It has been another busy, successful year for NWORTH. Having undergone major transitions over the past 12 months, we are proud to have continued to deliver our projects to time and target.

Nationally, the research reset agenda has been moving forward looking to reduce the pressure on research delivery within the NHS. The capacity of the NHS to support and deliver research has been impacted by the elective backlogs, workforce pressures and the need to complete ongoing COVID-19 research. Fortunately, projects on the NWORTH portfolio have not been substantially affected under this research reset programme but it has emphasised the need to ensure our research teams are attentive to the requirements and needs around them and their studies.

We’ve begun to emerge from the cloud of the pandemic with new focus and ability to drive work forwards. We’ve achieved recruitment in some really difficult sectors such as care homes and continued to ensure underrepresented populations have been incorporated into research, this is expanded upon later in the report.

Face to face engagements have begun again with the first face to face meeting of PARC-Bangor in 3 years and a visit to 1st Glan Conwy Brownies on International Women’s Day. We will be reinvigorating our public and patient involvement and engagement over the next 12 months and are excited to see what the future holds for this vital research element.

We are delighted to have welcomed new members of staff, as well as promoting staff from within. We also look forward to welcoming more new members to the team in the coming months.

I have now been in post as Interim Director for just over a year and I am incredibly proud of the commitment and dedication of the teamwork demonstrated across NWORTH this year. Our success is largely due to the huge effort of this team.

Dr Zoë Hoare
NWORTH interim Director
NWORTH’S AIMS AND MISSION

This report highlights our successes and achievements during 2022-2023 and revisits the aims and objectives that we set out to achieve over this funding period. NWORTH’s mission is to conduct clinical trials and studies of complex interventions of the highest quality, delivering research and impact for Wales and beyond, as well as advancing methodological developments in clinical trials research.

The Unit’s overarching aim is to make a difference to people’s health across Wales and beyond and align to key Welsh policy principles. In addition, we seek to contribute to methodological developments to understand local research priorities, promote Patient and Public Involvement (PPI) and Engagement in North Wales and the delivery of trials in rural and isolated communities.

We identified an ambitious programme of work for the period of 2020 – 2023 which was driven by five key work streams:

1. Collaboration Development - where we seek to maintain our consistently high success rate whilst also increasing grant activity and grant capture in Wales. Further details on our portfolio development and grant capture activity can be found below.

2. Trial Oversight and Delivery - where we will maintain the high standards of quality, timeliness, and governance of all our deliverables and outputs.

3. Professional and methodological development - where we are focusing on methodological approaches to stakeholder engagement and building research capacity in North Wales.

4. Patient and Public Involvement and Engagement – this is central to everything we do at NWORTH and is embedded in all our activities. We plan to expand our public involvement and engagement group, Population Advice for Research Committee, (PARC-Bangor) with special emphasis on diversity.

5. Research through the medium of Welsh – we will continue our work to increase greater awareness and access to research opportunities through the medium of Welsh and the “active offer” of this.

Through these work packages, we aimed to increase the level of Welsh-led activity at the Unit and build local research capacity to foster a healthy research environment across North Wales.

We sought to understand the local research environment and the barriers that many healthcare professionals experience in starting out on their research journey.

Only by understanding these local issues would we be able to address them and take the steps required to foster research development and growth.
NWORTH ORGANOGRAM FOR REPORTING YEAR 2022-2023

Interim Director:
Dr Zoe Hoare
(0.5fte)

CTU Manager:
Dr Kirstie Pye
(0.8fte)

Community of Scholars Facilitator:
Dr Karolina Rusiak
(0.5fte)

Principal Statistician:
Dr. Zoe Hoare
(0.5fte)

Senior Statistician & RDCS Lead:
Rachel Evans
(1.0fte)

Trial Statisticians:
Dr. Andrew Brand
(1.0fte)
Dr. Nia Goulden
(1.0fte)

Trial Development RPSO:
Dr Karolina Rusiak
(0.5fte)

Senior Software Engineer:
TBC
(1.0fte)

Trials IT Specialist:
Tom Goff
(1.0fte)

Trial Delivery Facilitator, Research:
TBA
(1.0fte)

Trial Manager:
Alison Jenkins
(1.0fte)

Trial Manager:
Greg Flynn
(1.0fte)

Trial Manager:
Appointed – Not Started
(1.0fte)

Trial Manager:
Appointed – Not Started
(1.0fte)

Process Evaluation Facilitator:
Dr Annie Hendry
(0.6fte)

断裂

QA Officer:
Appointed – Not Started
(1.0fte)

QA Officer:
Appointed – Not Started
(1.0fte)

Director of Trials IT Specialist:
Tom Goff
(1.0fte)

Trial Development Facilitator, Research (1.0fte):
Hayley Mansfield-Jones

Co-Applicants:
(all within Bangor University):
Welsh Language Lead: Beryl Cooledge
Ageing & Dementia Lead: Prof Gill Windle

Key:
- Bangor University Institutional Funding
- H&CRW Core Funding
- Project Funding
- Mixed Funding
NWORTH has a current staff of 13.4FTE who are delivering a portfolio of 14 active studies (with a further 4 studies awaiting contracts, 1 study in submission and 4 in development). A further 2 FTE will be starting in April 2023 and 5 FTE will be going out to recruitment.
Staffing is divided into the essential functions required for UKCRC registration: Statistics, Trial Management, Quality Assurance, IT and Management/Support functions.

NWORTH’s Executive plays a key role in the strategic oversight of the Unit and on-going governance. The Executive draws on key trialists and important stakeholders from the local research infrastructure along with a dedicated representative for PPI.

The Unit is located within a broader University structure that is embedded in its local community, with an over-arching research strategy and a developing clinical-academic programme linked to aspirations of developing a medical school.

We were pleased to welcome one new member of staff to the unit in this period and a further three appointments have been made to start in the next reporting period. In March, Tom Goff joined the IT function as a Clinical Trials Data Systems Officer. We are delighted Tom has joined the unit and in the first few weeks has impressed with his enthusiasm for the role and just wanting to get stuck in.

We have also had the pleasure of Dr Kirstie Pye, our QA Officer moving roles into the CTU Manager position. Kirstie brings with her a wealth of knowledge around the processes and procedures of NWORTH and regulatory compliance, which will help a smooth transition into the role.

During this year we have also said goodbye to staff. From our IT team Lexi Bastable moved to a position within digital services at central IT. Lexi has been part of our NWORTH team since 2013 and contributed greatly to the processes for development of MACRO data collection systems within the unit.

Dr Hana Pavlickova, trial manager for TOGETHER moved on to a more clinical role within the local health board. The TOGETHER trial had just achieved its recruitment target and moved into follow up and Hana ably supported this trial through these initial stages. We wish these staff members well in their new posts and positions.

Further recruitment is underway to further strengthen and bolster our team, particularly within the IT group.

**New Staff**

**Tom Goff** joined us in March 2023 as a Clinical Trials Data Systems Officer and has been eager to get into his role.

Tom completed his degree at Bangor University in Ocean Sciences, particularly enjoying the data and analysis aspects he is looking forward to using his skills in a practical way here at NWORTH. Here is what Tom had to say about joining NWORTH:

“I hope to develop my current skills to a higher standard and implement new software systems such as REDCap so they may be more effective to NWORTH.”

“I hope to continue to consistently give my support to the team and towards any projects I may be working on in the future.”
**HIGHLIGHTS:**

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**Collaboration Development**

During 2022-2023 we submitted 5 funding applications and added 3 new studies to our portfolio – with a total grant value of £3.74M.

We currently have 14 active studies on our portfolio with a total grant value of £23.55M. We have an active pipeline of 4 studies in development with another 1 study currently in submission. These studies are with both repeat and new collaborators who have approached us on recommendation.

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**Trial Oversight and Delivery**

Over this period NWORTH studies recruited 2697 participants with 61 (0.02%) of those being participants recruited from Wales.

Several studies were in recruitment for longer periods than expected and have now come to an end. It has been refreshing to see our study teams’ perseverance rewarded with sample size targets being achieved for a majority of trials in this period.

The quality and rigour of our internal processes and regulatory compliance have been maintained at a high standard again this year. Our robust internal processes and procedures ensure we can provide quality support and service provision to our studies.

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**Professional Development**

NWORTH staff members are now able to work flexibly between office and home as the demand and need warrants. Staff have reported this has enabled a better work life balance and increased productivity.

Continuous development of our quality processes requires staff to undertake ongoing training on all these processes particularly when they are reviewed and updated.

On the 11th August 2022, NWORTH had our first face to face staff team development meeting since before the pandemic. This meeting enabled the whole team to get together to have an update on the current and prospective portfolio, discuss the changes in NWORTH and engage in some team development activities to discuss the future possibilities for NWORTH. The afternoon was a huge success, with high levels of engagement and very useful suggestions from the team regarding future directions.

In November 2022, we appointed Dr Kirstie Pye as our new CTU Manager. Kirstie originally joined the NWORTH team in 2014 as a research officer. Kirstie gives a description of her career development and working within NWORTH.
From RO to CTU manager via QA

I joined the NWORTH team as a Research Officer in 2014 on a 12-month fixed-term contract, with no guarantee of an extended contract.

Fast forward 9 years and I am still at NWORTH, having worked in a variety of roles including trial management, data management, quality assurance and now as the Clinical Trials Unit manager. In my new role, I am responsible for the overall management and day-to-day operations as well as providing input to the strategic vision of the unit. The team approach at NWORTH is what makes us unique. There is an abundance of support, on a professional and personal level, and opportunities are plentiful. I am excited about my new path ahead in contributing to the future of NWORTH.
Patient, Public and Stakeholder Involvement and Engagement

NWORTH has been engaging with the newly developed North Wales Clinical Research Facility (NWCRF), northwalescrf.com, within Betsi Cadwaladar University Health Board (BCUHB).

Led by Dr. Orod Osanlou who was instrumental in the BCUHB involvement in the COVID vaccination clinical trials, the facility specialises in the delivery of early phase trials using experimental medicines. NWORTH and NWCRF are currently investigating ways in which we can support each other’s ambitions within the North Wales region.

Interim Director and Principal Statistician Dr Zoë Hoare was invited to 1st Glan Conwy Brownies to give a talk about her role within a CTU as part of International Women’s Day and the launch of the new girlguiding mission – ‘Girls can do anything’. Zoë was joined by a lady who had served as a helicopter mechanic in the WRENS in 1972 and a lady who made felt hats in a male dominated factory.

After describing her day-to-day role the brownies chose to investigate the ‘Avengers with Smelly feet’ clinical trial to gain a better understanding of clinical trials and how we do what we do. The girls really took to the task and enjoyed understanding the basic concepts of clinical trials and deciding that Avengers just need to wash their feet more often!
PARC-BANGOR

Population Advice for Research Committee, (PARC-Bangor) is our public involvement and engagement group.

Members are instrumental in reviewing and inputting to our studies in development. They use their experience as patients, service users, carers, or family members to feedback on research priorities, research design, funding applications, and study documentation. Members also contribute to study committees and management groups. PARC-Bangor has maintained membership at a total of 24, who come from all corners of North Wales. One third are Welsh speakers.

A hybrid meeting of the PARC-Bangor group was held on 14th September 2022 at the request of the PARC-Bangor group. Dr Zoë Hoare welcomed the group and updated them on activities at NWORTH since the last meeting.

We were joined by Greg Flynn, Trial manager of the iSupport trial, who spoke about the trial, PPI input and the recruitment process so far. Rebecca Burns and Emma Langley joined the group to discuss updates from Health and Care Research Wales.

Our final speaker was Karen Shepherd, member of PARC-Bangor who also sits on the NWORTH executive committee who gave a talk about attending a workshop around updating and improving guidance on the National Standards for PPI and patient information sheets. The afternoon was a success, ending with a useful group discussion of future directions for the PARC-Bangor group.

The national standards continue to guide all our PPI work. We consistently strive to offer inclusive opportunities and ensure that all our members can contribute in Welsh or English. We time our meetings to allow maximum attendance and are cognisant of the working, family, and caring commitments of members. We value all contributions and meetings encourage respectful debate that arrives at a consensus. We have a member of PARC-Bangor sitting on our Executive Committee and all our key strategic documentation and decisions are therefore reviewed by a public member.

Studies that have been added to NWORTHs portfolio are presented and discussed at the PARC-Bangor meetings ensuring engagement with the ongoing portfolio at NWORTH. There is an expectation that locally led studies will engage with PARC-Bangor to ensure they benefit from the valuable contribution the PPI representatives can make to not only the ongoing research portfolio but additionally now to the methodological work that NWORTH is delivering. The outputs from the research work streams are positively accentuated by the involvement of the voices of experience from our PARC-Bangor group.

nworth-ctu.bangor.ac.uk
RECRUITMENT

Care home recruitment

Care homes were hit particularly hard during the COVID pandemic and are still in the process of recovering. There are currently two dental studies set within care homes on the NWORTH portfolio, both of which were due to start recruiting prior to the lockdowns being enforced.

For both studies this meant pausing activity for a prolonged period and emerging onto a different landscape for research within care home settings. Care home populations are vulnerable and often difficult to reach and therefore often underserved by the research community.

Given the impact of the pandemic on care homes it would have been easy to identify these studies as too difficult to maintain but the two research teams supported by NWORTH were determined to see this through. Each study encountered different barriers but have now managed to navigate this new landscape and successfully recruit within the care home setting.

TOPIC Trial

Chief Investigator Prof Georgios Tsakos, University College London. Funded by National Institute Health Research Public (NIHR) Health Research (PHR) programme.

The ageing population is increasing in number, currently, half of all residents enter care homes with some of their own natural teeth and this proportion is likely to increase. Preventing dental disease for care homes residents is important for their function and quality of life. Good oral health affects the ability to eat and communicate, appearance and self-esteem through, for example, the willingness to smile. It also reduces the need to provide treatment in care homes, which is often difficult and costly. A national survey found that current prevention practices and services in care homes are poor. There are also large gaps in the scientific literature about how best to prevent oral disease among care home residents. This study aims to assess the feasibility of an intervention to improve the oral health of older people (defined as those who are 65 or older) in care homes, based on the NICE guidelines.

The TOPIC trial is a pragmatic study to determine the feasibility of a multi-centre cluster randomised controlled trial of a complex intervention based on a recent NICE guideline for the oral health of older people in care homes. This study is being run in 24 care homes within North London and Northern Ireland and 120 residents from the care homes will be recruited.

Care homes were randomly divided into two groups: intervention and control. The intervention consists of an oral health assessment of residents, daily “support worker assisted” tooth brushing with fluoride toothpaste, and a staff training package on how to improve oral health. Trained dentists collected clinical information at the start of the study. Other data will be collected via questionnaires administered by researchers. After 12 months, the health of the residents’ mouths will be re-assessed, and the questionnaires administered again, and findings will be compared to those at the start of the study. Residents, managers, and staff will be interviewed to assess the acceptability of the proposed intervention.

The trial was initially due to start in December 2018 and end in May 2022. With recruitment of care homes due to take place between May and November 2019, and the recruitment of residents between October and December 2019.

Unfortunately, the study was delayed due to several issues. The major issue was COVID-19 when everything had just ceased. The researchers on the trial changed roles and moved to different projects. Care homes were having similar problems, such as staff shortage due to Brexit, there were also staff shortages due to staff falling sick with COVID-19 or the staff leaving the stressful care home environment.
It was also during that time; the care home management were cautious of COVID outbreaks. After organising visits, the research team had to return several times from the care home sites without recruiting or screening any residents because they had outbreaks. Another issue was organising the visits. Previously, the research team relied on emails but the care home staff don’t always respond to them.

Another issue was the strict eligibility criteria and being unable to recruit participants lacking capacity and people who did not speak English. In Northern Ireland there were few care homes who had initially said yes after discussing the study with the community dental services. However, they later dropped out when they realised there was too much to do, as they were expecting something less. Moreover, in Northern Ireland, the distance to different care homes who were interested was also an issue as they were spread over a wide area, and it was difficult to manage time as travelling time took a considerable toll.

Despite all of this, recruitment for the study began in December 2021. At present, 22 care homes have been recruited. Of the 22 care homes, 11 are from London and 11 are from Northern Ireland.

Recruitment was able to open in London in December 2021 and opened in Northern Ireland in March 2022. Recruitment was due to be completed in April 2022, but due to issues was completed in October 2022. The target recruitment was 120 residents from at most 24 care homes.

The recruitment is currently at 119 residents from 21 care homes. Data collection was due to end in May 2023, with the study due to end July 2023. A request for an extension is being submitted, for data collection to continue until October 2023 and the trial to end January 2024. Despite operating this trial in an incredibly difficult context with lots of unexpected barriers, the team have secured a robust sample that will provide plenty of information for the development of the next phases of this research when it comes to analysis towards the end of 2023.
SENIOR Trial

Chief Investigator Prof. Paul Brocklehurst, Bangor University. Funded by NIHR Health Services and Delivery (HS&DR) programme

Poor oral health for older adults residing in care homes is a significant public health problem. Unlike previous generations, about half of all care home residents now have some of their own natural teeth, but their oral health is much worse than their community living peers. This can give rise to significant avoidable health and social care costs. Despite this, dental service provision in care homes is poor and extremely variable.

The aim of the SENIOR study is to undertake a cluster-randomised controlled trial to determine whether Dental Care Professionals (DCPs) could reduce plaque levels (improve the oral cleanliness) of older adults (over 65 years of age) residing in care homes over a 6-month period, when compared to ‘treatment as usual’ (commonly a reactive and ad hoc service provided by dentists). In addition, the researchers aim to determine whether this effect is sustainable over a further 6-month follow-up period. The study will be conducted in 40 care homes in Wales, England, and Northern Ireland.

They will be randomised (via NWORTH CTU) based on a 1:1 ratio (20 intervention and 20 control). From these care homes, 280 residents will be recruited. The SENIOR trial has faced similar issues as in the TOPIC trial. COVID-19 was a major issue as the care homes stopped all visits to the care home and to residents for their safety. There was a lot of staff shortages due to Brexit and also staff falling sick with COVID-19 or the staff leaving the stressful care home environment. We performed weekly remote training sessions for the care homes from April 2022 to January 2023 via Zoom, and for any care home that wanted to participate we held a remote one-to-one training session either via Teams or Zoom. Attempting to contact the care home managers was extremely difficult; the majority of managers were doing a number of roles, including assisting with the cooking in the kitchen, on the ward looking after the residents or even in the sluice room. We therefore had to rearrange a number of remote trainings on several occasions. Consent for the majority of the care homes was taken remotely.

We have been working closely with the care home managers as they are still being cautious of COVID outbreaks and arranging visits to recruit residents has been a slow process. Another issue we have faced is that a lot of the residents in the care homes lack capacity, we are therefore in the process of amending the trial documentation to include these participants as we want to be as pragmatic as possible. These issues have been faced by all three sites. The trial was due to finish in December 2023, this had been extended to June 2024, a request for a further 6-month extension is being submitted due to the recruitment delays. Recruitment of care homes was due to end in June 2022, however, this was extended to March 2023.

Despite all of the issues encountered, the research team have persevered, and have now recruited 43 care homes in total, with one care home withdrawing as they wanted to participate in the Gwên am Byth programme. Recruitment of 280 residents was due to be completed by August 2022 this has been extended to September 2023, currently 85 residents have been recruited up to March 2023. The research team have worked tremendously hard, and recruitment is looking positive, despite facing many obstacles along the way.

www.seniortrial.co.uk
Digital interventions

The COVID pandemic brought about a huge step change in the way research studies are conducted and also consideration given to how many of the interventions that were being trialled are delivered.

Digital interventions which were already being developed pre-pandemic were brought to the forefront. NWORTH are currently collaborating on a number of important studies where digital interventions and modes of delivery are being considered. Digital interventions may offer potential savings due to the ability to scale and deliver more widely than locally produced interventions, improving accessibility and reach. However, alongside these benefits each study must carefully consider the potential impact on digital divide and minimising the exclusion of those without access.

Evaluating the evidence-informed e-health intervention developed by the World Health Organisation designed to help dementia carers provide good care and take care of themselves.

The Impact Study, the largest research project of its kind, investigating the impact of support groups for people affected by rare dementias, delivered remotely and in person together with digital interventions.

Cognitive rehabilitation delivered remotely for those affected by Long COVID brain fog

Bringing together self-compassion and virtual reality to create a new treatment option for people affected by depression

Online interventions to support those affected by rarer dementias a continuation project from the RDS Impact study
SPS study

Chief Investigator – Prof. Mike Crawford, Imperial College London. Funded by NIHR Health Technology Assessment (HTA) Programme

NWORTH are proud to be collaborating with Prof Crawford and the team at Imperial College London on the SPS study (Assessing psychological support for people with emotional distress and difficulties in relationships) funded by the NIHR Health Technology Assessment Programme (NIHR133027).

The trial is a multi-centre, individually randomised, parallel group, researcher-blinded, randomised controlled trial, of Structured Psychological Support plus treatment as usual versus enhanced Treatment as Usual, including a parallel process evaluation and an integrated economic evaluation.

The main aims of the trial are:

1) To conduct a trial to test whether, for people with probable personality disorder, Structured Psychological Support is a clinically effective and cost-effective intervention for improving mental health and social functioning.

2) To conduct a parallel process evaluation to generate a contextualised analysis of the delivery of the intervention and outcome generation.

The trial will involve two linked phases:

- Phase 1 – A four-month internal recruitment pilot study.
- Phase 2 - Full trial over a further four-month recruitment period

All participants will be followed-up for 12 months and the trial will aim to recruit 308 study participants. The population will consist of people aged 18 and over who have probable personality disorder and are being treated by mental health staff working in primary or secondary care settings.

Eligible participants will require a score of four or more on the Standardised Assessment of Personality – Abbreviated Scale. People who have a co-existing organic or psychotic mental disorder, and those who are currently receiving psychological treatment for personality disorder or are on a waiting list for such treatment will be excluded.

For the parallel process evaluation, we will interview 40 trial participants, 10 non-participants and 45 clinicians and managers. The primary outcome of the trial is social functioning measured at baseline, and six and 12 months after randomisation using the total score on the Work and Social Adjustment Scale (WSAS). Social dysfunction is important to people with personality disorder because of the impact it has on quality of life and other long-term outcomes. The WSAS is a widely used measure for assessing social dysfunction among people with mental health conditions and rated more highly than other measures of social dysfunction by patients.

Secondary outcome measures include mental health using the 16-item Difficulties in Emotion Regulation Scale, 29 the nine-item Patient Health Questionnaire (PHQ-9) and the seven-item Generalised Anxiety Disorder (GAD-7). Suicidal thoughts and behaviour using items from the National Household Survey of Psychiatric Morbidity. Health-related quality of life will be assessed using the EQ-5D-5L. Patient experience, measured using the patient-rated global improvement and patient-rated satisfaction with care. Data on use of resources using the Adult Service Use Schedule (AD-SUS) adapted for use in this trial based on previous research involving people with personality disorders will also be collected.
All secondary outcome measures will be collected at baseline, six and 12 months after randomisation. SPS is an individual intervention delivered in six to ten sessions over a period of three to six months, delivered face-to-face or online. It is a person-centred approach, which allows therapists to determine the exact number, frequency, and duration of sessions based on clinical judgement and patient preference. SPS draws on the longer-term evidence-based treatments for people with personality disorder including Dialectical Behaviour Therapy and Mentalization Based Treatment and has five key components:

1. Information about personality and mental health and the role of health services;
2. Validation and radical acceptance aimed at reducing self-blame and motivating self-efficacy;
3. Support to help the participant develop psychological skill(s) for managing their main difficulties;
4. Discussion of the role of relationships and structured activities in achieving better mental health, and
5. Use of a ‘mentalizing stance’ to highlight the importance of mental states.

A launch meeting was held in November 2022 (SPS team launch day) and in February 2023 the SPS trial randomised its first participant. Recruitment and data collection is currently ongoing with the majority of the study sites now open to recruitment.

NWORTH have previously collaborated with Prof Crawford and the team at Imperial on other trials (REMEDY, CALMED) and look forward to helping to deliver this important study.
**Long COVID study**

Chief Investigator Dr. Dennis Chan, UCL. Funded by NIHR Long COVID call.

In the last period we reported on the funding award CICERO (Cognitive Impairment in Long COVID: PhEnotyping and RehabilitatiOn), led by Dr Dennis Chan from UCL. Up to 75% of people who whilst experiencing symptoms of long COVID report problems with memory, attention, or other cognitive functions – collectively known as ‘brain fog’. We are pleased to report that the randomised controlled trial of neuropsychological rehabilitation has opened for recruitment and has been undertaken at pace.

Dr. Aida Suarez Gonzalez, Co-lead for the CICERO study.

"I have worked with NWORTH in three clinical trials to date and my experience has always been excellent. The team has great expertise in non-pharmacological clinical trials and is able to advise on every methodological aspect along the way. Something I really appreciate is how responsive and supportive they are and how easy communication with them is."

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**Methodological developments**

Methodological developments focused on clinical trials in context and design is an important element of NWORTH’s work. This work stream is about increasing the rigour and quality of the work ensuring we remain abreast of the latest methodological developments but also identify areas for efficiencies.

**Cognitive assessments in Welsh**

IAITH, the Welsh centre for language planning has been undertaking a piece of work in collaboration with Dr Catrin Hedd Jones from Bangor University to look at the Validation of Welsh Language Dementia Assessment Tools.

Zoë Hoare has been engaging with this group to develop the next evaluative element of the project. A key element of this project is the incorporation of the bilingual context under which this work is being undertaken. Translation of the measures may not be enough to ensure adequacy of the assessments within the clinics they are designed for. Cognitive impairment can affect language processing in many ways and to ensure consistent assessment and scoring for individuals responding in a bilingual context it is vital that consideration is given to this during the development and evaluation of the tools. Therefore, it is anticipated that the evaluation element will also develop guidelines for applying and scoring the assessments within a bilingual context.
Public perception of Clinical research

NWORTH were represented at the 6th International Clinical Trials Methodology Conference 2022, in Harrogate from 3rd - 6th October 2022 where two colleagues presented work on “Public Perceptions of Clinical Research”. This was in the form of both a lightning talk and a poster session.

Senior statistician Rachel Evans and Research Project Support Officer, Dr Karolina Rusiak and Jean Ryan (former NWORTH CTU manager) conducted research on the views of the public on clinical trials, gathering information on the public perception and interest of clinical research.

Motivation behind the research: Issues of attitudes towards clinical research and concepts of trust in research are important if we are to better understand how to include, engage and communicate with the public on health research. Lack of trust in research is one of the main obstacles to research participation. We undertook an online survey to examine respondents’ attitudes, trust and understanding of clinical research and their willingness to participate as an enrolled patient or an advising lay member. Additionally, we explored whether COVID-19 has had an impact on the public’s interest and views on clinical research.

Participants completed a survey via Jisc online surveys consisting of 21 questions, taking around 20 minutes to complete. The survey was co-designed by authors with PPI input. Participants were members of the public aged 18+, residing in the United Kingdom.

There were 101 responses to the survey however two were excluded as they were outside the UK. Therefore, a sample of 99 was reached. Most respondents (>80%) felt that clinical research benefits our society, is important to improving our nation’s health and for the advancement of science. However, 28% felt that clinical research can harm society. Many stated that the most important reasons clinical research is undertaken is for the advancement of science (47%) and patient benefit (59%). Trust in publication of results varied with some respondents (33%) disagreeing that results of clinical trials are made available to the public.

Over a third (37%) agreed that funding bodies may manipulate research data and results. Many respondents (74%) agreed that clinicians would still provide best quality care if you decided not to participate in a trial, however some disagreed with this (15%). When asked if they would participate in a trial, 47% said it was somewhat likely, 32% very likely, 5% wouldn’t and 10% were not sure. 40% expressed they previously contributed to clinical research as a member of the public. Over 60% stated that their awareness, interest and trust in clinical research has increased following the COVID-19 pandemic.

The team concluded that much of the sample appeared to have some trust in clinical research, however, there were notably responses that contradicted this view. Educating the public on clinical trials with a focus on increasing trust should be a priority for those working in this area to increase participation in trials either as a lay member or participant. Research into how this could be best carried out should be prioritised.

The research was well received at the ICTMC with several delegates showing interest and enthusiasm in the results and conclusions. Further work to develop these ideas forms part of the ongoing research programme at NWORTH.
HIGHLIGHTS CONTINUED...

KEY ACHIEVEMENTS

Core metrics Reporting Period 2022-2023

£371,974 direct funding awarded

3 grants awarded

£3,738,513 Value

£1,786,702 funding to Wales

£322,706 funding to Group

9 additional jobs created for Wales

2 additional jobs created for group

Core Metrics
Reporting period: 2022/2023

Health and Care Research Wales infrastructure award to the group

Direct funding awarded

Jobs created through direct funding

Grants won during reporting period

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<td>Additional jobs created for group</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
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Number of publications 4

Number of public engagement events 2

Number of public involvement opportunities 45
Senior Statistician, Rachel Evans published a paper in Trials in January 2023 drawing on work conducted for her MPhil qualification looking into the impact researchers have in outcome measures when collecting data through interviews with participants.

The paper entitled "The impact of different researchers to capture quality of life measures in a dementia randomised controlled trial" was co-authored by Zoë Hoare, Paul Brocklehurst (previous director) and Jean Ryan. This paper covered the element of the work focused on whether there was a measurable effect of using different researchers to collect repeated assessments of quality of life. 

Using data from a previously conducted trial it was possible to establish that there was some evidence that there is an effect of researcher continuity on quality of life measures within a dementia trial. Further work would be required to prove causality of these exploratory results, but the implications could be important for the planning of empirical trials in dementia in the future.

A further aspect of Rachel’s work focusing on the gender of the researcher collecting the data has been accepted for oral presentation at the 7th UK Patient Reported Outcome Measures (PROMs) Research Conference: ‘PROMs Across the Lifespan’ in Sheffield in June 2023.
WHAT RESEARCH ARE YOU INTERESTED IN?
26 responses

LGBTQ HEALTH INFANT FEEDING
REALIST METHODOLOGY COLLABORATIVE
ATTACHMENT THEORY SERVICE EVALUATION
INNOVATIVE EVALUATIONS QUALITATIVE
MENTAL HEALTH HEALTH CARE
MENTAL HEALTH SERVICES
HEALTH SERVICES
AUTOIMMUNE MAINTAINING PHYSIOLOGY
DENTISTRY SEXUAL HEALTH
PARKINSONS DISEASE MIDWIFERY
AGING SOFTWARE DEVELOPMENT
CAMS RADIOLGY
SOFTWARE DEVELOPMENT STUDENT EDUCATION

Community of Scholars has steadily grown its membership over the year. The first in-person event since COVID-19 was on the 7th of December 2022, giving healthcare professionals and academics a space to network.

During the well-received event, attendees heard about collaborative research experiences and had the opportunity to network during roundtables. When discussing the most significant challenges faced at work, attendees agreed that workload and time issues came at the top, which affected their time to conduct research.

Dissemination and Engagement:

Bangor University Health and Care research summer school July 2022

NWORTH contributed their annual session to the Bangor University Health and Care Research Summer school with Zoe Hoare and Rachel Evans leading a session entitled evaluating complex interventions and innovations in trial design. The session covered what a CTU is, basic trial design considerations, an introduction to more complex trial designs before culminating in a session critically appraising an early published Remdesivir COVID-19 study. This summer school attracted over 25 national and international delegates with the programme covering a wide range of topics in health care research.
Research Design & Conduct Service

RDCS engagement over the past year has still been greatly affected by COVID and the pressures felt across the NHS and so contacts have been limited. Expertise has been shared across the Community of Scholars and stakeholder engagement events over the past year to ensure promotion and dissemination of both services and knowledge.

With the creation of the new Faculty, Health and Care Research Wales are looking at other ways of supporting researcher development and will no longer be funding RDCS from April 2023. As the RDCS provision in its current form comes to end those who have worked on the service, past and present would like to thank all the local clinicians that have contacted us over the years and used the service.

Social media update

Throughout the year, NWORTH has participated in Health and Care Research Wales, “Where would we be without research?” and #ResearchResolutions campaigns.

We promoted the Health and Care Research Wales Conference 2022 and shared the fun attendees had with our Clinical Trials Pitfalls marble labyrinth game, a popular challenge to get the marble over the finish line. We also celebrated the yearly International Clinical Trials Day with a short thank you video to all involved in clinical trials. In 2022 – 23, we had 79,500 impressions on Twitter and 530 engagements. We tweeted 81 times and gained 19 followers.
CONCLUSION

It has been an exciting and engaging year for NWORTH and our staff. NWORTH prides itself on our team work ethic which has been demonstrated repeatedly over the past year.

The support, knowledge sharing and care between each and every member of our team allows NWORTH to thrive year on year.

The support that Health and Care Research Wales have provided to the unit as infrastructure funding have enabled us to foster the environment that we all like to work in and provide exemplary collaboration with trials teams across the UK and beyond.

Whilst it is always good to reflect on the achievements for the past year and acknowledge the work that has gone into delivering all this, we should also continue to look forward to the exciting future possibilities for this CTU as a dynamic, adaptive, supportive entity with quality, rigour and care at our core.

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