

BIPOLAR LITHIUM IMAGING AND SPECTROSCOPY STUDY (BLISS)



PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Please read this information sheet carefully – the first part tells you the purpose of our study and what will happen if you take part; the second provides more detailed information about the conduct of the study.

It may take some time to fully digest the information and you might want to talk to others about the study. There's no rush and you can ask us if there is anything that is not clear. If you do want to get involved, or would simply like some more details before deciding, please get in touch – we'd be happy to answer any of your questions.

STUDYING THE EFFECTS OF LITHIUM ON THE BRAIN

Bipolar disorder is a serious mental illness that affects hundreds of thousands of people in the UK. Episodes of depression and mania have a profound effect on wellbeing, but patients can also struggle with poor memory and concentration. Preventing relapse is really important and we most often advise patients to take long-term 'maintenance' medication. Lithium can be very effective but it doesn't work for everyone. It can also have serious side effects, so it would be really useful to be able to predict who will respond well to lithium before they start taking it.

What is the purpose of the study?

We are trying to understand why lithium is an effective treatment for some patients with bipolar disorder but not others. Lithium responders may differ in their pattern of episodes, family history, genetic make-up and possibly brain structure. It might be that for a given dose, more lithium gets into the brains of those who respond. We don't know for sure. Finding out if there are differences between lithium responders and other patients is the first step toward being able to predict response.

Why have you been invited?

We are planning to investigate a large group of patients with bipolar disorder. In order to understand the effects of lithium on the brain, we also need to study a broadly similar group of people who are unaffected by mental illness and are not taking medications that might directly influence the brain.

Do you have to take part?

It is up to you to decide to join the study. If you are interested, we will describe the study and go through this information sheet with you. If you decide to take part, you are free to withdraw at any time, without giving a reason. This would not affect the standard of any future care you might need.

What will the study involve?

We are collecting data from three groups of people: patients with bipolar disorder who are taking lithium, patients with bipolar disorder who have never taken lithium, and healthy volunteers. We aim to recruit 160 people in total. Your involvement in the study would be as part of the healthy comparison group and you will not be asked to take any medication.

Meeting the research team

We will invite you to our research centre at the Campus for Ageing and Vitality, part of Newcastle University. You are welcome to bring a friend or relative with you. We will discuss the study in detail and address any concerns you might have. If you agree to take part, we will ask you to sign a consent form and give you a copy for your records.

Gathering information

In a structured interview that typically lasts less than an hour, we will talk to you about any periods of illness you might have had in the past, specifically those of a psychiatric nature. You will be asked to fill in some short questionnaires about your current wellbeing. We would like you to complete a standard questionnaire about childhood trauma – if this is a topic you don't feel able to discuss then you can skip this and still take part in the rest of the study.

A brief set of psychological tests

We will ask you to complete a few tasks designed to test your attention and memory. Some tasks are computer-based whilst others just use pen and paper. To make sense of the results we also need to measure your IQ (and yes, we can let you know what it is).

Arranging the next stage

Your first appointment at the research centre should last around two hours. We will try to make your visit as relaxed as possible, giving you plenty of breaks if you need them. The second part of the study involves you providing a sample of saliva, having a blood test and a magnetic resonance brain scan. These are best performed in the morning and so we will arrange an appointment that is convenient for you.

Having a brain scan

You will be invited to Newcastle Magnetic Resonance Centre, again on the Campus for Ageing and Vitality. The staff at the centre will greet you and check that it is ok for you to have a magnetic resonance imaging (MRI) scan. Every volunteer will have a scan that lasts about an hour, during which we will collect data about your brain structure and composition. More details about the scans can be found in the second part of this information sheet.

Collecting a sample of your saliva

We would like you to provide a sample of saliva (spit) on the morning of your scan. This sample will be frozen and stored anonymously for later testing. We will use it to measure the levels of stress hormones, for comparison against the patients with bipolar disorder.

A blood test

We will want to take a small sample of blood (10ml; about two teaspoons) for routine measurements. Experienced staff will take the sample. Blood sampling is a safe, very common and normal part of medical treatment and assessment. Some localised discomfort, bruising, blood clot formation and in rare instances infection may occur in the area where blood samples are taken.

Donating a sample of blood for genetic testing and storage

We will also be asking you to consider donating a sample of blood that we can store and analyse for genetic studies. You do not have to agree to this in order to take part in the main study – we need you to sign a specific consent form before we can take the sample. More details can be found in the 'BLISS genetics' information sheet.

We would like to stay in touch

Interview, psychological testing, blood sample and scan – that's all there is to it. We would, however, like to send you a picture of your brain by way of thanks for your participation. These take a while to prepare so we would ask that we keep your details on file for a short while after your last session.

THE CONDUCT OF THE STUDY

If the information in the first part of this document has interested you and you are considering taking part in the study, please read on. The next section describes the conduct of the study in more depth and provides details of how best to contact the team should you wish to do so.

Who is organising and funding the research?

The research is publicly funded, with no industry involvement. The Medical Research Council (MRC) awarded Dr David Cousins a Clinician Scientist Fellowship, and Newcastle University are administering the award. Northumberland Tyne and Wear (NTW) NHS Foundation Trust are sponsoring the research.

Has the study been reviewed?

All research in the NHS is looked at by a Research Ethics Committee, an independent group of people responsible for protecting your interests. Our study has been reviewed and given a favourable opinion by the North East - Newcastle and North Tyneside 1 National Research Ethics Service Committee. An international panel of experts, tasked by the MRC, has reviewed the scientific basis of the research.

How is recruitment being organised?

We recruit subjects for our research studies by accessing the Institute of Neuroscience's volunteer database (www.ncl.ac.uk/ion/involved/volunteer/). It may be that you are receiving this information pack because you have registered with Newcastle University in order to assist with one of our research programs. If that is the case, can we take this opportunity to thank you for your commitment, regardless of your decision about enrolling in our study.

What about confidentiality?

All information collected about you during the course of the research will be kept strictly confidential. We will ask your permission to notify your family doctor that you are taking part.

How will data be stored?

Instead of your name, we will use a code to identify you. All of the information, brain scan data and blood test results that we store will be labelled with this, and only this, code. The anonymised data collected on paper will be stored in a locked filing cabinet in a locked room, itself in a Newcastle University research facility accessible only by staff with an authorised swipe-card. In previous studies, structured interviews were recorded on paper but in this study, we will be entering data directly into the NetSCID, a web-based research tool.

This is a more powerful and flexible resource that substantially reduces the length of the interview and improves data management. No identifiable personal information is entered into the NetSCID; the data is coded, password protected and storage is fully HIPAA¹ compliant. Coded data in electronic format will also be stored on secure Newcastle University computer servers. Dr Cousins will be the custodian of the file linking your name to your study code and this file will be held separate to the stored data. The Medical Research Council require us to store the data for a period of ten years after the end of the study, following which it will be destroyed.

Will data be shared with other research groups?

The Medical Research Council has invested valuable public resources in this study, believing that it represents excellent science and addresses an important health care need. The Council expect and encourage us to collaborate with other groups, increasing the likelihood of a beneficial research outcome. We intend to share data with known colleagues in centres where we have established useful collaborations, and would consider applications for data access from other bone fide research groups. Use of the data would be restricted to the topic of our proposed research and Dr Cousins would personally review all applications. Data would not be released to scientists in countries with a lower standard of data protection than the UK. In all instances, only coded data will be made available for analysis.

What will happen to the results of the research?

We will analyse the results and submit them for publication in a scientific journal. Presentations may also be given at scientific conferences. You will not be identified in any publication or presentation. If you wish to know the outcome of our research, we will be happy to discuss our findings with you once the analysis is complete.

What if there is a problem?

In the event that something does go wrong and you are harmed during the research, you might wish to pursue a claim. There are no special compensation arrangements to cover non-negligent injury. If you are harmed due to someone's negligence, then you may have grounds for legal action for compensation against Northumberland Tyne and Wear NHS Foundation Trust, but you may have to pay your legal costs. If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions. If you do not feel able to do so, or are unhappy with their response and wish to complain formally, you can do so by following the NHS Complaints Procedure. Details can be obtained from the NTW Foundation Trust website (www.ntw.nhs.uk).

¹ Health Insurance Portability and Accountability Act (1996)

What is it like to have a brain scan?

Magnetic resonance scanners use powerful magnets and radiowaves to gather information about the structure and make-up of the brain. They do not use harmful radiation and are safe, so long as you don't have loose metal objects in your body or implanted electrical devices such as pacemakers. We would not perform the scan if you are pregnant, or if there is a chance that you might be pregnant. The scanner itself is a large tube that you go into headfirst. It is not uncomfortable but it is enclosed so if you suffer from claustrophobia then you should not volunteer for this study. Some of the scans we perform are noisy, so you will be given headphones to wear. You can listen to the radio or bring some music with you if you prefer. We will keep a close eye on you throughout the scan and we have a two-way intercom system and a buzzer, so if you become uncomfortable, you can let us know and we will stop the scan immediately.

What if 'something shows up' on the brain scan?

Almost everyone who has a scan worries that it will show some abnormality – this is unlikely but the anxiety is normal. During the scan, a senior radiographer will see the images of your brain and in the rare instance that they notice something wrong, it will be brought to the attention of Dr Cousins. Further scans and a review by a clinical radiologist may be required. You should be aware, however, that the scans we perform are designed for research studies, not for the purposes of detecting illness. Unlike a clinical scan, they will not be formally reviewed and your GP will not receive a report. The research team do not accept responsibility for detecting or missing abnormalities.

What are the benefits of taking part?

We aren't paying volunteers for taking part but we will reimburse expenses. Luncheon receipts to the value of £5 will be covered and you can claim for your travel on public transport. If you travel by car, we can refund you the equivalent of the return public transportation costs.

Taking part is unlikely to benefit you directly or immediately. Nevertheless, many people enjoy taking part in research, finding it fulfilling and informative – we do hope that you'll leave with this impression. What's more, as a small token of our appreciation, we will even send you a picture of your brain!

What happens next?

If you are interested in taking part in our study, then you should contact the research team for advice on how to proceed. Should you have any unanswered questions about the study or if you want to meet the team before you reach a decision, please let us know – our contact details can be found below.

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