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Study title: internet *S*elf-*H*elp, *U*nderstanding and *S*upport for *H*yperacusis (i*SHUSH*): Online evaluation of questionnaires for hyperacusis

PARTICIPANT INFORMATION SHEET

IRAS Project ID: 324377

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We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This information sheet describes the study in detail, and we will be happy to answer any questions you may have about the information provided. Please take time to read this carefully and discuss it with others if you wish. Ask us anything that is not clear.

How do I sign up? If after reading the information below, you want to sign up for the study or find out more, then please:

- complete the online form to tell us that you are interested in taking part - click on QR code or https://app.onlinesurveys.jisc.ac.uk/s/nottingham/ishush-eoi

OR

- contact Kathryn Fackrell (Kathryn.fackrell@nottingham.ac.uk)

Dr Kathryn Fackrell

What is the purpose of the research?

Hyperacusis is a hearing disorder where people experience a reduced tolerance to sound(s) that are perceived as normal to the majority of the population or were perceived as normal to the person before their onset of hyperacusis, where “normal” refers to sounds that are generally well tolerated.

The main way to assess hyperacusis and check whether treatments are working is to use self-report questionnaires that ask questions about the symptoms associated with hyperacusis and the impact of hyperacusis on daily lives. Currently, there are a number of questionnaires that measure hyperacusis being used in clinical practice and research: these include the Hyperacusis Questionnaire, Inventory of Hyperacusis Symptoms, Sound Sensitivity Symptoms Questionnaire and Hyperacusis Impact Questionnaire. When using questionnaires, it is important to make sure that these questionnaires can be used reliably in different situations, for example when completed on paper versus in digital format (on a computer, tablet or smartphone), and that they are relevant, useful, valid and reliable to use with adults living with hyperacusis. We are currently developing an online educational website to provide

support and information for adults living with hyperacusis, named internet Self Help, Understanding, and Support for Hyperacusis (i*SHUSH*). For the website, we need to include a questionnaire that measures hyperacusis, but we do not know which one is most relevant and appropriate for adults living with hyperacusis. Therefore, we want to check how well the current questionnaires (listed above) measure the impact of hyperacusis and changes in symptoms over time, how they compare to other questionnaires measuring tinnitus and anxiety and depression and find out your views and opinions of the questionnaires measuring hyperacusis and whether you think they are relevant to your experiences. By checking these things, we can ensure the questionnaires that are used in clinical practice and research can reliably assess hyperacusis and we can select the most relevant and appropriate questionnaire to use on the i*SHUSH* website and in turn help people to access the right support.

To do this, we have created an online survey with the questionnaires listed above so that you can complete the questionnaires on two separate occasions and tell us your views and opinions on them from wherever you are.

Why have I been invited to take part?

You have been invited to take part in this research because you are an adult who experiences hyperacusis.

You may be able to take part if you:

- are aged 18 years or above
- have been formally diagnosed with hyperacusis by a healthcare professional or have lived experience of hyperacusis (self-reported)
- do not have hearing loss (diagnosed or as indicated by hearing score)
- have a sufficient command of English to read, understand and independently complete the questionnaires
- are able and willing to take part in an online survey

To understand whether the questionnaires are useful, appropriate, relevant and reliable, we are inviting 250 adults experiencing hyperacusis to complete the online survey on two separate occasions.

Do I have to take part?

No, it is up to you to decide if you want to take part in this research. This information sheet describes the study in detail, and we will be happy to answer any questions you may have about the information provided. If you agree to participate and are eligible, we will ask you to sign an electronic consent form as part of the survey. However, you would still be free to withdraw from the study at any time, without giving a reason, simply let the research team know.

What will happen to me if I take part?

If you would like to take part, we will ask you to let us know by completing an online form (https://nottingham.onlinesurveys.ac.uk/eoi-form-hy-quest-eval) where you will be asked to provide us with some basic information about you so we can check that are eligible for the study. Or you can contact Kathryn Fackrell (Kathryn.Fackrell@nottingham.ac.uk) to register your interest and to ask any questions or raise concerns you may have about taking part in the study.

If you are eligible, a member of the research team will send you a personalised link to access the online survey with a username and password. You will be asked to complete the online questionnaire survey over two separate sessions:

- On the day you receive your personalised link to the survey (session 1)

- Two weeks after you completed the questionnaire survey the first time (the research team will email you with personalised survey link so you can complete session 2)

You will be asked to complete the below questionnaires on both occasions:

- The Hyperacusis Questionnaire, Inventory of Hyperacusis Symptoms, Sound Sensitivity Symptoms Questionnaire and Hyperacusis Impact Questionnaire.
- The Patient Health Questionnaire, with questions about general symptoms of depression
- The Generalised Anxiety Disorder scale with questions about general symptoms of anxiety
- The Tinnitus Functional Index with questions about the impact of tinnitus.

You will only be asked to complete questions about what you think (views and opinions) about the questionnaires that measure hyperacusis and whether you felt they were relevant to your experiences the first time you complete the questionnaires. We will also ask you general questions about you, your lifestyle and other health conditions, and how much your hyperacusis has changed.

It is expected that it will **take less than 40 minutes** to complete the questionnaire survey the first time and less than 20 minutes to complete it the second time as there are less questions.

Are there any risks in taking part?

There are no anticipated disadvantages to taking part in this research other than giving up your spare time to help us make sure the questionnaires being used in practice are reliable and relevant for adults living with hyperacusis. There are minimal risks to taking part in this study. You may find that answering questions about your hyperacusis may upset you. If this happens, you can contact Kathryn Fackrell at any time with any queries, questions or concerns following the administration of the questionnaires.

Are there any benefits in taking part?

We cannot promise the study will help you but the information we get from this study may help researchers to understand the reliability and validity of the questionnaires and importantly we may be able to identify which questionnaires are most relevant and appropriate to use with adults living with hyperacusis, such as yourself, and make recommendations on this. As a thank you for taking part in the study, you will be offered the opportunity to be entered into a prize draw to receive one of five £50 Amazon gift vouchers.

If you would like to receive updates on this project and future studies, then please let us know that you are happy for us to keep your contact details on our participant database. You can ask us to remove your details at any time.

Will my time/travel costs be reimbursed?

Participants will be offered a chance to enter a prize draw to win one of five £50 Amazon gift vouchers for taking part in the study. There are no travel costs.

What happens to the data provided?

When you have clicked the submit button at the end of the questionnaire, it will be uploaded into a password protected database with a code number. Your research data will be stored confidentially in a password protected and/or encrypted folder on a restricted access server at the University under the terms of its data protection policy. All information which is collected about you during the course of the research will be kept on a password protected database and is strictly confidential. Only the research team will have access to your personal/sensitive data/research data. All research data and records will be stored for a minimum of 7 years after publication or public release of the work of the research.

To help ensure your privacy, you will be assigned a volunteer study identification number (for example P01 for participant number 1), and it will be used instead of your name. We will save all the research data using that volunteer study identification number so that none of the data will have your real name or other individual identifiers associated with them. Your name and any information about you will not be disclosed outside the study centre. We would like your permission to use fully anonymised direct quotes in research publications.

We would also like to seek your consent so that the anonymised research data you have given may be stored and used in possible future research during and after 7 years and shared with other researchers in other Universities and organisations both inside and outside the European Union. – this is optional (please indicate whether or not you agree to this on the consent form). Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

What will happen if I don't want to carry on with the study?

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason. Any personal data will be destroyed. If you withdraw, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses.

Who will know that I am taking part in this research?

Data will be used for research purposes only and in accordance with the General Data Protection Regulations. Any electronic data will be anonymised with a code as detailed above. Electronic storage devices will be encrypted while transferring and saving of all sensitive data generated in the course of the research. All such data are kept on password-protected databases sitting on a restricted access computer system and would only be accessed by the research team.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights, we will use the minimum personally–identifiable information possible. You can find out more about how we use your personal information and to read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx/

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. With your consent, we will keep your personal information on a secure database in order to contact you for future studies.

What will happen to the results of the research?

This study is part of a larger research project to develop and evaluate "internet *S*elf *H*elp, *U*nderstanding, and *S*upport for *H*yperacusis (i*SHUSH*)". The results will inform the selection of a questionnaire for the iSHUSH website and will be included in the report for NIHR (funders for the work) about this larger project. The results of the study will also be published in scientific journals and presented at national and international conferences. All study data will be anonymised, and you will not be identified in any arising reports or publications.

If you would like to receive updates on this project and future studies, then please let us know that you are happy for us to keep your contact details on our participant database. You can ask us to remove your details at any time.

Who has reviewed this study?

All research involving people 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 East of England, Cambridge South Research Ethics Committee.

Who is organising and funding the research?

This project is funded by the National Institute for Health Research (NIHR) Post-Doctoral Fellowship awarded to Dr Kathryn Fackrell (PDF-2018-11-ST2-003). It will be managed by researchers based at the NIHR Nottingham Biomedical Research Centre and University of Nottingham.

What if there is a problem?

Our staff always try to conduct research in a way that is caring and respectful. If you have a concern about any aspect of this project, please speak to the Principal Investigator, Kathryn Fackrell, or the hearing theme lead (Dr Derek Hoare) who will do their best to answer your query. The researcher should acknowledge your concern and give you an indication of how he/she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting:

Patient Advice and Liaison Service (PALS), Freepost NE 14614, Nottingham University Hospitals NHS Trust (QMC), Nottingham, NG7 1DR.

In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Dr Kathryn Fackrell – Chief Investigator
NIHR Nottingham Biomedical Research Centre
Ropewalk House, 113 The Ropewalk, Nottingham, NG1 5DU
Kathryn.Fackrell@nottingham.ac.uk
Tel: +44 (0)115 823 2600
Kathryn will have overall responsibility for study management.

The research team also includes co-investigator Dr Derek Hoare, clinical advisors and patient advisors. The research team are happy to answer any questions you have before you agree to take part or when you are taking part.