

Study title: BrainWaveBank usability for young adult
Patients [UHR/ARMS]

PARTICIPANT INFORMATION SHEET

Focus group evaluation of the BrainWaveBank platform for heathy young 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 18-35. 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, through the use of 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 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. Until now, the BrainWaveBank platform has been designed with older adult users in mind. However, the age profile of those who experience first-episode psychosis is much younger (typically 18-35). This study is intended to guide a redesign of the platform for younger adult users, who we believe have (as a group) different needs, levels of experience and expectations of such a technology than older adults (40+). We want to find out what younger adults think of the current state of the platform and gather feedback on planned updates before they are released. In addition, we want to identify any issues which might discourage or prevent younger adults from using the platform.

The role of the participant

You are invited to view, use and provide feedback on the technology as part of a small focus group. This may include playing games on a tablet and wearing the wireless EEG headset to give us feedback and answering some questions from the facilitator, who will guide the session. We will use video and audio recording to help us capture your valuable feedback in full and analyse it in detail after the session has ended.

- A typical session will begin with a full explanation of the aims of the project and the nature of participation in the current session, followed by gathering of written consent (15 mins).
- You will be asked to try out the equipment (including the headset and tablet app) and think aloud while doing so (30 mins).
- In addition, you will be asked a series of predefined questions in a semi-structured interview format, relating to 1) your interest in using the platform over an extended period of time; 2) motivational factors which would keep you engaged; 3) specific features of the current set of games which you like/dislike; 4) your impressions of concept art and prototypes of games still in development (up to 45 mins).

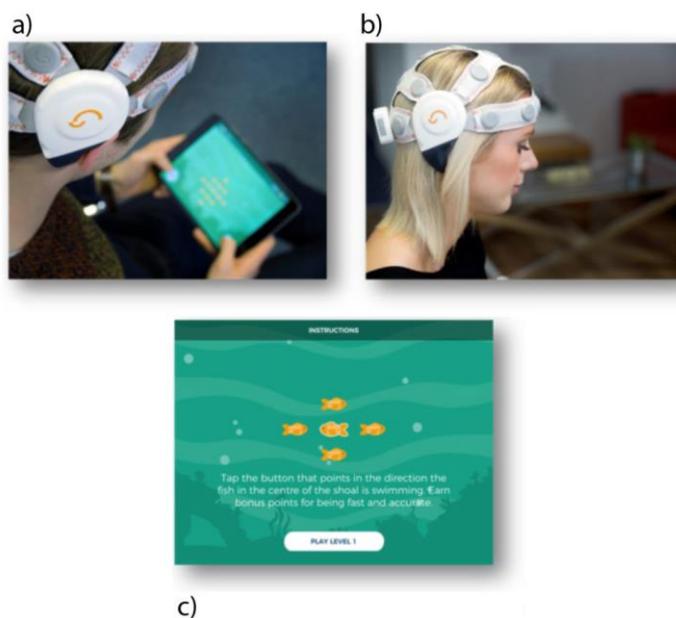
This focus group session will last no longer than 1hr 30 mins in total. There will be refreshments and opportunities for breaks, if needed, throughout.

The session will take place at the offices of BrainWaveBank at 32-36 Dublin Road, Belfast.

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) screenshot of an example game.



Can I sign up to take part?

You can sign up if you are:

- ✓ Aged between 18-35 years
- ✓ Male or female

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.

What should I expect?

- 1) *On arrival (15 mins):* First, you will be reminded about the nature and purpose of the study before you give written consent to take part. Next, you will complete a short questionnaire designed to measure the presence of low-level symptoms of psychosis. Please see a copy of the consent form included as part of this information pack. **You are free to withdraw from the study at any stage of the session, without giving a reason.**
- 2) *Think-aloud user testing (30 mins with breaks as needed throughout):* This period will incorporate the setup of the headset, trying it on your head, and playing some games on a tablet which require tapping on a touch-screen. During this, you may be asked to verbalise your thoughts and reactions to the headset and games. Audio and video will be recorded throughout.
- 3) *Focus group discussion (up to 45 mins with breaks as needed throughout):* This is intended to allow you to share your feedback to help us make the product better and more user-friendly. We will ask several questions (about the look of the device, ease of use, your experience of using mobile technology, etc). This may take place in a small group of people, alternatively as a one-to-one interview with the researcher. This will be audio/video recorded and stored for later analysis.

Refreshments and breaks will be available throughout the session, which should last no longer than 1 hour, 30 minutes.

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 Ltd premises to participate in a focus group session. Please see the information in point no. 3 on the previous page, 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.

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.

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.

As part of this study we will ask you to complete a questionnaire (‘The 16-item Prodromal Questionnaire’ – PQ-16) which is designed to detect early warning signs of a psychotic illness. The questionnaire is used in this study for research purposes only – to enable us to describe the overall psychiatric health of a group of participants recruited from the general

public (you are in this group). This will allow us to characterise your group of participants next to a separate group who are being treated for early signs of psychotic illness. This questionnaire is not a diagnostic tool, and we cannot use it to tell if you, individually, are healthy or ill. Furthermore, no member of staff at BrainWaveBank is a trained clinician and as such we cannot interpret questionnaire scores. The questionnaire will not be scored by BrainWaveBank staff until the end of the study, at which point the scores will be anonymous.

If, during your participation in the study, we have reason to believe you are at any risk of psychiatric illness, we will consult with our clinical research partners, Dr. Ciaran Mulholland (Consultant Psychiatrist in the Northern Health and Social Care Trust) and Dr. Ciaran Shannon (Clinical Psychologist in the Northern Health and Social Care Trust), who may decide to contact your GP on your behalf. For this reason, we will ask you to provide contact details for your GP.

For more information on the PQ-16, please see the relevant research paper – Ising H.K. Schizophrenia Bulletin, 2012; 38(6): 1288–1296. This can be accessed freely at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3713086/> and the questionnaire itself can be viewed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3713086/table/d35e1186/?report=objectonly>

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

Will my data be shared? With your consent, transcribed sections of your data may be shared in the form of text. All data will be anonymised and you will not be identifiable from it.

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.

Additionally, 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 able to consent to your data being shared with third parties inside and outside the EU who are carrying out studies of a similar nature.

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, including on the 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 data being stored and used for research purposes (as detailed on the consent form). In addition, you will have the option of being contacted to continue with the study at a later date and will be under no obligation to take part.

What happens if I damage the equipment? We understand that accidents happen, and you will not be held liable for the cost of a headset or tablet should either get damaged during the session.

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).