



Study title: Evaluation of the BrainWaveBank platform for detecting risk of psychotic illness

PARTICIPANT INFORMATION SHEET

At-home use of the BrainWaveBank platform by healthy adult users

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You are being invited to take part in a research study. It is not expected or required of you to participate. This study is recruiting healthy adults between the ages of 18-45. Before you decide whether you would like to take part, please read through this information sheet. The purpose of the study is explained as well as details about how you can be involved.

The purpose of the study

BrainWaveBank Ltd. have developed a new system for monitoring brain health at home, using a wireless EEG (electroencephalography, or “brainwave” recording) headset combined with mobile/tablet games. By taking cognitive neuroscience out of the lab and making it suitable for daily use in the home, we hope to detect early signs of diseases which affect brain function, and predict the efficacy of certain treatment options. This scientific study represents our first major attempt to test if we can do this for psychosis.

This study is part of a Small Business Research Initiative (SBRI) project funded by the Northern Ireland Department of Health, which aims to develop new technologies for early detection and monitoring of psychotic disorders, like schizophrenia. We hope to be able to detect the neural markers of psychotic illness at different stages of severity, from the experience of mild symptoms to severe. We are recruiting a group of patients with symptoms of psychosis, along with a ‘control’ group of participants who are not experiencing any symptoms of psychotic illness. Everyone in the study will take the equipment home and perform their own recordings, a few times per week. We will compare between these separate groups to look for differences in certain brainwave patterns. In addition, we want to ask participants about any issues they experienced during the study which might discourage or prevent people from using future iterations of the system.

This study is the first step towards validating our system for detection of psychotic illnesses. We hope that one day, clinicians or GPs will be able to use an EEG headset as part of their diagnostic tool set, and in doing so, more rapidly get patients into the right form of treatment. The earlier treatment is initiated, the better the outlook for patients.

The study is explained in more detail in the following pages.

The role of the participant

You are invited to use and provide feedback on the technology. This will include playing games on a tablet and wearing the wireless EEG headset at home, for 25 minutes per day, on 3 days per week, for six weeks. As part of these daily sessions, you will also be asked to complete a short questionnaire covering aspects of general wellbeing and lifestyle. All equipment required to take part in the study will be provided during an introductory tutorial session.

At the end of the six weeks, you will be asked to provide feedback on your experience using the equipment at home, in a short interview or small focus group. We will use video and/or audio recording to help us capture your valuable feedback in full and analyse it in detail after this session has ended.

A typical daily session, using the equipment at home will begin with:

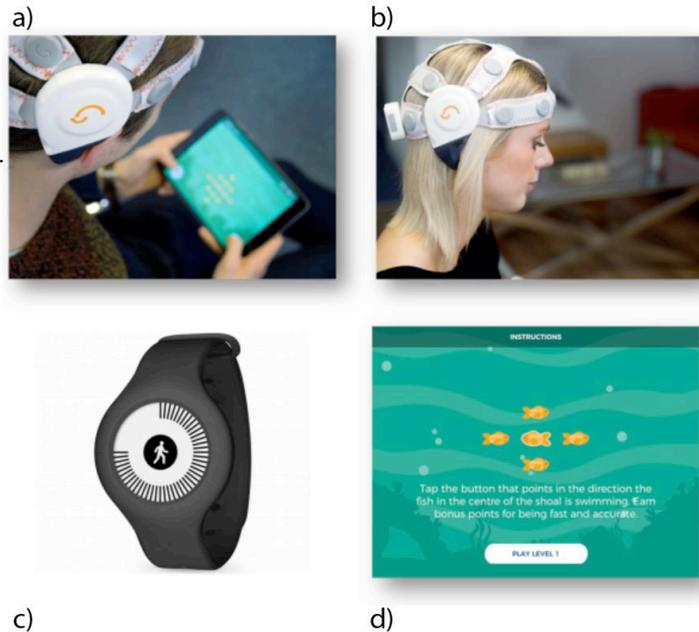
- Putting on the EEG headset and logging in to the tablet with your unique username and password.
- Calibrating the headset to ensure good signal quality.
- Completion of a short daily questionnaire about lifestyle and wellbeing (~3 mins)
- Playing two short (6-8 mins) games on the tablet.
- Watching a 15-minute video on the tablet while listening to bleeps.
- Completing a two-minute 'brain baseline' resting state recording.

The introductory session and follow-up feedback session will take place at the offices of BrainWaveBank, at Catalyst, Unit 4, The Innovation Centre, Queens Rd, Belfast BT3 9DT.

What is EEG?

EEG stands for electroencephalography which is simply, "brainwave" technology. EEG is a cheap, safe and passive recording technology which is widely used in hospitals and universities. The technology has existed for over a century now, and it works by simply measuring the tiny electrical signals that your brain naturally produces. Advances in technology (mobile communication, dry sensor designs and miniaturization) now mean that EEG is available as a consumer product for everyday use in the home.

This figure (right) shows elements of the BrainWaveBank platform: a) someone wearing the headset while playing games on the tablet; b) side view of the headset on the head; c) fitness-tracker wristwatch and d) screenshot of an example game



Can I sign up to take part?

You can sign up if you:

- ✓ Are aged between 18-45 years
- ✓ Are a native or fluent speaker of English
- ✓ Have wireless internet (wi-fi) in your home

Unfortunately, we are unable to include everyone in the current study. Please exclude yourself from the study for any one of the following reasons. There is no need for you to contact us; we do not need to know why you have excluded yourself from the study. You should not take part if you:

- × Have had recent contact (within the past year) with mental health services in any Northern Ireland health and social care trust.
- × Have a current or past history of any neurological, movement or neurodegenerative condition/disease affecting the brain (e.g. MS; epilepsy or seizures; Parkinson's disease)
- × Have had one or more seizures without a clear and resolved explanation
- × Have any symptomatic or uncontrolled medical illness likely to alter brain morphology and/or physiology (e.g. uncontrolled hypertension, diabetes)



- × Have recently (last 3 months) undergone intensive treated for, or experienced life-threatening complications associated with, an eating disorder
- × Are a current or previous user of antipsychotic medication equivalent to a total cumulative haloperidol equivalent of ≥ 15 mg
- × Are a current and consistent user of prescribed medication that affects the brain (e.g. mood stabilisers, anti-depressants, anxiolytics, sedatives, muscle relaxants, pre-maintenance GR therapy hormones, opioid painkillers or medicines to treat seizures).
 - Use of the contraceptive pill and/or common cold/flu remedies and occasional sleeping/alertness aids are acceptable.
 - Alcohol, nicotine and caffeine use is acceptable.
- × Have recently (in the 14 days before the first session) consumed or been exposed to a schedule 1-5 drug covered under The Misuse of Drugs Regulations (NI) 2002.
- × Have a history of a substance use disorder involving alcohol or illicit drugs.
- × Have ever been treated with electroconvulsive therapy (ECT).
- × Have received treatment with any medical device involving brain stimulation (e.g. transcranial magnetic stimulation; neurofeedback) within the last year.
- × Have taken part in a clinical trial within the 30 days prior to the first session.
- × Have previously experienced a severe traumatic brain injury
- × Have a severe learning disability

What should I expect?

Initial visit to BrainWaveBank

- 1) *On arrival (20 mins)*: First, you will be reminded about the nature and purpose of the study before you give written consent to take part. We will ask you about any medications you are currently taking. Please see a copy of the consent form included as part of this information pack. **You are free to withdraw from the study at this stage, and indeed at any stage, without giving a reason.**
- 2) *Neuropsychiatric questionnaire and cognitive assessment (up to 30 mins)*: You will be asked to complete a questionnaire which asks symptoms of anxiety and depression, complete a reading task and item-naming task.

(procedure continued on following page)

- 3) *Automated cognitive assessment (1 hour 15 mins, including breaks):* You will be asked to complete a computerised cognitive assessment on a handheld iPad. This will incorporate several tasks, which measure cognitive functions such as reaction time, information processing, memory, multi-tasking, planning and emotion recognition. All tasks automatically scale in difficulty based on your performance, so as to avoid being too mentally taxing. There will be a scheduled break at the halfway point.
- 4) *BrainWaveBank platform introduction (up to 30 mins with breaks as needed throughout):* You will be shown the equipment that you will take home with you: the EEG headset, tablet and wristwatch fitness-tracker (optional). We will take you through each of the components and then we will run through the full set of activities that you will be asked to do at home. This consists of a lifestyle questionnaire and some short tasks, including games, all performed on the tablet.
- 5) *Sample session (30 mins):* You will wear the headset and perform a session much like that which you will perform at home over the following two weeks.

Refreshments and breaks will be available throughout the session, which should last no longer than 3 hours, 15 minutes.

At-home sessions

You will then take the technology home with you and will be asked to use it on a regular basis for the following six weeks (minimum 3 times per week for about 25 minutes each time).

You can contact the research team at any stage throughout if you have questions or require any assistance.

Debrief and feedback session

For this final session, you will be asked to return to BrainWaveBank to return the equipment and provide feedback on your experience in an interview or small focus group.

Refreshments and breaks will be available throughout the session, which should last no longer than 1 hour.



If you have any questions about the research, please contact the research team below to discuss your participation:

BrainWaveBank Trial Researcher

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Principal investigator:

Dr. Brian Murphy
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Tel: +44 (0)28 9264 6600



Here are a few more questions and answers to help you decide if being involved in this study is something you might like to consider.

What will happen if I take part? You will be invited to the BrainWaveBank office to participate in an introductory/screening session. This session will involve some questionnaires, doing some cognitive tests on a tablet, and learning how to use the BrainWaveBank EEG headset and tablet games. Please see the information on page 4, in the section entitled, ‘What should I expect?’ for timings and details. Travel expenses will be reimbursed for all participants in the form of payment up to a maximum of £20 per session.

What are the risks and benefits in taking part in this study? There are no major risks or benefits to taking part in this study.

Has this study gained ethical approval? Yes. Ethical approval has been granted by the Office for Research Ethics Committees Northern Ireland (ORECNI) – see <http://www.hscbusiness.hscni.net/orecni.htm>. This study is funded by a Department of Health grant.

What if something goes wrong? It is highly unlikely that anything will go wrong as a result of taking part in this study. In the event that something does go wrong, and you are harmed because of someone's negligence then you may have grounds for legal action. If you have any concerns about any aspects of the study, you can contact the Chief Investigator of the study, Dr Brian Murphy (Telephone 028 9264 6600; email brian@brainwavebank.com)

How can I be sure that my personal information remains confidential? Care is taken to ensure all records identifying you will be kept confidential. You will be assigned an anonymous code and all person-identifiable information gathered at the consent stage will be stored in hard-copy form only, and kept in a secure locked location designated for all paperwork pertaining to this study in the BrainWaveBank offices. Access to any of your identifiable information will be only given to the named individuals on this form. Audio and video recordings will be kept only on password and firewall protected computers owned by BrainWaveBank Ltd. and will never be shared outside of the company. Individuals who have access to these computers are aware of their responsibilities and of data protection obligations.

The fitness tracker used in this study is a commercially available Withings product. Therefore, as with all fitness trackers, when you sign up to use the product, you will consent for Withings to have access to the data you generate through your use of the fitness tracker. For the purposes of this study, Withings will, with your consent, share this data with BrainWaveBank. To see Withings’ privacy policy in full, please visit <https://www.withings.com/uk/en/legal/privacy-policy>. We will use the fitness tracker to contextualise daily variation in brainwave patterns (e.g. to characterise changes due to



exercise or lack/abundance of sleep. The fitness tracker is an optional part of the study and you can still take part if you would prefer not to use it.

If you wish to raise a complaint on how we have handled your personal data, you can contact the Principal investigator, Brian Murphy (Chief Scientific Officer of BrainWaveBank) at brian@brainwavebank.com who will investigate the matter. If you are not satisfied 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) at ni@ico.org.uk.

*Individually identifiable information **will not** be given to third parties or made available through publications.*

Will my data be shared? With your consent, the EEG and behavioural data which we gather from recordings with the system may be published in scientific journals and/or presented at conferences. Data sharing brings great benefits to researchers in similar fields. Sharing data provides researchers in the wider scientific community with the opportunity of exploring other research questions regarding a particular condition. In this study, you will be asked to consent to your anonymised data being shared with third parties inside and outside the EU who are carrying out studies of a similar nature. Any and all data published outside the company will be fully anonymised and it will not be possible to use it to identify you. With your consent, transcribed sections of your feedback on the platform may be shared in the form of text. Quotations will not be attributed to you, nor will any potentially-identifying information be quoted.

Your anonymised data (in text, as quotations, or in aggregate as statistics) will be made available to staff in BrainWaveBank Ltd. As partners in this study and developers of the technology, they will have access to all anonymised data collected as part of this study. This data will be used to help with the development of future versions of the headset and games.

What if I change my mind and wish to leave the study? You are free to leave the study at any time during the process, on any day or mid-session. Your participation in the study is completely voluntary and therefore, you may withdraw from the study at any stage, without giving reason and without consequence.

In the event of having to withdraw from the study, for personal or medical reasons, you will have the option to consent to your existing data being stored and used for research purposes (as detailed on the consent form).

Due to the nature of the study, we are required to obtain certain information from you. Please be assured that your anonymity is guaranteed. Please feel free to ask any questions you may have.

Thank you for taking the time to read through this information sheet.

If you are satisfied with the information given and you are happy to proceed with the study, please refer to the consent form (separate form attached).