

Communication Strategies for Increased Social Participation Participant Information Sheet (PIS)

You are being invited to take part in a research study investigating the use of communication strategies (tips or tactics to hear better) by people with hearing difficulties. We are keen to explore whether increasing the use of communication strategies will lead to people with hearing loss achieving greater communication success. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

About the research

Who will conduct the research?

Dr Gabrielle Saunders, Dr Antje Heinrich, Dr Karolina Smeds and Gemma Perfect.

Dr Saunders, Dr Henrich, and Gemma Perfect are based at the Manchester Centre for Audiology and Deafness at the University of Manchester; Dr Smeds is based at WS Audiology, a hearing aid manufacturing and research company, in Stockholm, Sweden.

What is the purpose of the research?

We are investigating whether providing personalised advice and a booklet about communication strategies to people with hearing difficulties will help them use strategies to hear better when having conversations, compared to providing general standard advice to all people.

You have been selected as a potential participant as you have identified that you are over 60 years of age, have some hearing difficulties, and do not use a cochlear implant. We hope to recruit 90 participants to the study.

Am I suitable to take part?

You are suitable to take part if you are 60 years old or over and feel you have some hearing difficulties. We would like you to be involved either if you have never sought any help for your hearing or if you currently wear hearing aids.

You will need to be able to converse, read, and write in English to complete the study.

You are not suitable to take part if you use a Cochlear Implant (an implantable hearing device that provides sound perception to people who have severe-profound hearing loss).

Will the outcomes of the research be published?

The results of the study may be published in scientific journals and shared at scientific conferences.



Who has reviewed the research project?

This project has been reviewed by The University of Manchester Proportionate Research Ethics Committee (number 2025-21787-40165).

Who is funding the research project?

The study is being funded by WS Audiology, a company that manufactures hearing aids.

What would my involvement be?

What would I be asked to do if I took part?

If you would like to take part, you will first be asked to complete an online survey about your hearing difficulties. You will be invited to attend two sessions at the Manchester Centre for Audiology and Deafness in the Ellen Wilkinson Building at the University of Manchester. The first session will take between 45 mins - 1 hour, the second session will take around $1 - 1 \frac{1}{2} \text{ hours}$.

At the first session, we will ask you to fill in three questionnaires to collect information about your experience of hearing loss. We will also ask you to provide some optional anonymous general information for example your gender and ethnicity.

The study will have three groups of participants, each group will receive slightly different advice.

Depending on the group you are assigned to, you may be asked to talk about your hearing difficulties in more detail with the researcher, or you may be provided with some reading material to take home. You may also be asked to bring some photographs to the session depicting places you may struggle to hear.

At the second session 4 weeks later, you will be asked to complete the same 4 questionnaires you completed at the first session and online, with the possible addition of a 5th questionnaire depending on which study group you are in.

You will be asked to discuss your experience of listening difficulties with the researcher.

You will be offered a full hearing test at this appointment if you wish to know your hearing levels.

Depending on the group you are assigned to, you may also be asked to share your experiences of the study with a different member of the research team at the end of the second session.

Optional:

At the end of the study, we will also provide a link to a short online form to collect information about you such as age, gender, occupation and other protected characteristics. The purpose of this form is to collect anonymous information about the people who consent to take part in our research studies. The National Institute for Health Research Manchester Biomedical Research Centre (NIHR BRC) is committed to ensuring that its research projects are accessible to everyone regardless of race, gender, ability, religion, sexual orientation or age. The information you give on this form will help us comply with our policy of ensuring equality in our work. This form is optional and you do not have to complete all/any of the questions if you do not want to. The responses are completely anonymous so we won't know who has completed or not.



Summary of participant involvement:

ONLINE

- Sign consent form and provide contact details
- Compete questionnaire about hearing difficulties

Session 1

- Attend the University of Manchester in person for your first session
- Complete 3 questionnaires
- Depending on your group allocation, you may discuss listening difficulties in more detail with the researcher

Session 2 4 weeks later

- Attend the University of Manchester in person for your second session
- Complete 4 or 5 questionnaires (depending on your group allocation)
- Discuss your listening difficulties with the researcher
- Hearing test
- Depending on your group allocation, we may ask you some additional questions about your experience of taking part in the research

Possible benefits and risks to being involved in the study:

Benefits

- ✓ Learn new strategies to help with your hearing
- Share your experience of hearing difficulties to help others

Risks

- ✓ Possibility of discussing prior events where you have felt anxious, stressed, or overwhelmed due to your hearing difficulties
- Will I be compensated for taking part?



Yes. In return for your participation in the study, we would like to offer you a £10 for attending the first session, and £15 when you attend the second session. We will also cover any travel expenses involving in attending sessions at the University, for example car parking charges, or bus, train, or tram fares up to a reasonable amount.

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 would like to take part, please continue to complete the online survey which is linked to this document. If you decide not to take part, you do not need to contact us. If you decide to take part you will be given this information sheet to keep and will be asked to tick a box on the survey to confirm your consent. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Name
- Age
- Record of consent
- Email address
- Phone number

We will also ask anonymously and optionally your:

- Gender
- Ethnicity
- Approximate earnings
- Education level achieved
- Postcode

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK 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.



If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our <u>Privacy Notice for Research:</u> <u>https://documents.manchester.ac.uk/display.aspx?DocID=37095</u>

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

To ensure confidentiality, your questionnaire and interview responses will be recorded under an assigned random ID number, in place of your name. The research team will know which number relates to your name whilst the research is taking place, however when data collection is complete, this link will be removed, and the data will be analysed anonymously. Therefore, after this time you will not be able to request your data is withdrawn as it will no longer be identifiable. Anonymised data will be held on University of Manchester secure servers for 5 years and will be shared with our collaborator at WS Audiology in Sweden.

With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

At the end of the study we will deposit a fully anonymised dataset [e.g. including de-identified interview transcripts] in an open data repository where it will be permanently stored. We will use the Open Science Framework (www.cos.io). Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

The data collected during this research may, in future, be used for secondary analysis in combined anonymised form. This means that your data is gathered together with everyone else's, with all personal identifiers removed to ensure your privacy and confidentiality. This work could support further research projects or educational activities (including training and capacity building), conducted by our research team or by others who have received our permission to use the data for their projects.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

Contact details for complaints



If you have a complaint that you wish to direct to members of the research team, please contact:

DR GABRIELLE SAUNDERS

gabrielle.saunders@manchester.ac.uk phone 0161 275 3386

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

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The 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 <u>Information Commissioner's Office about complaints</u> relating to your personal identifiable information Tel 0303 123 1113

https://ico.org.uk

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s)

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GEMMA PERFECT

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