Study Protocol and Statistical Analysis Plan

eSolutions Functions for Children and Young People

Version 2
(translated to English from original version)

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Protocol Title

eSolutions functions for children and young people

1 Background

The main goal of providing early hearing aids in childhood is to ensure that the child's language development is as normal as possible. However, children's hearing needs change as they grow older. A growing child is exposed to many new listening environments, which often include multiple sound sources and loud everyday noises. In such situations it can sometimes be very difficult for the child to understand speech clearly. The older a child gets, the more often communication usually takes place in acoustically complex environments in which the audibility of the speech signal can be significantly impaired. Numerous studies show that poor acoustic conditions impair the speech intelligibility of children with normal hearing more than that of adults with normal hearing (McCreery et al., 2010; Wroblewski al., 2012; Yang & Bradley, 2009). In addition, poor acoustic conditions have a negative impact on children's ability to learn and thus their academic success (Dockrell & Shield, 2004; Klatte, Hellbrück, et al., 2010).

Speech recognition and speech understanding in noisy environments is a challenge for people who are hard of hearing, but it is particularly difficult for children and young people. Especially in learning situations, directional microphones and noise cancellation functions in hearing aids can lead to improved speech recognition when speech and noise come from different directions.

However, these technologies offer only limited benefits and in certain cases the use of, for example, a directional microphone hearing aid mode can also have a detrimental effect. In recent years, initial studies have been carried out on the usability of directional microphone systems and noise suppression functions in pediatric care. However, so far there is little evidence about directional microphone use, spatial hearing and the possible benefits of directional microphones in children's everyday environments. The few studies that have been carried out so far also show contradictory results. While one study shows (Ching et al., 2009) that directional microphones are more effective than omnidirectional microphones in speech recognition when speech comes from the front and background noise occurs directly behind the listener, another study shows that omnidirectional microphones are more effective, when language comes from different directions, which is quite often the case with younger children, as they often have a different “head position” when listening
than adults. In one study, half of the children preferred directional microphones in most situations, whereas the other half preferred omnidirectional microphones (Ricketts et al., 2007). In another study, both children and parents rated both types of microphones equally well (McCreery et al. 2010).

Nowadays almost all modern hearing aids have automatic systems (e.g AutoSense), which are able to independently control the change between omnidirectional microphones and directional microphones. Overall, it appears that directional microphones can be useful in some of the many different acoustic environments that children and young people are exposed to, either at home, at school or in social situations. However, there are also situations in which directional microphones may not be advantageous or may even be disadvantageous (Wolfe et al., 2017). This applies both to adaptive systems in which the hearing aid makes the selection itself (AutoSense) and to systems in which the child is supposed to make the decision himself.

It is believed that directional microphones and noise cancellation functions could also

be beneficial for children and young people in general if there is more detailed knowledge about the extent and in which environments children need these functions. This study is intended to help understand when, to what extent and at what age these functions are beneficial for children and young people in order to be able to adapt the design of these functions and thus the programming of hearing aids more individually to children and young people.

2 Objectives

The primary objective is to evaluate the impact on speech intelligibility resulting from the changes that children and adolescents (aged 7 to 17 years) make to the microphone directionality and noise cancellation of their hearing aids using the myPhonak app.

3 Description of the investigational device

The devices used in this study are CE certified and commercially available: Phonak Sky M90-M or Sky M90-SP hearing aids and the myPhonak app. These are manufactured and maintained by Sonova, AG located in Stafa, Switzerland.
The overall intended purpose of the hearing aid device is to amplify and transmit sound to the ear and thereby compensate for impaired hearing. The myPhonak app is an accessory to a medical device (hearing aid with wireless functionality). It is used as a remote control to a hearing aid. The app is a software application which is installed and used on a smartphone with an Apple iOS or with an Android OS. The myPhonak app allows the end-user to adjust certain parameters of Phonak hearing aids, such as volume, program changes, microphone directionality, and noise reduction and is intended for use with compatible Android or Apple iOS devices. The app itself is classified as a medical device (class II) but is not needed to enable the hearing aids to be used according to their intended purpose.

4 Design of the clinical investigation

This investigation is a single-group, single site, interventional study.

5 Risks and benefits of the investigational device and clinical investigation

There are minimal risks associated with both the investigational device and participating in the clinical investigation. Identified risks are no greater than those associated with the daily use and wear of approved, available hearing aids. The device used presents non-significant risk per FDA.
The benefits of participating in the investigation include the possibility of hearing sounds that have not been previously heard, such as speech and environmental sounds, which may improve communication in daily life. Subjects may experience the benefit of personal satisfaction for participating in research to improve hearing instrument technology. Subjects will also be compensated for their time in participating in this study.
There are no known or anticipated risks to subject hearing ability associated with participation in this study. All sounds used in this study will be presented at safe listening levels. While using hearing aids, the following are possible occurrences:

- •Cerumen impaction
- •Ear discomfort, pain or soreness
- •Sweat or moisture accumulation in the ear canal or pinna

•A feeling of pressure or fullness in the ear
•Itching, blisters, or sores in the ear canal or pinna
•Headache
•Redness of tissue

The research personnel will review these risks with the subjects and answer any questions they have. Hearing aids are not a significant risk investigational device as defined in the FDA 21 CFR 812.3(m).

6 Endpoints

The primary endpoint will be the difference in SRT- 50 levels using the adaptive Oldenburg Sentence Test (OLSA) between the following conditions:

1. Hearing aid Autosense Sky OS
2. Hearing aid Preferred setting (manual adjustments to the Noise Reduction and Directionality)
3. Hearing aid extreme setting with the Noise Reduction set to maximum and the Directionality set to minimum.

7 Inclusion and Exclusion Criteria

The participants will be recruited from the clinic's patient population.

Inclusion Criteria
• Children and adolescents between the ages of 7 and 17 years old.
• Bilateral mild to severe hearing loss
• Experienced hearing aid users for 6+ months

Exclusion criteria
• Any additional disabilities to the hearing impairment
• Inability to complete the study procedures

8 Measurements and procedures

The investigation will have two lab visits and one home trial. The procedures are as follows:

Visit 1	Home Trial ~ 2 weeks	Visit 2
Audiogram, if needed Obtain informed consent from parents Fit study devices to match that of personal devices, verified with coupler measurements Download myPhonak Jr app to personal or loaner smartphone and pair with	Participant instructed to use the app in five different situations and rate the ease of each situation, using the Assessment of hearing situations in children's every day lives".- To be completed after one week, and then after the second week.	Repeat dB SNR testing using OLSA (randomized order) : 1. AutoSense Sky OS 2. Preferred Setting 3. Extreme setting Interview and discussion of questionnaire results

study hearing aids Train on app use dB SNR obtained using the OLSA test with study devices in the following conditions: (randomized order): 1. AutoSense Sky OS 2. Preferred Setting Extreme setting Give 2 copies of "Assessment of hearing situations in children's every day lives" to complete during home trial		

The test environment is set up as follows:

Cafeteria noise at 65 dBA, from four speakers (-50°, +50°, -130°, +130°)
Speech presented at 70 dBA, from front speaker (0°)

9 Statistical design and analysis

The variance known from the OLSA manual between normal hearing subjects aged 7-9 years is 3 dB, and 1.5 dB for adults over the age of 18.
A significance level of 0.05, a power of 0.8 and the approximate variance of 3 dB, a sample size of 24 is needed.

A non-paremetric RM-ANOVA will be used for comparing the group OLSA results for the different conditions. Durbin-Conover pairwise comparisons will be used for post hoc analysis.

10 Investigation Duration

The study is expected to last approximately 12 months to account for recruitment.
Each participant's expected study duration is approximately 4-6 weeks.
Each clinic appointment is expected to last between 1-2 hours.

11 Data handling and management

Paper based CRFs will be used to capture the participant data. Both the objective data and the subjective data from the questionnaires will be manually transferred by the investigator to an electronic system, such as Microsoft Excel.

All CRFs are kept current to reflect the subject's status at each phase during the course of study. Participants cannot be identified in the CRF by name or initials and birth date but an appropriate coded identification is used. All study team members are authorized for the CRF entries and it is assured that any authorized person can be identified both for pCRFs and eCRFs. If pCRFs are used, the investigator's initials and subject ID are documented and data are entered into an electronic file for analysis by the respective investigator and data will be monitored by the assigned monitor. In case of a self-evident correction, either the subject does it by himself or the investigator undertakes the correction by crossing out the word/sentence with a single horizontal line and by adding the correction including his personal identifier and the date.

The pCRFs are only available to the local study team and to the monitor of the study.
In the case of an audit or a serious adverse event, the CRFs may need to be de-anonymized and sent to the governing or notified body.
All paper-based data will be stored in a locked filing cabinet at the investigation site. All electronic data will be stored on an access-restricted computer owned by the investigation site. Permission to access data will be limited to study manager, monitor, PI, and essential research staff, as designated by the principal investigator.
During data collection of the investigation, physical copies of the data may be compiled and digitized by the investigator.
Data will be reviewed for mis-entries or inaccuracies as each data set is entered.
The extent and nature of monitoring appropriate for the clinical investigation including the strategy for source data verification (SDV) are based on considerations such as the objective, design, complexity, size critical data points and endpoints of the clinical investigation. A detailed plan for monitoring arrangements is provided separately from this CIP.

12 Amendments to the CIP

Any necessary amendments to the CIP will be communicated to the study manager/sponsor. A new version of the CIP will be written, with the necessary changes and justification. The amended CIP will go through the necessary approval process.

13 Deviations from clinical investigation plan

Deviations from the CIP to protect the rights, safety and well-being of human participants under emergency circumstances may proceed without prior approval of the sponsor and the EC – such deviations will be documented and reported to the sponsor representative (Study Manager) and the EC as soon as possible. Apart from that the investigator is not allowed to deviate from this CIP unless that deviation does not influence the investigation data.

14 Device accountability

Sonova, in its capacity as sponsor, will maintain a log of all investigational devices, including the date of shipment from Sonova to the site, serial number, receiving study site, and date returned to Sonova.

The site will maintain a log of the devices provided by Sonova, including the date of receipt,serial number, date of fitting, participant identification, date of return to site by participant, and date returned to Sonova. Sonova will provide each site a template with which to record such information.

If a device needs to be replaced due to a device deficiency, the PI or sub-investigator will add the new device serial number, date of receipt, and date of return of the defective device on the Device Accountability Log.

In the case of a device deficiency, the Adverse Event-Device Deficiency form will be completed by the study manager and the PI or sub-investigators together.

15 Informed consent process

Informed consent will be obtained from the legal guardians of the participants prior to any study participation in accord-ance with the ethics guidelines. The legal guardians will be granted sufficient time to read through the consent in full and ask any questions they have before signing. After the legal guardian signs the consent form, the researcher will sign and provide a copy to the legal guardian.

16 Adverse events, adverse device effects and device deficiencies

Device deficiencies and all **adverse events (AE)** including all **serious adverse events (SAE)** are collected, fully investigated and documented in the source document and appropriate case report form (CRF) during the entire investigation period, i.e. from participant's informed consent until the last protocol-specific procedure, including a safety follow-up period (ISO-14155, 2020). Documentation includes dates of event, treatment, resolution, assessment of serious-ness and causal relationship to device and/or investigation procedure.
Information on AEs is systematically collected during the regular investigation visits, and phone calls (if applicable).

The reporting of Serious Adverse Events and Device Deficiencies follows the Regulation (EU) 2017/745 and the MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.
The causality assessment of the SAE will be conducted according to MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

17 Vulnerable populations

This investigation includes children age 7 to 17.

18 Suspension or premature termination of the clinical investigation

The study will be terminated if the majority of the participants are not able to wear the devices for the study visit.
The study will be terminated if the participants or researchers are exposed to safety risks other than those outlined in this document.
The study may be terminated in the event natural disasters, widespread outbreak of illness, compromised structure of the investigation site, etc. that would make continuation of the study impossible or impractical. The study will be suspended within 5 days of determination that the study or device put participants at an unreasonable risk.
If a participant is suspended, terminated, or withdraws from the study, their data can be traced with their unique study identification number.

Follow up of any SAEs will be conducted by the study manager and/or the PI until the nature of the event is resolved.

19 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by U.S. regulations.
An internal report of the results of this investigation will be completed and uploaded to eQMS.
The PI may publish results at the completion of the investigation.