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University of Nottingham: Information and Consent for Research Study

Study Title: PLUS-Optimal for Adults with Listening Difficulties: Investigating the Roles of Listening and Thinking Skills in Online Training Across Different Groups

Please note: This study is funded by the NIHR Nottingham Biomedical Research Centre. Nottingham Trent University is providing access to the online study platform (Gorilla).

Research Team:

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University of Nottingham,

Faculty of Medicine & Health Sciences Research Ethics Ref: FMHS 245-0925

What is the purpose of this study?

It can be hard to hold conversations with others in noisy places, like restaurants or family gatherings. In these situations, it's sometimes difficult to hear what people are saying.

Evidence has shown that listening and thinking games can help by training the brain to listen better. The main goal of these games is to improve everyday listening.

In these games, people practise listening and responding to speech. For example, listening for specific words in sentences and selecting them from a list.

In this study, we will be testing two new games in the 'PLUS' program.

PLUS stands for **Practice Listening and Understanding Speech**. The PLUS listening and thinking games were developed with people who experience listening difficulties due to hearing loss'.

We don't yet know which settings in the PLUS games help people the most with everyday listening. We want you to test one of four different settings in PLUS. Some settings are easier, and some are harder. This will help us study how listening and thinking skills make a difference to progress.



We are inviting people who have trouble listening in noisy places to try out different settings in PLUS. This will help us find out which settings work best.

Those who are willing may also join a focus group to share their thoughts about the games.

Why have I been invited to take part?

Thank you for your interest. We are looking for people who have trouble hearing speech in noisy places, including those who use hearing aids. This study is not suitable for people with cochlear implants because the way sounds are processed is different. You will do a quick test to make sure you can take part. More information about this test is provided below.

You are eligible to take part in this study if you:

- Are 18 years of age or over
- Have a good understanding of written and spoken English
- Have internet access at home
- Have a computer, laptop, or tablet that can play sound

Please read this information before you decide to take part. You can ask the researchers any questions before you decide to take part (see contact details below). Taking part is completely voluntary.

Do I have to take part in this study?

No. It is up to you to decide if you want to take part in this research. This information sheet describes the study. If you have any questions about the research, please contact us and we can go through this information sheet with you to answer any questions you may have.

If you agree to participate, we will ask you to complete an electronic consent form.

If requested, we will send you a copy of the consent form for you to keep.

However, you will still be free to withdraw from the study at any time, without giving a reason and without any negative consequences, by advising the researchers of this decision.

What will I be asked to do?

Section One (approx. 1 hour)

Initial Screening (5 minutes)

You will first complete a short listening test where you hear numbers spoken in background noise.



This test checks if you meet the study requirements. If you do not meet the study requirements in this first task, you will not continue to the main part of the study, and you will not receive a voucher.

If the initial screening shows that you have trouble listening in noisy places, you will be invited to take part in the study.

It is recommend that you use headphones or earphones for this test. If you wear hearing aid(s), you will be asked to remove them for this test. Please keep your hearing aid(s) nearby, as you will need them later in the study.

Consent (1 minute)

For all participants, you will then:

- Be asked to give your consent for participation in the study.
- Be offered the opportunity to be selected to take part in a focus group about the research after the study.

Demographic Questionnaire (3 minutes)

You will then be asked to answer a few short questions about yourself.

These include:

- Your age
- Your sex
- Any experience you have with listening difficulties
- Whether you use a hearing aid
- What device you will use for the training
- Which internet browser you will use for the training

Initial Assessments (approx. 45 minutes)

You will then complete a series of tasks and questionnaires (no prior knowledge is needed):

- Your ability to understand speech in noise
- Your thinking and memory skills
- How listening difficulties affect your daily life



For many of these assessments, you will need to use your device speakers, headphones or earphones to be able to hear sounds. If you have hearing aid(s) you will need to wear them throughout. If you require glasses, please wear them to complete these assessments.

Section Two

PLUS Games

You will then:

1. Be asked to provide your email address.
2. Receive an email with your PLUS training login and an instruction booklet so you can start the program right away.
3. Asked to train online for **30 minutes a day, 5 days a week, for the next 2 weeks.**

Section Three

Final Assessments (approx. 45 minutes)

After playing the PLUS games for 2 weeks, you will get a link by email to complete a final set of assessments. These are the same as the initial assessments (see above). Again, for many of these assessments, you will need to use your device speakers, headphones or earphones to be able to hear sounds. If you have hearing aid(s) you will need to wear them throughout. If you require glasses, please wear them to complete these assessments.

Once you finish the final assessments, you will have the opportunity to enter a prize draw for the chance to win a shopping voucher worth between £10 and £150. The odds of winning a voucher are about 1 in 2. If you choose to enter and are selected to win, you will be notified and will receive the voucher electronically via email. Each participant may win a maximum of one voucher.

Focus Groups

The focus groups will take part online via Microsoft Teams. If you are selected to take part in a focus group, you will be emailed a separate consent form. You will be asked to send this consent form back by email. Once we have your consent, you will receive a calendar invite by email for an online meeting. After the meeting, you will receive a £10 shopping voucher by email as a thank you.

Your Participation



The research team will be available to answer questions, help with setup, and keep a record of any issues during the study. Data will be collected by the online study platform (Gorilla) and the PLUS games throughout. Once a section is completed, your data for that section cannot be withdrawn. You can withdraw from the study at any time before submitting your responses by clicking the **EXIT** button below or closing your browser.

What are the disadvantages of taking part?

There are no known or perceived potential risks to participating in this study. Please take time to think carefully about whether you wish to proceed with the study, especially with respect to the time commitment.

What are the advantages of taking part?

The research team cannot promise that taking part will help you directly. But the information from this study will help us make tools that provide the greatest possible benefit to patients in the future.

Who will know I have taken part in the study?

No one outside the research team will know that you took part in this study. We will not ask for your name, and your study data will be anonymous. The only personal information we will collect is your email address, so we can contact you to:

- a) send you your login, instructions and a link for the PLUS games,
- b) if you win in the prize draw, send you your shopping voucher(s) at the end of participation, and
- c) contact you if you are selected to take part in a focus group.

This will be received and handled separately from your anonymised study data, and it will not be possible to link the data sets. Your IP address will not be visible to or stored by the research team, because the online study platform removes it before sending us your data. As with any online activity, there is a small risk that data could be accessed by others, but we are using a secure, encrypted website to keep this risk as low as possible.

What will happen to your data?

This research is being conducted for a PhD project and the data received from all participants will be combined in a password protected database ready for analysis.

Anonymous electronic data from the online study (hosted by Gorilla) and PLUS games is held securely under the provisions of the General Data Protection Regulation (GDPR) and the Data Protection Act. Your e-mail address will only be kept as for the purposes described above for the duration of your study participation, after which it will be destroyed. For



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further information about how the university processes personal data please see:

<https://www.nottingham.ac.uk/utilities/privacy.aspx/>

When you click **FINISH** at the end of the experiment, your anonymised data will be saved in a secure, password-protected database. The research team will not be able to identify you from this data. For this reason it will not possible to withdraw the data at this point. Your data will be stored securely on a restricted-access server at the University under the terms of its data protection policy. Data will be kept for at least 7 years and then destroyed.

The results will be written up in a student report and may be used in academic papers and presentations. The overall anonymised data from this study may be shared for use in future research and teaching (with approval).

Who will have access to your data?

The University of Nottingham is the data controller (legally responsible for data security) and the Supervisor of this study (Helen Henshaw) is the data custodian (manages access to the data) and as such will determine how your data is used in the study. Your research and personal data will be used for the purposes of the research only. Research is a task that we perform in the public interest.

Responsible members of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure it is being carried out correctly.

If you have any questions or concerns about this project, please contact the Lead Investigator:

Natalie Lerigo-Smith E-mail Natalie.Lerigo-Smith1@Nottingham.ac.uk



or if you have any concerns about any aspect of this study please contact the Research Supervisor: Dr Helen Henshaw Email Helen.Henshaw@Nottingham.ac.uk





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If you remain unhappy and wish to complain formally, you should then contact the FMHS Research Ethics Committee Administrator, E-mail: FMHS-ResearchEthics@nottingham.ac.uk