<insert Trust Logo>

SUPPORTER 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**

Version 4.0 10th October 2024

Why have I been invited?

We are inviting you to take part because you have been nominated as a supporter to your relative or friend who is taking part in a clinical trial of adult Attention-deficit/hyperactivity disorder (ADHD). This trial aims to find out how effective two different medications are in patients who have been diagnosed with ADHD and who also have a history of psychosis or bipolar. We would also like to find out how supporting a close person with ADHD affects your health and lifestyle.

We would like you to take part as long as you are aged 18 or over and provide support to the participant in the snapper trial.

Do I have to take part?

No, this is entirely up to you. Taking part is voluntary. You do not have to take part if you do not want to. We have provided this information for you to consider before you make your decision. Please feel free to discuss it with your relative or friend. If there is anything that is not clear, do not hesitate to speak to a member of research team.

What would taking part involve?

If you decide to take part, you will be asked to complete a short questionnaire about your health and lifestyle. We expect that this questionnaire will only take about 5 minutes to complete. We will ask you to complete the same questionnaire in 6 months' time and again in 12 months' time.

What will I be asked to do now if I agree to participate in the trial?

1. Complete the online Supporter Informed Consent Form as soon as possible
2. Complete the online Self-Registration Form
3. Complete the first questionnaire about health and lifestyle.

If you agree to take part, you can either enter the link or scan the QR code which will take you directly to the Supporter Consent Form. You should only do this if you are happy that you understand the trial and want to take part. You will be given a printed paper copy of your signed consent form or you can choose to receive this via e-mail.

A paper copy is provided for you to see but the form must be completed online by either entering the link or scanning the QR code. Once you have done this, you will receive a confirmation with a link to the Self-Registration Form. Once this is done this you can complete the first questionnaire. You can receive the links either by e-mail or text message. This should take around 20 minutes altogether.

Your participation will end after you have completed the questionnaire at 12 months. However, if for any reason your relative or friend decides they don't want to participate in the trial anymore, this may mean that you are also no longer required to participate. If this happens, we will let you know.

Will I get paid for taking part?

If you wish to accompany your relative or friend to clinic visits as part of the trial, then we can pay for your travel expenses. Please speak to a member of the research team for more details.

What are the possible benefits of taking part?

This trial will help us to find out if the symptoms of ADHD reduce better with either of the two choices of medications, a stimulant drug or a non-stimulant drug. Whilst there may be no immediate benefits to you, the aim is to improve the longer-term care for people with ADHD and psychosis or bipolar. We also want to find out how supporting someone with ADHD affects your health and lifestyle.

What are the possible disadvantages and risks of taking part?

There should be no risks involved in taking part as a supporter in the snapper trial. The only disadvantage we envisage is that it will take up to half an hour of your time in total over the next 12 months.

What will happen to the results of the research trial?

We will publish our results in medical journals, to help other doctors to learn, and patients to benefit. This will be in an anonymous manner, so you cannot be identified. Names and participant details will be kept confidential and won't be included in the results.

After the completion of the research trial, the results will be published on the trial website.

What if I do not want to carry on?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have. For information on your rights in relation to your data, please see the relevant section in this Supporter Information Sheet. Data collected until withdrawal will be used anonymously as part of the trial.

What if something goes wrong?

We do not envisage any problems as a result of your participation in the trial. However, if you wish to complain about any aspect of the way you have been approached or treated during this trial, the normal NHS complaints mechanisms will be available to you. Copies of these guidelines are available on request. If you wish to complain about how you have been treated

during this trial please contact the Patient Advice and Liaison Service (PALS) or the Complaints Team at your local hospital. The PALS contact details can be found on the end of this Patient Information Sheet or via this website: https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/
For NHS Trusts in Scotland, please contact Patient Advice and Support Service (PASS) at https://www.cas.org.uk/pass

What data will we be collecting and for what purpose will we use it?

We will ask for your consent before collecting your personal data listed in the table below. This is only for use in the trial.

When	What data will be collected
Consent	• Full name (first, middle & surname) • E-mail address (for a copy of the consent form to be e-mailed to you) • Contact details: e-mail address or mobile phone number
Registration Form	• Partial date of birth • Gender • Your relationship to the participant
Questionnaires at baseline, 6 months and 12 months	• No personal data

Your data will have an anonymised supporter ID number. We will keep all information about you safe and secure. Once we have finished the trial, we will keep some of the data so we can check the results. We will not share any data that can identify you with any other third party. We will write our reports in a way that no-one can work out that you took part in the study.

How will my personal data be kept secure?

If you decide to take part in **snapper**, you details entered on the consent form, registration form and questionnaires will be stored securely on our University of Birmingham servers that are password protected and kept strictly confidential under the Data Protection Act 2018.

The only people at the University of Birmingham who will have access to information that identifies you will be people who need to contact you to complete questionnaires or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

How long will my personal data be kept?

Your data will be kept for 25 years once the trial has finished. If you withdraw from the trial, we will keep the information we have already obtained but, to safeguard your rights, we will use

the minimum personally-identifiable information possible. Your contact details will be deleted after your participation in the trial is complete.

Who is the data controller?

The University of Birmingham, Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you. This means that the University is responsible for looking after your information and using it properly.

What is our legal basis for processing your data?

The legal justification we have under data protection law for processing your personal data is that it is necessary for our research, which is a task we carry out in the public interest. This means that it is a legal requirement that the data we collect about you will only be used for research purposes to benefit public health.

What are your choices about how your information is used?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Staff receive regular data protection training and the University has organisational and technical measures so that personal data is processed in accordance with data protection law. More information on how the University processes personal data can be found on the University's website on the page 'Data Protection – How the University Uses Your Data' (http://www.birmingham.ac.uk/privacy/index.aspx).

Where can I find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- in the 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 is organising and funding the trial?

The trial is sponsored by the University of Birmingham, which means the University of Birmingham has certain legal and ethical responsibilities for the trial (reference RG_19-246). It is being coordinated by the Birmingham Clinical Trials Unit (BCTU) and it is funded by the government through the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: NIHR 129817). The chief investigator for the trial is Professor Steven Marwaha, Professor of Psychiatry, based at the University of Birmingham.

Will my relative who has enrolled in the trial be informed of my involvement?

Yes, we will send them an e-mail so that they know you are also taking part.

How have patients and the public been involved in this trial?

The trial has been developed with input from a Patient & Public Involvement (PPI) representative who has lived experience of bipolar and extensive research experience as well as being a member of the McPin Foundation. In addition, a PPI consultation group based in Birmingham and Solihull mental Health Trust (BSMHT) and members of the Institute for Health Young Patient Advisory Group (YPAG) helped to develop this application in a number of important and significant ways. The conduct of the trial is entirely in the hands of very experienced researchers.

Who has reviewed the trial?

All research which takes part 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 or their supporters to join, this trial was reviewed and approved by Central Bristol Research Ethics Committee.

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:

Name	
Job title	
Contact Details	

Alternatively, you can contact the **snapper** trial team:
snapper Trial Office
Birmingham Clinical Trials Unit
Public Health Building
University of Birmingham
Edgbaston
B15 2TT
Email: snapper@trials.bham.ac.uk

This trial is funded by the National Institute for Health Research (NIHR) Heath Technology Assessment programme (project reference NIHR129817). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.