The cap-mem study.

Exploring the cause and prevalence of memory problems in people with mental health, neurodevelopmental and neurodegenerative disorders

Participant Information Sheet

We would like to invite you to take part in a research study. Before you decide, you need to understand why the study is being done and what it will involve for you. Please take the time to read the following information carefully. Please feel free to ask us if there is anything about the study that is not clear or if you require further information. Take your time to decide whether or not you would like to take part.

What is the purpose of this study?

It is known that people with mental health, neurodevelopmental and neurodegenerative disorders may have more problems with memory and concentration. We do not understand why this happens.

The autonomic nervous system regulates the way that our heart, lungs and digestive system work. If these systems are not working in the usual way then the blood supply to the brain will be slightly different. This change may be enough to affect memory and concentration.

We would like to know if the autonomic nervous system works differently in people with mental health, neurodevelopmental and neurodegenerative disorders. We would like to invite to the study people with and without such disorders to evaluate whether the autonomic nervous system is affected by the severity of the disorder or by medication use.

Why have I been approached?

You have been approached either because you have contacted us or because you have received care by health services in the past or because you have no mental health problems.

Do I have to take part?

Your participation is entirely voluntarily and if you decide not to take part, this will have no impact upon your current and future care or treatment within the NHS. No one will be aware that you have not agreed to take part in the study. Even if you take part now, you can later decide to withdraw from the study without any reason for doing so.

What will happen to me if I take part?

We would like to ask everyone who takes part to complete a few questionnaires. They are included in your pack. The questionnaires ask about symptoms that are caused by an upset autonomic nervous system and your experience of fatigue (tiredness). It will take you up to 15 minutes to complete the questionnaires.

We would also like you to decide whether you want to complete the tests of memory and concentration. These tests are done with a member of the research team who will be using a computer. It will take you up to 20 minutes to complete these tests and could be done either in NHS trust buildings or university (and in that case your travel expenses will be covered). If you prefer to undertake the memory tests at home, we may be able to arrange that for your convenience.

You will also be asked if you consent to be contacted about future research and if you agree for your medical notes to be accessed by the NHS Trust and regulatory authorities, and the research team (only if necessary).

I would like to take part. What do I have to do?

Please complete the questionnaires and the consent form, remember to tick the box to say whether you want to complete the memory tests and if you would like to be contacted about future research. Return the forms.

Continue your life as normal and take any medication as you would usually.

Will you tell me if my tests show an upset autonomic nervous system or memory problems?

The tests assess some aspects of autonomic nervous system and memory. They will show how well your autonomic nervous system is working and how well you are performing the memory tasks. The tests may highlight the possibility of having an upset autonomic nervous system or memory problems. If they do, we will talk to you about this and give you advice about any further tests that you may need.

What are the benefits of taking part?

There are no benefits to you personally, however the information that we gather from this study may help us to develop further treatments for mental health patients in future.

What are the possible disadvantages of taking part?

You will be giving up your free time to complete the questionnaires and, if you decide to do so, to do the memory tests.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Please, contact a research team member (Magdalena Glod or Layla Nugent) or Stuart Watson who leads this study or your local Patient Advice and Liaison Service (PALS) (details below) if you are unhappy with any aspect of this study.

Will my taking part in this study be kept confidential?

All information that you give us will be kept confidential and private. Your name will not be mentioned in any reports. We will ask your permission to contact your doctor to inform him or her that you are involved in the study. This is only for their information.

All data will be stored in accordance with data protection requirements and will be kept either in a locked filing cabinet in a secure office or in the case of electronic data on a secure server with a password protected computer and files and only accessed by the research team. Patient identifiable data (including consent form) will be destroyed 1 year after completion of the study. Patient identifiable data will not be published.

What will happen to the results of the study?

The data that you provide will be anonymised, so your name will be removed from the data. The results of the study may be presented at conferences and submitted to a scientific journal for publication. We expect this to happen within 6 months of the end of the study. You will not be identified in any reports or publications.

What will happen if I lose capacity to consent?

If, after completing the study, you become unwell, or for any other reason lose the ability to make a reasoned decision about whether you would want to participate in the study, we will keep the results of the questionnaire and/or memory tests that you had completed already.

Who are you?

The study is led by researchers who work for Newcastle University, the NHS and the Clinical Research Network. The study was funded by the Newcastle upon Tyne Hospitals NHS Trust with further support from Lundbeck who have supplied the computers and software for the memory tests. The study is sponsored by NTW Foundation NHS Trusts. The study lead is Stuart Watson who is a Clinical Senior Lecturer at Newcastle University and an Honorary Consultant Psychiatrist. The study is running in a number of centres across the UK, including: Berkshire Healthcare NHS Foundation Trust, Cornwall Partnership NHS Foundation Trust, Leeds and York Partnership NHS Foundation Trust, Northumberland Tyne and Wear NHS Foundation Trust, Somerset Partnership NHS Foundation Trust, Southern Health NHS Foundation Trust and Tees, Esk and Wear Valley NHS Foundation Trust.

The study has been reviewed by a Hampshire B Research Ethics Committee.

Who can I contact

If you have any questions about taking part in this study, please, contact:

Magdalena Glod

email: magdalena.glod@ncl.ac.uk

Address: Academic Psychiatry and Regional Affective Disorders Service
Newcastle University
Wolfson Research Centre
Campus for Ageing and Vitality

Layla Nugent

email: Layla.Nugent@ntw.nhs.uk

Address: Academic Psychiatry and Regional Affective Disorders Service
Newcastle University
Wolfson Research Centre
Campus for Ageing and Vitality

In case of complaint, please, contact:

Patient Advice and Liaison Service (PALS)

Please, find your local PALS:

www.nhs.uk/Service-Search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363

Dr Stuart Watson

Email: **stuart.watson@ncl.ac.uk**

Telephone: +44 (0) 191 2081388

Address: Academic Psychiatry and Regional Affective Disorders Service
Newcastle University
Wolfson Research Centre
Campus for Ageing and Vitality
Newcastle upon Tyne
NE4 5PL, UK