AMBIENT-BD

PARTICIPANT INFORMATION SHEET

Prioritising outcomes and testing different methods with people with bipolar disorders- A co-production study

What outcomes matter to people with bipolar disorder?

You are being invited to take part in research on co-producing different outcomes important for people with bipolar disorder. We are conducting a co-production to involve the lived experiences of people with bipolar disorders within our overall research design. Dr. Aja Murray and Dr. Maria Gardani at the University of Edinburgh are leading this research. Raahat Manrai will be developing and co-producing the study sessions. Before you decide whether to take part it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully. For more information, you can contact Raahat at RManrai@ed.ac.uk.

WHAT IS CO-PRODUCTION IN THE CONTEXT OF THIS STUDY?

Co-production is a method used to co-design and co-construct research methodology in collaboration with people with lived experience with bipolar disorders. We aim to co-design and co-construct the research design to be used in an upcoming study to be conducted with people with bipolar disorders. We will design sessions that will help us to understand the outcomes that are important to people with lived experience of bipolar disorders.
Co-production essentially means that you will be involved in designing and informing the core research team about different methods and processes that are relevant to approach, engage and retain people with bipolar disorders during long research studies.

WHAT IS THE PURPOSE OF THE STUDY?

This co-production study is part of a bigger project called AMBIENT-BD. The purpose of the study is to understand the functional and clinical outcomes which are considered important for people with bipolar disorders. The study will also test different methods like 'Axivity' watches or 'Somnofy' radar devices to understand different types of sleep testing methods appropriate to conduct research with people with bipolar disorders. You will help us co-produce sessions which will help us with designing upcoming study in our overall project. You can find out more information about AMBIENT-BD project on our designated website ambientbd.com. You can also find more information about the devices we are using on Axivity.com and Somnofy.com, respectively.

WHY HAVE I BEEN INVITED TO TAKE PART?

You are invited to participate in this study because you are considered to have a diagnosis of bipolar disorder and have shown interest in taking part this co-production

study. You will be referred as 'Co-producers' throughout the process of this study as you would be helping in co-designing the research design in our upcoming study.

INCLUSION/EXCLUSION

Please look at the following criteria to check if you are eligible to take part in the study.

Inclusion:

- Individuals with a diagnosis of Bipolar Disorders (Type I or Type II)
- Individuals over the age of 18 years.

Exclusion:

- Individuals with any other mental health diagnosis
- Individuals who are undergoing (current) episodes of mania or depression and are not eligible to consent

DO I HAVE TO TAKE PART?

No – it is entirely up to you. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect your medical care, legal rights or benefits.

If you wish to withdraw, you can either email the study team or inform the session facilitator and we would be able to organise this for you. You can withdraw your consent whenever you want however, we would not be able to entirely delete your data up to that point due to the group dynamics of the consultations. In case of a withdrawal, we would not use any of your data in our outputs and data dissemination.

It would be helpful for you to know that you don't have to decide on taking part in the study right away. You can contact the primary researcher on RManrai@ed.ac.uk in case you change your mind at a later date.

WHAT WILL HAPPEN IF I DECIDE TO TAKE PART?

If you do decide to take part, please keep this Information Sheet. You will be asked to complete an Informed Consent Form to show that you understand your rights in relation to the research, and that you are happy to participate. The informed consent form has been sent separately in the email with the Participant Information Sheet. Please let us know if you require an alternative format to provide your informed consent and we can arrange that for you.

You will be asked to attend several sessions in order to co-produce research process and design within the wider AMBIENT-BD project. The frequency, design and number of the sessions will be decided together with the co-producers, however you will be invited to take part in more than one session.

You will be asked a number of questions about how to engage people for longer periods of time, what are the important outcomes. As a part of some of the sessions we will also be asking for your opinions on testing some devices and measurement activities using Axivity wristwatches and Somnofy radars to monitor people's sleep for a short period of time. It is important to clarify that you will be testing these devices, which means we will be monitoring your sleep over a period of time. The testing time will be decided in collaboration with our co-producers, however, it is important to remember that there is some minimal time needed to get valid data from you. We would advice you to use the devices for at least a week to give us a chance to test their effectiveness and the data they generate.

The sessions can be conducted both in-person and online, depending on your availability to attend in-person sessions. Ideally, we would like to audio record your responses (and will require your consent for this). If the interview is conducted online, video will automatically be recorded, but you are free to turn off your camera if you wish. Use of the above-mentioned devices also means that we will capture your sleep and activity data. However, we will not be able to provide you with information regarding your sleep data till the completion of the study.

WHERE WILL THE SESSIONS BE CONDUCTED?

We will conduct sessions both in-person or online. The sessions online will be conducted using the university's Microsoft Teams platform. The venue for the in-person sessions could be the central campus of the university or any trusted physical space recommended by you.

HOW WILL DEVICES BE USED?

We aim to collect passive data using the sleep devices. The devices will be mounted in your rooms or you would be wearing the watches. This means that you would not be actively involved in data collection using those devices and they will automatically capture your sleep/activity data.

All the data collected from you during the study will be anonymised and de-identified. We aim for the sessions to be conducted fairly regularly on a monthly basis and the overall study should take around 10-12 months to complete. It is important to note that the study spans over a long period of time. You might not necessarily feel well to take part in the study. We will be sending emails before and after each session to check in with you ensuring you can take part throughout the study. Missing a session would not withdraw consent from the study.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The data collected in this study will be used to determine the research design in the upcoming studies. Since you will be co-producing prospective research design your contribution will be recognised by the study. You will be awarded £25 per hour for taking part in every session through bank transfer. It would be important to clarify that you will ONLY be paid for attending the sessions- online or in person. We will not be

paying you separately for using and testing sleep devices as they will be collecting your data passively (without any active involvement).

Please note that this amount has been based on guidelines by National Institute of Health Research (NIHR) and have been allocated within the Wellcome Trust- funding body of the AMBIENT-BD project.

ARE THERE ANY RISKS OR DISADVANTAGES ASSOCIATED WITH TAKING PART?

There are no significant risks associated with participation. We will not be asking you for your personal experiences. However, we will be testing some low intensity sleep measurement devices. If you are uncomfortable in being a part of sleep testing, you can let us know and we will accommodate your request.

Please note that it is not a requirement for you to take part in sleep testing to participate in the rest of the co-production.

FOR PARTICIPANTS ON BENEFITS

As you will be compensated for your participation in the study, this might have an impact on your benefits.
You are currently entitled to working 15 hours per week without affecting your benefits. However, you are strongly advised to look into it before consenting to taking part in the study. You can find more information about benefits at https://www.gov.uk/browse/benefits.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you for this research project.

This information will include your name, address, contact details and bank details. People will use this information to do the research.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. It is important to let you know that we will be testing low intensity sleep devices as a part of the co-production. These devices are manufactured by 'Vital Things' who are also the collaborators in the project. They will have access to your raw sleep data but will not be using it for any commercial use.

The recordings will be anonymised and de-identified in order to maintain confidentiality. You will be given a participant number or a pseudonym of your choice as a reference throughout the transcripts. If you consent to being audio recorded, all recordings will be retained till the end of the study to ensure accuracy and clarification of the data during the analysis stage. The recordings will be immediately transcribed by the primary researcher keeping in line with the principles of data protection. The identifiable data (including personal details, audio recordings and bank details) will be deleted after the analysis, writing up and dissemination of the study.

Your data will only be viewed by the researcher/research team. All electronic data will be stored on the University of Edinburgh secure network and all paper records will be stored in a locked filing cabinet at the University premises. Your consent information will be kept separately from your responses in order to minimise risk. Your anonymised data will be stored in the University of Edinburgh sharepoint folder for the next 5 years. This data will be stored for any future ethically approved research.

Once we have finished the study, we will keep anonymised data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

How will your data be processed?

The audio recordings generated from the sessions will be stored on encrypted folders using OneDrive. The recordings will then be anonymised and de-identified and transcribed verbatim. The transcriptions will also be stored in encrypted folders using OneDrive.

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, but we will keep information about you that we already have.
- 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.

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

You can find out more about how we use your information at
https://www.ed.ac.uk/records-management/privacy-notice-research

- our designated project website [AmbientBD.Com]
- by contacting the postdoctoral research associate on this project at [RManrai@ed.ac.uk]
- by sending an email to [ambient-bd@ed.ac.uk]

The University of Edinburgh is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Edinburgh will keep identifiable information about you till the duration of the study and your anonymised data for a minimum of 10 years.

WHAT WILL HAPPEN WITH THE RESULTS OF THIS STUDY?

The results of this study may be summarised in published articles, reports and presentations. You will not be identifiable from any published results. Quotes or key findings will always be made anonymous in any formal outputs unless we have your prior and explicit written permission to attribute them to you by name. With your consent, your anonymised information may also be kept for future research. A summary of the findings from the study will be made available to participants who indicate they would like to receive this. This summary will be sent to participants by post / email. We will also conduct a feedback session in order to discuss the findings of this study with our co-producers.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This study has been organised by AMBIENT-BD Research Team, Division of Psychiatry and sponsored by the University of Edinburgh.

The study is being funded by Wellcome Trust, (Reference ID- 226944/Z/23/Z)

WHO HAS REVIEWED THE STUDY?

The study proposal has been reviewed by the School of Health in Social Sciences ethics committee at the University of Edinburgh.

WHO CAN I CONTACT?

If you have any further questions about the study, please contact the lead researcher, Raahat Manrai at RManrai@ed.ac.uk.

If you would like to discuss this study with someone independent of the study, please contact Dr. Angus MacBeth (Senior Lecturer in Clinical Psychology) at Angus.Macbeth@ed.ac.uk.

If you wish to make a complaint about the study, please contact:

Matthias Schwannauer at headofschool.health@ed.ac.uk or Research Governance Team (cahss.res.ethics@ed.ac.uk).

In case you feel distressed whilst taking part in the sessions please seek the following information for support:

In case of any emergency, you are strongly encouraged to consult your GP/psychiatrist.

Mind
Mind helps provide information and support to people with mood disorders. You can find more information on their website: https://www.mind.org.uk/.

Bipolar Scotland
Bipolar Scotland provides informal and peer support to people with bipolar disorders all over Scotland. You can find more information about them on their designated website: https://bipolarscotland.org.uk/.

Bipolar Edinburgh
Bipolar Edinburgh also provides informal and peer support to people in Edinburgh and the Lothians. They organise monthly quizzes, chats, walks for people to come and get to know more people along with giving information on carers as well. You can find out more on their website: https://www.bipolaredinburgh.org.uk/.

Samaritans
In case of an emergency, Samaritans helps you provide support if you need some help with managing a crisis. You can find more information on their website: https://www.samaritans.org/?nation=scotland.