

---

## Research Currently Recruiting in NTW

---

<b>Mental Health</b>	<b>p 2 onwards</b>
<b>Dementias and Neurodegenerative Diseases</b>	<b>p 14 onwards</b>

## Useful Contacts

### NTW Research delivery teams

Mental Health: Jill Davison (Team Lead) 0191 246 7390

Dementia: Jill Davison (Team Lead) 0191 246 7390

Neurology: Lyndsey Duke (Advanced OT) 0191 287 5100

Lorraine Henderson (Research Team Administrator): 0191 2081360

### R&D

Simon Douglas: (Joint Director of Research, Innovation And Clinical Effectiveness)  
0191 246 7224

Lyndsey Dixon: (Research and Development Manager) 0191 246 7221

Victoria Ternent: (Research Coordinator) 0191 246 7228

Karol Adams: (Research Secretary & Team Administrator) 0191 246 7222



TRIANGLE is a multicentre randomised controlled trial to examine whether the addition of a patient and carer skill sharing intervention improves long-term patient wellbeing following hospital treatment for Anorexia Nervosa.

Patients and carers will take part over 18 months, and the intervention will take place over a professionally supported website. Carers and patients receiving the intervention will have access to workbooks, videos and skill based resources; as well as having access to mediated chat forums and skype sessions.

#### **Inclusion criteria:**

- Consecutive admissions for in/day patient care (at least 4 days a week)
- Aged 17 or over
- DSM-5 diagnosis of Anorexia Nervosa or Atypical/subclinical Anorexia Nervosa and a BMI <18.5 kg/m<sup>2</sup>
- With a carer (family or friends) willing to participate and able to provide some aftercare support.
- Consent signed within 2 months from admission.
- Participant able to access an electronic device (e.g. mobile phone, computer, laptop, tablet) and internet access.

**Contact:** Jamie Rea (Research Nurse): [Jamie.rea@ntw.nhs.uk](mailto:Jamie.rea@ntw.nhs.uk)

**Sponsor— Kings College London**

---

## **Lithium versus Quetiapine in Treatment Resistant Depression**



The Lithium versus Quetiapine in Depression (LQD) study is trying to work out which of two medications (lithium or quetiapine) added to an antidepressant is best in helping people with TRD. These two treatments are not new and are currently both recommended by NICE (the National Institute for Health and Care Excellence). Patients in the LQD study will be given either lithium or quetiapine alongside their antidepressant. Which drug they will be given will be decided randomly, but the patient and their doctor will know which one they are on. Patients will be followed up over 12 months to establish which treatment is more likely to improve TRD.

#### **Inclusion criteria**

- Diagnosis of major depression
- Not responded to (or relapsed whilst taking)  $\geq 2$  antidepressants in the current episode
- On current antidepressant for at least 6 weeks
- Aged 18 or over
- Willing and able to consent
- Willing to complete self-assessment and attend study visits

#### **Exclusion criteria**

- \* Bipolar disorder
- \* Current psychosis
- \* Pregnant or lactating
- \* Adequate use of lithium or quetiapine during current episode
- \* Known contraindications to either quetiapine or lithium

#### **Contact for enquiries or referral:**

Kimberley Nortey (Research Assistant) [Kimberley.Nortey@ntw.nhs.uk](mailto:Kimberley.Nortey@ntw.nhs.uk) Tel: 0191 208 1367  
Or Susan Wilson (Research Nurse) [susan.wilson1@ntw.nhs.uk](mailto:susan.wilson1@ntw.nhs.uk) Tel: 0191 208 1356



## Lifestyle Health and Wellbeing Survey

### Study Summary:

The aim of this survey is to provide information about the health and wellbeing of people with Severe mental illness (SMI).

The Lifestyle Health and Wellbeing Survey has two main objectives:

1. To benchmark current health related behaviors of people with severe mental ill health.
2. To provide a platform for future research with this population.

### Inclusion Criteria:

The inclusion criteria for this survey are broad to capture the views of a range of people with SMI.

- Aged 18 or over
- Have a recorded diagnosis of schizophrenia; bipolar or associated disorders.

**Contact:** Jamie Rea (Research Nurse): [jamie.rea@ntw.nhs.uk](mailto:jamie.rea@ntw.nhs.uk), , Tel: 0191 208 1367

**Sponsor— University of York**

---

## BLISS : Bipolar Lithium Imaging and Spectroscopy Study

### Study Summary:

This study aims to find out if there are differences between responders and non-responders to lithium so that in the future, psychiatrists will have a better idea who should be offered lithium; patients will be able to make more informed choices.

### Inclusion criteria

- Diagnosis of Bipolar Disorder
- Currently euthymic
- Able to have an MRI scan If prescribed, they should have been established on lithium for at least one year. We can always keep people in mind to invite at a later date, if they have been recently prescribed lithium.

### Exclusion criteria

- Previously prescribed lithium but now on other medication
- Learning disability
- Harmful drug or alcohol use
- Co-morbid diagnosis
- Current detention
- History of stroke
- History of head injury

**Contact:** Jamie Rea (Research Nurse) [jamie.rea@ntw.nhs.uk](mailto:jamie.rea@ntw.nhs.uk), Tel: 0191 208 1367

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**

## The Adult Autism Spectrum Cohort-UK research study (AASC-UK)



**Study Summary:** a research project to learn much more about the life experiences of adults with an autism spectrum disorder and their relatives .

The study will collect information from adults on the autism spectrum and relatives regarding their life experiences. Participants will join the nationally recruited cohort and will be asked to update their information from time to time, to see how people's lives change over time. They will also be informed at regular intervals about the progress of the study.

**Inclusion and Exclusion Criteria:** Adults on the autism spectrum, aged 16 or over

Relatives can be involved in two ways: (1) **Relatives/carers of adults on the autism spectrum who are unable to consent for themselves can join the study as consultees on behalf of the adult lacking capacity** (2) **Relatives of adults on the autism spectrum can join the relatives cohort, and give information about themselves**

**Contact:** Jahnese Hamilton, Clinical Studies Officer,

0191 2081367, [jahnese.hamilton@ntw.nhs.uk](mailto:jahnese.hamilton@ntw.nhs.uk)

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**

## Bipolar Disorder, Pregnancy and Childbirth Research



BDRN is the largest network of individuals with bipolar disorder in the world. 6000 individuals in the UK have now taken part in their studies and in their current research they are hoping to find out more about the factors that make some women with bipolar disorder more or less likely to experience episodes of illness in relation to childbirth.

### **Inclusion criteria:**

- Pregnant women with bipolar disorder
- Women with bipolar disorder who have experienced postpartum psychosis or any other mood episode featuring mania following childbirth that required hospital treatment
- Women without a bipolar diagnosis who have experienced postpartum psychosis or any other mood episode featuring mania following childbirth that required hospital treatment

Participation involves an interview with a researcher about experiences relating to mental health and childbirth, providing a blood sample, and completion of questionnaires. If pregnant then participation also includes a follow up contact after the birth.

Contact: Jahnese Hamilton (Clinical Studies Officer): [jahnese.hamilton@ntw.nhs.uk](mailto:jahnese.hamilton@ntw.nhs.uk)

**Sponsor— Cardiff University**

## The cap-mem study Exploring the cause and prevalence of memory problems

We would like to invite you to take part in our research study if:  
you are over 16, have mental health, neurodevelopmental or neurodegenerative disorder (such as schizophrenia, bipolar disorder, anxiety disorders, autism or dementia);  
or  
you are over 16 and do not have a mental health disorder  
(your responses would be used in a comparison group).

The study involves completing a short questionnaire about nervous system symptoms such as dizziness. You may also be offered the chance to complete brief memory tests.

If you would like to find out more about the study, contact: [cap.mem@ncl.ac.uk](mailto:cap.mem@ncl.ac.uk)

Or Kelly McGurk (Research Assistant) [Kelly.mcgurk@newcastle.ac.uk](mailto:Kelly.mcgurk@newcastle.ac.uk)

Jamie Rea (Research Nurse) [jamie.rea@ntw.nhs.uk](mailto:jamie.rea@ntw.nhs.uk)

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**



## Evaluation Of Parent Intervention For Challenging Behaviour In Children With Intellectual Disabilities (EPICC-ID)



EPICC-ID is a trial of a parenting intervention for parents of children with intellectual disabilities and challenging behaviour. The study will include young children aged 30-59 months with moderate to severe intellectual disabilities. The study is a randomised controlled trial so that 60% of participants will receive the intervention and 40% treatment as usual.

Stepping Stones Triple P (SSTP) is an intervention for parents of children with intellectual disabilities and challenging behaviour. It provides parents with information and support about how to manage such behaviours in their child. Trained therapists follow a manual and deliver the intervention in groups of 5-7 parents for 5 weeks, followed by 3 individual sessions and a final group meeting.

One parent (the main caregiver for the child) will attend each of the groups.

Chief Investigator: Professor Angela Hassiotis, UCL

NTW Principal Investigator: Dr Adi Sharma

Research Assistant: Abi Coulson

Research delivery team Support: Emily Clare, Clinical Studies Officer and Susan Wilson, Research Nurse

Abi Coulson is contactable on 0191 208 1394 if you would like to discuss referrals in more detail or request participant information leaflets or expression of interest forms.

Please direct expressions of interest to the [epicc.id.ne@ncl.ac.uk](mailto:epicc.id.ne@ncl.ac.uk) or [Abigail.coulson@ntw.nhs.uk](mailto:Abigail.coulson@ntw.nhs.uk)

**Sponsor— University College London Hospitals NHS Foundation Trust**

## Alleviating Specific Phobias Experienced by Children Trial

### ASPECT aims & objectives

- ◆ **The ASPECT trial aims to;**
- Investigate the clinical effectiveness of OST for specific phobias in children when compared to CBT
- Examine the cost effectiveness of OST in comparison to CBT
- Understand the impact of OST and CBT on the quality of life and functioning and children and young people taking part in the trial
- Establish the acceptability of OST to the children and young people taking part, their families and the therapists delivering the treatment using qualitative interviews.

### Inclusion criteria

- Is your child between the ages of 7 and 16 years old?
- Does your child have high levels of anxiety in the presence of a specific object or situation?
- Does your child avoid that object or situation when they can?
- Does this anxiety and avoidance affect your child's life to a significant degree (e.g. does it affect their sleep, school attendance, eating etc.)
- Has this problem been present for 6 months or longer?
- In order to be deemed eligible for participation, the parent/guardian will need to answer 'yes' to all questions and will be asked to provide the researcher with information about the nature of their child's phobia.

Contact: Joseph Horne; [Joseph.Horne@ntw.nhs.uk](mailto:Joseph.Horne@ntw.nhs.uk); 07976639951

### Sponsor— Leeds and York Partnership NHS Foundation Trust

#### One Session Treatment (OST)

- One Session Treatment (OST) is a variant of CBT and uses similar treatment techniques
- Unlike CBT, OST does not require an extensive treatment period.
- Instead, a combination of treatment techniques are consolidated into a single three-hour session
- OST has been shown to be clinically effective in children with specific phobias following a number of randomized controlled trials.
- However, to date OST has;
- NOT been tested in the UK
- NOT been compared to CBT, the gold standard treatment.
- NOT been tested in a pragmatic setting (i.e. no effectiveness RCTs to date)

Contact: Joseph Horne; [Joseph.Horne@ntw.nhs.uk](mailto:Joseph.Horne@ntw.nhs.uk); 07976639951



## Addressing intolerance of uncertainty in children with autism spectrum disorder: An intervention feasibility trial

### What is the aim of the study?

NTW is recruiting to the CUES research study, which aims to determine the feasibility and acceptability of a recently developed intervention helping parents of children with ASD to support their child to cope with uncertain situations. Children with Autism Spectrum Disorder (ASD) often experience difficulty with uncertainty which can lead to anxiety. We are looking to recruit parents of children aged 6-16 with a diagnosis of ASD and who experience some anxiety. Parents will be randomised to receive either the CUES intervention or an Understanding Autism group. The CUES intervention group involves eight group sessions for approximately 10 parents, covering a range of topics including strategies to cope with uncertainty and planning for the future. The sessions last around two hours each and will occur weekly, with breaks during school holidays. The Understanding Autism group will receive two one-hour parent group sessions, focusing on psychoeducation, emotional literacy and relaxation. Parents will be given an Information Sheet and if interested in participating, will complete an Expression of Interest form and return to their clinician or the research team at Newcastle University.

### Inclusion Criteria

We are looking for parents of children who have a diagnosis of Autism Spectrum Disorder (ASD) and:

- Are aged 6-16
- Experience some anxiety
- Either have no intellectual disability OR a mild-moderate intellectual disability
- Parents must have sufficient spoken and written English to provide written informed consent, complete assessments and participate in the intervention

### Exclusion Criteria

- Child has severe and complex anxiety disorder
- Child has severe intellectual disability
- Child has complex health conditions

Parents have significant mental health difficulties

For any more information about the CUES study, or to refer parents who are interested in participating, please contact Joseph Horne on [joseph.horne@ntw.nhs.uk](mailto:joseph.horne@ntw.nhs.uk) or 0191 208 1381.

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**

## DMS: Digital Medicine Study

### Aims of the study

This research is investigating the use of innovative digital technology for supporting individuals with serious mental illness and assisting clinicians in clinical decision making. The study will assess the usability and acceptance of the technology with service users and clinical staff

### The technology consists of:

1. An ingestible sensor which, along with an antipsychotic medication is over-encapsulated and swallowed
2. A wearable patch that captures adherence and physical health data
3. a secure mobile and cloud based software (smartphone app)



### Inclusion Criteria

- Aged 18-65
- Clinical diagnosis of schizophrenia disorder or schzoaffective disorder or first episode psychosis.
- Possess smartphone
- Be prescribed at least 1 pf olanzapine, risperidone, quetiapine, aripiprazole.

### Exclusion Criteria

- Allergy to adhesive tape..
- Prisoner or patient who is an in-patient on a secure psychiatric ward.
- Patient who is prescribed a LAI/depot that is the same as the oral equivalent.

### For further information or queries about this study please contact:

Principal Investigator Dr Rajesh Nair: [rajesh.nair@ntw.nhs.uk](mailto:rajesh.nair@ntw.nhs.uk) or

Emily Clare, Clinical Studies Officer: [emily.clare@ntw.nhs.uk](mailto:emily.clare@ntw.nhs.uk)

**Sponsor— Otsuka Pharmaceutical Co. LTD**

## **PAT-A Exploring the effectiveness of personalised non-pharmacological anxiety treatment for adults with autism:**

In this study, we will conduct a national autism and anxiety survey, gathering the views of autistic people and professionals. Using this information, we will 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. (Dr Jeremy Parr and Dr Jacqui Rodgers)

### **Inclusion criteria:**

Adults aged 18+ who are able to consent to take part in a research trial

- With a diagnosis of autism spectrum disorder (or previous subcategories e.g. Asperger Syndrome)
- Who is currently experiencing clinically significant anxiety based on clinical judgement

### **Exclusion Criteria:**

- People with insufficient verbal ability to take part in interviews and talking therapy
- People with physical or mental health conditions which would interfere with their ability to engage in talking therapy (CBT-based)
- People who have received talking therapy for anxiety within the last 3 months

**Further information about how to refer someone to the study and expression of interest forms are available from your team manager. For general inquiries about the study, contact:**

Dr Sam Brice, Clinical Research Associate and Trial Co-ordinator ([anxiety.autism@ncl.ac.uk](mailto:anxiety.autism@ncl.ac.uk), tel: 0191 282 1349) or

Susan Wilson, Local Clinical Research Network lead for PAT-A ([susan.wilson1@ntw.nhs.uk](mailto:susan.wilson1@ntw.nhs.uk), tel: 0191 208 1356)

Dr Barry Ingham, Consultant Clinical Psychologist and NTW Principal Investigator ([barry.ingham@ntw.nhs.uk](mailto:barry.ingham@ntw.nhs.uk))

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**



Managing Adolescent first episode Psychosis:  
a feasibility Study

### **Aims of the study**

Our primary aim is to determine whether it is feasible to conduct a study to examine the effectiveness of psychological therapy, antipsychotic medication or a combination of the two, in adolescents with first episode psychosis.

The relevance and validity of the measures to assess effectiveness, safety and acceptability in a subsequent definitive trial

### **Inclusion criteria:**

1. aged 14-18 (to ensure adolescent status)
  2. In contact with Early Intervention Services/Child and Adolescent Mental Health Services (to ensure appropriate safety considerations can be implemented)
  3. Competent to provide written, informed consent, with additional parental consent for those aged <16 (for ethical considerations).
  4. Either meet ICD-10 criteria for schizophrenia, schizoaffective disorder or delusional disorder or meet entry criteria for an Early Intervention for Psychosis service (operationally defined using PANSS) to allow for diagnostic uncertainty in early phases of psychosis
  5. Within one year of presentation to services with psychosis (to ensure first episode status)
  6. Score 4+ on PANSS delusions or hallucinations [for a minimum duration of seven consecutive days] (to ensure current psychosis)
- Help-seeking (for ethical considerations)

### **Exclusion criteria**

1. A primary diagnosis of alcohol/substance dependence \*
2. A diagnosis of moderate or severe learning disability \*
3. A diagnosis of ICD-10 organic psychosis \*
4. Score 5+ on PANSS conceptual disorganisation / disorganised speech (since majority of participants will be randomised to a talking therapy, we require capacity to answer questions in an interview situation and engage in a conversation)
5. Non-English speaking (since majority of participants will be randomised to a talking therapy)
6. Received APs or structured PI within the last 3 months (to ensure treatment naivety)
7. Immediate risk to self or others (to ensure appropriate safety considerations can be addressed)

\* These exclusions are to ensure that the participant population are representative of young people with a primary problem of first episode psychosis

### **For further information or queries about this study please contact:**

Rob Dudley (Principal Investigator): [Rob.dudley@ntw.nhs.uk](mailto:Rob.dudley@ntw.nhs.uk)

Jamie Rea (Clinical Research Nurse): [Jamie.rea@ntw.nhs.uk](mailto:Jamie.rea@ntw.nhs.uk)

**Sponsor— Greater Manchester Mental Health NHS Foundation Trust**



## MRB: Managing Repetitive Behaviours

Currently there is no parent group-based intervention targeting Repeat Repetitive Behaviour for young children with ASD as most ASD parent groups focus on social communication skills. We have developed, with parents and professionals, a new parent-based group intervention, called Managing Repetitive Behaviours (MRB), which focuses on identification, understanding and management of challenging RRB in young children with ASD.

### Aims of the study

This study aims to test the effectiveness of the MRB intervention for parents of young children with ASD against Learning About Autism group sessions. The long-term objective is to enable parents to have a better understanding of why children with ASD may show several repetitive behaviors, and manage those behaviors which cause difficulty for the family.

### Inclusion Criteria

Parents/carers aged 18 years and over who:

- Have a child aged between 3 years and 7 years and 11 months at the time of consent with a clinical diagnosis of Autism or Autism Spectrum Disorder.
- Have sufficient spoken and written English to: provide written informed consent complete the assessments including being able to identify one or more challenging RRB participate in the group-based intervention.
- Are willing to be randomised and attend all the group sessions for the allocated arm of the study.
- Agree to maintain their child's current medication regime.
- Agree not to participate in any other trials while involved in this trial up to 24 weeks.

### Exclusion Criteria

- Parent and child currently taking part in another parent group-based intervention.
- Parent with a current severe learning disability or a severe disabling mental illness that interferes with ability to take part in group-based intervention.
- Sibling taking part in this study.

**For further information or queries about this study please contact:**

Magdalena Glod (Research Associate): [magdalena.glod@newcastle.ac.uk](mailto:magdalena.glod@newcastle.ac.uk)

Dr Victoria Grahame (Principal Investigator): [victoria.grahame@ntw.nhs.uk](mailto:victoria.grahame@ntw.nhs.uk)

Susan Wilson (Clinical Research Nurse): [susan.wilson1@ntw.nhs.uk](mailto:susan.wilson1@ntw.nhs.uk)

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**

## **ORBIT: Online Remote Behavioural Intervention for Tics**

### **Aims of the study**

To evaluate the clinical effectiveness of BiP Tic: a therapist-guided, parent-assisted behavioural intervention programme for tics in young people with Tourette syndrome and chronic tic disorder, compared with usual care plus online education.

### **Inclusion Criteria**

1. Aged 9 to 17: patient confirmed through screening.
2. Suspected or confirmed Tourette syndrome/ chronic tic disorder:
3. Including Moderate/severe tics: Score >15 on the Yale Global Tic Severity Scale (YGTSS) Total Tic Severity Score (TTSS); TTSS score >10 if motor or vocal tics only: researcher confirms at screening appointment
4. Competent to provide written, informed consent (parental consent for child aged <16): researcher confirms at screening appointment.
5. Broadband internet access and regular PC/ laptop/Mac user, with mobile phone SMS: patient confirmed through screening.

### **Exclusion Criteria**

1. Previous structured behavioural intervention for tics e.g. HRT/CBIT or exposure and response prevention within last 12 months: Patient confirmed through screening.
2. Change to medication for tics (start or stop tic medication) within the previous 2 months: Patient confirmed through screening and subsequent medication/interventions commenced throughout out the trial are recorded at each time point for analysis.
3. Diagnoses of alcohol/substance dependence, psychosis, suicidality, or anorexia nervosa: Confirmed through parent DAWBA. DAWBAs that score people as being likely to have these conditions will be second reviewed by the CI (who is a medical expert) to ascertain that they should definitely be excluded from the trial. If the child is considered at immediate risk of suicide, the research team will inform the GP or usual treating clinician.
4. Moderate/severe intellectual disability: Confirmed through qualitative judgement of the assessor at the telephone screen (and confirmed at baseline through CAIDS-Q) through questions relating to type of school the child attends and previous diagnoses.
5. Immediate risk to self or others: Confirmed through screening questions and DAWBA. The participants GP will be informed of this.
6. Parent or child not able to speak or read/write English: Patient confirmed through screening by the assessor.

**For further information or queries about this study please contact:**

Joseph Horne [Joseph.horne@ntw.nhs.uk](mailto:Joseph.horne@ntw.nhs.uk) Tel 0191 2081379

**Sponsor— Nottinghamshire Healthcare NHS Foundation Trust**

## **WHAT IS THE CHILD AND ADOLESCENT PSYCHIATRY SURVEILLANCE SYSTEM (CAPSS)?**

CAPSS was launched in Spring 2009 with the support from the Royal College of Psychiatrists Faculty of Child and Adolescent Psychiatry and, importantly, the British Paediatric Surveillance Unit who have had over 20 years experience in rare disease surveillance. The aim of CAPSS is to encourage the study of rare mental health conditions in young people.

The identifiers used will depend on where you live:

England and Wales – NHS Number, date of birth, gender, ethnicity, and first part of postcode.

Scotland- CHI Number, date of birth, gender, ethnicity and first part of postcode

Northern Ireland – H&C Number, date of birth, gender, ethnicity and first part of postcode

Ireland – Date of birth, gender, ethnicity and first part of postcode (in Dublin only)

Joseph Horne [Joseph.horne@ntw.nhs.uk](mailto:Joseph.horne@ntw.nhs.uk) Tel 0191 2081379

**Sponsor— Northumberland Tyne and Wear NHS Foundation Trust**

---

**A register for collecting and measuring outcomes of licensed  
Anti-Epileptic Drugs in patients with Epilepsy and Intellectual  
Disability and/or Pervasive Developmental Disorders**



**Northumberland,  
Tyne and Wear  
NHS Foundation Trust**

**Epilepsy & learning disability register:** collecting and measuring outcomes of licensed Anti-Epileptic Drugs in patients with Epilepsy and Intellectual Disability (ID) and/or Pervasive Developmental Disorders (DD)

Patients with a diagnosis of intellectual disability Pervasive Developmental Disorders AND epilepsy, aged 18+ (no upper age)

If lacking capacity to consent, inclusion will be under opinion from their consultee

Currently focusing on patients who have been prescribed Levetiracetam

This involves Informed consent / opinion from consultee only (15 minutes)

Research data subsequently collected from medical notes by researcher.

Contact: [Andrew.hamilton@ntw.nhs.uk](mailto:Andrew.hamilton@ntw.nhs.uk) Tel. 01912081381

**Sponsor: Cornwall Partnership NHS Foundation Trust**

## **BRIGHtMIND—BRAIN IMAGE GUIDED TRANSCRANIAL MAGNETIC in DEPRESSION**

Are you living with moderate to severe depression?  
Have you been unable to find a treatment that works?

We're looking for volunteers to join a new trial to help find new ways to treat depression that has previously been resistant to medical treatment.

This research is being funded by the National Institute for Health Research and is a non-invasive trial lasting 26 weeks and will use pulses of magnetic stimulation to target the parts of the brain connected with symptoms of depression.

Inclusion criteria:

Aged over 18 years

Living with depression that has been resistant to antidepressant treatment

If you would like to take part please contact:

Andrew Hamilton—[Andrew.hamilton@ntw.nhs.uk](mailto:Andrew.hamilton@ntw.nhs.uk); Tel. 01912081381

**Sponsor— Nottinghamshire Healthcare NHS Foundation Trust**

---

## **Improving the Health of Older Autistic People (IHOAP) using Tailored Healthcare Adjustments (THA)**

Feasibility study of delivering the Tailored Healthcare Adjustments intervention to older autistic adults to improve access to physical healthcare

### **Inclusion Criteria**

Adults who are aged 50 or older

Diagnosis of ASD

Currently have at least two long term physical health conditions

Able to speak English

### **Exclusion Criteria**

Too unwell in their mental health to engage (e.g. too depressed, psychotic)

Contact: [Emily.Clare@ntw.nhs.uk](mailto:Emily.Clare@ntw.nhs.uk) / [Jahnese.Hamilton@ntw.nhs.uk](mailto:Jahnese.Hamilton@ntw.nhs.uk) Tel. 01912081367

**Study sponsor—Northumberland Tyne and Wear NHS Foundation Trust**

# THE SAFETY AND EFFICACY OF PSILOCYBIN IN PARTICIPANTS WITH TREATMENT-RESISTANT DEPRESSION



Northumberland,  
Tyne and Wear  
NHS Foundation Trust

**Principle Investigator: Professor Hamish McAllister- Williams**

**Sub Investigator: Dr Mourad Wahba**

Psilocybin is a naturally occurring chemical found in particular species of mushrooms, sometimes referred to as 'magic mushrooms'. It is one of a group of drugs known as 'psychedelics' which may have the potential to change perceptions and facilitate insights. A recent preliminary, open-label study has shown significant improvement in depressive symptoms following psilocybin administration with psychological support. Over 40% of participants' sustained response at 3 months and 32% had no need for further antidepressants or therapy at 1 year.

NTW is now recruiting to a multinational research study which involves any current antidepressants being tapered off prior to administration of a single dose of psilocybin alongside psychological support. Participants will be supported by 2 trained facilitators for 6 hours on the dosing day, in a quiet safe environment. Preparation and follow up visits will last over a 12 week period.

## **Inclusion Criteria**

18 years of age or older

At least moderate severity of major depressive disorder (MDD).

Single or recurrent episode of 3 months to 2 years duration

Failure to respond to an adequate dose and duration of 2, 3, or 4 pharmacological treatments for the current episode. (Failure includes failure to reach an adequate dose and duration due to lack of tolerance).

Able to discontinue all serotonergic medications during the study, at least 2 weeks prior to baseline, with support from study staff.

## **Brief Exclusion Criteria:**

Current or past history of schizophrenia, psychotic disorder (unless substance induced or due to a medical condition), bipolar disorder, delusional disorder, paranoid personality disorder, schizoaffective disorder, or borderline personality disorder.

Prior electroconvulsive therapy and/or intravenous ketamine for current episode.

Current cognitive behavioural therapy (CBT) that will not remain stable for the duration of the study.

Alcohol or drug abuse within the last year.

Significant risk of suicide.

*General Medical Exclusion Criteria: Pregnancy, cardiac arrhythmia or uncontrolled hypertension, seizure disorder, uncontrolled OR insulin-dependent diabetes*

## **For further information or potential referrals please contact:**

Wendy Hall (Study Nurse) [wendy.hall@ntw.nhs.uk](mailto:wendy.hall@ntw.nhs.uk) 0191 2081362 OR

Susan Wilson (CRN) [susan.wilson@ntw.nhs.uk](mailto:susan.wilson@ntw.nhs.uk) 01912081356

**Sponsor— Compass Pathways Limited**

## **Dementias and 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.

The Clinical Research Network:  
North East and North Cumbria  
can help you by:

- Promoting research in your clinics
- Signing your patients up to the Case Register
- Identifying suitable patients for your research studies
- Taking patient consent and providing information about studies and trials
- Carrying out research including study set-up
- Managing the Case Register
- Sending regular newsletters to Case Register members

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 send out information and obtain consent.

### **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    or    **Email:** [dendron@ntw.nhs.uk](mailto:dendron@ntw.nhs.uk)

### **Data protection and confidentiality**

- All data is stored securely on a restricted access, password protected database
- We maintain accuracy through biennial re-contact and sending out regular 'change of circumstances' forms
- The database is used by members of the Clinical Research Network only
- Patient information is only released with the patient's agreement
- We record clinical studies discussed with each patient in order to avoid overloading individuals with requests
- Patients are free to withdraw from the Case Register at any time; we inform you of their withdrawal or death and remove their details from the database



## Alzheimer's Disease (AD) Genetics

### Study summary:

This study is looking at the influence of genes in relation to the deterioration and presentation of early on-set AD. Participants are visited at a time and place convenient for them, usually in their own homes. It's a straightforward study with one visit: The blood samples, interviews and memory tests take less than 2 hours. The participant's partner, carer or family member will be interviewed at the same time.

### Inclusion:

People who are diagnosed with probable Alzheimer's disease with on-set of symptoms between ages of 66 and 70.

### Contacts:

Clinical Studies Officer: David Green - [David.green@ntw.nhs.uk](mailto:David.green@ntw.nhs.uk)

Clinical Studies Officer: Victoria Hetherington [Victoria.hetherington@ntw.nhs.uk](mailto:Victoria.hetherington@ntw.nhs.uk)

On 0191 2081348

**Sponsor - Cardiff University**



## iCST in people with Intellectual disabilities and dementia

**A feasibility randomised multi-site trial of individual cognitive stimulation therapy compared to “Treatment as usual” in participants with dementia and intellectual disabilities.**

### **Objectives:**

1. To adapt and modify a manualised individual Cognitive Stimulation Therapy (iCST) intervention for people with ID that can be delivered by carers
2. To carry out a feasibility randomised controlled trial of iCST, administered by carers in a home environment, compared to treatment as usual, and to determine the tolerability and acceptability of the intervention

### **Inclusion criteria**

- Aged 40 or over
- Premorbid mild or moderate Intellectual disabilities (based on clinical notes)
- ICD-10 diagnosis of mild or moderate dementia (assessed using the diagnostic tool from the CAMDEX-DS)
- Has a carer (paid or informal) who knows the person with dementia well and is willing to deliver the intervention
- Is able to provide informed consent or where the participant lacks capacity, he/she has a personal or nominated consultee who has agreed to the participant taking part in the study.
- Participants receiving anticholinesterase inhibitors as part of their usual treatment, will not be excluded.

### **Exclusion criteria**

- Severe intellectual disabilities
- Severe or late stage dementia
- Has a visual impairment or hearing impairment that may interfere with the participant taking part
- Has significant physical illness or disability preventing their participation
- Has significant behavioural problems that could affect participation (e.g. aggressive behaviour)

Please be advised that this is a 20 week intervention and that participants are given a £10 voucher for each research assessment.

### **For further information please contact :**

Sarah Edwards: [sarah.edwards@ntw.nhs.uk](mailto:sarah.edwards@ntw.nhs.uk) / 0191 2467392  
Jahnese Hamilton: [jahnese.hamilton@ntw.nhs.uk](mailto:jahnese.hamilton@ntw.nhs.uk) / 0191 2081367

## **THE IDEAL-2 STUDY**

### **Improving the experience of dementia and enhancing active life: a longitudinal perspective on living well with dementia.**

#### **Person with dementia:**

##### **Inclusion criteria**

1. Have been participating in IDEAL and not exiting that study due to withdrawal or loss to follow up.
2. Have previously agreed to being contacted should resources become available to find out how well they are doing after a long period.
3. People who lack capacity to consent will be eligible to take part.
4. Participating in the IDEAL-2 cohort will not preclude participation in intervention trials or other observational studies.

##### **Exclusion criteria**

1. Any known potential for home visits to pose a significant risk to NHS research network staff or members of IDEAL-2 study team
- 2.

#### **New participant:**

1. Clinical diagnosis of dementia.
2. MMSE score  $\geq 15$ .
3. Have a good understanding of the English language to allow completion of the assessment measures (unfortunately we do not have provision within the study to translate the measures to other languages).
4. Being from at least one of these groups:  
diagnosis of a rarer type of dementia: Frontotemporal dementia, Dementia with Lewy bodies, Parkinson's disease dementia, OR  
being  $\geq 90$  years old at the time of recruitment into the study OR  
being  $< 65$  years old at the time of recruitment into the study.
5. Living in the community on entry to the study.
6. Participating in the IDEAL-2 cohort will not preclude participation in intervention trials or converse and communicate in English
4. Has the ability to give informed consent

If you have any queries about this study please contact:

**June Pearson, Clinical Studies Officer: [june.pearson@ntw.nhs.uk](mailto:june.pearson@ntw.nhs.uk)**

**Sponsor: University of Exeter**

## Supporting Memory Services to enable people with dementia and their families' timely access to assistive technology.

**Aim:** The overall aim of this project is to enable families living with dementia more timely access to Assistive Technology (AT) and, via co-design techniques, develop practical and acceptable information and referral pathways to support translation into practice. This work stream aims to explore Memory Service professionals practice around AT using a survey and then focus groups and telephone interviews.

### Inclusion criteria

1. Professionals involved in the care provided by Memory Services
2. A good command of written English.

**Exclusion criteria** - None

If you have any queries about this study please contact:

Barbara Wilson, Clinical Studies Officer: [Barbara.wilson@ntw.nhs.uk](mailto:Barbara.wilson@ntw.nhs.uk)

**Sponsor : Northumberland Tyne and Wear NHS Foundation Trust**



### Enroll-HD:

A prospective Registry Study in Global Huntington's Disease Cohort  
Subjects include individuals 18 years or older who are HD gene expansion mutation carriers independent of the phenotypical manifestation or the stage of HD and controls who do not carry the HD expansion mutation and who comprise the comparator study population. For individuals under the age of 18 years, those with clinically diagnosed features of HD in the setting of a confirmatory family history or a positive genetic test result may be included in this study.

### Inclusion Criteria:

1. Carriers: This group comprises the primary study population and consists of individuals who carry the HD gene expansion mutation.
2. Controls: This group comprises the comparator study population and consists of individuals who do not carry the HD expansion mutation.

### Exclusion Criteria:

1. Individuals who do not meet inclusion criteria,
2. Individuals with choreic movement disorders in the context of a negative test for the HD gene mutation.
3. For Community Controls: those individuals with a major central nervous system disorder will be excluded (e.g. stroke, Parkinson disease, Multiple Sclerosis, etc.).

If you have any queries about this study please contact:

Sarah Edwards, Clinical Studies Officer: [Sarah.edwards@ntw.nhs.uk](mailto:Sarah.edwards@ntw.nhs.uk)

June Pearson, Clinical Studies Officer: [June.pearson@ntw.nhs.uk](mailto:June.pearson@ntw.nhs.uk)

## FREE-COG

**A novel, free to use, measure of combined cognitive and functional abilities**



**Northumberland,  
Tyne and Wear  
NHS Foundation Trust**

### **Aim**

**The purpose of this study is to compare the scores on this new instrument with those on existing ones already used in the clinic. In this way we will be able to test how this new assessment, called Free Cog (because it will be free for anyone to use) compares to existing ones which are currently in use.**

### **Inclusion criteria**

1. People with suspected cognitive impairment/dementia:
2. Over the age of 18 years old.
3. Referred to the memory service for a memory assessment or has a diagnosis of dementia/memory impairment

### **Exclusion criteria**

1. Under the age of 18

If you have any queries about this study please contact:

Clinical Studies Officer: Victoria Hetherington: [Victoria.hetherington@ntw.nhs.uk](mailto:Victoria.hetherington@ntw.nhs.uk)

**Sponsor: Greater Manchester Mental Health NHS Foundation Trust**



## Improving support for younger people with dementia and their families

**We are interested in recruiting people with young onset dementia and their family members/supporters across England. Young onset dementia is any form of dementia that is diagnosed before the age of 65.**

Taking part in the study would involve completing a questionnaire.

Participants can complete this on a computer or on a paper copy that will be sent to their homes.

To take part on-line please refer patients to:

<https://bradford.onlinesurveys.ac.uk/the-improving-support-and-service-use-survey>

To arrange for a paper questionnaire to be sent out via post or for further information on the study please contact:

Dr Barbara Wilson via email: [barbara.wilson@ntw.nhs.uk](mailto:barbara.wilson@ntw.nhs.uk) or telephone: **0191 2081337**

June Pearson via email: [june.pearson@ntw.nhs.uk](mailto:june.pearson@ntw.nhs.uk) or telephone: **0191 2081350**

**Sponsor: University College London**

## Parkinson's Families Project (PFP)

### Objectives

**Primary:** To identify genetic variants that predispose to or cause Parkinson's disease or Parkinsonism (Parkinson's diseases – PD);

**Secondary:** To identify families that may be prepared to participate in translational research related to PD, its aetiology, biology, progression and future treatment

### Inclusion criteria

- Age 16 years or over
- *Either* (1) Affected Parkinson's disease / Parkinsonism (PD) and either age at onset <45 years; or first or second degree family member affected by PD
- *Or* (2) Relative of (1) affected or unaffected by PD

### Exclusion criteria

- Lack of capacity to consent to participate in project

Dr Barbara Wilson via email: [barbara.wilson@ntw.nhs.uk](mailto:barbara.wilson@ntw.nhs.uk) or telephone: 0191 2081337

**Sponsor: 3-D Mtarix Ltd, 3M Deutschland GmbH, 4 SC AG, 4D Pharma Research Limited**

---

## PROSPECT—PROgressive Supranuclear Palsy CorTico-Basal Syndrome Multiple System Atrophy Longitudinal Study UK

### Inclusion criteria

- Written informed consent obtained prior to any study-related procedures. A consultee process will be used where participants lack the mental capacity for consent, either due to cognitive or communication deficits.
- Fulfills clinical criteria (PSP, MSA, CBD/CBS) or clinically defined allied disorders (at-risk states or intermediate disorders, as above) or a healthy control participant recruited from local volunteer databases or next of kin where they have expressed a wish to participate.
- Participant is 18 years old or older.
- Participant has an identified informant.

### Exclusion criteria

- Participant has another significant medical or psychiatric illness that would interfere in completing assessments
- Participant is pregnant.

Dr Barbara Wilson via email: [barbara.wilson@ntw.nhs.uk](mailto:barbara.wilson@ntw.nhs.uk) or telephone: **0191 2081337**

## The SUPeR Study

### <sup>123</sup>I-MIBG Scintigraphy Utility as a biomarker for Prodromal DEmentia with Lewy Bodies

This study follows on from the **Lewypro Study** to **identify biomarkers and clinical predictors of DLB** in people with **MCI and symptoms of Lewy body disease**

**Inclusion Criteria:** We will recruit older adults (≥60 years) with prodromal DLB, that is people who have cognitive and non-cognitive symptoms consistent with Lewy body disease but are not severely impaired with regards to cognitions and ADL's (MMSE ≥20 and CDR 0 or 0.5).

<b>Age ≥60</b>	<b>Diagnosis of MCI/early dementia</b>	<b>No P.D.</b>
<b>Stable medically</b>	<b>At least 1 symptom of DLB</b>	<b>No Hx stroke</b>
<b>MMSE ≥20</b>	<b>Mental Capacity to consent</b>	<b>Able to lie flat</b>
<b>CDR 0 or 0.5</b>	<b>Preserved activities of daily living</b>	<b>No warfarin (may be on ChEI)</b>

If you have any suitable subjects who may be willing to take part please contact:

Dr Barbara Wilson via email: [barbara.wilson@ntw.nhs.uk](mailto:barbara.wilson@ntw.nhs.uk) or telephone: **0191 2081337**

---

## SYMBAD

Study of mirtazapine and Carbamazepine for Agitation in Dementia:

A pragmatic, multi centre, double-blind, placebo controlled randomised trial to assess the safety, clinical and cost effectiveness of mirtazapine and Carbamazepine in patients with Alzheimer's Disease (AD) and agitated behaviours.

### **Patient inclusion criteria:**

- Clinical diagnosis of probable or possible Alzheimer's Disease using NINCDS/ADRDA criteria.
- Co-existing agitated behaviours.
- Cohen Mansfield Agitation Inventory (long form) score of 45 or greater.
- Evidence agitated behaviours not responded to management according to the AS/DH algorithm.
- Patients may be taking stable (3m+) cholinesterase inhibitors and/or Memantine.
- Written informed consent to enter and be randomised into the trial.
- Informant (family or paid carer) to provide information on care-completed outcome measures and who consents to take part.

### **Patient exclusion criteria:**

- Current (or within 2 weeks) treatment with antidepressants including (MAOIs) anticonvulsants and antipsychotics.
- Contradictions to the administration of Carbamazepine and Mirtazapine as per current SmPCs.
- Patients with antioventricular block, a history of bone marrow depression or history of hepatic porphyrias.
- Cases too critical for randomisation (ie where there is a suicide risk or when the patient presents a risk of harm to others)
- Female subjects under the age of 55 of childbearing potential.

**Contact for referral: Bryony Storey: [Bryony.storey@ntw.nhs.uk](mailto:Bryony.storey@ntw.nhs.uk)**



**TONIC**  
Trajectories of Outcome in Neurological Conditions  
[www.tonicstudy.org](http://www.tonicstudy.org)

## Trajectories of Outcome in Neurological Conditions

### Objectives:

To develop a biopsychosocial model of factors affecting quality of life (QoL) in different neurological conditions: multiple sclerosis (MS), motor neurone disease (MND), traumatic brain injury (TBI), spinal conditions, first stroke and neuromyelitis optica (NMO).

To examine the validity of the model over time.

To develop scales that measure different aspects of QoL in neurological illnesses, where generic scales are not available.

To test the validity of some existing generic measures.

Contact for referral: June Pearson: [June.Pearson@ntw.nhs.uk](mailto:June.Pearson@ntw.nhs.uk)



## PostGas—A multi-centre evaluation of the post-gastrostomy management in patients with Amyotrophic Lateral Sclerosis

### Patient inclusion criteria:

- Age >18 years.
- A diagnosis of definite, probable, laboratory supported or possible ALS, as defined by the revised El-Escorial criteria.
- A decision has been taken to refer the patient for a gastrostomy, regardless of indication.
- Participant is willing and able to give informed consent for participation in the study. If the participant is unable to provide written consent due to physical disability, an independent witness will be present at the informed consent discussion and sign the consent form on the participant's behalf.

### Patient exclusion criteria:

Age <18 years.

- Patient declines gastrostomy.
- Contraindication to gastrostomy.
- Underlying significant co-morbidity (e.g., thyroid disease, cancer or other disease) that would affect survival or metabolic state, independent of ALS.
- Patients who have undergone a successful gastrostomy (or are enterally fed via a nasogastric tube) before the start of the study.
- Significant decision-making incapacity preventing informed consent by the potential participant because of a major mental disorder, such as major depression or schizophrenia, or dementia.

Contact for referral: Andy Hamilton: [Andrew.hamilton@ntw.nhs.uk](mailto:Andrew.hamilton@ntw.nhs.uk)

## ProSec3—A multi-centre evaluation of excessive saliva management in patients with motor neurone disease

### Aim:

To assess the burden of secretion problems and efficacy of treatments for secretion problems in MND patients.

### Inclusion criteria

- Age 18 or older.
- ALS/ PLS/ PMA/ PBP as diagnosed by a consultant neurologist.

### Exclusion criteria:

- Inability to give informed consent.

Contact for referral: **Andy Hamilton: [Andrew.hamiltom@ntw.nhs.uk](mailto:Andrew.hamiltom@ntw.nhs.uk)**

---

## **BRAINS FOR DEMENTIA RESEARCH**

Increasing knowledge - Finding a cure

A partnership between Alzheimer's Research UK and Alzheimer's Society  
In association with the Medical Research Council

Web link: [www.brainsfordementiaresearch.org.uk](http://www.brainsfordementiaresearch.org.uk)

### Study Summary:

Patients can self-refer to the Brain Donor Register.

### Inclusion Criteria:

- Any dementia and normal elderly controls, aged over 65.
- Dementia patients without mental capacity can be referred if their personal consultee feels it in their best interest and not contrary to their previously expressed opinions .

Contact for referral: [dendron@ntw.nhs.uk](mailto:dendron@ntw.nhs.uk) Tel. 0191 223 2740