



## Research Study: Assessing the feasibility of a clinical trial of an online audiological rehabilitation program

### We invite you to take part in a research study

- We would like to invite you to take part in our research study looking at an online program that aims help people with hearing loss to use their hearing aids and improve social interactions.
- Before you decide we would like you to understand why the research is being done and what it would involve for you.
- Please read the following information carefully. You might also like to discuss it with family or friends.
- Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

### Contents

1. What is the purpose of the study?
2. Why have I been asked to take part?
3. Do I have to take part in this study?
4. What will happen if I take part in the study?
5. What are the possible disadvantages of taking part?
6. What are the possible benefits of taking part?
7. What happens to the results of the research study?
8. Who is organising and funding the study?
9. Who has reviewed the study?
10. Will my results be kept confidential?
11. Who do I speak to if problems arise?

### How to contact us



If you would like to discuss the research beforehand (or have questions afterwards) please contact **Dr David Maidment**, who is one of our researchers.

**Address:**

Nottingham Hearing Biomedical Research Unit, Ropewalk House, 113 The Ropewalk, Nottingham, NG1 5DU.

**Tel:** +44(0) 115 823 2600

**Fax:** +44(0) 115 823 2618

**Email:** [mszdm@nottingham.ac.uk](mailto:mszdm@nottingham.ac.uk)

**Web:** [www.hearing.nihr.ac.uk](http://www.hearing.nihr.ac.uk)

**IRAS project ID:** 214225

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## 1 What is the purpose of this study?

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This study is looking at an online program for people with hearing loss. The program aims to help people use their hearing aid(s) and interact in social settings more effectively. The program is made up of 5 modules that cover different topics, such as hearing aids, communication strategies, and relaxation techniques.

Each module takes at least one hour to complete, and you will have up to one week to complete a module.

We are interested to see whether a study assessing the program can be done in people with hearing loss in the UK. Your participation will help us to improve our study. You can also help us to make sure that the program is clear and that it covers the right topics. This will help us prepare for a research study where we will test how effective the program is in larger group of people.

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## 2 Why have I been asked to take part?

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We are looking for people with hearing loss who currently use hearing aids. We are inviting up to 60 people to take part. You are eligible to take part in this study if you:

- Are 18 years of age or over
  - Have good written and spoken English
  - Own hearing aids, and have either:
    - 1) Used them for at least one year or more, or
    - 2) Recently been given them and are using them for the first time
  - Do not have dementia, and as such, need assistance in completing questionnaires
  - Have access to the Internet.
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## 3 Do I have to take part in this study?

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It is up to you to decide whether or not to take part in the study. 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 do choose to take part you are still free to withdraw at any time without giving a reason. This will not affect any future standard of care you receive within the NHS.

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

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## 4 What will happen if I take part in the study?

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If you decide to take part, you will be invited to attend two sessions at the NIHR Nottingham Hearing Biomedical Research Unit, at Ropewalk House.

Each session should last no more than 1.5 hours. For both sessions, there will normally be one researcher who you will meet. You will be asked to complete a number of questionnaires about your hearing and how it affects your day-to-day life, as well as your experiences with hearing aids.

In the first session you will also be shown how to use the online program. After this session, you can complete up to 5 modules of the program. Each module takes at least one hour to complete, and you will have up to one week to complete a module. You will then complete the second session.

You may also be invited to take part in a small group discussion that will take place on a separate day. The group discussion will last no more than 1.5 hours. With the researcher and other participants you can share your views on the program, such as what you liked or disliked. There are no right or wrong answers; the important thing is for you to express your personal opinions on the program. You will be given opportunities to take breaks and to have refreshments.

We will record and transcribe the group discussion to make sure that we have an accurate record of what is said. The recording and the transcript will be confidential and will be stored securely. All feedback you provide (discussions or questionnaires) will be **anonymised** and may be used in study reports.

Reasonable travel expenses (up to £15) will be paid at the end of the visit. We will also pay you an inconvenience allowance of £7.50 per hour.

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## 5 What are the possible disadvantages of taking part?

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We do not anticipate any disadvantages or risks to taking part in this study. If you have any concerns after your participation in the study, we would be happy to discuss these with you.

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## 6 What are the possible benefits of taking part?

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There are no benefits to taking part but the information we get from this study will help us to improve our future study evaluating the online program in a larger sample.

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## 7 What happens to the results of the research study?

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The results of this study will be presented at national and international conferences. We also plan to publish the results in scientific journals and professional newsletters, but this can take 2-3 years from the end of the study. In addition, everyone who takes part in the study will receive a newsletter at the end of the study. Any results reported will be anonymised.

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## 8 Who is organising and funding the study?

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The study is organised by the Nottingham Hearing Biomedical Research Unit and funded by a grant awarded to the Eriksholm Research Centre from the Oticon Foundation.

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## 9 Who has reviewed the study?

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All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Yorkshire & The Humber - Leeds East Research Ethics Committee.

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## 10 Will my results be kept confidential?

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We will follow ethical and legal practice and all information about you will be handled in confidence. If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for up to 18 months after the end of the study so that we are able to contact you about the findings of the study unless you advise us that you do not wish to be contacted. All other data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

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## 11 Who do I speak to if problems arise?

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If you have any concerns or complaints about the way in which this study has been or is being conducted, please discuss them with the Chief Investigator, Dr David Maidment, using the address and telephone number on the 1<sup>st</sup> page or this email: [mszdm@exmail.nottingham.ac.uk](mailto:mszdm@exmail.nottingham.ac.uk).

If he is unable to rectify the problem, please put your complaint in writing, and send it to: Patient Advice and Liaison Service (PALS), Freepost NEA 14614, Nottingham University Hospitals NHS Trust (QMC), Nottingham, NG7 1BR.

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## Where to find us

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Nottingham Hearing Biomedical Research Unit is located in the heart of Nottingham, easily accessible by train, tram and bus routes and close to a number of city centre car parks. The unit is situated in the 'Castle Zone' of Nottingham City Centre, just off Derby Road and Maid Marian Way.

### By car

For GPS users:

- Post code NG1 5DU
- Street name The Ropewalk
- Co-ordinates Longitude: -1.1599686145782  
Latitude: 52.95479219521181

### Parking

Follow signs for the city centre and the 'Castle Zone'. Nearest car parks are Mount Street and St James's Street. There are a number of pay-and-display parking places immediately outside the main Ropewalk House building with additional pay-and-display parking in nearby streets. There are also free disabled parking spaces outside the main building. Parking is limited to a maximum of two hours.

### By bus

There are no bus stops located directly outside Ropewalk House, however Ropewalk House is located in the centre of Nottingham, with local public transport links nearby. The nearest bus stops to Ropewalk House are on Toll House Hill and on Maid Marian Way. Access via a gentler gradient can be found from the bus stops on Canning Circus.

### By tram

The 'Market Square' and 'Royal Centre' tram stops are the two closest stops to Nottingham Hearing Biomedical Research Unit .

### On arrival at Ropewalk House

Nottingham Hearing Biomedical Research Unit is situated in the mezzanine floor of Ropewalk House. On entering the foyer at ground level, follow the red signs for Nottingham Hearing Biomedical Research Unit. There is a lift. Disabled clients who require assistance at Ropewalk House to access the basement should telephone 0115 823 2600 in advance to make appropriate arrangements.

