

INFORMATION SHEET

Evaluation of in-home monitoring using the BrainWaveBank platform for people with Mild Cognitive Impairment

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You are invited to take part in a research study, it is not expected or required of you to participate. This study is recruiting people who have recently received a diagnosis of Mild Cognitive Impairment (MCI), also a separate group of people who do not have any cognitive impairment. 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 to monitor brain health at home through the use of a wireless EEG (electroencephalography, or “brainwave” recording) headset combined with mobile/tablet games. By taking this type of technology and making it suitable for daily use in the home, our research has the potential to lead towards the early identification and ongoing monitoring of diseases that affect the brain. To do this, we need to find out more about brain patterns at the early stages of cognitive impairment, and how these differ from brain patterns in people who don’t have cognitive impairment. We also want to identify any issues which might discourage or prevent people from successfully using the product.

The Role of the Participant

You are invited to use our technology to monitor your brain and general health in your own home, for 20 minutes each day, 5 days per week for a period of 6 weeks. This will include playing games on a tablet whilst wearing the wireless EEG recording headset to measure brain function. We will also ask you to wear a fitness tracker on your wrist over the course of the study to monitor aspects of general health (exercise, sleep, etc) and ask you to complete a very short (3 minute) daily questionnaire covering aspects of general health and wellbeing on each of the 5 days that you perform the game tasks. All equipment required to take part in the study will be provided.

Before you begin the trial at home you will be asked to come in to BrainWaveBank premises in Belfast for a baseline session. Similarly, at the end of the trial you will also be invited back to give feedback on your experience and return the equipment.

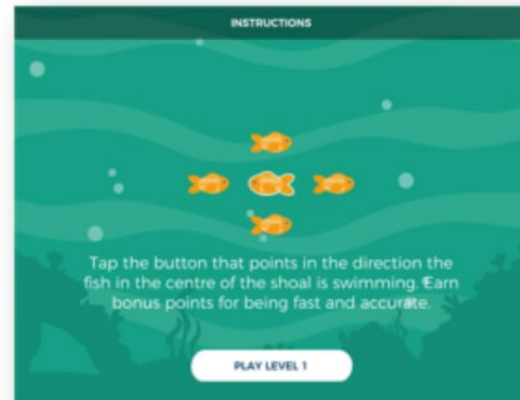
a)



b)



c)



d)

Figure showing elements of the BrainWaveBank platform: a) photo of someone wearing the headset whilst playing games on the tablet; b) side view of the headset; c) fitness tracker wristwatch; d) screenshot of an example game

What is EEG?

EEG stands for electroencephalography which is simply, "brainwave" technology. EEG is a cheap, safe, 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 reach your scalp from your brain's natural activity. 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. The EEG signals that are collected using our headset are securely transmitted to the tablet using Bluetooth technology. From the tablet, the data is then encrypted and transferred to our secure servers via wifi connection.

Can I sign up to take part?

You can if you are:

- ✓ **Aged 55+**
- ✓ **Male or Female**
- ✓ **If you have been recruited as someone with MCI: a diagnosis of MCI as affirmed by a senior clinician in the Belfast Trust**

Unfortunately for the purposes of this study, we are unable to include everyone. 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.

- × **Current or past history of neurological condition or event other than mild cognitive impairment (e.g. MS; stroke; epilepsy; Parkinson's; or any brain trauma)**
- × **Current or past history of psychiatric treatment or substance abuse**

What To Expect

Baseline Visit

This baseline session will introduce you to the research team, the technology and ensure that you are comfortable with everything that's involved.

1. *On arrival:* Introduction to the research study and the researchers involved. You will be reminded about the nature and purpose of the study and have the opportunity to ask questions before giving consent to take part. **You are free to withdraw from the study at this stage, and indeed at any time, without giving a reason.**
2. *Cognitive Assessment:* We will then ask you to take part in a number of computerised and pen-and-paper tests so that we can get a good idea of your baseline cognitive ability (this will last approximately 1.5 hours). Please note that these tests are only being conducted for research purposes and cannot diagnose any underlying conditions. However, we will share your results with you and if there is any area of concern, we will contact your GP to follow up on this.
3. *BrainWaveBank platform introduction:* You will then be shown the equipment that you will take home with you: the EEG headset, fitness tracker and the tablet. 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 questionnaire about your general health, sleep, caffeine intake, how you feel today, etc. Then you will put on the EEG headset, ensure it's working properly and play a series of games on the tablet. We will then record you at rest, first with your eyes open and then with eyes closed for a few minutes. This introduction may last up to 1.5 hours.

To help you plan your visit, we would recommend allocating around 3.5 hours for this baseline session. There will be refreshments provided and opportunities for breaks, if needed, throughout. These sessions will take place at BrainWaveBank Ltd premises at 32-36 Dublin Road, Belfast.

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 6 weeks (5 times per week for about 20 minutes each time).

At the halfway point (3 weeks in), we will contact you by phone to check that everything is going smoothly and we will ask you for some feedback on your experience thus far (this phone call is expected to last about 20 mins).

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

Final session

For this final session, you will be asked to return to BrainWaveBank to repeat steps 2 and 3 from the baseline session. After this, you will be asked to give feedback on your experience, to help us improve and refine our technology for future use. It is expected that this session will last a similar time to the baseline and again there will be refreshments provided and opportunities for breaks, if needed, throughout.

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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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.

Will I be reimbursed for my time and travel if I take part? A token contribution of £20 towards travel expenses will be given to all participants for every session which requires travel in to BrainWaveBank premises.

What are the risks and benefits in taking part in this study? There are no major or minor health risks or benefits to taking part in this study. The research is early stage and is not designed to diagnose any underlying clinical conditions. However, in the unlikely event that any of your responses or patterns in the brain activity look unusual, the research team will consult with a Consultant Geriatrician at the Belfast Trust and, if appropriate, we will then contact your GP for further investigation. You will also be notified. Before you begin this research study, you will be asked to supply GP details and give consent for us to contact them.

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).

Has this study gained ethical approval? Yes. Ethical approval has been granted from ORECNI (Office for Research Ethics Committee NI).

How can I be sure that my 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 paper work pertaining to this study. If you have been given a clinical diagnosis of MCI, information relating to this diagnosis will be securely transferred to the BrainWaveBank research team. Access to any of your identifiable information will be only given to the named individuals on this form (the BrainWaveBank research team). Other information (including demographic information, EEG data recordings, information from medical records) will be kept in anonymised form only on password and firewall protected computers owned by BrainWaveBank Ltd. 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 Nokia product. Therefore, as with all fitness trackers, when you sign up to the product you will consent for Nokia to have access to your data associated with the fitness tracker.

For the purposes of this trial, Nokia will, with your consent, share this data to BrainWaveBank. For more information on Nokia's privacy policy, please see

<https://health.nokia.com/gb/en/legal/privacy-policy>

<https://health.nokia.com/gb/en/legal/privacy-policy-supplement>

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

Will my data be shared? With your consent, your data may be shared. All data will be anonymised, and you will not be identifiable from it. 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. 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. If you wish to withdraw your data from the study, you may do so and it will be deleted from BrainWaveBank systems (though not removed from results that it has already been aggregated into).

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.

If this has raised any questions for you personally or you feel you would like to speak to someone further about your recent diagnosis:

- Please contact your Senior Clinician or GP.
 - The Alzheimer's Society also has a dedicated office in Northern Ireland and staff are available to answer your questions. Their website (<https://www.alzheimers.org.uk>) can also direct you to information online where you can find help in your local area.
- National Helpline: 0300 222 1122**

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).