

NWORTH CTU



Newsletter

Issue no. 2 - Spring 2025



Welcome to the second issue of our NWORTH newsletter.

Keeping you up to date on the team and research being undertaken here at North Wales Organisation for Randomised Trials in Health & social care (NWORTH) within the North Wales Medical School in Bangor University.

In this issue we share an insight into our collaboration request process, some notable updates from our studies, updates from across the CTU team and the latest publications and outputs.



Dr Zoë Hoare
NWORTH Director

What's inside?

10 years of collaboration requests

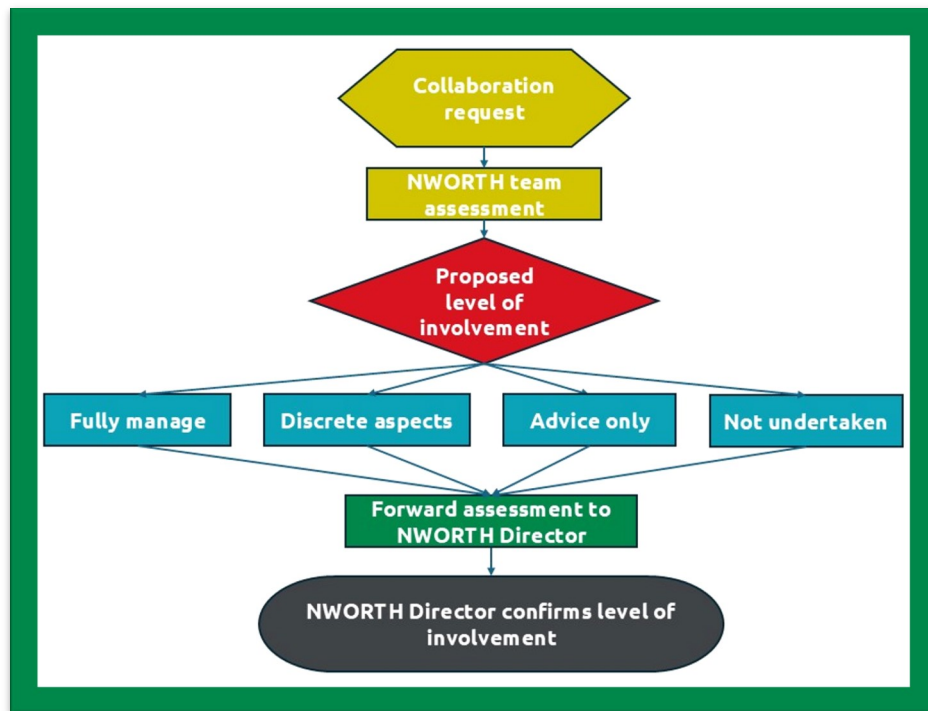
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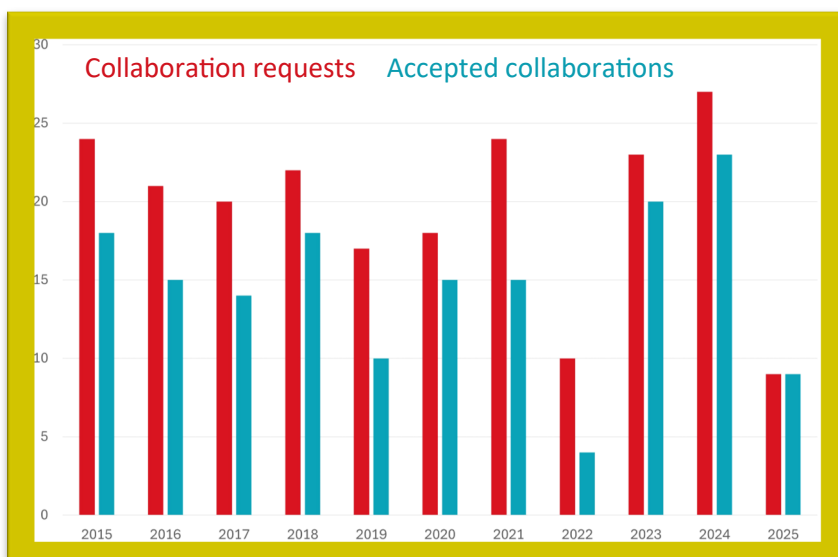
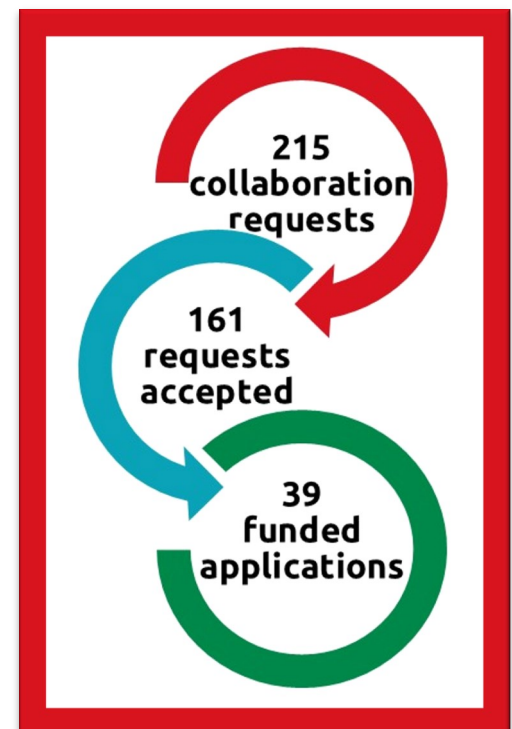
Ten years of collaboration requests



In 2015 NWORTH introduced an official collaboration request process as part of streamlining and harmonising processes at the unit. The objective of the process was to ensure that all requests to work with NWORTH were managed efficiently and fairly.

Each collaboration request is assessed against criteria clearly set out in our [charter](#). If successful the study is adopted onto our portfolio and NWORTH will provide methodology and design support into the proposed grant application.

There have been 215 requests to collaborate over the last 10 years with the busiest year being 2024, seeing 27 individual requests of which 23



were accepted onto the portfolio; many are currently in submission awaiting a funding outcome. Data to mid-March 2025 demonstrates we are already on course for a busy year in collaborations with both known and new faces.

Study News

SENIOR trial hits completion target

As with most studies recruiting participants to trials has its own challenges and SENIOR was no different, the remit was to consent and randomise 40 care homes and from these care homes to recruit 280 residents, into control and intervention group. The primary outcome being that the 6-month dental assessment would be completed on 200 residents.



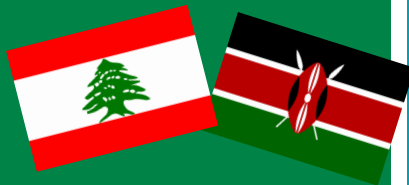
Although the trial was impacted by COVID which caused many delays, we used this time to consent and set up care homes remotely. When we were able, we then went out to recruit residents. Not all eligible residents wanted to participate, some reasons given were that they didn't like dentists! We finally recruited 327 participants, however, due to the population, only 284 baseline clinical assessments were completed.

After months of weekly monitoring by the study team and the trepidation of constantly contacting the care homes for an update on the participants enrolled at their home, we have 213 participants who have received their 6-month clinical assessment.

The study team is now collecting all the data from the care homes which does bring its own problems as many of the homes are research naive and its not a priority for them to keep research documentation safe!

SUMMIT trial hits targets in Lebanon and Kenya

The study aims to assess whether culturally-adapted group interpersonal therapy (g-IPT) has a greater impact than high quality standard care (HQ-SC) on child developmental outcomes, maternal depression and the mother-child relationship for mothers with post-natal depression.



In February 2025 the trial completed follow up and data collection of participants. Of the 412 mothers randomised into the trial across the two countries, 310 participants have completed the primary outcome at 12 months follow up. The trial is moving into the final data cleaning stages ready for analysis this summer and we look forward to providing study results.

"The incredible efforts and determination shown by the teams in both countries to carry on with data collection is highly commendable and we remain in awe of the team's courage and commitment to the trial in such incredibly challenging circumstances" - Study Lead Prof. Peter Fonagy

Funded by: National Institute for Health Research (NIHR) Research and Innovation for Global Health Transformation (RIGHT) Programme

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MOAM Trial outcome

A new psychological therapy designed by a team of UCL-led researchers has been found to reduce rates of violence and aggression among male offenders with antisocial personality disorder (ASPD).

The study, published in *The Lancet Psychiatry* and funded by the National Institute for Health and Care Research (NIHR), investigated whether aggression and antisocial behaviours could be improved by a modified form of mentalisation-based treatment (MBT).

NWORTH played a key role in this research by managing and ensuring the quality of the data from different sources. The study utilised our bespoke randomisation system which employed a specially designed randomisation algorithm that is unique to NWORTH. NWORTH is proud to be able to support evaluations of complex interventions within settings such as prisons. We are able to offer the systems and expertise to be ensure important studies like these are delivered to the highest quality.

Read the press release [here](#)



NEWS FROM THE TEAM

Widening experience - Alison Jenkins

Having worked in clinical research for more than 30 years; as a trial manager for most of those years, I was interested in applying to become a member of the UKCRC Trial Managers Operation Group and was given a lovely early Christmas present on 20th December 2023 of becoming a fully-fledged member of the group.

As a member you are initially appointed for a term of up to three years and can stand for a maximum of two terms. This means that the operation group always remains fresh and invigorated with new ideas, activity development, opportunities for trial managers and offering continual development mentoring. The group is only small with six members: a chair, a deputy and a representative from the UK Trial Managers' Network (UKTMN) to ensure cross organisational learning and efficiencies.

Joining this group has allowed me to work with trial managers from other CTU's who have varying degrees of experience, enabling me to learn new skills, and pass on a few of my own.

I've also had the opportunity to discuss the problems faced by trial managers irrespective of the size of their CTUs. Being a member of the Operations group has been a really positive experience.



REDCap: NWORDH's New Electronic Data Capture (EDC) System coming soon

We are excited to announce the imminent release of REDCap in the coming weeks, NWORDH's new Electronic Data Capture (EDC) system, that will replace MACRO. This upgrade will bring a more flexible, efficient, and user-friendly platform for managing clinical trials. REDCap offers improved data collection, enhanced collaboration, and greater efficiency with real-time validation, automated workflows, and seamless data exports. Its customisable features and scalability make it ideal for trials of complex interventions, strengthening our data quality and streamlining our processes.

QA news—an update from the team

Quality Assurance is vital in running clinical trials and studies. Although the QA team may appear as strict and rigorous, this is done to ensure the health and safety of all patients and participants is protected as well as the quality of data collected from research overseen by us. We have some upcoming developments in clinical trials research standards with the update to [ICH GCP E6 \(R3\) Guidance and Medicine for Human Use \(Clinical Trials\) \(Amendment\) Regulations 2024](#). So, bear with us when we start implementing new guidance and regulations later in the year.

Farewell to our CTU administrator

Towards the end of 2024 NWORDH said a sad farewell to our CTU administrator Karen Law who has been a part of the team since it was first accredited in 2007. Her depth and breadth of knowledge of both clinical trials and university processes were an asset to the unit and she will be sorely missed. We wish Karen all the very best in her (early) retirement!



More farewells...

NWORDH has also recently said farewell to Bethan Lewis, Annie Hendry, Greg Flynn and Aparajitha Yathavakilla. All have moved onto new positions and we wish them all the best - it was a pleasure having you at NWORDH



Recent Publications

1. Clinical effectiveness and cost-effectiveness of Structured Psychological Support for people with probable personality disorder in mental health services in England: study protocol for a randomised controlled trial. [BMJ Open](#)
2. 'ThinkCancer!': randomised feasibility trial of a novel practice-based early cancer diagnosis intervention [BJGP Open](#)
3. A Theoretically Informed Process Evaluation in Parallel to a Feasibility Study of a Complex Oral Health Intervention Using NICE Guidelines in a Care Home Setting. [Community Dental Oral Epidemiology](#)
4. Mental Health and Personality Functioning of People With Probable Personality Disorder Who Have Coexisting Complex Post Traumatic Stress Disorder. [Personal Mental Health](#)
5. Being kind to ourselves: group compassion-focused therapy (CFT) versus treatment as usual (TAU) to improve depression and anxiety in dementia – a protocol for a mixed-methods feasibility randomised controlled trial within the NHS. [BMJ Open](#)
6. Telehealth-delivered cognitive rehabilitation for people with cognitive impairment as part of the post-COVID syndrome: protocol for a randomised controlled trial as part of the CICERO (Cognitive Impairment in Long COVID: Phenotyping and Rehabilitation) study. [Trials](#)
7. The UK Breast Cancer in Pregnancy (UKBCiP) Study. Incidence, diagnosis, management and short-term outcomes of breast cancer first diagnosed during pregnancy in the United Kingdom: A population-based descriptive study. [NIHR Open Research](#)
8. Mentalisation-based treatment for antisocial personality disorder in males convicted of an offence on community probation in England and Wales (Mentalization for Offending Adult Males, MOAM): a multicentre, assessor-blinded, randomised controlled trial. [The Lancet Psychiatry](#)
9. Bridging the gap: a qualitative study exploring the impact of the involvement of researchers with lived experience on a multi-site randomised control trial in the National Probation Service in England and Wales [Health Expectations](#)
10. Evaluating the effects of the World Health Organization's online intervention 'iSupport' to reduce depression and distress in dementia carers: a multi-centre six-month randomised controlled trial in the UK. [The Lancet Regional Health—Europe](#)
11. The experiences of minority language users in health and social care research: a systematic review. [Int Journal of Health Planning Management](#)



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a Gofal Cymdeithasol Gogledd Cymru



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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](#).

