



NORTH CTU

Newsletter

Issue no. 5 - Autumn 2026



Directors update

It's been a particularly busy few months, with both longstanding and new collaborators keeping us occupied as we develop a range of exciting new funding applications.

In this issue, we take a step back and look at why you might want to collaborate with a Clinical Trials Unit.

Our study news highlights the outcomes of the CICERO study and the inclusion of one of our studies in a Senedd briefing.

Team news features our summer picnic, a light relief look at real world data, and the contribution of our fantastic work experience student.

As we look ahead to the end of the year, we're excited to celebrate 20 years as a registered Clinical Trials Unit. Keep an eye out for the events and activities we have planned to mark this milestone.

Dr Zoë Hoare, NORTH Director

SAVE THE DATE
May 20th—21st 2027



**Celebrating 20 Years of
accreditation**

**Join NORTH as we celebrate 20
years of accreditation, making
two decades of excellence in
research, collaboration and
innovation.**

Why collaborate with a Clinical Trials Unit?

Clinical Trials Units (CTUs) are part of the UK's research infrastructure, bringing together specialist expertise and established systems to help researchers design and deliver high-quality clinical trials and other complex studies.

UK Registered Clinical Trials Unit Network



The **UK Registered CTU Network** brings together CTUs across the UK to promote high standards in trial design and delivery, share expertise and best practice, and support high-quality, efficient and sustainable research. At Bangor University, NWORDH has been a registered CTU within the UK Registered CTU Network since 2007, reflecting a longstanding commitment to developing the expertise and infrastructure needed to support high-quality research.

A CTU is therefore not simply an administrative or statistical service. Registered CTUs provide expertise across the research lifecycle, including study design, methodology, governance, trial management, data management, analysis and reporting. They also provide access to established processes and infrastructure developed through experience of delivering multicentre and complex studies.

So, when might working with a CTU add value?

1. Get the study design right. High quality research starts with good design. CTUs can provide specialist methodological input to help researchers think through the design, outcomes, recruitment, randomisation, sample size, analysis and practical delivery of a study. This can be particularly valuable for studies involving complex interventions, multiple sites, or less familiar trial designs.

2. Complement — not replace — your expertise. Researchers bring essential expertise in their population, intervention and clinical or scientific area. CTU involvement is not about replacing that expertise, but complementing it with specialist trial methodology and experience. Bringing different areas of expertise together at the design stage can help identify potential challenges early and strengthen the overall study.

3. Support participants and good governance. Research involving participants needs appropriate systems for consent, safety, data protection, monitoring and reporting. This can become particularly important when studies involve vulnerable populations, multiple sites or interventions with potential risks. CTUs can help develop proportionate processes that protect participants while remaining practical for research teams and sites.

4. Access established infrastructure. Running a study requires more than a protocol and a research team. Depending on the study, this may include randomisation systems, databases, data management processes, standard operating procedures, monitoring arrangements and mechanisms for study oversight. Working with a CTU can provide access to established infrastructure and experience rather than requiring each research team to develop everything from scratch.

5. Think beyond the current study. Research studies should be designed not only to answer the immediate research question, but also to generate information that will inform future research. This might include understanding recruitment and retention, intervention delivery, outcome collection, resource requirements, acceptability, and the practical and methodological considerations needed to develop subsequent studies.

The bottom line

Not every research study needs CTU involvement, and CTU input should be proportionate to the needs of the study. The question is not whether a CTU is required as a badge of quality, but **what expertise, infrastructure and support the study needs, and where a CTU can add genuine value.**

A good CTU partnership should complement the expertise of the research team, bring specialist trial knowledge where it is needed, and ultimately help researchers deliver studies that are rigorous, practical and useful.

NWORTH study included in welcome pack for incoming Senedd members

CaSE—the Campaign for Science and Engineering—with the support of its sponsor organisations, sent a personalised welcome letter and information pack to every Member of the Senedd (MS). The pack highlighted the importance of research and development (R&D) in Wales and encouraged MSs to continue championing the sector, both within their constituencies and across Wales.



NWORTH contributed one of the featured case studies to the welcome pack: RHINO (Respiratory Health Outcomes in Neonates), also known as the Born Early Breathe Easy (BEBE) study. This case study showcased NWORTH's collaboration with Chief Investigator Professor Kotecha on a Wales-wide study investigating the long-term respiratory health of children born prematurely. Conducted exclusively in Wales, the research generated valuable evidence to inform best practice and improve treatment outcomes for patients both within Wales and beyond. The programme has since expanded beyond the original trial, continuing to enhance understanding of this population and the effectiveness of different treatment approaches. More information can be read at the link: [RHINO/BEBE contribution to MS welcome packs](#)

CICERO Trial Shows Cognitive Rehabilitation Improves Functional Recovery in Adults With Long COVID

CICERO study results were published in [JAMA Network Open](#), evaluating whether individualised, goal-oriented cognitive rehabilitation (CR) improves functional outcomes for adults with post-COVID-19 condition experiencing cognitive impairment ("brain fog").

This single-blind, multi-centre randomised controlled trial across four NHS sites in England allocated 78 adults aged 30 to 60 to either standard treatment as usual or 10 weekly, 1-hour sessions of therapist-guided CR targeting three self-selected daily goals.

At the primary 3-month endpoint, participants receiving CR demonstrated statistically significant and clinically meaningful improvements in functional goal attainment compared to control. These improvements were sustained at 6 months follow-up, alongside positive secondary trends in quality of life.

The authors concluded that tailored cognitive rehabilitation is a safe, effective, and durable non-pharmacological intervention, offering NHS services a practical framework to support long COVID recovery and return to daily living.

Women's health portfolio

On 4th March 2026, our Senior Statistician and Trials Unit Manager had the pleasure of attending the North Wales Women's Health Conference at Bangor University.

Timed perfectly alongside International Women's Week 2026 and Endometriosis Awareness Month, the day was a vibrant celebration of the inspiring women and dedicated teams transforming health and wellbeing across our region.

We had the opportunity to connect and heard from colleagues and inspirational leaders from Betsi Cadwaladr University Health Board (BCUHB), Social Care Wales, and voluntary sector champions.

Managing one of over 70 information stalls, we enjoyed fantastic conversations with attendees, sharing how our CTU's clinical trial portfolio actively supports women's health research.

Powerful presentations throughout the day highlighted critical health challenges, community strategies, and the vital role of evidence-based care for women across North Wales.

It was an energising and productive day of networking, shared learning, and celebrating local progress - bringing back fresh motivation and stronger connections to our trials unit!

NEWS FROM THE TEAM

The Staircase Trial: A Prospective N=1 Investigation

Background: Most people after a fall think, *"Looks nasty. Hope it gets better."* A clinical trial statistician, however, thinks, *"Let's establish a baseline, collect serial images, document the mechanism of injury, assess trajectory, and perform follow-up."* Following an unplanned descent of approximately 10 wet stone steps while carrying a mug of tea, the participant sustained a substantial thigh contusion and extensive bruising. Serial photographs documented the progression, alongside careful assessment of swelling, discolouration, mobility and pain. Supplementary evidence included the staircase itself and a potentially confounding variable: the mug. The resulting dataset effectively constituted a single-subject longitudinal observational study.



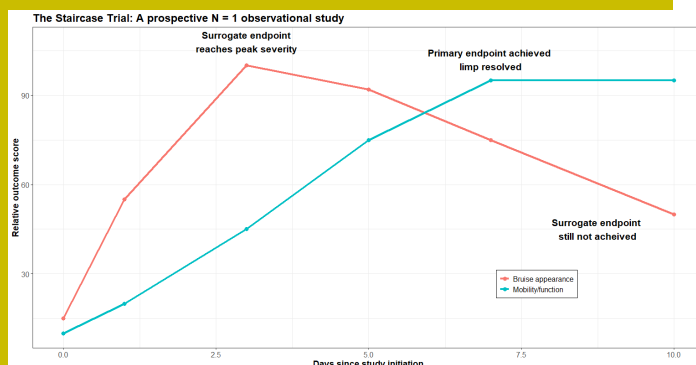
Study mascot

Outcome: Favourable recovery at one-week follow-up, with resolution of the limp and improving pain. The bruise, however, continued to look increasingly dramatic. Mug integrity was maintained throughout, although tea retention failed at baseline before subsequently being restored. No serious adverse events were reported. The key finding was the divergence between the visually dramatic surrogate endpoint and the clinically meaningful functional endpoint: mobility improved substantially faster than bruise appearance. A useful reminder that the most striking endpoint is not necessarily the most clinically relevant.

Study limitations: The study lacked randomisation, blinding and a control group. A definitive trial was considered infeasible, as ethics approval was unlikely for:

Arm A: Use the handrail appropriately

Arm B: Tumble unaided down wet stone steps while carrying hot tea



Surrogate versus clinically meaningful endpoints

Conclusion: The participant recovered uneventfully. The study highlights the value of serial assessment, appropriate endpoint selection and caution when drawing causal conclusions from observational data. The mug served as independent adjudication throughout using its inscription of "I'm Fine! Everything is fine!" as a guiding principle. **Biased? Perhaps. Consistent? Absolutely.**

NWORTH summer team meeting and picnic



The NWORTH team recently came together for a staff away day, combining business updates with team building and future planning. The morning included updates on the NWORTH portfolio, preparations for CTU re-accreditation, an interactive regulatory quiz, and a discussion on the opportunities for using AI within NWORTH. Staff also collaborated on ideas for celebrating NWORTH's forthcoming 20th anniversary. The day concluded with a team walk through the beautiful grounds of Penrhyn Castle, followed by a picnic, providing an opportunity to relax, connect with colleagues, and enjoy the surroundings.

Work experience placement

In July, we welcomed Jac Jones, a Year 12 student from Ysgol David Hughes for a week long work experience placement. Jac worked through a fictional SWEET (Sweet Equivalence Evaluation Trial), gaining insight into data and trial management, research databases, quality assurance and statistics. The week culminated in Jac giving a presentation showcasing what he had learnt.





CTU Publications

Our latest research making a difference

Six new studies.
real world impact!



Craving and personal functioning as mediators of extended-release buprenorphine efficacy: A four-way decomposition analysis from a randomised trial.

Addiction



Cognitive rehabilitation and functional outcomes in Long COVID-related cognitive impairment.

JAMA Network Open



Cost-effectiveness of a mentalisation-based treatment for antisocial personality disorder in males convicted of an offence on community probation in England and Wales: multicentre, assessor-blind randomised controlled trial.

PLOS One



Using role substitution to improve oral health of dependent older people residing in care homes and assisted living settings in the United Kingdom.

Community Dentistry and Oral Epidemiology



Neuropsychological evaluation and rehabilitation in multiple sclerosis (NEuRoMS): A mixed-methods, multi-centre feasibility randomised controlled trial.

Multiple Sclerosis Journal: Experimental, Translational and Clinical



Participant recruitment and retention in studies investigating pregnancy-related pelvic girdle pain: A methodological systematic review.

Trials



QUALITY
RESEARCH



BETTER
EVIDENCE



HEALTHIER
LIVES



KEEP IN CONTACT WITH NWORTH

Website: www.bangor.ac.uk/nworth

Email: NWORTH@bangor.ac.uk

Phone: 01248 388095

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

X (Twitter) : @NWORTH_CTU



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



PRIFYSGOL
BANGOR
UNIVERSITY

ABOUT US

NWORTH is a UKregistered 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](#).

