

Participant Information Sheet

Study Title:

HOUDINI-BD: High-resolution Ongoing Unsupervised Data-efficient Identification of Novelties within Individuals – Bipolar Disorder

Lay Title:

ALERT-BD: Advanced Longitudinal Evaluation and Real-time Tracking for Bipolar Disorder

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REC Number:

Chief Investigator: Dr Filippo Corponi

Short title: **HOUDINI-BD**

'You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.'

- Section 1 tells you the purpose of this study and gives an overview of what will happen to you if you take part, including a summary of the study visits.
- Section 2 gives you more detailed information about the conduct of the study and how we will be handling your data.

If, after reading this, you would like more information or any clarification, please do let us know. Take time to decide whether or not you wish to take part. Participation in this study is entirely voluntary. Please only volunteer if you have time to complete the whole study.

Thank you for your interest in this research study.

Do I have to take part?

'It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you are receiving, now or in the future.'

SECTION 1: PURPOSE OF THE STUDY AND OVERVIEW OF WHAT WILL HAPPEN

Bipolar disorder (BD) is a common mental health condition characterized by significant shifts in mood, energy, and sleep patterns during recurring episodes, interspersed with periods of relative stability. One of the main challenges in care is that changes in mood, energy, and sleep often begin between clinic visits, while patients struggle to recognise and report their symptoms. This makes new episodes difficult to detect and address early, leading to worse outcomes.

The "Blood Sugar" Analogy – At present, there is no simple, objective test for monitoring bipolar disorder—nothing comparable to the finger-prick blood sugar test used in diabetes care. As a result, early warning signs can be missed, thus limiting opportunities for timely support or intervention.

A Modern Solution – Smart wristbands (such as smartwatches) offer a potential way to bridge this gap. By tracking sleep and activity levels continuously and with minimal effort, they provide an ongoing view of everyday patterns. Subtle changes in these rhythms may signal that a person's mental state is beginning to shift.

• What is the purpose of the study?

In this study, we will collect data from people with BD over 12 months using a smart wristband and a smartphone app. We aim to develop computer models that learn each person's typical daily patterns and detect possible BD episodes by spotting changes from those patterns, such as disruptions in sleep-wake cycles.

As studies into energy levels and sleep-wake rhythms in BD are limited to only a few days, we also aim to characterise long-term patterns that may only be noticeable over extended periods of time.

Speech patterns can also reflect changes in mental state in bipolar disorder. Research has shown that features of speech—such as the rhythm, pace, tone, and word choice—may differ between mood states. By analysing brief speech recordings collected over time, we aim to detect early warning signs of new episodes alongside wearable sensor data. This multi-modal approach (combining wearable sensors with speech) may provide a more comprehensive picture of your health status.

• Who can take part?

We are looking for subjects aged between 18 and 65 who meet the following criteria:

- A diagnosis of bipolar disorder (type I or II).
- At least two bipolar disorder episodes in the past two years, regardless of the polarity (i.e. (hypo)mania or depression). If we find it difficult to find enough participants in the first two months, we may change the entry requirements to include anyone who has had at least one mood episode in the past two years.
- Clinically stable (i.e. euthymic) for at least 4 weeks.

IRAS Version: 6.4.3, Protocol Version: 1, Protocol Date: 28/11/2025, Project ID: 353941

HOUDINI-BD study

Patient Information Sheet

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Deleted: Bipolar disorder (BD) is a common and serious mental health condition that shortens life expectancy and creates major personal and societal burdens. It involves recurring episodes of illness marked by major changes in sleep patterns, energy levels, and mood. These episodes can severely disrupt daily life, yet they are difficult to predict. As a result, treatment often starts too late, leading to worse outcomes. Today, early detection mostly depends on people noticing and reporting their own symptoms or attending occasional clinic visits, which often miss the early warning signs.¹

Wrist-worn wearable devices are becoming increasingly popular and contain sensors that track information such as physical activity, light exposure, and skin temperature—features that can reflect different phases of BD. These devices can collect data automatically as people go about their everyday lives. Importantly, the information they capture—like step counts and sleep patterns—is far less sensitive than data from other digital devices, such as speech samples, text messages, or browsing history.¹

Artificial intelligence (AI) can identify patterns in large and complex datasets, including those collected from wearables. Although previous attempts to use AI in BD research have shown encouraging results, they have not yet produced tools that can be used in routine care. This is partly because BD varies greatly from person to person

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Participants should also:

- Have their own smartphone and internet access.
- Be able to travel to West London NHS Trust (1 Armstrong Way, Southall UB2 4SD) for quarterly appointments over 12 months.
- Be willing to wear a wristband in daily life for the study period, i.e. 12 months. The wristband will be given by the researchers; it has a three-month battery life and does not restrict daily activities in any way.
- Be able to speak and understand English

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You are NOT eligible to take part if you:

- Are a shift worker.
- Are pregnant
- Have a mental health condition other than bipolar.
- Have a severe learning disability.
- Have a severe neurological impairment.
- Are currently experiencing substance dependence.
- Are currently taking part in a Clinical Trial of an Investigational Medicinal Product

- **Why have I been chosen?**

You may have been invited to take part if we believe you meet the requirements for study participation, or you may have registered your interest. We aim to recruit 40 participants.

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- **Will I receive any reimbursement?**

If you decide to take part, you will be given 30,00 GBP at each study visit. The study comprises five quarterly appointments over 12 months. The baseline appointment takes 70 to 80 minutes, including breaks in between. The remaining follow-up appointments take approximately 30 to 40 minutes. If you withdraw from the study before completing it, you will retain compensation given up to that point.

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Individual researchers will not receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research.

- **What will happen to me if I take part?**

The study will include:

- One in-person baseline assessment at the West London NHS Trust (1 Armstrong Way, Southall UB2 4SD).
- Four in-person quarterly follow-up appointments at the West London NHS Trust (1 Armstrong Way, Southall UB2 4SD).
- Wearing a wristband on your non-dominant wrist for 12 months. This is water-resistant, does not constrain your daily life in any way. While we recommend continuous wear throughout the study (including at night) to maximise the knowledge that can be gained from this study, you can remove the wristband at any time and put it back on if you wish.
- Using the MindCraft app over 4 weeks at the start of the study. This app will prompt you to complete brief self-reports on mood and sleep twice daily; it will also collect passive data (e.g. step count, background noise or ambient lighting) in the background. You can control what data we collect in the background and change your preferences at any point. Collection

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4 weeks at the start of the study of daily mood tracking and passive data collection (e.g., step count) via the digital app MindCraft.
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of self-reports will stop after four weeks, where passive data collection will continue for the remainder of the study.

- Brief speech recordings during quarterly in-person appointments (approximately 2-3 minutes per visit).
- Weekly phone calls about your well-being and health during the first month from an AI voice assistance collecting brief speech samples (approximately 3-5 minutes per call).

Baseline appointment — During this appointment, your eligibility and consent to participate in the study will be confirmed. We will give you a fully charged wristband to wear on your nondominant wrist until study completion. We will use validated questionnaires and collect info on your lifestyle, clinical history, sleep patterns, cognitive functioning. We will also ask you to complete a brief survey, designed in collaboration with patients with BD, to understand your experience and preference with technology. Lastly, you will also complete a brief speech task (5 minutes) where you will be asked to speak about neutral topics. This will be audio-recorded using a secure system. The entire baseline appointment will take up 60-70 minutes.

Wristband — During the baseline appointment, after confirming eligibility and consent, we will give you the Axivity AX6 wristband. The AX6 is a small, water-resistant, research-grade wristband specifically designed for the objective measurement of human physical activity and sleep in daily life. It has already been used across a variety of previous studies. The device contains a tri-axial accelerometer, a tri-axial gyroscope (which will not be used in this study), a temperature sensor, and an ambient light sensor. We will set the accelerometer sampling rate to 12.5Hz, in other words, it will collect 12.5 samples per second. With this setting, the AX6 has a battery life of approximately three months. When we contact you to schedule your follow-up visit, we will remind you to recharge your Axivity AX6. It takes approximately two hours for a full charge, meaning you will only need to recharge the device once in between quarterly follow-up visits. We will also send you occasional reminders (via text message) to wear the wristband. Acceleration, defined as the velocity rate of change, is a proxy of human activity. From acceleration, it is possible to infer information about the activity levels (e.g. step counts, burnt calories) and the sleep-wake patterns of the person wearing the device. Acceleration also allows us to establish retrospectively whether the person was wearing the device. The AX6 has a built-in data logger. This means that data is stored locally on the AX6 device and is not streamed in real-time to us. You do not need to download any app on your smartphone towards using the wristband. We will download the data from the data logger during the follow-up appointments. Upon study completion or withdrawal from the study, we will collect the Axivity AX6 we gave you.

MindCraft — During the baseline appointment, you will receive a link to download the MindCraft app from the App Store or Play Store, along with a unique login. MindCraft was developed by the Brain & Behaviour Lab, Department of Bioengineering, Imperial College London, in collaboration with Lived Experience Experts. This is a user-friendly app designed to passively collect data from smartphone sensors (e.g., step count, ambient noise, or location). You will set your data-sharing preferences when setting up the app but can also, adjust them at any time through the app's settings. MindCraft will also prompt you twice daily to respond to brief questions about your mental health (e.g., sleep and mood). MindCraft will cease to prompt you for self-reports on mood and sleep after four weeks. Background data collection, on the other hand, will continue throughout the study and, as said before, you have a chance of controlling what data we collect and update your preferences at any point.

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Moved up [1]: ~~<#>~~Wearing a wristband on your non-dominant wrist for 12 months. This is water-resistant, does not constrain your daily life in any way. While we recommend continuous wear throughout the study (including at night) to maximise the knowledge that can be gained from this study, you can remove the wristband at any time and put it back on if you wish.¹

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Speech — During the first four weeks of the study, you will receive a weekly phone call from an AI voice assistant. These calls will last approximately 3-5 minutes. The voice assistance will ask you simple questions about your well-being, symptoms and activities. Your responses will be audio-recorded for research purposes only. You can decline any call or end it at any time. Calls will be made from a dedicated research phone number that will be provided to you at baseline.

Follow-up appointments — You will have four follow-up appointments, one every three months. During this appointment, we will download data collected in-between appointments with the wristband. We will ensure the wristband is fully charged. We will use a questionnaire to determine whether any mood episode took place in between assessments or is ongoing. We will ask you about your experience with the wristband. Lastly, you will also complete a brief speech task (5 minutes) similar to the one completed at baseline. Follow-up visits take approximately 30 to 40 minutes. Your feedback on technology use and the speech will be recorded for analyses.

A summary of the procedures involved in the present study is given in Figure 1 below.

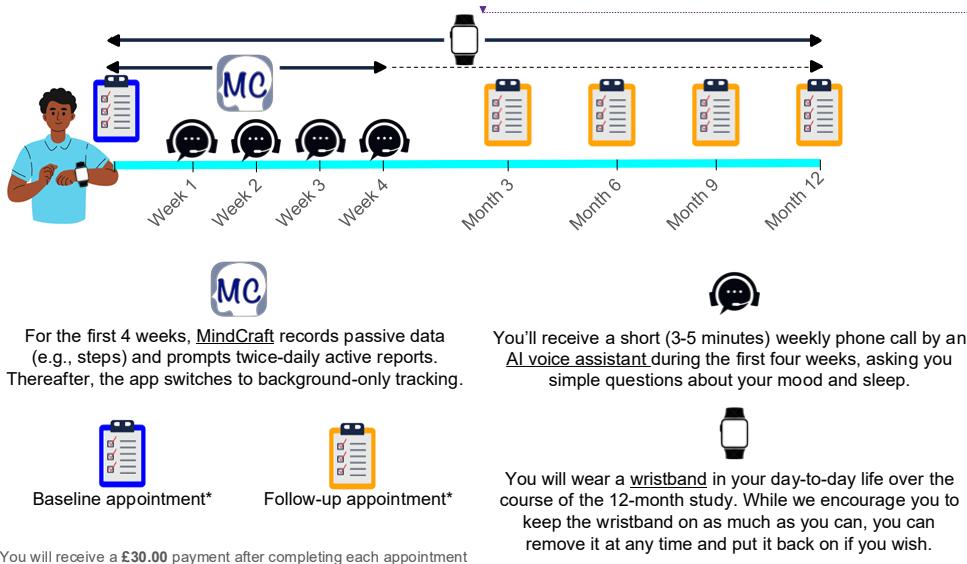


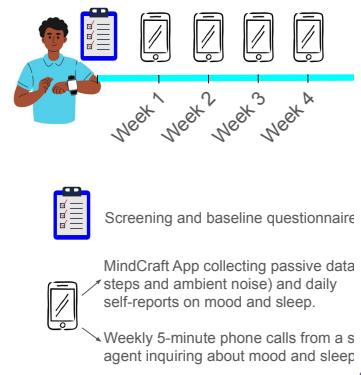
Figure 1. Study timeline. The figure illustrates the procedures involved in this study.

- **What do I have to do?**

If you wish to take part in the study, you need to be able to complete the study procedures. Described above.

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Acceleration, defined as the velocity rate of change, is a proxy of human activity. From acceleration, it is possible to infer information about the activity levels (e.g. step counts, burnt calories) and the sleep-wake patterns of the person wearing the device. Acceleration also allows us to establish retrospectively whether the person was wearing the device. The AX6 has a built-in data logger. This means that data is stored locally on the AX6 device and is not streamed in real-time to us. You do not need to download any app on your smartphone. We will download the data from the data logger during the follow-up appointme... [2]



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- **What are the possible disadvantages and risks of taking part?**

In the screening session and follow-up interviews, we would be asking you questions about any current and past difficulties you have experienced in relation to your general mental health. This includes your thoughts and feelings during times of distress and experiences such as suicidality and self-harm. Some people might find this upsetting. If you find this upsetting, you may stop the study at any time without having to give a reason, and you will not have to answer any questions that you do not want to. However, the majority of studies have found that people generally find it helpful to talk about difficult experiences in their lives when it is for a clear purpose. Moreover, any potentially distressing questions will always be asked in a supportive way by well-trained researchers.

Some individuals find it difficult and tiring to concentrate when filling in questionnaires. During our assessments, we would encourage you to take breaks to try and make this easier, and you could also choose to stop the study at any time.

All information that you share with us is confidential. We will only have to share this information in the case of having serious concern about: (a) your safety; (b) the safety of other persons who may be endangered by your behavior; or (c) the health, welfare or safety of children or vulnerable adults. This means that we will disclose the information only to either "prevent serious harm to you or others". We will check that you are happy with this and ask you to consent to this disclosure statement before starting with the study.

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Information arising from the screening session may suggest that this study may not be suitable for you. In such cases, we would discuss this with you.

The wristband used in this study (Axivity AX6) does not store any personal information. It only records the study data—acceleration, ambient light, and temperature. This means that if you lose the device, someone who finds it will not be able to identify you from the data on it. However, as with most wearable data, there is a small possibility of "cross-identification" if someone already has access to another dataset that includes your personal information and similar wrist-sensor data. In that unlikely situation, they could try to match the patterns between that dataset and data on the Axivity AX6 you wore.

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Your voice will be recorded during in-person visits and phone calls. While these recordings contain only your speech and not your name, voices are inherently identifiable. We take steps to protect your privacy (see data storage section below), but you should be aware that voice is a biometric identifier.

- **What are the possible benefits of taking part?**

You will collaborate on the development of a tool for the early detection of new mood episodes in bipolar disorder, which could benefit you and possibly many patients in the future. We cannot promise the study will help you directly, but the information we get might help improve the early identification of new episodes of bipolar disorder.

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Following each follow-up appointment, we will provide you with a summary of your energy and sleep-wake patterns recorded during the study. This summary is not medical advice, but it may help you better understand your own perceptions of your energy levels and sleep-wake rhythms.

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• What if new information becomes available?

In this study, we are not testing any intervention or medical device. Therefore, we do not anticipate that any new information will become available that could change your treatment and care or influence the clinical decisions made by your healthcare team.

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• What happens when the research study stops?

On your final appointment, we will collect the Axivity AX6 device.

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This study is non-interventional. This means that, apart from following the procedures outlined in the "What will happen to me if I take part" section, such as wearing the wristband and engaging with the MindCraft app, we will not administer any medical intervention or alter your usual treatment plan in any way. After the study is complete, you can continue your life as usual.

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Once you have completed the study, we will provide you (tentatively within three months) with a summary of your recorded energy expenditure and sleep-wake patterns throughout the study. Although this is not medical advice and will not include any specific recommendations, it can help increase your personal awareness of these patterns.

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• What happens if you want to leave the study?

You can withdraw from the study at any point without needing to give any reasons by emailing the research team.

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You may also be withdrawn from the study by the Research team if it emerges during any study procedure that your participation in the study might be affecting your health or if your eligibility changes. No further data will be collected after you leave the study.

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Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study, then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team'.

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experiencing an undiagnosed mood episode, they will encourage you to contact your NHS services. If clinical circumstances require it, the research team may contact your GP after informing you.

SECTION 2: STUDY CONDUCT

• Will the answers I give be confidential?

All the answers you give will be strictly confidential and will not be shared with anyone unless it is judged that you or someone else is at current risk of serious harm, or you need urgent care, in which case the relevant parties will be informed. We will discuss this with you first, although your permission may not be required.

• Are the answers I give anonymous?

All information you give during this study will be **anonymous**:

- The only people in Imperial College London who will have access to information that identifies you will be people who need to contact you about the study or to audit the data collection process.
- Your data is identified by a number and the people who analyze the information will not be able to identify you and will not be able to find out your name or contact details.
- Imperial College London will use your name, date of birth, and contact details to contact you about the research study.
- Individuals from Imperial College London and regulatory organizations may look at your research records to check the accuracy of the research study.

You will be given a unique participant code at the beginning of the study and all of your data will be pseudonymized.

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Imperial College London is the sponsor for this study and will act as the Data Controller with 'NIHR Imperial Biomedical Research Centre and Imperial College London Faculty of Medicine' for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in October 2027.

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED**' for contact information.

We will need to use information from you, during engagement with the procedures reported in "What will happen to me if I take part", for this research project.

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This information will include your:

- Name and contact details
- Clinical-demographic info (e.g. number of past episodes, current medications) and answers to questionnaires.
- Data generated engaging with the MindCraft App.
- Data from the Axivity AX6 wristband.
- Data from the speech tasks during quarterly appointments and the weekly 5-minute phone call during the first month.

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People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate. 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.

Imperial College London/Imperial College Healthcare NHS Trust is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Screening questionnaires will be collected with the GDPR (General Data Protection Regulation) compliant software Qualtrics. This data will be stored on a server owned by Qualtrics, whose data storage is compliant with OECD privacy rules and the European Union Directive on Data Protection. Once we have acquired data into the Imperial College local server, it will be deleted from Qualtrics. If we believe participants do not meet eligibility criteria or they do not wish to participate in the study, data will be destroyed and not stored.
- Personal Identifiable Information such as consent forms and contact details will be stored in locked cabinets at the study locations.
- Any phone calls between (prospective) participants and the research team—for example, when participants request information or when the research team contacts participants for study-related purposes (such as confirming eligibility or scheduling a follow-up appointment)—will **not be recorded**.
- Clinical demographic data will be stored and managed within the GDPR compliance software REDCap.
- Speech recordings, during quarterly in-person assessments and weekly automated phone call in the first month of the study, will be collected using HIPAA-compliant digital voice recorder software (Psyrian Inc., encrypted storage) for in-person sessions and a secure, HIPAA-compliant cloud-based telephony and voiced agent system (using daily.co and Pipecat Cloud with end-to-end encryption) for automated calls, provided by Psyrian Inc. According to Psyrian Inc. and Google Business Associate Agreement, conversation data cannot be used in any form by Google, including training AI models.
- Data from the Axivity AX6 data logger will be downloaded onto an Imperial College-owned laptop during follow-up visits and then uploaded onto a secure server at Imperial College London.
- The data collected by the MindCraft app (e.g., app use, and behaviour data) will be transferred directly from the app to the secure data server located in the Imperial College data center.
- If you choose to make your anonymised data publicly available by selecting the relevant option on the Informed Consent Form, your data will be shared in an anonymised format. Public data sharing helps ensure transparency in research and can accelerate progress in understanding bipolar disorder by allowing other researchers to analyse and build on the data. To prevent (cross)identification, as done in previous studies, time stamps from the

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Axivity AX6 data logger will be shifted by a small amount, and data will be resampled. Data on ethnicity and employment will be aggregated over the study population (e.g. with an average over all the study participants) and shared only in this aggregated form; no individual-level information on these variables will be released. Age will be shared only in 5-year bands (e.g., 21–25 rather than 23). No smartphone location data, in case you choose to provide this via the MindCraft app, will be shared. Your voice recordings will not be shared either, we will only share anonymized transcripts.

Once we have finished the study, we will keep some of the 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.

As a university we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - “performance of a task carried out in the public interest”: Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data i.e. finger prints or facial recognition and genetic data, racial and ethnic data etc.), Imperial College London relies on “scientific or historical research purposes or statistical purposes

INTERNATIONAL TRANSFERS

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We may share data about you outside the UK for research related purposes to:
Where necessary to provide access to for speech data processing and analysis.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Psyrin Inc, a company founded by King's College London alumni, partnering with our research team on this study to support speech analysis.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK

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- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- the following Research Collaborators / Partners in the study
 - Third Party Company, Psyrin Inc. We will transfer only the following data: a) speech data from weekly 5-minute automated phone call in the first month of the study; b) speech data from speech tasks during quarterly follow-up appointments; c) speech data collected during quarterly follow-up appointments as participants are asked to reflect on their experience with the wristband. Speech data shared with Psyrin will not be paired with participants' details but with a randomly generated ID. The dictionary pairing participant's personal details to the randomly generated ID will only be available to the Chief Investigator and will be kept safe in locked files at Imperial College London. Psyrin is partnering with us on this study and will be in charge of pre-processing speech data, including transcribing the recordings and extracting prosody features.

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POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

IMPERIAL

Data (delete as required) from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

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.
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to f.corponi@imperial.ac.uk, or
- by ringing us on **0207 594 1069**.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to f.corponi@imperial.ac.uk, or by ringing us on **0207 594 1069**.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

- What will happen to the results of the research study?

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Commented [CW5]: Refer to and use the latest GDPR approved wording from section "HRA GDPR Approved wording in the PIS or document provided to participants" of the RGIT PIS template [RGIT_TEMP_031_Guide-to-Writing-a-Participant-Information-Sheet.docx](#)

Commented [FC5R2]: I contacted ICL DPO for advice regarding anonymised vs pseudo-anonymised data.

Deleted: When the study is complete, the data will be analysed and written up for publication in scientific journals and presented at scientific meetings or in talks at academic institutions. Results will always be presented in such a way that data from individual participants cannot be identified. 

 When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework- health-social-care-research/>). 

 Speech recordings from in-person visits will be stored on encrypted, password-protected digital server. All audio files will be encrypted at rest and identified only by your unique participant code. 

 This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. 

 If you choose to make your anonymised data publicly available by selecting the relevant option on the Informed Consent Form, your data will be shared in an anonymised format. Public data sharing helps ensure transparency in research and can accelerate progress in understanding bipolar disorder by allowing other researchers to analyse and build on the data. To prevent (cross)identification, as done in previous studies, time stamps from the Axivity AX6 data logger will be shifted by a small amount, and data will be resampled. Data on ethnicity and employment will be aggregated over the study population (e.g. with an average over all the study participants) and shared only in this aggregated form; no individual-level information on these variables will be released. Age will be shared only in 5-year bands (e.g., 21–25 rather than 23). No smartphone location data, in case you choose to provide this via the MindCraft app, will be shared. Your voice recordings will not be shared either, we will only share anonymized transcripts. 

 How is my data stored? 

 Imperial College London is the sponsor for this study based in the United Kingdom. We will be using information from you to undertake this study and will act as the data controller for this study. This means ... [4]

IMPERIAL

When the study is complete, the data will be analysed and written up for publication in scientific journals and presented at scientific meetings or in talks at academic institutions. Results will always be presented in such a way that data from individual participants cannot be identified.

- **Who is organizing and funding the research?**

NIHR Imperial Biomedical Research Centre and Imperial College London Faculty of Medicine have contributed to funding this study.

- **Who has reviewed the study?**

This study was given a favorable ethical opinion for conduct in the NHS (or private sector) by xxx REC.

- **Contact for further information**

A copy of this written information and your signed Informed Consent form will be given to you. If you require any further information, please contact the researcher, Filippo Corponi (f.corponi@imperial.ac.uk)

To take part

Please email the researcher on f.corponi@imperial.ac.uk to communicate your interest and arrange your first visit.

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Thank you for taking part in the study!

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