

## Studies currently recruiting in CNTW

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### USEFUL RESEARCH CONTACTS


#### CNTW NIHR Portfolio Research Delivery Teams

|                    |                                   |                                   |
|--------------------|-----------------------------------|-----------------------------------|
| Sarah Edwards:     | Mental Health Studies (Team Lead) | 0191 22467388 and leave a message |
| Sarah Edwards:     | Dementia Studies (Team Lead)      | 0191 22467388 and leave a message |
| Lyndsey Duke:      | Neurology Studies (Advanced OT)   | 0191 287 5100                     |
| Lorraine Henderson | Delivery Team Admin               | 0191 2467388 and leave a message  |


#### Research and Development Team

|                |   |               |
|----------------|---|---------------|
| Simon Douglas: | (Joint Director of Research, Innovation and Clinical Effectiveness) |               |
| Paula Whitty:  | (Joint Director of Research, Innovation and Clinical Effectiveness) |               |
| Lyndsey Dixon: | (Research and Development Manager)                                  | 0191 246 7221 |
| Bryony Stokes  | (Quality Assurance Lead)  | 07812493306   |
| Emma Bowron    | (Research Coordinator)  | 07974589504   |


## Postpartum Care Studies

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| <p><b>The COSI STUDY</b><br/>A multi-site randomised controlled trial (RCT)</p> <p><b>Planned Rec End date:</b><br/><b>04/09/2023</b></p> | <p>A multi-site randomised controlled trial (RCT) to explore the clinical and cost effectiveness of the Circle of Security Intervention for mothers in perinatal mental health services.</p> <p><b>Recruitment Pathway:</b> Via specialist community perinatal services (CNTW)</p> | <p>CNTW Principal Investigator:<br/>Dr Louise McCarron</p> <p>Study Lead: Emily Clare,<br/>0797 0993186 /<br/><a href="mailto:Emily.clare@cntw.nhs.uk">Emily.clare@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
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## Perinatal Mental Health Studies

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| <p><b>BDRN</b> <u>On hold due to Covid</u><br/>Molecular genetic investigation of bipolar disorder and related mood disorder in nuclear families</p> <p><b>Planned Rec End date:</b><br/><b>31/12/2022</b></p> | <p>The study aims to find genes and other factors, such as stressful life events, which make some people more likely than others to become ill. We hope that their study will improve the understanding of mental illness and help researchers find better treatments in the future.</p> <p><b>Recruitment Pathway:</b> Clinician gives information leaflet to participant and gains permission to contact</p> | <p>Principal Investigator:<br/>Dr Andrew Cairns</p> <p>Study Lead: Emily Clare,<br/>0797 0993186 /<br/><a href="mailto:Emily.clare@cntw.nhs.uk">Emily.clare@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
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## Trauma Studies

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| <p><b>THE RESTART PROJECT</b></p> <p><b>Planned Rec End date:</b><br/><b>01/11/2022</b></p> | <p>A mixed-method study to examine the emotional and psychological impacts of trauma and resolve barriers to trauma therapy in people with an at risk mental state</p> <p><b>Recruitment Pathway:</b> Clinician to gain permission to pass contact details to delivery team</p> | <p>Principal Investigator: Dr Laura Rollisson</p> <p>Study Lead: Michael Kelly,<br/>07970993197/<br/><a href="mailto:Michael.Kelly@cntw.nhs.uk">Michael.Kelly@cntw.nhs.uk</a><br/>Or Study Lead: Jahnese Hamilton<br/><a href="mailto:Victoria.Wilson3@cntw.nhs.uk">Victoria.Wilson3@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p> <p>The University of Manchester</p>  |
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## Secure Care Services Studies

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| <p><b>Weight management</b> in adult secure care mental health settings: A mixed methods study to inform future weight management interventions</p> <p><b>Planned Rec End date:</b><br/><b>12/05/2023</b></p> | <p>The research will explore with adult patients, staff and carers their priorities for tackling unhealthy weight, and what would make this easier and harder to achieve.</p> <p><b>Recruitment Pathway:</b> Via Secure Care Services and Service User and Carer Involvement (CNTW)</p> | <p>Principal Investigator: Dr Susanna Mills</p> <p>Or Study Lead: Jahnese Hamilton<br/><a href="mailto:Jahnese.Hamilton@cntw.nhs.uk">Jahnese.Hamilton@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
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## Bipolar Disorder Studies

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| <p><b>R-LiNK</b> - Optimizing response to Lithium treatment through personalised evaluation of individuals with BIPOLAR I disorder</p> <p><b>Planned Rec End date: 10/01/22</b></p> | <p>Aims to identify biomarkers of response to treatment in bipolar disorder. Optimising response to Lithium treatment through personalised evaluation of individuals with bipolar 1 disorder. The R-LiNK team can provide advice on the indication of lithium, assist with reminders for blood monitoring and support your patients with a detailed, regular follow-up throughout their participation.</p> <p><b>Recruitment Pathway:</b> via prescribing clinician/ through caseload/liaison with clinicians.</p> | <p>Principal Investigator:<br/>Dr David Cousins</p> <p>Study Lead: Jamie Rea,<br/>0797 0993189 /<br/><a href="mailto:Jamie.Rea@cntw.nhs.uk">Jamie.Rea@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
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## (TRD) Treatment Resistant Depression Studies

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| <p><b>RESTORE-LIFE</b></p> <p>A Global Prospective, Multi-Center, Observational post-market Study to assess short, mid and long-term Effectiveness and efficiency of VNS Therapy®</p> <p><b>Planned Rec End date: 31/07/2023</b></p> | <p>A Global Prospective, Multi-centre, Observational post-market Study to assess short, mid, and long-term Effectiveness and efficiency of VNS Therapy® as adjunctive therapy in real-world patients with difficult to treat depression.</p> <p><b>Recruitment Pathway:</b> Via RADS</p>                                 | <p>Principal Investigator:<br/>Dr Hamish McAllister Williams</p> <p>Research Nurse: Samantha Bulmer, 07824 100801 /<br/><a href="mailto:Samantha.Bulmer@cntw.nhs.uk">Samantha.Bulmer@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
| <p><b>PAX-D</b></p> <p>Randomised Placebo-controlled Treatment Trial</p> <p><b>Planned recruitment end date: 31/03/2023</b></p>  | <p>Randomised placebo-controlled trial evaluating the efficacy and mechanism of pramipexole as add-on treatment for people with treatment resistant depression</p> <p><b>Recruitment Pathway:</b> Clinician approach via community/ inpatient/specialist services. Recruitment pathway may broaden once established.</p> | <p>Principal Investigator:<br/>Dr Stuart Watson</p> <p>Study Lead: Nadia Burman,<br/>07971030758/<br/><a href="mailto:Nadia.Burman@cntw.nhs.uk">Nadia.Burman@cntw.nhs.uk</a></p>                         | <p><b>Sponsor:</b></p>  |






## Research into Psychosis

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| <p><b><u>STAR</u></b><br/>Study of Trauma and Recovery Randomised Controlled Trial</p> <p><b>Planned Rec End date:</b><br/><b>31/07/2022</b></p>   | <p>A Multisite Randomised Controlled Trial of Trauma-Focused Cognitive Behaviour Therapy for psychosis and trauma. Aims to reduce post-traumatic stress symptoms in people with co-morbid post-traumatic stress disorder and psychosis through CBT, compared to treatment as usual.</p> <p><b>Recruitment Pathway:</b> Clinician referral, Identified through caseload screening.</p>   | <p>Principal Investigator: Dr Rob Dudley</p> <p>Study Lead: Jamie Rea,<br/>0797 0993189 /<br/><a href="mailto:Jamie.rea@cntw.nhs.uk">Jamie.rea@cntw.nhs.uk</a></p>  | <p><b>Sponsor:</b></p>                                      |
| <p><b><u>IPACCT</u></b> Improving prediction of psychosis in ARMS using a clinically useful prognostic tool (IPPACT): Phase 3 observational cohort Study</p> <p><b>Planned Rec End date:</b><br/><b>31/12/22</b></p> | <p>Aims to develop a prognostic model that predicts ARMS individuals at highest and lowest risk of psychosis using a brief set of non-invasive measures that are feasible in clinical practice and acceptable to service users and staff. To assess the external validity of these measures and the feasibility of implementing within clinical practice.</p> <p><b>Recruitment Pathway:</b> Service users accepted into ARMS Service unless explicit opt out</p> | <p>Principal Investigator: Dr Guy Dodgson</p> <p>Study Lead: Jamie Rea,<br/>0797 0993189 /<br/><a href="mailto:Jamie.rea@cntw.nhs.uk">Jamie.rea@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p> <p>The University of Manchester</p>  |
| <p><b><u>MUSE-FEP</u></b><br/>Managing Unusual Sensory Experiences (MUSE)</p> <p><b>Planned Rec End date:</b><br/><b>30/06/2022</b></p>  | <p>A feasibility trial of a targeted, psycho-education toolkit for distressing hallucinations, in people with a first episode of psychosis: MUSE FEP trial. A randomised controlled trial comparing 4-6 sessions of MUSE therapy to treatment as usual.</p> <p><b>Recruitment Pathway:</b> Via EIP services only. Contact Research worker Lucy O'Grady, or trial manager Charlotte Aynsworth, via <a href="mailto:PRU@cntw.nhs.uk">PRU@cntw.nhs.uk</a></p>        | <p>National Lead: Dr Robert Dudley</p> <p>CNTW Principal Investigator :<br/>Dr Guy Dodgson</p>  | <p><b>Sponsor:</b></p>                                      |




## Research into Learning Disabilities and Autism

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| <p><b><u>CIASP-ID</u></b><br/>The Clinical Anxiety Screen for Intellectual Disabilities</p> <p><b>Planned Rec End date: 01/10/2022</b></p>  | <p>The study aims to develop a clinical tool for the detection of anxiety in non-verbal people with learning disabilities via questionnaires. The study is recruiting parents &amp; carers of people aged 4+ with moderate to profound learning disabilities.</p> <p><b>Recruitment Pathway:</b> Study invite sent to family by delivery team on behalf of clinician.</p> | <p>Principal Investigator:<br/>Dr Barry Ingham</p> <p>Study Lead: Emily Clare,<br/>0797 0993186 /<br/><a href="mailto:Emily.clare@cntw.nhs.uk">Emily.clare@cntw.nhs.uk</a></p>  | <p><b>Sponsor:</b></p>  |
| <p><b><u>EPILEPSY LD REGISTER</u></b><br/>A register for collecting / measuring outcomes of licensed Anti-Epileptic Drugs in patients with Epilepsy and Intellectual Disability and/or Pervasive Development Disorders</p> <p><b>Planned Rec End date: 20/11/2024</b></p> | <p>To ascertain the safety and impact of AEDs in PWE on individuals with ID and/or PDD with specific focus on the intensity and frequency of seizures and the side effects associated with their use and to compare these findings with data collected for a control group of PWE who do not have ID and/or PDD.</p>  | <p>Principal Investigator:<br/>Dr Ian McKinnon</p> <p>Study Lead: TBC, please contact Sarah Edwards with any queries,<br/>07812483493/<br/><a href="mailto:Sarah.Edwards@cntw.nhs.uk">Sarah.Edwards@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
| <p><b>RE-ASCed</b></p> <p><b>Planned Rec End date: 31/08/2022</b></p>   | <p>A Realist Evaluation of Autism ServiCe Delivery (RE-ASCed): Which diagnostic pathways work best, for whom, when, and at what cost?</p> <p><b>Recruitment Pathway:</b> South of Tyne Children and Young People's Service's</p>  | <p>Principal Investigator: Dr Laura Rollisson</p> <p>Study Lead: Michael Kelly,<br/>07970993197/<br/><a href="mailto:Michael.Kelly@cntw.nhs.uk">Michael.Kelly@cntw.nhs.uk</a></p>                                       | <p><b>Sponsor:</b></p>  |


## Research into Alzheimer's / Dementia

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| <p><b><u>CREED</u></b><br/>Cholinergic ResponsE in Early lewy body Disease</p> <p><b>Planned Rec End date: 31/12/2022</b></p>  | <p><u>Interventional cross-over RCT</u></p> <p>Aims to find the best way of predicting response to treatment for a cognitive impairment in DLB disease or PD dementia, identify who will benefit the most from treatment with a cholinesterase inhibitor.</p> <p><b>Recruitment pathway:</b> Recruited via case register or clinician referral</p>   | <p>Principal Investigator: Dr Alison Yarnall</p> <p>Study Lead: Victoria Hetherington, 07816366456 / <a href="mailto:Victoria.hetherington@cntw.nhs.uk">Victoria.hetherington@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p> <p>The Newcastle Upon Tyne Hospitals NHS Foundation Trust</p>         |
| <p><b><u>COGSLEEP</u></b><br/>Understanding the relationship between cognitive fluctuations, sleep, and arousal in Dementia with Lewy Bodies.</p> <p><b>Planned Rec End date: 31/08/2022</b></p>   | <p><u>Observational Study</u></p> <p>The Overall aim of the study is to better understand cognitive fluctuations in Dementia with Lewy Bodies (DLB)</p> <p><b>Recruitment pathway:</b> Via case register, clinician referral and self-referral</p>   | <p>Principal Investigator: Dr Charlotte Allan</p> <p>Study Lead: Emily Nuttall, 07970 993 199 / <a href="mailto:Emily.Nuttall@cntw.nhs.uk">Emily.Nuttall@cntw.nhs.uk</a></p>                      | <p><b>Sponsor:</b></p> <p>Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust</p>    |
| <p><b><u>DETERMIND</u></b><br/>DETERMinants of quality of life, care and costs, and consequences of INequalities in people with Dementia and their carer's.</p> <p><b>Planned Rec End date: No set date- until recruitment target is met</b></p> | <p><u>Observational Study</u></p> <p>Longitudinal observational study to explore and understand inequalities in dementia care and what drives good and bad quality of life, outcomes, and costs for people with dementia and their carers following diagnosis via interviews.</p> <p><b>Recruitment pathway:</b> Via case register, clinician referral and self-referral</p>                     | <p>Local PI: Prof John-Paul Taylor</p> <p>Study Lead: Emily Nuttall, 07970 993 199 / <a href="mailto:Emily.nuttall@cntw.nhs.uk">Emily.nuttall@cntw.nhs.uk</a></p>                                 | <p><b>Sponsor:</b></p>   |
| <p><b><u>Enlist</u></b><br/>Diagnostic and Prognostic Biomarkers in Dementia with Lewy Bodies. A UK Longitudinal Study</p> <p><b>Planned Rec End date: 31/03/2023</b></p>  | <p><u>Observational Study</u></p> <p>The overall aim of this study is to examine clinical and biomarker predictors of the rate of cognitive decline in individuals diagnosed with dementia with Lewy bodies DLB.</p> <p><b>Recruitment Pathway:</b> Recruited via case register, clinician referral and self-referral</p>  | <p>Principal Investigator: Dr John-Paul Taylor</p> <p>Study Lead: Emily Nuttall, 07970 993 199 / <a href="mailto:Emily.Nuttall@cntw.nhs.uk">Emily.Nuttall@cntw.nhs.uk</a></p>                     | <p><b>Sponsor:</b></p>    |
| <p><b>SMARTPHONES AND DEMENTIA STUDY</b><br/>Assistive Technology in Dementia: exploring the views and experiences of patients and their carers of smartphones - a national survey</p> <p><b>Planned Rec End date: 11/11/2022</b></p>            | <p>To undertake a national survey of people with dementia and their carers to explore their experiences and opinions relating to the use of assistive technology – specifically smartphones in dementia.</p> <p><b>Recruitment Pathway:</b> only via Join Dementia Research website, <a href="https://www.joindementiaresearch.nihr.ac.uk/">https://www.joindementiaresearch.nihr.ac.uk/</a></p> | <p>Principal Investigator: Dr Robert Barber</p> <p>Study Lead: Victoria Hetherington, 07816366456 / <a href="mailto:Victoria.hetherington@cntw.nhs.uk">Victoria.hetherington@cntw.nhs.uk</a></p>  | <p><b>Sponsor:</b></p> <p>Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust</p>  |

## Research into Alzheimer's / Dementia

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| <p><b><u>PATHFINDER</u></b><br/>Problem Adaption Therapy for Individuals with Mild to Moderate Dementia and Depression</p> <p><b>Planned Rec End date: 01/07/22</b></p>  | <p>This interventional randomised controlled trial aims to develop an adapted Problem Adaptation Therapy Intervention, suitable for use with people with mild and moderate dementia and their main carer for delivery within the NHS. This is compared with care and treatment as usual.</p> <p><b>Recruitment Pathway:</b> Memory service, community treatment teams, case register</p>                                   | <p>Principal Investigator: Dr Charlotte Allan</p> <p>Study Lead: Jahnese Hamilton, 07584589669 / <a href="mailto:Jahnese.Hamilton@cntw.nhs.uk">Jahnese.Hamilton@cntw.nhs.uk</a></p>   | <p><b>Sponsor:</b></p>  |
| <p><b><u>Impass</u></b><br/>Improving the assessment of driving safety in cognitive impairment</p> <p><b>Planned Rec End date: 01/01/24</b></p>  | <p>This is a cross sectional study of people with cognitive impairment who are having a Driving Mobility assessment as part of their routine clinical care for participants with capacity to consent. Participants will complete a clinical and cognitive assessment and questionnaires are completed by approved friends/relatives.</p> <p><b>Recruitment Pathway:</b> Referral by clinician for a Driving Assessment</p> | <p>Principal Investigator: Dr John Paul-Taylor</p> <p>Study Contact: Kirsty Olsen, <a href="mailto:Kirstyolsen@nhs.net">Kirstyolsen@nhs.net</a></p> <p>CNTW Study Lead: Emily Nuttall, 07970 993 199 / <a href="mailto:Emily.Nuttall@cntw.nhs.uk">Emily.Nuttall@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
| <p><b><u>EVOKE/EVOKE+</u></b><br/>NB: Both the EVOKE and EVOKE+ studies are identical apart from the EVOKE+ study allowing a percentage of participants to have some degree of vascular changes on neuroimaging/vascular PMH.</p> <p><b>Planned Rec End date: 30/05/2022 – pending extension</b></p> | <p>A randomised double-blind placebo-controlled clinical trial investigating the effect and safety of oral semaglutide in subjects with early Alzheimer's disease:</p> <p><b>Recruitment Pathway:</b> Direct referrals from clinicians / research registers</p>  | <p>Principal Investigator: Dr Andrew Byrne</p> <p>Study Lead: Victoria Hetherington, 07816366456 / <a href="mailto:Victoria.hetherington@cntw.nhs.uk">Victoria.hetherington@cntw.nhs.uk</a></p>   | <p><b>Sponsor:</b></p>  |

## Research into Huntington's Disease

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| <p><b><u>ENROLL-HD</u></b><br/>Is a multi-centre, multi-national, prospective observational study of Huntington's Disease</p> <p><b>Planned Rec End date: 31/12/2031</b></p> | <p>The 3 main aims are to, to better understand HD as it happens in people to give insight into developing new drugs. To improve the design of clinical trials to rapidly provide clear outcomes – better, smarter, faster clinical trials will identify effective treatments as quickly as possible. To improve clinical care for HD patients by identifying the best clinical practices across all sites around the world and ensure that all families receive that standard of care.</p> <p><b>Recruitment Pathway:</b> Referral from Huntington Disease Consultants, nurses, support group and genetics clinic.</p> | <p>Principal Investigator: Dr Suresh Komati</p> <p>Study Lead: Sarah Edwards, 07812 483 493 / <a href="mailto:Sarah.edwards@cntw.nhs.uk">Sarah.edwards@cntw.nhs.uk</a></p> | <p><b>Sponsor:</b></p>  |
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## [Neurodegeneration Case Register](#)

To facilitate recruitment to studies we have a Case Register for people with all types of **dementia, mild cognitive impairment, Parkinson's disease, progressive supranuclear palsy and multiple system atrophy**. The Case Register holds information about patients interested in research. Members of the Case Register can be selected for suitable studies and asked if they would like to take part. Patients throughout the region should have opportunities to take part in clinical research. For clinicians, referring to the Case Register can be a step on the way to research activity.

Send the contact details of patients you have discussed research with to us.

Either write, copy us in to a clinic letter, telephone, or email. We will then process these referrals.

## How to refer patients

### **Please contact us at**

Clinical Research Network

North East and North Cumbria Dementias and neurodegeneration (DeNDRoN),

St Nicholas Hospital

Jubilee Road, Gosforth

Newcastle upon Tyne, NE3 3XT

**Copy us in to a clinic letter**      **Phone:** 0191 246 7388 and leave a message    or    **Email:** [dendron@cntw.nhs.uk](mailto:dendron@cntw.nhs.uk)

## Data protection and confidentiality

- All data is stored securely on a CNTW Server
- Patient information is only released with the patient's agreement.
- **Patients are free to withdraw from the Case Register at any time; we remove their details from the database**
- The database is used by approved Network and CNTW staff

**For more information on the MH Studies, please contact: Email:** [Researchdelivery@cntw.nhs.uk](mailto:Researchdelivery@cntw.nhs.uk)

*South locality - Susan Wilson [susan.wilson1@cntw.nhs.uk](mailto:susan.wilson1@cntw.nhs.uk) (07970 993 181) & Nadia Burman [nadia.burman@cntw.nhs.uk](mailto:nadia.burman@cntw.nhs.uk) (07971030758)*

*Central Locality - (Newcastle and Gateshead) Jamie Rea [jamie.rea@cntw.nhs.uk](mailto:jamie.rea@cntw.nhs.uk) (0797 0993189) or Victoria Wilson [victoria.wilson3@cntw.nhs.uk](mailto:victoria.wilson3@cntw.nhs.uk) (07974594910)*

*North Locality - Emily Clare [emily.clare@cntw.nhs.uk](mailto:emily.clare@cntw.nhs.uk) (07970993186) or Jahnese Hamilton [Jahnese.Hamilton@cntw.nhs.uk](mailto:Jahnese.Hamilton@cntw.nhs.uk) (07584589669)*

**NIHR Portfolio Research Delivery Team (Mental Health), Wolfson Research Centre, C.A.V. NE4 5PL, Tel. 0191 208 1356 and leave a message**