

NWORTH CTU

Newsletter

Spring-Summer 2024



Welcome to the Spring-Summer 2024 edition

Welcome to the Spring-Summer 2024 edition of our new newsletter, showcasing the work we do at the North Wales Organisation for Randomised Trials in Healthcare (NWORTH) at Bangor University.

In this newsletter, we share an insight into the latest updates from our clinical research studies, news from NWORTH team members, a spotlight on our recent public engagement activity and key publications.



Dr Zoë Hoare
NWORTH Director

What's inside?

Recap of 2024 so far

Welcome to our new team members

Research updates

News from the team

Public Engagement spotlight

Key Publications

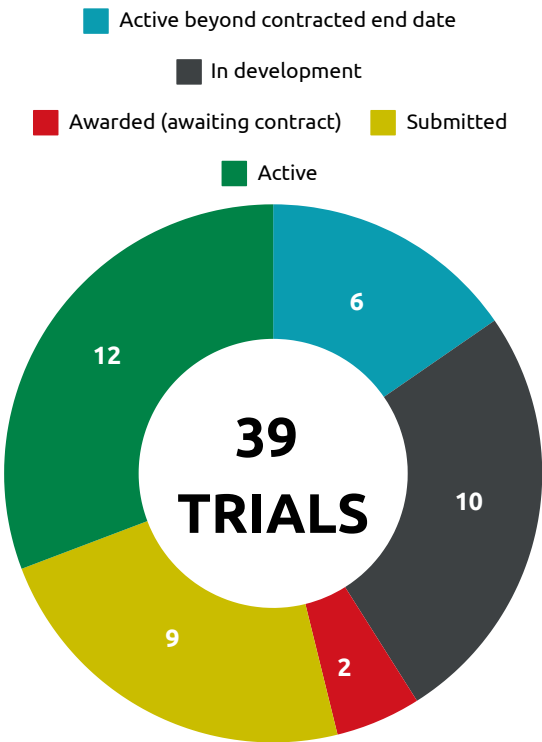
Keeping in contact

A LOOK BACK AT OUR YEAR SO FAR

It has been a busy and successful first half of the year for NWORD, continuing to deliver our projects to time and target. Since the start of 2024, four of the studies on our portfolio have been awarded or become active, with a total grant value of £4.5m. We co-hosted our first public and patient involvement event in March, joining the North Wales Medical School and Health and Care Research Wales to explore our vision for public involvement moving forwards. We are also delighted to have welcomed new members of staff, as well as promoting staff from within the unit.

OUR 2024 TRIALS PORTFOLIO

Below is a snapshot of our 2024 Trial portfolio. We currently have 12 active studies, with a total grant value of £17.2m. We have a pipeline of 10 studies in development, with a further nine submitted. We are continuing work beyond the contracted end dates on six studies, and awaiting the contract on a further two studies.



6

Trials open to recruitment

At present, we have six trials that are open to recruitment.

13

Trials in analysis/dissemination

We are currently in the analysis and dissemination phase on 13 of our trials.

4

Publications

This year, we have had four publications published in high-impact peer reviewed journals. See our full list of publications [here](#).

over
2800

Participants recruited

Across our 12 active studies, we have recruited over 2800 participants to our trials, including patients, GP clinics and care homes.

WELCOME TO OUR NEW TEAM MEMBERS

At the end of 2023, we were joined by 3 new members of staff: **Casey Nolan** (IT Delivery Facilitator), **Aparajitha Yathavakilla** (Trial Development Research Project Support Officer) and **Bethan Lewis** (Portfolio Research Project Support Officer).

Casey, Aparajitha and Bethan have fully settled into their roles and have impressed with their excellent support in the IT and research support functions.



ELIZABETH DENIS APPOINTED AS QA OFFICER

We have had the pleasure of **Elizabeth Denis**, QA Support Officer, moving into the QA Officer position, covering for Karolina Rusiak while she is on maternity leave.

Lil brings with her great knowledge of regulatory compliance and quality assurance systems, which has enabled a smooth transition into the role.





SPS STUDY EXCEEDS RECRUITMENT GOALS

The SPS study, funded by NIHR and led by Professor Mike Crawford at Imperial College London, has surpassed its recruitment goal, reaching 336 participants. Dr Zoë Hoare and Rachel Evans from NWORD have led the design and analysis of all quantitative data from the trial.

The study is a multicentre, randomised controlled trial, evaluating the effectiveness of Structured Psychological Support (SPS) for people with personality disorders. It is the largest ever clinical trial of its kind, aiming to improve mental health and quality of life for those with complex emotional needs. Positive results could lead to wider implementation of this more effective care.

The study has now closed for recruitment, and the results are expected in 2025.

RESEARCH UPDATES

STUDY LAUNCHED TO EXAMINE IMPACT OF EXCESSIVE NOISE ON NEWBORN HEALTH & STAFF PERFORMANCE

The NOISE study, led by Dr Artur Abelian, Consultant Paediatrician at Wrexham Maelor Hospital (Betsi Cadwaladr University Health Board) and funded by BCUHB charity and Cherish, launched in January this year.

The study aims to understand neonatal staff opinions on whether excessive noise has an impact on their professional performance and on the health and wellbeing of babies in the unit.

Noise environments are more stressful for newborns and their parents, and can make it difficult for staff to focus, potentially impacting on the provision of high-quality care.

During the study, a specially-designed questionnaire will be distributed via phone, email, letter & website to doctors, nurses & allied healthcare professionals across nine neonatal units in Wales, to understand if staff are concerned about the impact of excessive noise. The results will inform future research looking at the impact of noise on morbidity and mortality rates, and will help inform clinical guidance and policy.

The study is due to complete in December this year. NWORD are supporting the development of the survey platform, calculate sample size and facilitate analysis of the results. Stay tuned for more.

CFT FOR DEMENTIA STUDY RECRUITS ITS FIRST PARTICIPANTS

The Compassion Focused Therapy (CFT) feasibility trial for people with dementia, led by Prof. Aimee Spector at UCL, has recruited its first 17 participants!

Rachel Evans, NWORD Senior Statistician is leading the statistical design and analysis.

The study aims to assess the feasibility of conducting a full-scale randomised controlled trial of CFT for people living with dementia and depression or anxiety. It will assess recruitment, intervention delivery, and data collection, to assess if a larger trial should go ahead.

It is anticipated that CFT could fill a critical treatment gap for depression and anxiety in dementia, helping to reduce stigma, reduce carer burden and increase independence of those living with dementia, compared with other treatments.



TOGETHER STUDY NEARS COMPLETION

The TOGETHER study, investigating the effectiveness of a group-based parenting programme, is set to complete in August 2024. The multi-centre randomised controlled trial aims to assess if the 'Strengthening Families, Strengthening Communities' (SFSC) parenting programme, developed by the Race Equality Foundation in the UK, improves parental and child social and emotional well-being. It is hoped that the study will add to the literature of low-intensity parenting programmes and build the evidence base for SFSC.

As the study enters its final stages, data analysis will continue and results are expected to be published in 2025.



NEWS FROM THE TEAM

DR ANNIE HENDRY, PROCESS EVALUATION RESEARCHER, EARNS PRIZE AT PRIME CENTRE WALES ANNUAL MEETING



Dr Annie Hendry, Process Evaluation Researcher on the SENIOR trial, earned a runner-up prize at the PRIME Centre Wales Annual conference, in November 2023, for her presentation on the early findings from a theoretically informed process evaluation as part of a the SENIOR trial with care home residents.

SENIOR is a cluster-randomised controlled trial to determine whether other members of the dental team (not a dentist) could improve the oral health of dentate older adults over 65 years-of-age residing in care homes. The trial is being run by Bangor University, along with partners UCL, QUB and the NHS. More [here](#).

Annie's paper has been published in the Gerodontology journal, Volume 1, Issue 42, which can be viewed [here](#).

NEW COMMUNICATIONS & MARKETING STRATEGY

Over the past few weeks, Bethan Lewis, Portfolio Research Project Support Officer, has been developing NWORTH's Communications & Marketing Strategy and action plan.

This has been developed to set out the strategic direction for NWORTH's communications and marketing, our objectives and what our stakeholders can expect from us.

We will be working on the actions identified in our plan, including developing NWORTH's [webpages](#) on the Bangor University website, over the coming months. Keep your eyes peeled!

UPDATING OUR ELECTRONIC DATA CAPTURE SYSTEM

Over the next six months, we will be validating a new electronic data capture (EDC) system called REDCap. REDCap is a web-based tool, used to securely capture and analyse research data from clinical studies.

Huw Williams, NWORTH's Digital Systems Officer, will lead the transition to REDCap, which will ensure our continued support in our trials in the design, collection and archiving of study data.

NWORTH is available to discuss your trial's data management and randomisation needs. Contact us for more information at NWORTH@bangor.ac.uk.

NWORTH TEAM MEMBERS' FUNDRAISING CHALLENGES

Several members of the NWORTH team have been busy completing challenges, to raise money for local & national charities. Rachel Evans (Senior Statistician) ran the Chester Half Marathon for [Conwy Mind](#), Greg Flynn (Trial Manager) completed the 42km Welsh 3000s route for [Samaritans](#), and Grzegorz Suldecki (Trial Manager) has been hosting weekly pub quizzes to raise money for [WWF](#). Well done!



PUBLIC ENGAGEMENT SPOTLIGHT

NWORTH HOSTS SWEET TRIAL ACTIVITY FOR CHILDREN AT THE BANGOR SCIENCE FESTIVAL

Earlier this year, we attended the annual Bangor Science Festival, to engage with families in the community and inspire future researchers.

The Science Festival, organised by the [British Science Association](#) takes place each year as part of British Science Week.

Aparajitha Yathavakilla, Trial Development Research Project Support Officer, and Grzegorz Suldecki, Trial Manager, attended the festival from NWORTH, to run a 'Sweet Equivalence Evaluation Trial' activity; testing whether sweets hidden in two separate jars elicited the same feelings of happiness for those who tried them. Everyone who had a go loved the activity, and it was a great opportunity to explain to young people and families the basic concepts of how a clinical trial is run. Aparajitha commented:

'It was a really rewarding experience to see the curiosity and enthusiasm of everyone who came along, and hopefully we've done something to inspire the next generation of clinical researchers!'



NWORTH & NORTH WALES MEDICAL SCHOOL CO-HOST PUBLIC INVOLVEMENT EVENT

On 21 March 2024, NWORTH and the North Wales Medical School (NWMS) hosted an event, focusing on the public's role in healthcare research.

The session included reflections on PARC-Bangor, our former public involvement group and a discussion on NWORTH's future PPI strategy, led by Dr Zoë Hoare (NWORTH Director & Principal Statistician).

We were joined by Dr Nia Jones (Clinical Senior Lecturer in Medical Education) and Prof. Stephen Doughty (Professor in Pharmacy) to share updates on the North Wales Medical School's development, and Rebecca Burns (Public Involvement Manager, Heath and Care Research Wales), for insights into public involvement in research in Wales.

Attendees provided valuable feedback, emphasising the importance of clear communication of PPI objectives and broader engagement with underrepresented groups. We are currently embedding the ideas into NWORTH's new PPI Strategy to ensure inclusive practices.

We plan to hold further outreach activities with the NWMS as it develops. Keep an eye out on the [NWMS webpages](#).



CELEBRATING #RED4RESEARCH

NWORTH joined in the #Red4Research celebrations on 7th June 2024, to recognise all those participating, undertaking and supporting research. To mark the event, we posted each day on our Twitter page, outlining NWORTH's role in clinical research and to celebrate those we work with who make it possible.

As part of celebrations, we asked some of our team members 'Why do you enjoy working in clinical research?'. Take a look at our Twitter page (@NWORTH_CTU) to see the responses.



RESULTS OF EXPO STUDY PUBLISHED BY ECLINICALMEDICINE

We are pleased to share that the results of the EXPO trial have been published in EClinicalMedicine.

The Expo trial, launched in 2019 and led by Professor John Marsden at King's College London, aimed to determine both the clinical and economic effectiveness of extended-release buprenorphine (BUP-XR) versus oral (liquid) methadone (MET) or Sublingual tablet buprenorphine (BUP-SL) for opioid use disorder (OUD). NWORTH led the statistical design and analysis in the study.

Results demonstrated that BUP-XR led to more opioid abstinence, greater retention and total time in treatment, and greater likelihood of early remission from OUD. The study is one of the largest RCT studies of OUD treatment outcomes, with these findings being of relevance for clinical practice and treatment policy.

RECENT PUBLICATIONS

See the full list on our [webpages](#).

RESULTS OF THE COLO-DETECT ACCEPTED FOR PUBLICATION IN THE LANCET GASTROENTEROLOGY & HEPATOLOGY (LGH) JOURNAL

We are pleased to share that the results of the COLO-DETECT trial, led by Professor Colin Rees at Newcastle University, has been accepted for publication in the [Lancet Gastroenterology & Hepatology](#) (LGH) journal 2025.

The trial evaluated whether colonoscopy assisted with the GI Genius™ Intelligent Endoscopy Module improves the detection of colorectal cancer, compared to standard colonoscopy. It is the biggest trial to date exploring the real-world implementation of artificial intelligence for the improvement colorectal cancer outcomes.

This is a trial funded by Medtronic and sponsored by South Tyneside and Sunderland NHS Foundation Trust. We would like to congratulate Professor Colin Rees for this achievement and the team at Newcastle University & STSFT for their work on this trial. More about the study can be viewed on the [COLO-SPEED website](#).

KEEP IN CONTACT WITH NWORTH

Website: nworth-ctu.bangor.ac.uk

Email: NWORTH@bangor.ac.uk

Phone: 01248 388095

Address: NWORTH CTU, Y Wern, Normal Site, Holyhead Road, Bangor University, Bangor, Gwynedd, LL57 2PZ

Twitter: @NWORTH_CTU

ABOUT US

NWORTH is a UKCRC registered clinical trials unit, which specialises in the design, conduct, analysis and reporting of multicentre trials of complex interventions. We are based in the North Wales Medical School at Bangor University.

If you'd like to collaborate on a study, please [get in touch](#).



North Wales Organisation for
Randomised Trials in Health & Social Care
Sefydliad Hap-Dreialon Iechyd
a Gofal Cymdeithasol Gogledd Cymru



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