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## Plan Overview

*A Data Management Plan created using DMPonline*

**Title:** The Effects of Hearing Adjustment on Ease and Effectiveness of Communication, and the Role of Cognitive Resources

**Creator:**Stephanie Loukieh

**Principal Investigator:** Stephanie Loukieh

**Data Manager:** karolina Kluk-de Kort

**Project Administrator:** Antje Heinrich

**Contributor:** Josef Schlittenlacher

**Affiliation:** University of Manchester

**Template:** University of Manchester Generic Template

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### Project abstract:

*Introduction:* Older adults face various multifaceted challenges including hearing impairment, cognitive decline, and sleep disruption; and when occurring together, unexpected consequences may arise. This study investigates the effect of adjusting hearing, a factor that may deplete cognitive resources, on aspects of communication, wellbeing, and sleep.

*Methods:* To attempt to annul the effect of one of the depletors, 30 hearing-impaired older adults will be fitted with hearing aids, and go through a pretest-posttest assessment of cognitive resources, listening effort, fatigue, wellbeing and sleep, and will be compared with a matched control group.

*Expected results:* Aiding hearing is expected to liberate cognitive resources, and reflect positively on the other outcome variables, and indirectly improve sleep.

*Implications:* Addressing causes of cognitive resource depletion should reflect positively on the quality of everyday life by improving communication and wellbeing. If additive effects of multiple depletors are observed and associated with poor outcomes, a model of cognitive resource depletion will be explored and expanded to other potential depletors.

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**Copyright information:**

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# The Effects of Hearing Adjustment on Ease and Effectiveness of Communication, and the Role of Cognitive Resources

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## Manchester Data Management Outline

**1. Will this project be reviewed by any of the following bodies (please select all that apply)?**

- Ethics
- Funder

**2. Is The University of Manchester collaborating with other institutions on this project?**

- Yes - Part of a collaboration and owning or handling data

SONOVA AG is an industrial partner that can request access to the data based on an agreement developed by the legal teams between the University of Manchester and SONOVA.

**3. What data will you use in this project (please select all that apply)?**

- Acquire new data

New data will be collected in the form of multiple choice answers to questions about sleep, wellbeing, and hearing, and in the form of response times and accuracy rates to an attention task.

**4. Where will the data be stored and backed-up during the project lifetime?**

- Other storage system (please list below)
- P Drive (postgraduate researchers and students only)
- University of Manchester Research Data Storage Service (Isilon)

Fully anonymous equality diversity and inclusion (EDI) monitoring data will be stored on OneDrive.

**5. If you will be using Research Data Storage, how much storage will you require?**

- < 1 TB

All the data will be stored in the form of spreadsheets and text files.

**6. Are you going to be receiving data from, or sharing data with an external third party?**

- Yes

Some pseudonymised data might be shared with our industry partner (who is also our funder) at their request.

- In such a case data would be shared through Business Dropbox and accessed only through institutional credentials.

**7. How long do you intend to keep your data for after the end of your project (in years)?**

- 0-4 years

***Guidance for questions 8 to 13***

Highly restricted information defined in the [Information security classification, ownership and secure information handling SOP](#) is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in key industrial fields at particular risk of being targeted by foreign states. See more [examples of highly restricted information](#).

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation.

Please note that in line with [data protection law](#) (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de-identified) as soon as practically possible. You must obtain the appropriate [ethical approval](#) in order to use identifiable personal data.

**8. What type of information will you be processing (please select all that apply)?**

- Special category personal data, or criminal offence data
- Personal information, including signed consent forms
- Pseudonymised personal data

Personal data: Please note that this data is not "for processing" but rather so that we can communicate with participants to schedule visits to the lab, to check on their device usage during the experiment, and allow them to communicate with us whenever they have any comments or requests.

- Expression of Interest: Not all participant who might contact us will be eligible participants, we need to screen for their eligibility over the phone and then confirm it in the lab, prior to officially recruiting. Therefore, when a potential participant calls to express their interest, the PI will go through a few questions to see if they are eligible. If they are, the PI will request to keep only the name and phone number in a secure place, for the sake of confirming an appointment for them at

the lab, where they will then receive the PIS and consent form. Answers to the questions will not be kept. Ineligible participants will not have any of their information saved and their names will not be requested.

- Consent form: This will include the participant's name, date, and signature.
- Participant contact information form: this document will contain a participant's name, phone number or alternate preferred method of communication, preferred calling times, and any accessibility needs, and finally, the name and number of a designated contact in case of emergency (described in more detail in the experiment's distress protocol).
- Participant Log: This is a log that will help the PI keep track of the participants, their appointments, as well as any contact that was made. It will include the participant's name, date of next appointment and the date in which the appointment was set.
- Pseudonymisation key: This table will include each participant's name and designated private ID.

This information will be stored on the PI's University of Manchester secure P Drive, and will not have any association with the experimental information, and will be deleted at the end of the project by 2026.

Pseudonymised special category data:

- The experimental data will be collected based on the pseudonym of each participant, and stored on the RDS and will be deleted at the end of the project by 2026. The experimental data and the personal data will be kept separate at all times. The experimental data includes: information about age, gender, sleep quality, wellbeing, and hearing status, in addition to comprehension questions following a story a speech in noise test, response times and accuracy scores to an attention test. The experiment will also collect data from a step and sleep tracking device, specifically: sleep efficiency per night throughout a 6 week period, and step count per day throughout the same period. This device is secure and does not store information anywhere other than inside the device itself, and can only be retrieved through a programmed pod that the manufacturers provide that transfers the information into the PI's encrypted university laptop.
- A GDPR compliant experiment building online system will provide the user interface that will collect the data from the participants using their pseudonyms, and download them to the PI's P Drive.

Anonymised data:

- At the completion of the project, an anonymised dataset will be uploaded to a data repository with no identifiable information or even a pseudonym and made publicly available.
- Participants can optionally provide fully anonymous data about protected characteristics for the purposes of equality diversity and inclusion (EDI) monitoring. This data will be fully anonymous (never associated with a study ID or any identifiable information) and fully optional (does not affect participation in study). This fully anonymous data will be stored on University servers and managed by the departmental team responsible for oversight of EDI. Fully anonymous data summaries will be made available to relevant parties for monitoring purposes.

## **9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?**

- Anonymise data
- Pseudonymise data and apply secure key management procedures
- Store data on University of Manchester approved and securely backed up servers or computers
- Store data in encrypted files, folders, computers or devices

Personal data: Please note that this data is not "for processing" but rather so that we can communicate with participants to schedule visits to the lab, to check on their device usage during the

experiment, and allow them to communicate with us whenever they have any comments or requests.

- Expression of Interest: Not all participant who might contact us will be eligible participants, we need to screen for their eligibility over the phone and then confirm it in the lab, prior to officially recruiting. Therefore, when a potential participant calls to express their interest, the PI will go through a few questions to see if they are eligible. If they are, the PI will request to keep only the name and phone number in a secure place, for the sake of confirming an appointment for them at the lab, where they will then receive the PIS and consent form. Answers to the questions will not be kept. Ineligible participants will not have any of their information saved and their names will not be requested.
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**10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?**

- No

**11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?**

- No

**12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?**

- Not applicable

**13. Are you planning to use the personal information for future purposes such as research?**

- No

**14. Will this project use innovative technologies to collect or process data?**

- No

**15. Who will act as the data custodian for this study, and so be responsible for the information involved?**

Karolina Kluk-de Kort

**16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).**

2025-01-31

## **Project details**

**What is the purpose of your research project?**

The purpose of this research project is to see whether aiding hearing using hearing aids reflects positively on cognitive resource availability, and whether that results in improvements in daily life

communication, wellbeing, and sleep.

### **What policies and guidelines on data management, data sharing, and data security are relevant to your research project?**

The policies and guidelines on data management, data sharing, and data security that are relevant to my research project are the following:

- The University of Manchester Data Protection Policy
- The University of Manchester Research Data Management Policy
- UK GDPR
- The University of Manchester Records Management Policy
- The University of Manchester Publications Policy
- The University of Manchester IT policies and guidelines
- The University of Manchester Intellectual Property Policy

These policies inform our project's consent form, participant information sheet, data storage, management and sharing, data archiving and open science, publication considerations and copyright and IP decisions.

## **Responsibilities and Resources**

### **Who will be responsible for data management?**

The PI Stephanie Loukieh is responsible for the data management plan, supervised by her academic supervisors Karolina Kluk-de Kort, Antje Heinrich, and Josef Schlittenlacher.

### **What resources will you require to deliver your plan?**

The university laptop and desktop, secured by my student login details, and linked to a Virtual Private Network provided by the IT team at the University of Manchester, in addition to the university appointed secure P Drive and Research Data Storage.

The tracking devices and their programming pod provided by the manufacturers.

A subscription to the experiment building platform is also required and funded by the division.

When the project is completed, the experimental material and the anonymised data will be shared on a data repository (Figshare).

## **Data Collection**

### **What data will you collect or create?**

Logistics and contact:

The data will be collected in person in the lab, using the PI's encrypted secure laptop over a period of 10 months or until the sample size is met, whichever happens first. On the laptop the PI will access the experiment platform online on a GDPR compliant system using the participants Private ID, and then download the pseudonymised data to the university encrypted computer and stored in the P Drive. For communication purposes the participants' names and phone numbers will need to be kept securely stored for the duration of the study, as well as the name and number of a designated contact in case of distress at the lab.

The experimental data:

Demographic information such as age, gender and language proficiency (only as much as is relevant for the speech tests).

Assessments of sleep quality, hearing ability, wellbeing, fatigue and effort through questionnaires, and response times and accuracy rates through an attention task, and multiple choice comprehension questions.

Sleep and movement tracking through steps per day and sleep efficiency score calculated through actigraphy using an actigraphy device. The monitoring will happen over a period of 45 days, during which the hearing aids will be trialed for one month. This involves using a device worn on the wrist that collects information that is stored within the device, and can only be accessed through a device kept with the PI.

The above will be stored in the form of spreadsheets (.xlsx), pdf documents (.pdf), and MS Word documents (.docx), and stored after anonymisation.

Institutional EDI Monitoring:

Participants can optionally provide fully anonymous data about protected characteristics for the purposes of equality diversity and inclusion (EDI) monitoring.

The total storage volume for the digital data is estimated to be less than 1 GB.

## **How will the data be collected or created?**

- The data will be collected through an online experiment platform, Gorilla Experiment Builder, which is GDPR compliant, based in the UK, and is consistently used by the psychology divisions at the University of Manchester (with divisional subscriptions for PGRs). Qualtrics and Redcap are not applicable in this case because there are experimental tasks included in the experiment that measure accuracy and response times. This will be done in person, in our lab, using a university encrypted laptop.
- The data collected include accuracy rates and response times in an attention test, comprehension multiple choice answers to questions after listening to an audiobook snippet, answers to standardised questionnaires (multiple choice) and typed text in response to a speech perception exercise. The data will all be alphanumerical with anonymised participant IDs, displayed in one spreadsheet downloaded off of the experiment website on to the P Drive and transferred on to the RDS.
- Steps per day and a sleep efficiency score will be measured using one actigraphy monitoring device developed for research purposes and clinical trials. This device will be reset by myself at the end of the trial with all the data in it permanently deleted. The devices used in this study are both subject to strict compliance regulations, one of them is a set of hearing aids for the intervention and the other is an actigraphy monitoring device. SONOVA AG confirms that the hearing aids that this study will trial meet the requirements of the Medical Device Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU, while the actigraphy device GENEActiv is FDA 510(k) exempt and is a European Class I Medical Device.
- Version control will be used in the naming of files. We will begin with Version 1.0 followed by the date, and any minor adjustments will increase the number after the decimal (1.1-1.2...) followed by their date; whereas major adjustments will require a change in the number before the decimal

(2.0-3.0...). A table will be kept (in .xlsx format) detailing the changes in versions which will be shared in the data repository with the rest of the material.

For quality control, the instruments and questionnaires selected are standardised with permissions granted where applicable. When instruments were programmed from scratch they followed strict guidelines and are accompanied by detailed (.pdf) explaining all the settings that they were made in. Finally, the whole experiment will be trialed 3 times by the researcher and staff and any missed issues adjusted before it is launched. The data will be subject to peer review when output is created from this.

The optional information about protected characteristics will be gathered by online survey on the Qualtrics platform. This link will be made available to participants after completion of the other elements of the study and it will be clear that it is entirely optional.

## **Documentation and Metadata**

### **What documentation and metadata will accompany the data?**

The types of documentation that will accompany the data include xlsx spreadsheets, MS Word documents, and pdf documents. These documents would include the raw data prior to analysis, and text explanations of the research context, methodology, analytical procedures, and an explanation of the variables and assumptions, as well as the research questions. An explanation of the consent given by participants (the content of the consent form) and the information in the participant information sheet will accompany the data in pdf format. There will be a document describing the data architecture and explaining the naming and the version control. There is a document for every assessment explaining the standardisation of it, the programming of it, or the quality assurance done for it. One README file (basic text file) will be included to describe the data architecture and files.

## **Ethics and Legal Compliance**

### **How will you manage any ethical issues?**

- Participants will be pseudonymised prior to beginning the experiment, and the data that will be downloaded will be anonymised prior to processing and storage. A protocol of the study will be referred to the Divisional or School Research Ethics Committee for review and clearance.
- Only necessary personal and otherwise identifying information will be collected and the participant will be asked to provide consent to this collection if they agree. Personal information, namely names, a designated contact, and phone numbers, as well as the pseudonymisation key will be kept separate, confidential, and stored on the secure university P Drive, and kept until the end of the study by the end of 2025. The reason for keeping the personal information is that participants will attend 3 different sessions at the lab and therefore the PI has to schedule convenient dates with them. In addition to this, the participants might need to call in case they are experiencing any trouble with the hearing aids they are trialing and the PI has to take note of that and keep it in a secure log. This sheet is called Participant Log. A designated contact is

needed in case of distress as described in the distress protocol.

- The devices used in this study are both subject to strict compliance regulations. SONOVA AG confirms that the hearing aids that this study will trial meet the requirements of the Medical Device Regulation (EU) 2017/745 as well as the Radio Equipment Directive 2014/53/EU, while the actigraphy device GENEActiv is FDA 510(k) exempt and is a European Class I Medical Device.
- The participants will receive an information letter explaining their rights, what they should expect, how they will be compensated, the legal basis for our data collection, and where to get more information or report a complaint. They will receive an explanation about the platforms that the study is using, and what regulations they follow. They will receive an explanation about their anonymity upon entering the experiment platform through a participant ID provided by the PI. They will confirm their consent by signing a consent form that includes statements that detail our research, publication, storage and sharing intentions.
- Only GDPR compliant and secure platforms are used for data collection, and only secure platforms provided by the University of Manchester are used for storage, and this is for data security.
- Compensation will occur through a cash sum of money or an equivalent voucher handed in person, depending on the department's regulations.

### **How will you manage copyright and Intellectual Property Rights (IPR) issues?**

This research study will comply with the legally signed studentship agreement, that is the University contract with the student and the funding company. This legal agreement has been signed by the PI, the funding company, and the University of Manchester.

It indicates that the IP belongs to the University of Manchester, and a license belongs to the funding company. If any publications arise out of this pilot then the authorship will be given to the student who is also the PI.

Any data publishing will be postponed till after the study is published.

### **Storage and backup**

#### **How will the data be stored and backed up?**

The anonymised data will be downloaded from the experiment platform in the form of a spreadsheet at weekly intervals during the data collection period, and transferred to the RDS. The computer used to collect this data is encrypted and provided by the university. It is the same computer that will be used to download and transfer this data to RDS using the university server, both accessed only using the university's student credentials. The data collection process will take 2 years or until the sample size is

met, whichever is shorter.

Additionally: Participants can optionally provide fully anonymous data about protected characteristics for the purposes of equality diversity and inclusion (EDI) monitoring. This data will be fully anonymous (never associated with a study ID or any identifiable information) and fully optional (does not affect participation in study). This fully anonymous data will be stored on the University's OneDrive and managed by the departmental team responsible for oversight of EDI. Fully anonymous data summaries will be made available to relevant parties for monitoring purposes. The fully anonymous optional information about protected characteristics will be stored on the University's OneDrive and university servers (including presence on the Qualtrics platform) and managed by the departmental team responsible for oversight of equality diversity and inclusion.

### **How will you manage access and security?**

If requested, transferring the anonymised aggregated data to the collaborating industry would be done through the University of Manchester OneDrive for Business, and the collaborator can access it through institutional credentials only, using the University's virtual private network.

The security provided by the University of Manchester encrypted laptops, P Drive, OneDrive, and OneDrive for Business service, are in line with recognised information security standards such as ISO 27001. The collection of data is done in person in the lab, on an encrypted secure laptop that is accessed only through the PI's institutional credentials. The experiment builder platform can be accessed only using the PI's institutional credentials and is GDPR compliant, this platform does not collect names or any personal identifying information.

Additionally: The fully anonymous optional information about protected characteristics will be accessible to the departmental team responsible for oversight of equality diversity and inclusion, via secure spaces on OneDrive/University servers. Fully anonymous data summaries will be made available to relevant parties for monitoring purposes.

### **Selection and Preservation**

#### **Which data should be retained, shared, and/or preserved?**

For a period of up to 5 years after our findings are published, we will retain raw anonymised data (the results of all the tests), as well as protocols and methodologies, and specifications of software settings. Everything else will be deleted.

#### **What is the long-term preservation plan for the dataset?**

The anonymised dataset, methodology, specifications, data architecture, and protocol will be made publicly available on Figshare.com once the study is published and the course of study is completed. The pseudonymisation will be removed to make the dataset fully anonymous.

## **Data Sharing**

### **How will you share the data?**

Anonymised data (subject to participants' initial consent), methodology and protocol, analysis scripts, and assessment-specifications will be made publicly available on a data repository through Figshare.

### **Are any restrictions on data sharing required?**

No restrictions required on data sharing. Anonymised datasets are required to be shared in order to contribute to open science within my copyright and IP agreement with collaborators, and the participants will only take part if they consent to the anonymised aggregated data to be shared.