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# SCREENING PARTICIPANT INFORMATION SHEET

## snapper trial

A randomised controlled trial to evaluate the clinical and cost-effectiveness of **S**timulant compared with **N**on-stimulant medication for adults with **A**ttention-deficit/hyperactivity disorder and a history of **P**sychosis or bi**P**olar disord**ER: SNAPPER**

**Invitation to take part in screening for a clinical trial to investigate how effective a stimulant medication is compared to a non-stimulant medication in patients who been diagnosed with attention deficit hyperactivity disorder (ADHD) and also have a history of either psychosis or bipolar disorder.**

**Version 3.0 10th October 2024**

## What is this trial about?

We are inviting you to take part in screening for a clinical trial. This involves answering some questions about you and your health to see if you would be suitable to take part in the **snapper** trial.

Taking part is voluntary. We are giving this information for you to consider carefully before you decide. Please feel free to discuss it with others. If there is anything that is not clear, do not hesitate to speak to a member of the research team or care team.

## What is the purpose and background of the trial?

ADHD is a common neurodevelopmental health disorder that usually starts in childhood and can persist into adulthood. Patients diagnosed with ADHD have symptoms such as mood swings, problems with attention, being over active (hyperactive) and acting impulsively. ADHD in adults can occur alongside bipolar or psychosis which are both severe mental health illnesses.

There are two main classes of treatment for ADHD, stimulant medication and non-stimulant medication:

- Stimulant medication temporarily increases alertness, confidence, mood and general activity.
- Non-stimulant medication helps to improve concentration and control impulsive behaviour.

Doctors are not sure how effective or safe these treatments are in people who also have psychosis and bipolar. This is because ADHD medications can sometimes make the symptoms of bipolar and psychosis worse rather than reduce them. At the moment, there is very little information or guidance on the best treatment for this group of patients.

The aim of the **snapper** trial is to investigate how effective a stimulant medication (Lisdexamfetamine) is compared to a non-stimulant medication (Atomoxetine) in reducing the symptoms of ADHD in patients who also have bipolar or psychosis.

## Why have I been invited?

We are asking you to take part in this screening because you have a diagnosis of ADHD, or have been newly diagnosed with ADHD, and also have bipolar or psychosis. The screening assessments are to confirm your diagnosis to see if you could be eligible to enter the main trial and receive one of the treatments as part of the trial.

We aim to recruit 244 patients who are under the care of an NHS mental health care team to take part in the trial.

## What will happen to me if I agree to take part?

We will ask you to sign a Screening Consent Form to confirm you are happy to take part in screening. If you are female and of childbearing potential, you will be asked to do a urine pregnancy test. This urine sample will only be used for the pregnancy test and will then be thrown away.

You will then be asked to answer some questions about you and your ADHD. This is expected to take around one to one and half hours (1 hour 30 mins). You will be given the option to be sent a copy of your signed consent form to the e-mail address you provide on the consent form.

## What will happen next?

The answers you provide will help the research team to confirm whether you are eligible for the main trial. If you are eligible, we will give you the full information sheet (you can ask for one of these now, if you wish) and explain the main trial to you in more detail. If you are not eligible, you will continue with your standard care as normal.

As part of the trial we are also interested in learning how carers or supporters help you with your condition. If you have a carer or supporter (family member, relative, friend, close-person) aged 18 or over you can nominate them to take part in the trial. They will need to complete some short questionnaires about their own personal health and lifestyle. A separate information sheet is provided for carers/supporters and copy of this is also available for you to read. If you have a supporter, you can give the 'Supporter Pack' to this person which explains everything about how they can join the trial.

## Do I have to take part?

No, this is entirely up to you. You do not have to take part if you do not want to and this will not affect the standard of care you receive. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will not be obliged to take part in the main trial if you are suitable for it and this will not affect the standard of care you receive. You are free to withdraw at any time without giving a reason.

## Does my supporter have to take part?

No, it is entirely up to your supporter if they wish to take part. You are not obliged to ask them to take part if you do not want them to.

## What information will you use and what will you use it for?

We will need to use information from you and from your medical records for this research. Your personal information will include your full name (from the screening consent form) and e-mail address (if you wish to receive a copy of the signed consent form via e-mail).

People who do not need to know who you are will not be able to see your name or contact details. If you enter the main trial, your data will be assigned an anonymised code participant identification (ID) number instead. We will keep all information about you safe and secure (further information about how we will keep your data secure is given in the main trial Participant Information Sheet). Once we have finished the trial, we will keep some of the data so we can check the results. No personal information about you will be included in our reports, we will write our reports in a way so that no-one can work out that you took part in the study.

Responsible individuals from the University of Birmingham Clinical Trials Unit (BCTU), the Sponsor (University of Birmingham), regulatory organisations or the NHS may look at relevant sections of your medical records to check and make sure that the research is being done properly.

## What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you enter the main trial, then we will keep information about you that we already have. If you don't enter the main trial, this information, namely your screening consent form will no longer be visible in the database to the research team, nor the SNAPPER Trial Office after 35 days of the screening consent date.

## Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by contacting the University of Birmingham Data Protection Office:

The Data Protection Office, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT.
Email: dataprotection@contacts.bham.ac.uk Telephone: 0121 414 3916

## Who has reviewed the study?

All research which takes place in the NHS is looked at by an independent group of people who protect patient interests. This group is called a Research Ethics Committee. Before we

asked any patients to join, the study was reviewed and approved by Central Bristol Research Ethics Committee.

## Who is organising and funding the research?

The study is sponsored by the University of Birmingham, which means the University of Birmingham has certain legal and ethical responsibilities for the study (reference RG_19-246). It is being coordinated by Birmingham Clinical Trials Unit and is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: NIHR 129817).

## Who can I contact for further information?

Thank you for taking the time to read this information sheet and for considering taking part in this trial. Should you require further information or would like to speak to someone about the trial please contact:

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|---|---|
| Name | |
| Job title | |
| Contact Details | |

Alternatively, you can contact the trial team:
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