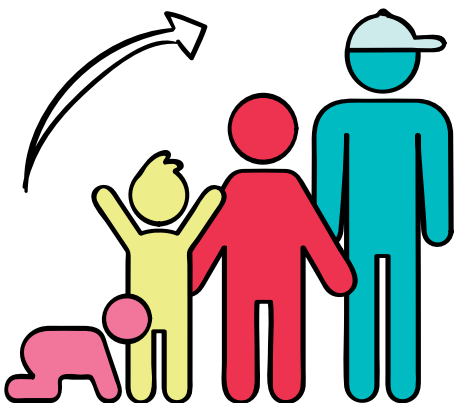
Building Blocks: 2-6

Chief Investigator: Professor Mike Robling

Funder: NIHR Health Technology Assessment Programme

In February, the NIHR Journals series published the results of the Building Block: 2-6 study which evaluated the longer-term impact of the specialist home-visiting programme, the Family Nurse Partnership (FNP).

Researchers in the Centre led by Mike Robling began studying the effects of FNP not long after it was introduced into the UK as a way of supporting teenage mothers expecting their first child. The Building Blocks trial started in 2008 and followed over 1600 families in England for about two and a half years. The research team have now followed the families recruited into the trial until children were assessed at Key Stage 1, at ages six to seven years old. Their report shows the impact of the programme on abuse and neglect, as well as child development outcomes. The study has benefitted from the on-going model of employment in the Centre enabled by core funding, providing continuity and the ability to develop and retain high-quality research staff.



CABS

Covid Health and help seeking behaviour study.

Chief Investigator: Professor Kate Brain

Funder: Economic and Social Research Council through UKRI's rapid response to COVID-19



CABS is measuring cancer attitudes and behaviours in adults aged 18+ across the UK. Funded by UKRI and working in close partnership

with Cancer Research UK, the study addresses concerns about the impact of Covid-19 upon the public's response to potential cancer symptoms. Seeking help early including responding to invitations to screening can allow treatments to start sooner and improve outcomes.

A first survey round involved over 8,000 respondents from across the UK, including a large number identified via HealthWise Wales. Early results reported in preprint form have already informed public health campaigns such as #GetChecked.Wales

Further results will continue to develop clear public health messages encouraging people to act on the early signs of cancer, take up cancer screening when it becomes available, and engage in healthy behaviours. The study also represents the shared ground between the Centre's Divisions of Population Health and Cancer, an area that both Divisional Directors are keen to further develop in future studies.



TRUFFLE 2

A trial looking at the difference in neurodevelopmental outcomes at 2 years old of babies who show signs of poor health between 32 and 36 weeks of pregnancy.

Chief Investigator: Professor Christoph Lees, Imperial College London

Funder: National Institute for Health Research Health Technology Assessment Programme

In the last months of pregnancy, babies who are smaller or who grow more slowly than expected are at higher risk of dying in the mother's womb. Some of these smaller babies who survive may have developmental problems later in infancy. Doctors have many ways to monitor such babies in the womb but, until the baby is born, the only treatment available is to deliver the baby. If the pregnancy has reached its full term, induction of labour is the usual option. If the baby is preterm (before 37 weeks of pregnancy) the right course of action is less clear. Delivering the baby early, as soon as there are signs of problems, will minimise any damage due to lack of oxygen in the womb, but the baby may suffer harm as a result of being born prematurely. This study is looking at the balance of risks linked with continuing the pregnancy a little longer or delivering the baby early.



Despite the Covid-19 pandemic, the trial opened to recruitment in October 2020. The Centre for Trials Research have played a pivotal role in co-

ordinating this trial, with support from data and trial management, statistics and administrative teams. To date we have opened 37 sites across Europe (9 in the UK), recruited 364 women, of whom 44 have been randomised. The funder recently commended the trial team on this achievement.

WORK PACKAGE 5:

Ensuring methodological and professional development

Developing new ways to answer important clinical questions and sustaining a dynamic and professional workforce



Methodology

Methodology is about how we do the research rather than the outcome of the research. Our areas of methodological interests can be split into five main areas:

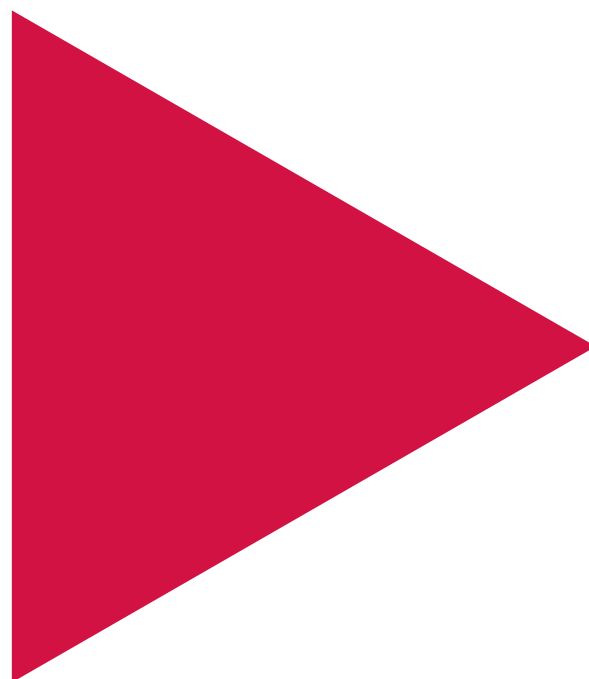
1. Outcome development and measurement
2. Trial conduct
3. Novel trial design and analysis
4. Implementation
5. Routine data

Improvements in methodology can bring direct benefits to our portfolio of trials at CTR. Work within outcome development can ensure best practice for which outcomes to measures and working closely with trial participants to ensure the acceptability and feasibility of the outcome measurements. Trial conduct helps to understand the trial participant experience of the trial and a deeper understanding of how to take consent in challenging populations. Novel trial designs have allowed trials to be more flexible by reviewing the accumulating trial to make decisions to stop the trial early or to add in additional treatment arms. Implementation helps with the assessment of fidelity and adherence of our trials and the understanding of contextual variation. Finally, the use of routine data alongside traditional data collection can lead to great efficiency gains and less research waste.

MELD-ATG trial in type 1 diabetes

People living with type 1 diabetes (T1D) have abnormal blood sugars which is usually controlled by a hormone called insulin. A previous study has shown that a medicine called Anti-thymocyte globulin (ATG) at a 2.5 mg/kg dose helps the treatment of people aged 12-45 who have just been diagnosed with T1D. Our trial called MELD-ATG (minimal effective low dose-ATG) wants to investigate whether ATG can be given to younger participants and at lower doses, to prevent any side effects or toxicities. The design needed to be novel and adaptive during the trial using the accumulating data. We randomise cohorts of participants to several different doses or placebo, then evaluate the results at the end of each cohort.

The evaluation of the results by the dose determining committee indicates which doses will be used in subsequent cohorts: either 2.5mg, placebo or a middle dose that is looking most promising. Our primary objective is to check whether 2.5mg of ATG works in a European population and in participants as young as 5 years old but also to investigate whether a lower dose is good at controlling C-peptide, which is a biomarker of insulin. This trial has experts from our novel trial methodologists help create a robust design that can work in practice.



Professional development

Dr Julia Townson

Julia realised her ambition of achieving a PhD in the summer of 2020, following over 20 years of working in clinical trials at Cardiff University (CU) and after joining the Centre for Trials Research in 2009. Julia had wanted to pursue a PhD after completing her undergraduate degree as a mature student, but with three young children to support this was not possible. The support and guidance she received from her colleagues at CTR and CU was fundamental, and allowed her to work towards making her submission for her PhD by published works.



She found one of the advantages of pursuing a PhD in this way, was that it enabled her to continue to build her reputation in this area, making successful applications for funding, which in turn led to her promotion to Senior Research Fellow in 2020. She was awarded her first grant as a Chief Investigator in 2015, from the Novo Nordisk UK Research Foundation, to conduct a study using routinely collected data, to evaluate the prodrome to diagnosis of type 1 diabetes in childhood in primary care.



Julia supports and collaborates with external Chief Investigators, with the aim of securing successful funding applications, whilst undertaking the role of CTR study lead. Recently this has led to the successful funding of two high profile studies, during the coronavirus pandemic. Both were funded under the UKRI rapid funding call, the first was to create a global registry of women with suspected Covid-19 or confirmed SARS-CoV-2 in pregnancy (PAN-Covid). This study has found Covid-19 infection in pregnancy is not associated with stillbirth or early neonatal death.

The second is a Covid health and help seeking study (CABs) to investigate potential cancer symptoms individual's may have experienced during the lockdown period and evaluate if this affected their help-seeking behaviour. Both studies have reported early findings leading to media interest.

Dr Claire Nollett

Claire began her career as a mental health researcher, before training as a Psychological Wellbeing Practitioner in the NHS. She joined the Centre for Trials Research, following a period of 3 years researching in the School of Optometry, Cardiff University in 2014. CTR colleagues were supportive of her ambition to pursue a PhD by published works.

To achieve this, she needed to author around six published papers on a single theme. She already had three good quality publications from her previous research position and was supported by the CTR to produce three more. A CTR statistician worked with her to conduct secondary data analysis from her depression and sight loss study, and she was encouraged to apply for grant funding to develop a new, associated research study. The study sought to understand whether optometrists attempt to identify and manage depression in their low vision patients, and the barriers to them doing so in practice. This additional study helped her to complete the required work for a PhD. Her findings have been recognised by the College of Optometrists, who invited her to provide training on depression screening and referral for its members, and are currently considering how to incorporate depression management into their guidelines.

She submitted her thesis entitled 'Improving the recognition and management of depressive symptoms in individuals with low vision' in January 2021, nine years after her research in this topic first began.





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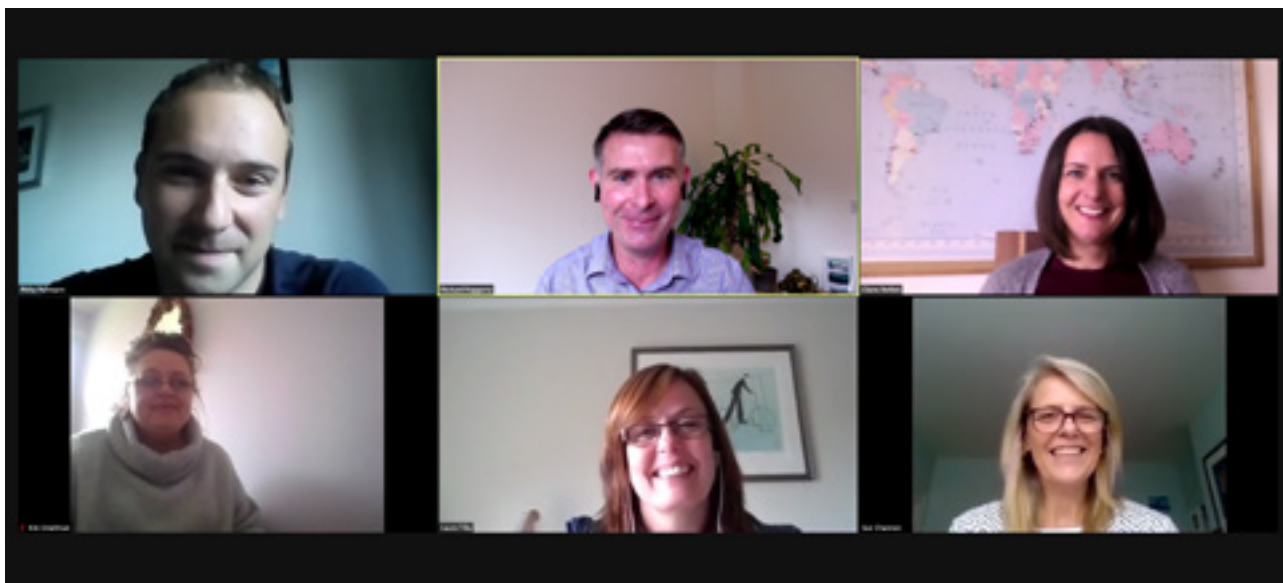
Health and Care
Research Wales



WORK PACKAGE 6: RDCS and NHS

Supporting 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





Supporting 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.

RDCS and Covid-19



The pandemic changed the work of the RDCS over the last year: With every practitioner focusing on dealing with the crisis, there were far fewer traditional requests for support with funding applications in the first half of the year. The RDCS team therefore adapted the service to offer methodological support to our NHS partners, helping practitioners to develop evaluations of their service responses to the crisis, often at great speed, to capture the impact of the work that they were doing. We also supported academic colleagues, normally not eligible for RDCS support, in developing urgent Covid-related research and applying for funding. In total there were 14 of these Covid-19 projects which involved activities ranging from development of ideas, collection and analyses of data, to design and UKRI applications. One example of this was Kim Smallman's work with a team in Cwm Taf Morgannwg Health Board on the use of virtual reality to support mental health.

In amongst the Covid-related activity there was also some RDCS "business as usual", supporting clients to develop funding applications and building research capacity.

One of the teams we have been supporting across a portfolio of work has been the Vascular Surgery team in Aneurin Bevan University Health Board, working to improve the care of people with lower limb amputation. The lead for this project, Dave Bosanquet, has described the impact of RDCS involvement over several years on the development of the research in a case study included in this report.



The Research Design and Conduct Service (RDCS)



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.



70

requests for support



16

submissions



Clients from

8

NHS organisations plus social care



Funding

£595,997



3

successful submissions





Going online with events



In usual times, we hold three workshops across the year aimed at helping clients to understand the funding landscape and to prepare them for applying for research grants. Soon after Covid-19 hit, we were forced to cancel our first face-to-face workshop of the year and adapted by taking our workshops online. Our first two online workshops were to support practitioners applying for funding in the autumn. We ran one session for social care staff applying for the Health and Care Research Wales Social Care Fellowship and one for those applying for health-related funding.

We have also taken the opportunity that Covid presented to hear from our clients and refresh our programme of events for 2021, in line with their requirements. We circulated a survey to find out what type of support would be helpful in this new landscape. They have given us feedback on the types of funding calls they are interested in applying for and the range of topics they want us to cover. The move online comes with a change in preference for format, moving to shorter, 1-2 hour sessions on specific topics and funding calls with space for discussion. This bite-size approach reflects the move to something that practitioners can fit in with the rest of their day and we will be implementing this for all our 2021 events.

RDCS and CTR Chief Investigator project

An important part of our remit is to try and increase research capacity, including supporting NHS and social care researchers who are new to the role of being the lead researcher, a role described as Chief Investigator (CI). It can be a big step up from being part of a research team to leading the study and so we wanted to find out what new CIs need.

So far in this CI project we have scoped current resources e.g. websites and training as well as guidelines and academic papers to identify key components, and surveyed CTU and NHS research office staff in Wales to capture their views on the needs of new CIs. Our next steps will be to interview CIs with a range of experience, including those who work with CTR, but also those who have not worked with a trials unit to make sure we get a breadth of opinion and experience. When we have synthesised this information, we will be working with CTR colleagues to put together a training and support package proposal based on findings.

Case Studies

NHS staff tackling Covid-19 try out virtual reality to help reduce stress and anxiety



NHS staff tackling Covid-19 on the front line have, for the first time, used virtual reality to help support their mental health and wellbeing. Twenty-one staff working in intensive care units at the Royal Glamorgan and Prince Charles hospitals had access to a single-use VR headset for two weeks to evaluate if it was a useful aid to help with stress and anxiety.

Researchers from Centre for Trials Research, who worked with Cwm Taf Morgannwg University Health Board and Rescape Innovation, which uses VR to support patient recovery and rehabilitation, said the response had been positive - but a wider scale study was needed.

Lead author Dr Kim Smallman, Research Design and Conduct Service Consultant and Research Associate in the CTR, said: “The impact on the mental health and wellbeing of frontline healthcare workers - and the need to provide emotional support for those working in such exceptional and distressing circumstances - became clear very

early on in the pandemic. We decided to evaluate use of virtual reality to see if this could be a useful aid for staff and the results have been remarkably positive. Staff using VR said they found the experience to be enjoyable and relaxing and they found it helpful in reducing feelings of stress and anxiety.”

Evaluation co-author Dr Michelle Smalley, a clinical psychologist working in intensive care at the Royal Glamorgan and Prince Charles hospitals, said: “Being a clinical psychologist in unprecedented times has called for unprecedented measures to help support staff.

“From the moment I tried these headsets out myself, I realised their potential for helping with anxiety and stress - but we have to be evidence based in our approach. The results from this service evaluation are an important step in identifying an effective and user-friendly self-help tool for wellbeing.”



Developing research ideas

Dave Bosanquet is a Consultant Vascular Surgeon and Honorary Senior Lecturer working in Aneurin Bevan University Health Board.

Background

I have to go back to 2015 for my first interaction with the Research Design and Conduct Service (RDCS) South East Wales. Prior to this I had completed an MD in the basic sciences of wound healing, and had some experience with grant applications, but had no prior experience of running up an idea from scratch and applying for competitive funding.

I was a registrar at the time, and a research-active consultant and I had discussed the possibility of looking at evaluating a technique for reducing pain after major lower limb amputation – a tiny tube (catheter) placed next to the cut end of the major nerve at the time of surgery, with a continuous infusion of local anaesthetic via it for 5 days postoperatively.

Difference in practice

The impetus was in part driven by the difference in practice seen in different hospitals in Wales. We looked into the current data available and found only poor quality data on which to derive practice – so it was unsurprising to see different approaches in different units. However pain relief around the time of amputation is crucial; it is an important point determining how well people recover from surgery and it may influence how much people suffer with long standing phantom limb pain.

Initial contact

I initially contacted the Centre for Trials Research at Cardiff University, who pointed me in the direction of their RDCS team: a team of statisticians, qualitative researchers and experienced trial managers embedded within the registered clinical trials unit: they have access to over 160 professionals within the Centre for Trials Research.

Appointment

I arranged an appointment and went, data in hand, unsure as to what to expect. My first meeting presented the rationale, our background systematic review, and a broad proposal for an

evaluation. The consultant was excellent in every respect, and immediately was able to provide broad strokes suggestions.

Research meetings

We rapidly started convening research meetings, with RDCS members, the surgical team, patient representatives and other experts. An amputation charity (Douglas Bader Foundation) supported us with seedcorn funding, which was helpful in demonstrating to people that this was viewed as important in the amputation community.

Developing research idea

The RDCS were able to put flesh on the bones of the research idea, and to bring it to a stage where we were able to submit to CTU for adoption to their portfolio. This was a key step as it unlocks their support for the work up to a competitive funding bid. I was delighted when they adopted us.

We applied to the Research for Patient and Public Benefit grant, awarded by Health and Care Research Wales. RDCS and CTR worked in tandem and together we put in an application. We were successful in funding, and launched the feasibility trial (called PLACEMENT) in 2018. We recruited our target of patients ahead of time, and published our results in 2019.

Benefit of consultant support

Research is hugely rewarding, and given the relative lack of high quality research in the area of amputation, I believe that answering the kind of questions posed by PLACEMENT has the potential to dramatically improve outcomes for patients undergoing amputation. However it comes with challenges. Possibly the greatest is the binary outcome of funding applications. So much can hinge on the outcomes of these bids, and the difference in workload between a positive and negative outcome can be very large. Such uncertainty makes planning ahead challenging, which is why having a dedicated and experienced team like the RDCS to consult with - based in a registered clinical trials unit - is invaluable.

Conclusion

As a Centre, we have been at the forefront of the Covid-19 vaccine response and are incredibly proud of the way in which all our staff have adapted to the new ways of working imposed on us by a global pandemic.

Despite all the challenges, our research has gone from strength to strength and our capacity for All Wales, UK and international working has expanded. As highlighted in this report, we have actively engaged in developing Covid funded studies, opened several major studies and a range of ongoing studies have reported results. We have also continued to increase the numbers of postgraduate research students and fellows working alongside our trials and studies.

Our green initiatives which align with our goal of efficiency in research are now fully embedded. Our PI&E hub has grown in size and influence and our focus on engagement is now extending to inclusivity in research.

We hope that you have enjoyed reading about some of our successes and innovations and the wide range of activities that our researchers and investigators have been involved in over the very challenging last 12 months.



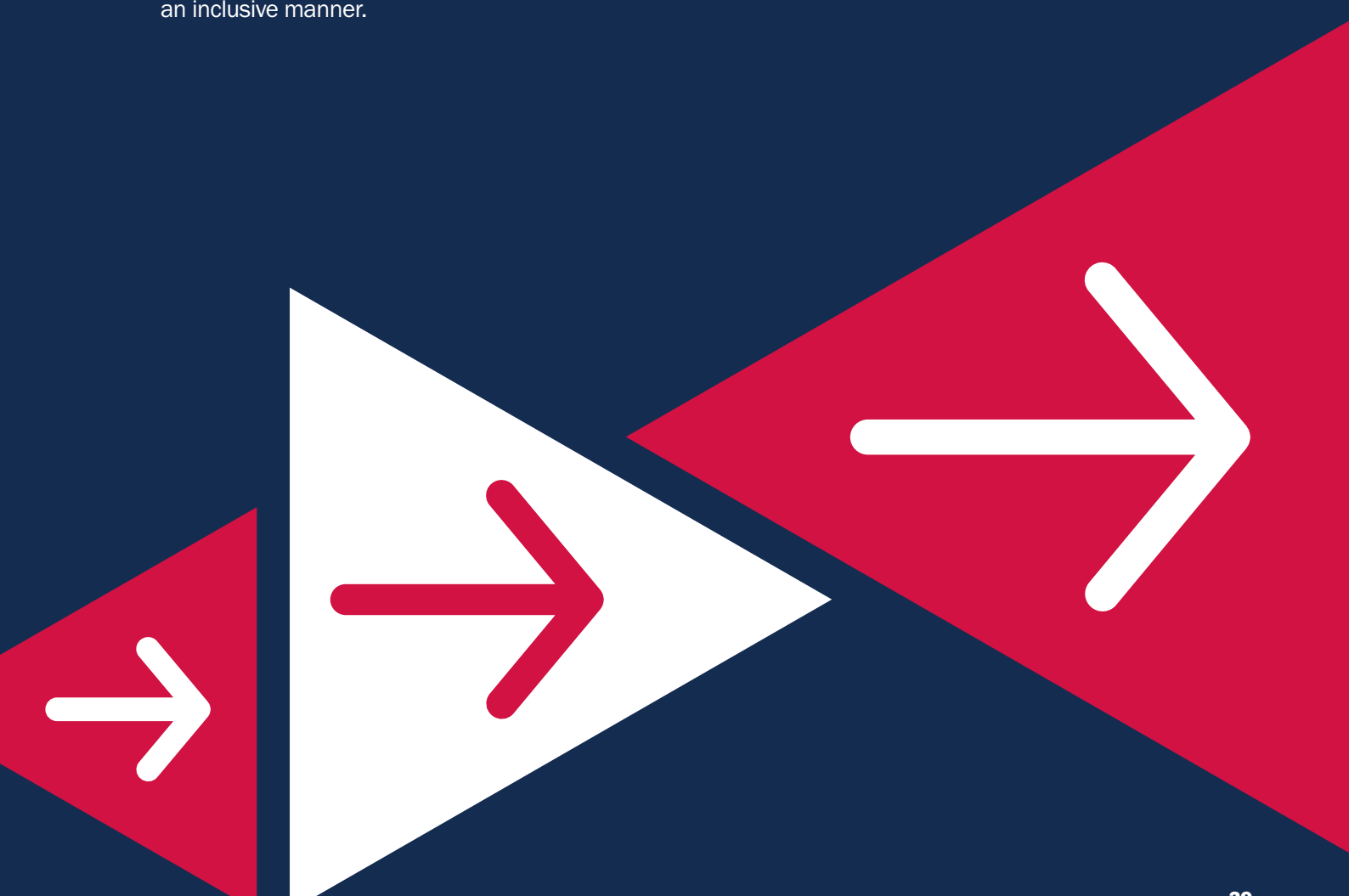
Looking forward

The local and global events of last year underline the difficulty of looking forward with absolute certainty. However, our long-term goals have only been re-enforced by the experience and demand placed on society by the pandemic. In some cases, pace against our targets has increased either out of necessity or opportunity. We expect to see similar rapid progress in key operational areas such as increased efficiency in running trials, even greater use of administrative data and meeting our own goals for green working.

As a trials unit, we expect to play a critical role in working with investigators in supporting post-pandemic recovery for Wales, the UK and internationally. The volume and quality of new study adoption requests we have supported in the last 12 months is an indication of our emerging work programme for the next few years. While there will be some focus on pandemic recovery, we equally need to support the enduring health and social care needs of the Welsh public, and for both to do so in an inclusive manner.

Moving to a post pandemic working model is likely to blend the benefits of both office and remote working. In the last year we have created new collaborations with investigators across the clinical research infrastructure in Wales and beyond. We intend for this to continue. Remote working has enabled public involvement and engagement with members of the public who may not have been able to engage previously. Looking forward a creative blended model of working may serve the needs of a broader spectrum of the public and enhance our ambitions for inclusive research.

In a period of demanding economic and social conditions, our role as a trials unit is to maximise the value of the research and public investment to the Centre to provide sustained benefit to the people of Wales. If certainty about the future may feel a little harder these days, our confidence in our staff and collaborators to deliver against our ambitious research agenda has grown through our experiences over the last year.



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 Research Partners who give their time to take part in study management groups, steering committees, and are both involved in delivering 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.

Particular thanks go this year to our amazing staff and students who have managed to keep an extensive portfolio of research running, re-engineering processes to minimise burden on the NHS and delivering essential COVID research rapidly whilst working from home, looking after their families and surviving the uncertainties of the last year.

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



Sue Campbell



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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