Plan Overview

A Data Management Plan created using DeiC DMP

Title: A validation of the UAud system for user-operated audiometry testing in a clinical setting: A blinded noninferiority randomised controlled trial.

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Project abstract:

Introduction: Accurate examination of hearing for clinical decisions is the bottleneck in the current clinical system. Thus, there is a need for expanding the capacity or improving efficiency to reduce the waiting time. One solution could be the implementation of a clinically validated user-operated audiometry system. The objective of this study is to validate the User-operated Audiometry (UAud) system for user-operated audiometry in a clinical setting, by investigating if hearing aids fitting based on UAud is non-inferior to hearing aids fitting based on traditional audiometry, and whether thresholds obtained with the automated version of the Audible Contrast Threshold (uACTTM) test correlates to traditional measures of speech intelligibility. Methods and analysis: This study's design will be a blinded randomized controlled trial. 250 adults referred for hearing aid treatment will be enrolled in the study. Study participants will be tested using both traditional audiometry as well as the UAud system and they will answer the questionnaire Speech, Spatial and Qualities of Hearing Scale (SSQ12) at baseline. Participants will be randomly divided to receive hearing aids fitted based on UAud or traditional audiometry. Three months after participants have started using their hearing aids, they will undergo a Hearing in Noise Test (HINT) with hearing aids to measure their hearing in noise performance and answer the following questionnaires: SSQ12, the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the International Outcome Inventory for Hearing Aids (IOI-HA). The primary outcome is the change in SSQ12 score from baseline to follow-up. Participants will undergo an uACTTM test of spectro-temporal modulations as part of the UAud system. The uACTTM test results will be compared to measures of speech intelligibility from the traditional audiometry session and follow up measurements. Ethics and dissemination: The project was evaluated by the Research Ethics Committee of Southern Denmark and judged not to be notifiable. The findings of this project will be submitted to an international peer-reviewed journal and presented at national and international conferences. Trial registration number: ClinicalTrials.gov: NCT05043207

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A validation of the UAud system for user-operated audiometry testing in a clinical setting: A blinded noninferiority randomised controlled trial.

Data Collection

What data will you collect or create?

The study will collect data on 250 participants.
All of the data will be in digital form logged in the RedCap database. All data will be quantitative obtained through generally known measurements, which ensures the reproducibility of data.
At baseline, the study will obtain demographic data for group comparisons. The data will include age, sex, educational level, etc.
Furthermore, the study will collect the following observational data for 250 participants. The observational data will consist of patient reported outcomes measures (PROM's) and more objectively assessed performance measures at both baseline and follow-up investigations.
Baseline data:

- Participants' age and sex (retrieved from CPR number)
- Performance measures: Audiometry thresholds (both traditional manual audiometry and user-operated audiometry), speech discrimination scores (DS) and uACT thresholds.
- PROM's: Speech, Spatial and Quality of hearing – 12 (SSQ12) and Tinnitus Handicap Inventory (THI) scores.

Follow-up data:

- Performance measures: Hearing In Noise test (HINT) thresholds, as well as variations targeting very soft and loud sounds.
- PROM's: : Speech, spatial and Quality of hearing – 12 (SSQ12) scores, : Speech, Spatial and Quality of hearing – 12 Benefit(SSQ12B) scores, International Outcome Inventory – Hearing Aid (IOI-HA) scores and Abbreviated Profile of Hearing Aid Benefit (APHAB) scores.

The study will also collect data from the hearing aids datalog (mean hearing aid use pr. day and days used), to monitor the treatment in the intervention groups and REM data from the hearing aid fitting to ensure transparency in that optimal hearing aid gain is given.

How will the data be collected or created?

Data collection: The demographic data will be obtained through patient's journal, and a small interview at baseline conducted by the research staff. Perfomance measurements will be conducted at OUH by research staff or clinical employees at Odense University Hospital, Denmark. Answers to questionnaires will be retrieved through an online mailbox.
Versioning: Each manuscript will have it's own folder containing a subfolder for manuscripts and data analysis files. These will be named numerical in the order they were started, e.g., will the first folder be called study1. These will also include a .md file (readme), containing a short description of the relevant study. The manuscripts will be written and stored in .docx files (word), while data analysis files will be stored in .do files (stata). The word files will be named after study and version, e.g., Study1_Version1.docx, Study2_Version2.docx, etc.. The .do files will be named after type of analysis and data used, e.g. ConstrainedLinearMixedModel_SsqpreSsqpost.do

Documentation and Metadata

What documentation and metadata will accompany the data?

This study is registered at ClinicalTrials.gov: NCT05043207.
The study protocol will entail details on the methodology used, analytical and procedural information, definitions of variables, vocabularies, and units of measurement. After completion, the study protocol will be submitted to BMJ OPEN with intend to publish. The study protocol will be named: A validation of the UAud system for user-operated audiometry testing in a clinical setting: A study protocol for a blinded randomised controlled trial.
Furthermore, each study folder will contain a .md filte (readme) with a short description of the study, which is intented to create an overview for a potential successor of the study.
Lastly, the raw data will be stored with definitions of variables in the RedCAP database.

Ethics and Legal Compliance

How will you manage any ethical issues?

The project was evaluated by the Research Ethics Committee of Southern Denmark and judged not to be notifiable.
The project will include data with personal informations. All participants will receive oral and written information about the purpose of the project before informed consent is signed. Participants can withdraw their consent at any time without this affecting their treatment course.
The informed concent form will be sent online, and the participant can therefore retrieve and reread it if it is necessary.
The signed informed consent form for participants willing to participate in the study will be stored in their electronic journals in the Department of Audiology, Odense University Hospital. All paper consent form will be disposed with seccure shredding after uploading in patient journal system

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

A legal agreement has been signed between project partners prior to the start of the project, which also deals with the potential copyright and intellectual property rights issues.

Storage and Backup

How will the data be stored and backed up during the research?

The project will use a mix of SharePoint, Google Drive and other cloud services for data management.

Project data that is not governed by the EU General Data Protection Regulation (GDPR) will be shared between project partners using the Google drive folder that was established at the beginning of the project application phase. The UAud project will
have subfolders for each Work Package (WP), and the respective WP leads are responsible for keeping the WP folder updated with documents and information relevant to the project. SDU will facilitate regular backup of the content UAud folder. Onedrive at SDU can be used for that purpose.

Handling of person sensitive data that is governed by General Data Protection Regulation (GDPR), will be conducted using the respective partner's pre-approved GPDR-compliant IT systems. Appropriate data manager agreements will be made with researchers from all partners that need access to the data. The study will use REDCap as the data collection tool whenever it comes to personal sensitive data governed by GDPR. The research project is registered at OUH, Region of Southern Denmark (20/50524). When data will be analyzed, the analysis of personal sensitive data will be through Odense Patient Explorative Network (OPEN) and the OPEN Analyze platform. In this way, personal sensitive data are kept on secure servers and not personal computers. OPEN storage can be used to store personal sensitive information as well.

How will you manage access and security?

The Google drive is accessible only to selected employees at the partners, thereby subject to the UAud collaboration agreement.
Extraction of the data from OPEN is restricted to the primary investigators. If it is deemed neccessary the data manager and staticians can be allowed access by the investigators.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All of the data are of long-term value.
It is relevant to save the data for possible recalculation of published results. Furthermore, it can be used to illuminate relevant audiological questions that goes beyond the scope of this project.

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

As a minimum, we will preserve all data sets underlying publications for 5 years after the end of the project. The project is planned to end 31st of december 2024. When the project is done, we will seek permission to store the data even longer.

Data Sharing

How will you share the data?

Key scripts will be published in peer reviewed papers, as well as in a PhD thesis. The data will also be presented at national and international conferences.
Furthermore, we will work towards a public sharing of the data. If this is possible, an appropriate electronic research data archive will be identified, with the purpose of sharing the anomized raw data. We will choose a data repository where we can add metadata, a unique and persistent identifier (e.g. DOI) and a license to our data sets, so they can be discovered and cited by others, and the terms for reuse are clear. Hopefully, the data will be available to the public after the end of the project period (the 31st of december 2024).

Are any restrictions on data sharing required?

If the raw data is shared with the public, it will be anonymized beforehand.

Responsibilities and Resources

Who will be responsible for data management?

Carl Pedersen will be responsible for implementing the DMP, and ensuring it is reviewed and revised throughout the projekt. The DMP will be updated every three months.
Jesper Hvass Schmidt is the principal investigator and will thereby be responsible for data capture, metadata production, data quality and data sharing.
OPEN (Odense Patien data Explorative Network) will be responsible for storage and backup, as well as data archiving.

What resources will you require to deliver your plan?

No additional resources are needed.