Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

Studies currently recruiting in CNTW

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
Joseph Horne:	(Commercial Studies Lead)	07973618424
Bryony Stokes	(Quality Assurance Lead)	07812493306
Ellie Drummond:	(Research Coordinator)	07974589504
Emma Bowron	(Research Coordinator)	07974589504
Karol Adams:	(Research and Development Secretary)	0191 246 7222

Urgent Public Health Studies			
BASIL C-19 Behavioural Activation in Social IsoLation **Planned Rec End date**: **30/06/2021**	Participants are randomised to a behavioural activation (BA) intervention (up to 8 sessions, via telephone or video call) compared to usual care and treatment. Study aims to assess effectiveness of BA in benefiting physical and emotional wellbeing of older adults with underlying physical health conditions and indicators of low mood who have become more socially isolated due to Covid-19. **Recruitment Pathway:** Identified directly from GP PIC sites, No CNTW referrals accepted.	Principal Investigator: Dr Robert Barber Study Lead**:** Susan Wilson 07769 245342, susan.wilson1@cntw.nhs.uk	**Sponsor:** NHS Tees, Esk and Wear Valleys NHS Foundation Trust
ISARIC CCP-UK ISARIC/World Health Organisation Clinical Characterisation Protocol for Severe Emerging Infections in the UK **Planned Rec End date**: **30/09/21**	A "sleeping study" activated in the event of an emerging unknown pathogen – and activated for COVID 19. Quickly gathers data on COVID-19 to inform clinical management and public health responses. A Sovereign Data Source that feeds directly to SAGE, PH England, PH Scotland, and many other groups. For inpatients diagnosed with COVID-19, anonymised data is collected on a range of physical health measures/medications/co-morbidities/outcome etc. **Recruitment Pathway:** Anonymised data collected remotely from a Rio; no referrals taken.	Principal Investigator: Jamie Rea, 07468 716186, Jamie.rea@cntw.nhs.uk Study Lead: Susan Wilson, 07769 245342, susan.wilson1@cntw.nhs.uk	**Sponsor:** University of Oxford World Health Organization
Perinatal Mental Health Studies			
Skylark Evaluating the Efficacy and Safety of Sage-217 In The Treatment Of Adults With Severe Postpartum Depression **Planned Rec End date:** **26/08/21**	A randomised, double- blind, placebo-controlled study evaluating the efficacy and safety of Sage-217 in the treatment of severe postpartum depression (major depressive episode within 4 weeks before delivery or up to a year after giving birth) Aims to evaluate symptoms of anxiety and depression and the safety and tolerability of SAGE-217 **Recruitment Pathway:** Via specialist perinatal services (CNTW).	Principal Investigator: Dr Andrew Cairns Study Lead: Joseph Horne, 0191 2081381 / Joseph.horne@cntw.nhs.uk	**Sponsor:** Sage Therapeutics™
BDRN On hold due to Covid Molecular genetic investigation of bipolar disorder and related mood disorder in nuclear families **Planned Rec End date:** **31/12/22**	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. **Recruitment Pathway:** Clinician gives information leaflet to participant and gains permission to contact	Principal Investigator: Dr Andrew Cairns Study Lead: Emily Clare, 0797 0993186 / Emily.clare@cntw.nhs.uk	**Sponsor:** Cardiff University Prifysgol Caerdydd
Bipolar Disorder Studies			
R-LiNK Optimizing response to Lithium treatment through personalised evaluation of individuals with BIPOLAR I disorder **Planned Rec End date:** **10/01/22**	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. **Recruitment Pathway:** via prescribing clinician/ through caseload/liaison with clinicians.	Principal Investigator: Dr David Cousins Study Lead: Jamie Rea, 0797 0993189 / Jamie.Rea@cntw.nhs.uk	**Sponsor:** Assistance Publique Hôpitaux de Paris

The PAX-BD study **Planned Rec End date: 01/10/21**	A double-blind, placebo-controlled, efficacy/mechanism study investigating the effect of adding pramipexole to antidepressant medication in patients with bipolar disorder who have depression that has not responded to other treatments. **Recruitment Pathway:** Clinician referral or approach to seek permission to pass on to research delivery team.	Principal Investigator: Dr Stuart Watson Study Lead: Emily Clare, 0797 0993186 / Emily.clare@cntw.nhs.uk	**Sponsor:** NHS Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
(TRD) Treatment Resistant Depression Studies			
PSILOCYBIN The Safety and Efficacy of Psilocybin in Participants with Treatment-Resistant Depression **Planned Rec End date: 30/07/21**	A multisite trial analysing the effects of a single administration of psilocybin at three doses (1mg, 10mg, 25mg) in patients with treatment resistant depression supported by a specially trained therapist. **The P-TRD study will shortly be reaching it's global recruitment target. Sites have therefore been requested to conclude dosing eligible patients by the end of June.** For further info: https://mood-disorders.co.uk/research/psilocybin-Study **Recruitment Pathway:** Clinician referral	Principal Investigator: Prof Hamish McAllister-Williams Study Lead: Susan Wilson, 07970 993 181 / Susan.Wilson1@cntw.nhs.uk	**Sponsor:** COMPASSION Navigating Mental Health Pathways
BRIGHTMIND Brain Image Guided Transcranial Magnetic Stimulation in Depression **Planned Rec End date: 01/12/21**	A study testing the effectiveness of a new approach to treat Treatment Resistant Depression (TRD) using magnetic stimulation applied via the scalp. It Compare the efficacy of Connectivity Guided Intermittent theta-burst stimulation (cgiTBS) vs standard Repetitive Transcranial Magnetic Stimulation (rTMS). **Recruitment Pathway:** Referral from any CNTW team, primary care referral pathway, self – referral.	Principal Investigator: Prof Hamish McAllister Williams Study Lead: Susan Wilson, 07970 993 181 / Susan.Wilson1@cntw.nhs.uk	**Sponsor:** NHS Nottinghamshire Healthcare NHS Foundation Trust
LQD Lithium versus Quetiapine in Treatment Resistant Depression **Planned Rec End date: 30/07/21**	Trying to work out which of two medications (lithium or quetiapine) added to an antidepressant is best in helping people with Treatment Resistant Depression. Patients in the LQD study will be given either lithium or quetiapine alongside their antidepressant. **Recruitment Pathway:** Self-referral or clinician referral	Principal Investigator: Prof Hamish McAllister-Williams Study Lead: Susan Wilson, 07769 245 342 / Susan.wilson1@cntw.nhs.uk	**Sponsor:** KING'S College LONDON
RESTORE-LIFE **Planned Rec End date: 31/07/23**	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. **Recruitment Pathway:** Via RADS	Principal Investigator: Dr Hamish McAllister Williams Research Nurse: Samantha Bulmer, 07824 100801 / Samantha.Bulmer@cntw.nhs.uk	**Sponsor:** LivaNova Health innovation that matters

Research into Psychosis			
STAR Study of Trauma and Recovery Randomised Controlled Trial **Planned Rec End date: 31/03/22**	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. **Recruitment Pathway:** Clinician referral, Identified through caseload screening.	Principal Investigator: Dr Rob Dudley Study Lead: Jamie Rea, 0797 0993189 / Jamie.rea@cntw.nhs.uk	**Sponsor:**
IPACCT Improving prediction of psychosis in ARMS using a clinically useful prognostic tool (IPPACT): Phase 3 observational cohort Study **Planned Rec End date: 31/03/22**	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. **Recruitment Pathway:** Service users accepted into ARMS Service unless explicit opt out	Principal Investigator: Dr Guy Dodgson Study Lead: Jamie Rea, 0797 0993189 / Jamie.rea@cntw.nhs.uk	**Sponsor:**
PREFER Participant Preferences for Voice-Hearing Therapies **Planned Rec End date: 30/11/21**	This questionnaire study aims to better understand patients' preferences regarding psychological therapies for distressing voices. This will aim to inform future service design and package of the way psychological therapies are offered to patients who hear distressing voices. **Recruitment Pathway:** Clinician to pass on information leaflet and gain permission to pass contact details to delivery team	Principal Investigator: Dr Nicola Branley Study Lead: Emily Clare, 0797 0993186 / Emily.clare@cntw.nhs.uk Or Study Lead: Jahnese Hamilton jahnese.hamilton@cntw.nhs.uk	**Sponsor:**
Current/recent user of mental health inpatient services			
SPRINT The Prevalence of **S**ocial Communication **PR**oblems in Adult Psychiatric **IN**pa**T**ients **Planned Rec End date: 30/06/21**	A study investigating how common social communication problems, such as autism, are in adults who have spent time in a psychiatric hospital, as well as their physical and mental health needs. Data collected via questionnaires and interviews for participant and their carer (family member/friend/staff). This aims to improve the understanding needed to improve services for adults with social communication problems who have been admitted to a psychiatric hospital. **Recruitment pathway:** Clinician to pass on information leaflet and gain permission to pass contact details to delivery team	Principal Investigator: Dr Barry Ingham Study Lead: Emily Clare, 0797 0993186 / Emily.clare@cntw.nhs.uk	**Sponsor:**
Research into Learning Disabilities and Autism			
BEAT-IT Recruiting in Cumbria Behavioural activation for depression in adults with severe intellectual disabilities. **Planned Rec End date: 30/09/21**	Study will examine if Behavioural Activation can be adapted for adults with more severe intellectual disabilities and depression, supported by their carers. Half the participants will take part in the Beat-It (behavioural activation) treatment, and half will receive usual NHS treatment. People who choose to take part will be involved for a maximum of six months. **Recruitment pathway:** via Community Learning Disability Teams in North Cumbria	Principal Investigator: Dr Dave Dagnan Study Lead: Jahnese Hamilton, 07584589669/ Jahnese.Hamilton@cntw.nhs.uk	**Sponsor:**

ClASP-ID The Clinical Anxiety Screen for Intellectual Disabilities **Planned Rec End date: 01/10/21**	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 & carers of people aged 4+ with moderate to profound learning disabilities. **Recruitment Pathway:** Study invite sent to family by delivery team on behalf of clinician.	Principal Investigator: Dr Barry Ingham Study Lead: Emily Clare, 0797 0993186 / Emily.clare@cntw.nhs.uk	**Sponsor:** Aston University BIRMINGHAM UK
EPILEPSY LD REGISTER A register for collecting/measuring outcomes of licensed Anti-Epileptic Drugs in patients with Epilepsy and Intellectual Disability and/or Pervasive Development Disorders **Planned Rec End date: 20/11/24**	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.	Principal Investigator: Dr Ian McKinnon Study Lead: Andrew Hamilton, 0797 0993197 / Andrew.Hamilton@cntw.nhs.uk	**Sponsor:** Cornwall Partnership NHS NHS Foundation Trust
PAT-A Exploring the effectiveness of personalised non-pharmacological anxiety treatment for adults with autism **Planned Rec End date: 30/06/21**	This is a national autism and anxiety survey, gathering the views of autistic people and professionals. Information gathered will be used to adapt current NHS anxiety treatments to make them 'fit for purpose' for use with autistic adults and test their efficacy in a randomised control trial. **Recruitment Pathway:** Survey recruited to via relevant database search	Principal Investigator: Dr Barry Ingham Study Lead: Susan Wilson, 07769 245 342 / Susan.wilson1@cntw.nhs.uk	**Sponsor:** NHS Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
Research for Children and Young Adolescents			
EOD-UK & ROI – Early Onset Depression in the UK and ROI in children aged 3-13 years **Planned Rec End date: 28/02/22**	Uses epidemiological surveillance to study the prevalence of Early Onset Depression (EOD) in children between the ages of 3 years and 13 in the UK and Republic of Ireland as well as describing the presentation and clinical features of children with EOD, examine pathways of referral, duration between symptom onset and first-time diagnosis and the current management strategies offered. **Recruitment Pathway:** via the Child Adolescent Psychiatry Surveillance System (CAPSS)	Principal Investigator: Dr Adi Sharma Study Lead: Joseph Horne, 07973618424/ Joseph.horne@cntw.nhs.uk	**Sponsor:** NHS Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
Research into Alzheimer's / Dementia			
CREED Cholinergic ResponsE in Early lewy body Disease **Planned Rec End date: 31/12/21**	interventional cross-over RCT 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. **Recruitment pathway:** Recruited via case register or clinician referral	Principal Investigator: Dr Alison Yarnall Study Lead: Victoria Hetherington, 07816366456 / Victoria.hetherington@cntw.nhs.uk	**Sponsor:** The Newcastle Upon Tyne Hospitals NHS NHS Foundation Trust
COGSLEEP Understanding the relationship between cognitive fluctuations, sleep, and arousal in Dementia with Lewy Bodies. **Planned Rec End date: 28/02/22**	Observational Study The Overall aim of the study is to better understand cognitive fluctuations in Dementia with Lewy Bodies (DLB) **Recruitment pathway:** Via case register, clinician referral and self-referral	Principal Investigator: Dr Charlotte Allan Study Lead: Emily Nuttall, 07970 993 199 / Emily.Nuttall@cntw.nhs.uk	**Sponsor:** NHS Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

DETERMIND DETERMinants of quality of life, care and costs, and consequences of INequalities in people with Dementia and their carer's. **Planned Rec End date: No set date- until recruitment target is met**	Observational Study 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. **Recruitment pathway:** Via case register, clinician referral and self-referral	Local PI: Prof John-Paul Taylor Study Lead: Emily Nuttall, 07970 993 199 / Emily.nuttall@cntw.nhs.uk	**Sponsor:** US UNIVERSITY OF SUSSEX
Enlist Diagnostic and Prognostic Biomarkers in Dementia with Lewy Bodies. A UK Longitudinal Study **Planned Rec End date: 28/02/22**	Observational Study 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. **Recruitment Pathway:** Recruited via case register, clinician referral and self-referral	Principal Investigator: Dr John-Paul Taylor Study Lead: Emily Nuttall, 07970 993 199 / Emily.Nuttall@cntw.nhs.uk	**Sponsor:** KING'S College LONDON
Impass Improving the assessment of driving safety in cognitive impairment **Planned Rec End date: 01/01/24**	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. **Recruitment Pathway:** Referral by clinician for a Driving Assessment	Principal Investigator: Dr John Paul-Taylor Study Contact: Kirsty Olsen, Kirstyolsen@nhs.net CNTW Study Lead: Emily Nuttall, 07970 993 199 / Emily.Nuttall@cntw.nhs.uk	**Sponsor:** NHS Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
PATHFINDER Problem Adaption Therapy for Individuals with Mild to Moderate Dementia and Depression **Planned Rec End date: 01/07/21**	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. **Recruitment Pathway:** Memory service, community treatment teams, case register	Principal Investigator: Dr Charlotte Allan Study Lead: Nadia Burman, 07971030758/ Nadia.Burman@cntw.nhs.uk	**Sponsor:** Camden and Islington NHS NHS Foundation Trust
Research into Huntington's Disease			
ENROLL-HD Is a multi-centre, multi-national, prospective observational study of Huntington's Disease **Planned Rec End date: 31/12/2031**	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. **Recruitment Pathway:** Referral from Huntington Disease Consultants, nurses, support group and genetics clinic.	Principal Investigator: Dr Suresh Komati Study Lead: Sarah Edwards, 07812 483 493 / Sarah.edwards@cntw.nhs.uk	**Sponsor:** CHDI FOUNDATION

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 into 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
- 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:

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

Central Locality - (Newcastle and Gateshead) Jamie Rea jamie.rea@cntw.nhs.uk (0797 0993189) or Andy Hamilton andrew.hamilton@cntw.nhs.uk (07970993197)

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