

## UoM Research Participant Information Sheet Ecological Momentary Assessment (EMA) Study

This Participant information Sheet (PIS) should be read in conjunction with the [University privacy notice](#)

You are being invited to take part in a research study that will be run by the Hearing Devices Research Centre at the University of Manchester and that has been funded by Oticon (a hearing aid company).

Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear to you or that you would like more information about. Make sure to take time to decide whether or not you want to take part.

### Who will conduct the research?

Dr Gabrielle Saunders (Senior Research Fellow in Audiology) is the lead researcher for this study. Melanie Lough and Helen Whiston (qualified RCCP registered Audiologists) will primarily do the testing. The researchers are based at:

Manchester Centre for Audiology and Deafness  
School of Health Sciences  
Faculty of Biology, Medicine and Health  
University of Manchester  
Oxford Road  
Manchester, M13 9PL

### What is the purpose of the research?

The study is taking place so that we can (a) compare two pairs of hearing aids manufactured by Oticon and (b) test out a new way of measuring hearing aid outcome (how well you are doing with your hearing aids). The new measure is referred to Ecological Momentary Assessment (EMA). With EMA you answer questions about a listening situation using your mobile phone *at the time the situation is happening*. This is different to standard questionnaires that you fill in long after you have left the situation. We think answers given using EMA might better reflect your experiences.

### Why have I been chosen?

You have been asked to participate because you

- are aged 25-85 years,
- have hearing loss which is similar in both ears,
- have been using hearing aids for at least 1 year,
- have a copy of a recent hearing test (no more than 2 years old) or we have the results of a recent hearing test in our Hearing Health Volunteer Database.
- speak English fluently
- own an iPhone model SE which runs on iOS V 12 or a later
- know how to download and use apps from an app store
- are able and willing to use zoom for video calls
- own a tablet, PC or laptop with a camera

### What would my involvement be?

You will wear two different pairs of hearing aid manufactured by Oticon for two weeks each. During that time you will answer questions about the hearing aids on your mobile phone and will take part in a short interview. Due to COVID-19, all research interactions will take place by video call or telephone in order to avoid face-to-face meetings.

The details of the study are:

**Video call 1.** It will involve:

- Confirming you are eligible to participate. This will involve you completing a 15-item questionnaire to check your ear and hearing health.
- Downloading study apps. The study requires you to download an app that will be used to program your hearing aids and an app that will be used to answer questions about the hearing aids
- Sizing your hearing aids. We will help you measure your current hearing aids so we know what size the study hearing aid earpieces need to be

You will then be sent the 1<sup>st</sup> pair of study hearing aids.

**Video call 2 (1-2 weeks later).** It will involve:

- Instructing you how to use the hearing aids and apps
- Making changes to how the hearing aids sound if you request it

**Wearing the 1<sup>st</sup> pair of study hearing aids**

You will wear the 1<sup>st</sup> pair of study hearing aids for two weeks. Every day you will receive six mobile phone prompts between 8am and 9pm requesting that you fill in a 7-item questionnaire about the hearing aids. These questionnaires will each take about 1 minute to answer.

**Email link**

After wearing the hearing aids for 7-10 days, you will receive by email a link to a hearing aid questionnaire. The questionnaire will take about 10 minutes to complete.

**Receiving 2<sup>nd</sup> pair of study hearing aids.**

After two weeks you will receive the second pair of study hearing aids in the post, along with a pre-paid envelope to be used to return the first pair of study hearing aids to us.

**Video call 3.** It will involve:

- Instructing you how to use the hearing aids and apps
- Making changes to how the hearing aids sound if you request it

**Wearing the 2<sup>nd</sup> pair of study hearing aids.**

You will then follow the same process as with the first pair of hearing aids, answering six short questionnaires each day and one longer questionnaire after 7-10 days.

**Email link:**

After two weeks of using the 2<sup>nd</sup> pair of hearing aids you will receive by email a third link to a questionnaire and another pre-paid envelope in which to return the hearing aids. The questionnaire will ask you to compare the two pairs of hearing aids you have worn. It will take about 10 minutes to complete.

**Video call 4.** It will involve:

- A short exit interview to find out what you thought of the hearing aids and the questionnaires. The interview will be recorded so we can accurately interpret your comments.

All of your short questionnaire answers will be stored on your mobile phone. At the end of the study you will need to download the data onto a computer so you can send it to us.

**Technology requirements for the study:**

- iPhone model SE which runs on iOS V 12 or a later
- Access to a computer
- Access to zoom

### **Will I be paid for participating in the research?**

- If you wish to, you will be able to keep one a pair of the study hearing aids. They will come with a warranty. However the University of Manchester will not be able to offer any other support. You will have to find a private Audiologist if you need additional support for the hearing aids.
- In addition, you will receive 25p for each additional survey you complete each day (up to a maximum of six per day) over and above a minimum of 4 per day. This could result in your receiving payment of up to £42. Any bonus will be paid at the end of the study via a bank transfer.

### **What is the duration of the research?**

Your participation in the study will last for approximately 6-8 weeks. Each video call will last about 45 minutes, you will fill in three questionnaires that will each take about 10 minutes, and you will be prompted to complete six short questionnaires each day that will each take about 1 minute to complete. Therefore, the total time spent on study activities will be about five hours over the 6-8 week period.

### **Where will the research be conducted?**

The research will be conducted from you home. You will not come to the University of Manchester or to an audiology clinic.

### **Will the outcomes of the research be published?**

The research findings may be published in an academic paper and presented at conferences. The research team will be happy to send you a link to the published article if you request it.

### **What happens if I do not want to take part or if I change my mind?**

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 give your consent. You can change your mind about taking part and withdraw at any time without giving a reason and without detriment to yourself.

If you do decide to withdraw you will need to return all study hearing aids to us immediately.

If you decide to withdraw, it will not be possible to remove your data from the project because it will be made anonymous and so we won't be able to identify your specific data. This does not affect your data protection rights.

### **Data Protection and Confidentiality**

#### **What information will you collect about me?**

In order to undertake the research project we will need to collect the following personal information/data about you:

- Name
- Date of birth
- Contact details (home address, telephone number, email address)
- Your electronic consent form
- Your answers to our hearing health questions including those provided through the smartphone app, including dates and times
- Details of the the sound environments (soundscapes) you have been, including dates and times
- Hearing test results
- Your opinions about the hearing aids stated during the exit interview
- Bank details for payment

Only the study team will have access to this information.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research

purposes” if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our [Privacy Notice for Research Participants](#).

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

- When you agree to participate in this study, your personal identifiable information, that is data which could identify you, will be recorded electronically against a participant number (or “ID”). Only the research team (named above) will be able to see this information. This document will be deleted at the end of the project, after publication.
- All your answers to our hearing health questions including those provided through the smartphone app, including dates and times, details of the soundscapes you are in and hearing test results will be recorded against your participant ID and will therefore be anonymous. This information will be stored separately from your personal identifiable information. Where anonymised information is recorded on paper, such as test results, it will be stored in a locked filing cabinet. This paper information will be kept for 5 years after publication of the research.
- Your electronically agreed consent and completed questionnaires will be kept securely in the password protected REDCAP system at the University of Manchester and retained for 5 years after study completion.
- The audio recordings of your exit interview will consist of voice only of both you and the interviewer.
- Your participation in this research will be recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the European Commission to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage immediately following the completion of data collection. Click here for the [Zoom privacy notice](#)
- Transcriptions of the recordings will be performed by either a member of the research team or a third party who is a UoM approved supplier and any personal identifiable information will be removed in the final transcript. Once the audio recordings have been transcribed, the recordings will be destroyed.

### **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

### **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our [privacy notice for research](#) and if you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](#), Tel 0303 123 1113.

### **Will my participation in the study be confidential?**

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above.

### **Will my data be used for future research?**

When you agree to take part in a research study, the anonymised information about your health and care may be provided to researchers running other research studies in this organisation. The future research

should not be incompatible with this research project and will concern communication and deafness. 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](#).

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 regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you.

### **Who has reviewed the research project?**

This study has been reviewed by the University of Manchester Research Ethics Committee (reference no. 10322).

### **What if I want to make a complaint?**

#### Minor complaints

If you have a minor complaint then you need to contact Gabrielle Saunders, Helen Whiston or Melanie Lough in the first instance (contact details given below).

#### Formal complaints

**If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:**

The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk) or by telephoning 0161 306 8089.

### **What do I do now?**

If you have any queries about the study or if you are interested in taking part then please contact one of the researchers: [gabrielle.saunders@manchester.ac.uk](mailto:gabrielle.saunders@manchester.ac.uk) [helen.whiston@manchester.ac.uk](mailto:helen.whiston@manchester.ac.uk)  
[melanie.lough@manchester.ac.uk](mailto:melanie.lough@manchester.ac.uk)