

Participant Information Sheet

Study Title: Assessment of the applicability of brain response to speech measurements using multichannel recordings

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ERGO number: 52472

What is the research about?

This study is part of a PhD project funded by the Engineering and Physical Sciences Research Council (EPSRC). The aim of the study is to explore the potential for brain responses to speech stimulus to be used in the assessment of hearing performance. Some techniques have already been suggested and appear to work using continuous speech. However, the robustness of these techniques, as well as their applicability across a range of hearing impairments has not been tested. These issues will be tackled with this experiment. Results of this study could help audiologists to better assess patients hearing ability, which may influence their approaches for optimising hearing aid devices, especially in cases where hearing impaired cannot give a voluntary response about how well their hearing aid device functions, such as infants or some elderly with dementia.

Why have I been asked to participate?

You have been chosen for this study as you are between 18 and 40 years old, and are native English speaking.

What will happen to me if I take part?

When you decide to take part, you will be asked to complete and return the attached questionnaire regarding any problems you have had with hearing or ear disease. The researcher will use this to assess if you fit the criteria to participate. If you have any difficulties or questions about completing the questionnaire, please contact the project researcher (see details below).

You will then be contacted by the researcher to meet him at the Institute of Sound and Vibration Research (ISVR, building 13) at the University of Southampton at a time that is suitable for you. The researcher will ask you if you have read and understood this information sheet and will answer any questions you may have. If you feel comfortable about participating, the researcher will ask you to sign a consent form to confirm your participation.

To assess your hearing, the research will perform a standard hearing test. This will include otoscopy, pure tone audiometry (PTA) and tympanometry. During otoscopy, an examiner will look into your ears to see if you are suffering from an infection and to ensure the path to the eardrum is clear (no blockage in the ear). During PTA, you will be asked to listen to a range of tones presented with headphones at different intensities and indicate the smallest sound you can still hear. With tympanometry, your middle ear function will be tested by placing an electrode in the ear canal and measuring how much sound of a tone is reflected back and picked up by the instrument. These tests are performed in accordance with the British Society of Audiometry (BSA) standards. After these screening tests are complete, it is possible that you will not be invited to take part in the study. In this case, you will still be paid for the time you have given.

Before starting the test, the researcher will place an electrode cap on your head. Electrodes will be placed in the holder on the cap to measure your electroencephalogram (EEG). These electrodes are placed to measure the activity of your brain. To optimise the measurement, an electrolyte gel will be used to improve the contact between the head and the electrodes.

Speech stimuli will be presented to you via earphones. These stimuli can range from short speech-like stimuli (tones, clicks or phonemes such as /da/) to words, sentences, running speech (e.g. an audiobook), and modulated broadband noise. Measurements will be performed over different tests lasting about 40 minutes. You will be instructed to respond either verbally, or using the interface

onscreen. Breaks will be provided between the tests, and you could ask for additional breaks if at any point during the study you feel uncomfortable. For all the tests, you will remain seated in a chair. The entire experiment will take about 3 hours across 2 sessions to be completed. After each session, the researcher will remove the cap and you will be given the opportunity to wash your hair. The second session will occur at least 12 hours or at most 7 days after the initial session

Are there any benefits in my taking part?

By taking part, you will receive the opportunity to have your hearing checked. You will receive £30 on completion of the experiment for your time. You will further help in expanding knowledge about brain responses to stimuli, which could potentially result in new assessment tools to optimise hearing aid fitting for future hearing impaired.

Are there any risks involved?

There are no anticipated psychological or physical risks involved in the experiment, and your safety will be ensured at all times. The researcher will stay with you throughout the experiment.

Otosopic examination has to be done prior to the testing, it may have a very small risk for grazing or cutting the ear canal, but the researcher will try his/her very best in avoiding this situation and pay attention during the examination.

Electrical cables will be used in the study. There may be a risk of falling down with the cables on the ground, please make sure to be careful in the test room, we will try our best to make the room tidy and clean. Since electrical equipment is used in this study, there is a theoretical chance of electrical shock. This would be very rare as the equipment is electrically insulated or battery-charged and tested for electrical safety according to the ISVR standards (FEE procedure 17 Portable Appliance Testing guidelines).

The EEG system is a commercial system and has been tested and approved for use with human participants. Sound stimuli intensity levels will be in accordance with the ISO regulation standards (2004) and the ISVR technical report guidelines (1996) and therefore will not exceed levels heard on a daily basis. There is a very small risk of having an allergic reaction to the electrolyte gel, which could lead to redness of the skin. Please inform the researcher if you are aware of any allergies. If you become uncomfortable at any point during the study or you wish to pause or stop the experiment, please inform the researcher.

What data will be collected?

You will be given a participant number, the record of participant numbers will be kept on a locked computer and will be deleted after completion of the experiment. Disclosed information such as date of birth and gender will be recorded anonymously. During the experiment we will objectively measure your ability to measure speech in noise as well as your subjective views about the test. Any data recorded will also remain anonymous.

Will my participation be confidential?

Yes. The team carrying out the experiment will maintain a record of your details in a secure location. All recorded data for further analysis will be anonymized. As this study is part of a governmentally funded research project, it is expected that the anonymized information collected during your participation will be stored in the University of Southampton's repository (ePrints) for at least 10 years after the end of the study. This repository also has highly advanced security measures in place to protect these data. All files will be kept in compliance with the University Data Protection guidelines before being deposited on ePrints. Informed Consents forms and any other personal information will be kept in a secure and locked office and not be deposited on ePrints. If you would prefer that your data are not accessible to third parties at any time during or after the study, please inform the researcher.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part. If at any point you

change your mind during the experiment, please inform the researcher verbally and the experiment will stop, and any data recorded will be destroyed.

What happens if I change my mind?

Your participation is voluntary and you may withdraw from the study at any time. You do not have to give a reason for withdrawal and it will not affect your legal and medical rights.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Where can I get more information?

Should you require any further information regarding this study, please contact:
Suwajak Deoisres sd1n17@soton.ac.uk Postgraduate
researcher

What happens if there is a problem?

In the unlikely case of concern or complaint, you should contact the Head of Research Governance (02380 595058, rgoinfo@soton.ac.uk). Please note that the researchers, supervisors or any other persons involved in the study will not deal with any complaints.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it

properly. The University of Southampton will keep identifiable information about you until the completion of the experiment in September 2019, after this all data will be destroyed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for spending the time to read the information sheet and considering taking part in this study, any questions please get in contact, my email is s.w.perry@soton.ac.uk