

Postpartum Care Depression: Observational Study Depression: Observational Study The COSI STUDY **RESTORE-LIFE BDRN** - Bipolar Disorder Research A multi-site randomised controlled trial (RCT) to **Network Pregnancy and Childbirth** Sponsor: LivaNova explore the clinical and cost effectiveness of the Circle Study - On hold of Security Intervention for mothers in perinatal A Global Prospective, Multi-Center, Observational postmental health services. market Study to assess short, mid and long-term **Sponsor:** Cardiff University Effectiveness and efficiency of VNS Therapy® as adjunctive therapy in real-world patients with difficult to **Sponsor**: Anna Freud National Centre for Children and Families Molecular genetic investigation of bipolar disorder and related treat depression. mood disorder in nuclear families. **Inclusion Criteria** Women and other birthing parents who: **Inclusion Criteria Inclusion Criteria** Are accessing a community PMHS from one of the recruiting Aged 18+ Aged 18+ sites, Have a child aged 0-12 months with no severe illness or Currently pregnant or Primary diagnosis of chronic (>2 years) or recurrent (2 or Have ever experienced an episode of postpartum psychosis or developmental disorder, Score 1.1 or more as their average more prior episodes) major depressive episode that has any other mood episode following childbirth that required score on the CORE-10 [2], Score 12 or more on the general factor not adequately responded to antidepressant treatments hospital or home treatment. of the Postnatal Bonding Questionnaire PBQ) [3], Are aged at Diagnosis confirmed using the Mini-International And also: Neuropsychiatric Interview (MINI). least 18 and are willing and able to give informed consent, Are Have experienced one or more episodes of mania/hypomania at able to attend groups without being under the influence of Be able to provide informed consent any time in the past lasting at least 4 days (who may have, or Currently be receiving at least one antidepressant substances. may have had, a diagnosis of bipolar I disorder, bipolar II treatment or mood stabilizing treatment for bipolar disorder or schizoaffective disorder). **Exclusion Criteria** Women and other birthing parents who: Able to comply with the clinic visits to complete all **Exclusion criteria** Do not meet the inclusion criteria, Do not have a minimum of valuations Unable to provide informed consent. conversational English, Have received COS-P previously, Are **Exclusion criteria** Unable to speak English fluently due to semi-structured nature The investigator should refer to the (local applicable) experiencing active psychosis. of the interview VNS Therapy Physician's Manual. Known to have a blood borne infection e.g. HIV Participant must satisfy all inclusion and exclusion Recruitment Pathway: Via specialist community perinatal services (CNTW) criteria Recruitment Pathway: Clinician gives information leaflet to participant and gains permission to contact. **National Lead: Professor Peter Fonagy Recruitment Pathway: Via RADS CNTW Principal Investigator: Dr Louise McCarron** National Lead: Dr Katherine Gordon-Smith Delivery Team Lead: Emily Clare Emily.clare@cntw.nhs.uk National Lead: Prof. Koen Demyttenaere PI: Dr Andrew Cairns PI: Dr Hamish McAllister Williams **Delivery Team Lead: Emily Clare** Emily.clare@cntw.nhs.uk Recruitment end date: 04/09/2023 Research Nurse: Samantha Bulmer Samantha.Bulmer@cntw.nhs.uk Recruitment end date: 31/12/2022 Planned Rec End date: 31/07/2023





Psychosis - Observational Study	Psychosis - Randomised Controlled Trial
IPACCT	MUSE-FEP Managing Unusual
	Sensory Experiences
Improving prediction of psychosis in ARMS using a clinically useful prognostic tool (IPPACT): Phase 3 observational cohort Study. To predict ARMS individuals at highest and lowest risk of psychosis using accessible, acceptable measures. Inclusion Criteria Aged 16+ Attending secondary care services in the NHS who meet ARMS criteria, as defined by the CAARMS (regarding intensity, frequency duration of psychotic-like experiences and functional impairment). (Age range is included in the ARMS criteria and reflects that most psychotic disorders have their onset in late adolescence early adulthood) In contact with NHS Early Intervention Services or Child and Adolescent Mental Health Services Exclusion Criteria History of a treated or untreated psychotic episode of one week's duration or longer Previous or current treatment with antipsychotics at dose of over 5 mf of haloperidol or equivalent for over 3 weeks Recruitment Pathway: Service users accepted into ARMS Service unless explicit opt out	Sponsor: Cumbria, Northumberland, Tyne & Wear NHS Foundation Trust Managing Unusual Sensory Experiences (MUSE): 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. Inclusion Criteria EIP patient with identified CPN as care co-ordinator Schizophrenia/schizoaffective disorder/entry criteria for an EIP service; History of auditory hallucinations for at least four weeks; Aged 16 and above; Capacity to provide informed consent; Clinically stable for the preceding 4 weeks; No major changes in antipsychotic medication in previous month Exclusion Criteria Hallucinations/psychosis with a known biological basis Insufficient command of English to complete the study procedures; A primary diagnosis of substance misuse/dependency; Engaged in CBT currently or within past 6 months
National Lead: Alison Yung Co CI: Filippo Varese	Recruitment Pathway: Via EIP services only Contact Research worker Lucy O'Grady, or trial manager
PI: Dr Guy Dodgson Delivery Team Lead: Jamie Rea Jamie.Rea@cntw.nhs.uk	Charlotte Aynsworth, via PRU@cntw.nhs.uk
Recruitment end date: 31/12/2022	National Lead: Dr Robert Dudley CNTW Principal Investigator : Dr Guy Dodgson
	Recruitment end date: 30/06/2022





Neurodevelopmental: Register Trial	Neurodevelopmental: Questionnaire study	Autism – Observational Study
EPILEPSY LD REGISTER Sponsor: Cornwall Partnership NHS Foundation Trust A register for collecting/measuring outcomes of licensed Anti-Epileptic Drugs in patients with Epilepsy and Intellectual Disability and/or Pervasive Development Disorders. 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. Inclusion Criteria: Aged 18+ Diagnosis of epilepsy Prescribed a current study medication or treatment (in a live arm of the study) It is Imperative that individuals who remain/remained on the study AED or treatment for 12 months and individuals who did not remain on the study AED or treatment for 12 months are approached. Exclusion Criteria: None Listed National Lead: Dr Rohit Shankar PI: Dr Ian McKinnon Delivery Team Lead: TBC. Please contact Sarah Edwards sarah.edwards@cntw.nhs.uk with any queries Recruitment end date: 20/11/2024	Clasp-ID - The Clinical Anxiety Screen for Intellectual Disabilities Sponsor: Aston University The study aims to develop a clinical tool for the detection of anxiety in non-verbal people with learning disabilities. The study is recruiting parents & carers of people aged 4+ with moderate to profound learning disabilities Inclusion Criteria: Parents & carers of patients aged 4+ with moderate to profound learning disabilities under the care of community secondary care services. Exclusion criteria: Parent or carer unable to provide informed consent Recruitment Pathway: Study invite sent to family by delivery team on behalf of clinician. National Lead: Dr Joanne Tarver PI: Dr Barry Ingham Delivery Team Lead: Emily Clare Emily.clare@cntw.nhs.uk Recruitment end date: 01/10/2022	RE-ASCed A Realist Evaluation of Autism ServiCe Delivery (RE-ASCeD): Which diagnostic pathways work best, for whom, when, and at what cost? Sponsor: Sussex Community NHS FT Inclusion Criteria Child and family currently involved in the diagnostic pathway for possible Autism (parents/guardians of children already in, or just completed pathway also able to take part) All school ages (5 - 16) Provides informed consent Under management of local NHS clinical care team Agrees to have clinical records accessed (data collection form to extract useful data) by research staff or research staff from NU/SCFT/KU Exclusion criteria Over the age of 18, outside of school age Does not provide informed consent Not under the management of NHS local care services Recruitment Pathway: South of Tyne Children and Young People's Service's National Lead: Dr Ian Male CNTW Principal Investigator: Dr Laura Rollisson Delivery Team Lead: Michael Kelly michael.kelly@cntw.nhs.uk Recruitment end date: 31/08/2022



Recruitment End Date: 31/03/2023



Secure Care Services DEMENTIA Trauma Longitudinal Observational RESTART Weight management **ENLIST Study** A LEWY BODY DEMENTIA NETWORK in adult secure care mental health settings: A mixed methods Sponsor: Manchester University LONGITUDINALSTUDY IN THE UK study to inform future weight management interventions. A mixed-method study to examine the emotional and **Sponsor:** Kings College London The research will explore with adult patients, staff and carers psychological impacts of trauma and resolve barriers to their priorities for tackling unhealthy weight, and what would trauma therapy in people with an at risk mental state (participants can go from COGSLEEP into ENLIST) make this easier and harder to achieve. Aims to examine clinical and biomarker predictors of the rate **Inclusion Criteria** of cognitive decline in individuals diagnosed with dementia Sponsor: CNTW 16 years of age or older, Meeting ARMS criteria as defined with Lewy bodies DLB. by the CAARMS, Capacity and willingness to provide **Inclusion Criteria** informed consent, Reported exposure to at least one Inclusion Criteria Inpatient in secure mental health services with diagnosed potentially traumatic life events, as assessed by the Alzheimer's Disease and Dementia with Lewy Bodies mental health condition (for former service users – now Trauma and Life Events checklist (TALE) Age 50+; Happy to have bloods; Living at home; has a carer discharged). Age 18 years and above, capacity to consent to research involvement / Staff employed at CNTW or TEWV with **Exclusion Criteria Exclusion criteria** a role in adult secure services / Carers who udertake a formal Under 16 years of age, Non-English speaking or requiring Severe physical or life-threatening conditions, including cancer or informal caring role for an adult inpatient/former inpatient an interpreter for the intervention (the assessment battery or other conditions with suspected survival time less than three in secure mental health services at CNTW or TEWV at present can only be delivered in English), Evidence of years. Other intracranial pathology. Other physical or recent or past transition from ARMS status to first episode psychiatric conditions which may contribute to cognitive **Exclusion criteria** psychosis (FEP), operationally defined as meeting CAARMS impairment; Diagnosis of possible DLB with negative dopamine Diagnosis of an eating disorder/likely to experience distress transition criteria (i.e. history of a treated or untreated transporter scan (DaT scan); >five years use of antipsychotic through addressing weight management issues/ acutely unwell psychotic episode of one week's duration or longer) and/or drugs prior to diagnosis; Contraindications to Lumbar Puncture and exhibiting unpredictable or violent behaviour/ Lacking previous or current treatment with antipsychotics at dose including warfarin and anticoagulant. Study Partner who is capacity to consent to participate of over 5 mf of haloperidol or equivalent for over 3 weeks unable to attend all study visits with the participant. **Recruitment Pathway: Via Secure Care Services and Service** Recruitment Pathway: Clinician to gain permission to Recruitment Pathway: Recruited via case register, clinician **User and Carer Involvement (CNTW)** pass contact details to delivery team referral and self-referral **National Lead: Dr Susanna Mills** National Lead: Dr Filippo Varese National Lead I: Professor Dag Aarsland **CNTW Principal Investigator: Dr Susanna Mills** PI: Dr Guy Dodgson PI: Prof John-Paul Taylor Susanna.mills@cntw.nhs.uk **Delivery Team Leads: Michael Kelly Delivery Team Lead: Emily Nuttall** Delivery Team Lead: Jahnese Hamilton, Michael.Kelly@cntw.nhw.uk Emily.nuttall@cntw.nhs.uk Jahnese.hamilton@cntw.nhs.uk and Victoria Wilson Victoria.Wilson3@cntw.nhs.uk

Recruitment end date: 12/05/2023

Recruitment end date: 01/11/2022



DEMENTIA Observational Study	DEMENTIA Observational Study	DEMENTIA Observational double-blind placebo-control cross-over design study
COGSLEEP: Understanding the relationship between cognitive fluctuations, sleep and arousal in dementia with Lewy bodies	DETERMIND: DETERMinants of quality of life, care and costs, and consequences of INequalities in people with Dementia and their	CREED Cholinergic Respons in Early lewy body Disease Sponsor: The Newcastle upon Tyne Hospitals
Sponsor: CNTW NHS Foundation Trust The study Aims to better understand cognitive fluctuations in Dementia with Lewy Bodies (DLB)	Sponsor: University of Sussex	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.
Inclusion Criteria Aged 60+ years / A diagnosis of probable DLB or AD in accordance with recognised criteria for dementia groups. Capable of providing informed consent, or if lacking capacity, having a suitable consultee (in accordance with 2005 Mental Capacity Act) / Fluent in the English language / Have remained stable on relevant medication for a period of	good and bad quality of life, outcomes and costs for people with dementia and their carers following diagnosis via interviews.	Inclusion Criteria Aged 60+ years / Prodromal Dementia with Lewy Bodies, dementia with Lewy Bodies, Parkinson's Disease Dementia, Parkinson's Disease with MCI; Need an informant 2x weekly; Living in own home; MOCA <26; Cholinesterase inhibitor naïve 3months prior to
four weeks prior to participation (DLB/AD groups) Exclusion criteria Metallic implants in the head/neck area, or electronic implants of any type (including pacemakers); A history of other neurological illness including, but not limited to stroke, intracerebral pathology and epilepsy; Past of present delirium; A history of excess alcohol intake;		Main Exclusion criteria History of significant cerebrovascular disease; neurological diseases which may cause cognitive / major depression; Physical comorbidities; cognitive enhancing medications (e.g. cholinesterase inhibitors); High dose benzodiazepines, antipsychotics or
Presence of severe disease and significant physical co-morbidities; The presence of relevant visual; Impairments with the potential to interfere with attentional or visuoperceptual testing, or moderate-to-severe visual impairment secondary to glaucoma, cataract or macular degeneration.; Psychotropic and other medications which may	if we are unable to identify an appropriate personal or nominated consultee.	anticonvulsants; anticholinergics with significant central effects; inability to lie flat for 30 minutes, claustrophobia; Severe kidney disease; History of deep brain stimulation; Severe parkinsonism. Hypersensitivity to donepezil or piperidine derivatives.
significantly interfere with cognitive & TMS-EEG testing Recruitment pathway: Via case register, clinician referral and self-referral	Recruitment pathway: Via case register, clinician referral and self-referral	Recruitment pathway: Recruited via case register or clinician referral National Lead: Prof John-Paul Taylor
National Lead: Prof John-Paul Taylor/ Dr. Greg Elder Pl: Dr Kirstie Anderson	National Lead: Prof Sube Banerjee Local PI: Prof John-Paul Taylor	PI: Dr Alison Yarnall Delivery Team Lead: Victoria Hetherington Victoria.hetherington@cntw.nhs.uk
Delivery Team Lead: Emily Nuttall Emily.nuttall@cntw.nhs.uk Recruitment End Date: 31/08/2022	Delivery Team Lead: Emily Nuttall Emily.nuttall@cntw.nhs.uk Recruitment end date: No set date- until recruitment target is met.	Recruitment End Date: 31/12/2022





SMARTPHONES AND DEMENTIA STUDY

Dementia – Questionnaire Study

Assistive Technology in Dementia: exploring the views and experiences of patients and their carers of smartphones - a national survey

Sponsor: CNTW NHS Foundation Trust

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.

Inclusion Criteria

Anyone over the age of 18 years who has dementia or is caregiver of someone with dementia.

Exclusion Criteria

Over 18 years of age

We are only approaching people who have identified themselves as either having a dementia or being carer for someone with dementia

Recruitment Pathway: only via Join Dementia Research website.

https://www.joindementiaresearch.nihr.ac.uk/

National Lead: PI: Dr Robert Barber

Delivery Team Lead: Victoria Hetherington

Victoria.hetherington@cntw.nhs.uk

Recruitment End Date: 11/11/2022

Dementia - randomised double-blind placebocontrolled

EVOKE/EVOKE+

A randomised double-blind placebo-controlled clinical trial investigating the effect and safety of oral semaglutide in subjects with early Alzheimer's disease:

Sponsor: Novo Nordisk A/S

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.

Inclusion Criteria

Aged 55-85 years MCI or mild AD MMSE ≥22

Amyloid positivity established with either amyloid PET or CSF A β 1-42 (conducted at screening).

If on an acetylcholinesterase inhibitor or memantine the dose must have been stable for at least 3 months prior to screening.

Main Exclusion Criteria

Evidence of significant cerebral vascular disease on MRI Evidence of clinically relevant or unstable psychiatric disorder, Type 1 diabetes or unstable type 2, Some prohibited meds (assessed at screening), Contraindications to MRI

Recruitment Pathway: Direct referrals from clinicians / research registers

National Lead: Naji Tabet PI: Dr Andrew Byrne

Delivery Team Lead: Victoria Hetherington

Victoria.hetherington@cntw.nhs.uk

Recruitment End Date: 30/05/2022 – extension pending

HUNTINGTON'S DISEASE Longitudinal Observational

ENROLL-HD

Sponsor: CHDI Foundation

A multi-centre, multi-national, prospective observational study of Huntington's Disease

Inclusion Criteria

Informed consent from potential participant or legal representative is a pre-requisite for study participation. Individuals eligible for Enroll-HD will be in two major categories: Carriers: consists of individuals who carry the HD gene expansion mutation, whether they are currently experiencing any symptoms or not. Controls: Individuals who do not carry the HD gene expansion mutation; Genotype unknown- a first or second degree relative, Genotype Negative: A 1st or 2nd degree relative, related by blood to a carrier, who has had testing for HD and known not to carry HD expansion mutation or Family Control: Family members or individuals not related by blood to carriers

Exclusion Criteria

Individuals who do not meet inclusion criteria. Individuals with chronic movement disorders in the context of a negative test for the HD expansion mutation; those individuals with a history of or concurrent major central nervous system disorder will be excluded (e.g. stroke, Parkinson disease, Multiple Sclerosis, etc.)

Recruitment Pathway: Referral from Huntington Disease Consultants, nurses, support group and genetics clinic.

National Lead: Prof Anne Rosser PI: Dr Suresh Komati

Delivery Team Lead: Sarah E

Delivery Team Lead: Sarah Edwards Sarah.Edwards@cntw.nhs.uk

Recruitment End Date: 31/12/2031



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 into a clinic letter Phone: 0191 246 7388 and leave a message or Email: dendron@cntw.nhs.uk

Data protection and confidentiality

• All data is stored securely on a CNTW Server

- The database is used by approved Network and CNTW staff
- 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

For more information on the MH Studies, please contact: Email: Researchdelivery@cntw.nhs.uk

South locality - Nadia Burman <u>nadia.burman@cntw.nhs.uk</u> (07971030758) & Michael Kelly Michael.Kelly@cntw.nhs.uk (07970993197)

Central Locality - (Newcastle and Gateshead) Jamie Rea <u>jamie.rea@cntw.nhs.uk</u> (0797 0993189) or Victoria Wilson <u>victoria.wilson3@cntw.nhs.uk</u> (07974594910)

North Locality - Emily Clare emily.clare@cntw.nhs.uk (07970993186) or Jahnese Hamilton 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