Study protocol for upload to ClinicalTrials.gov

Standard PMCF study WSA @ HzO 2024

NCT06700512

Date of study protocol D00325215: 2024-06-12

1. General

1.1 Introduction

The goal of this study is to investigate speech intelligibility and the perception of sound with a CE-marked test hearing aid (HA) in the universal program and compare the results to results obtained with the participants' own hearing aids (speech test and questionnaires) and without hearing aids (speech tests).

This study goes under the existing PMCF umbrella approval of the Hörzentrum Oldenburg gGmbH at the medical ethics committee (Oldenburg University, Votum 2022-033). For this purpose, the subjects will listen to the HA in different acoustic scenes in real-life situations, undergo laboratory speech tests in quiet and noise, and answer questionnaires.

1.2 Sponsor

Sponsor of this study is **WSAudiology (WSA)**, Henri-Dunant-Str. 100, 91058 Erlangen. For the avoidance of doubt WSA shall be understood as **Sivantos GmbH, reg.-no. DE30144051** hereinafter referred to as "WSA", "we", "us", "our".

1.3 Study Site

The study will be conducted at **Hörzentrum Oldenburg gGmbH**, Marie-Curie-Str 2, 26129 Oldenburg

1.4 Overall synopsis of the clinical investigation

This study will investigate speech understanding, spatial reception and satisfaction with a current hearing aid of WSA as part of the PMCF Process.

The main objective of the study is to investigate if speech understanding with the WSA Hearing Aid (HA) is better than without a hearing aid and not inferior to speech understanding with the participants' own hearing aids.

The study uses a direct approach where n = 20 adult test subjects, all being experienced hearing-aid users with mild-to-moderate sensorineural hearing loss, will be fitted with test hearing aids.

The subjects will complete a test battery in the lab and an assessment in real life with the test hearing aids and their own hearing aids. The study protocol includes two visits to the lab (of duration up to two hours) and a home trial with a duration of 10-14 days. Objective speech tests performed in the lab provide measures of speech intelligibility in quiet and in noise. Subjective self-assessment performed in real-life are done by use of questionnaires where self-perceived performance of the test hearing aid and the subjects' own hearing aid is rated within the main domains of speech intelligibility, listening effort and sound quality. In addition in-situ measurements will be performed to assess the quality of WSAUD fitting to a clinical target (NAL NL2). All these measurements are described in the PMCF

umbrella approval of the Hörzentrum Oldenburg gGmbH at the medical ethics committee (Oldenburg University, Votum 2022-033). Statistical analysis of both speech-test outcomes and self-assessment ratings will be done to test the overall main hypothesis that the test hearing aid offers improved speech understanding over the unaided condition and non-inferior speech understanding and performance ratings compared to the subjects' own hearing aids.

2. Identification and description of the investigational device

The study will be conducted with **CE-marked Signia Pure C&G 7IX** hearing aids with M-Receivers, together with the compatible CE-marked Pure Portable Charger. The hearing aids will have one or more programs: the universal program is programmed by default and will be used for all speech tests. More programs can be added for the home-trial upon request of the subject as per standard-of-care fitting.

2.1 Manufacturer

Manufacturer of the devices is WSAudiology (WSAUD A/S, Nymoellevej 6, DK-3540 Lynge, Denmark).

2.2 Model/Type

Investigational devices PURE C&G 7IX M are rechargeable behind-the-ear hearing aids with receiver in the canal (RIC). For all subjects a M receiver will be used, length will be selected according to individual anatomy. Depending on hearing loss, devices will be fitted with open, semi-open or power (closed) earwear. For charging the devices the portable charger RIC is provided. User guide and data are available on-line. The user guide is also available as printed version for all subjects.

As benchmark the subjects' own devices will be used with the fitting that has been provided by the hearing care professional of the subject.

2.3 Traceability

Study HA are traced by serial numbers. All study HAs will be shipped to the study partner prior to study start and will be returned to the sponsor when the study is completed.

3. Justification for the design of the clinical investigation

Listening to speech in background noise is a challenging task for people with hearing loss. The loss of audibility and the reduction of temporal and spectral resolution, which are the typical consequences of a sensorineural hearing loss, will result in degraded ability to understand speech, in particular in background noise. For people with hearing loss not using hearing aids, "trying to follow conversations in noise" is the situation among several daily-life situations where the lowest listening satisfaction was observed in the MarkeTrak 10 survey (Picou, 2020). Even though use of hearing aids improves the level of satisfaction, the level of listening satisfaction is still lower for noisy conversations than in most other situations among people with hearing loss who use hearing aids (Picou, 2020).

In the development of hearing aids, use of noise reduction and directionality has for decades been used to improve speech-in-noise performance by offering signal-to-noise improvements and improved comfort in noise.

When fitting hearing aids, the compensation of hearing loss is accomplished by fitting formulas that translate the audiogram data into a recommendation of gain for different input levels. Fitting formulas aim to restore audibility while maintaining comfortable loudness (Byrne and Dillon, 1986; Keidser et al 2012; Scollie et al 2005) to ensure benefit for the user.

Ensuring hearing loss compensation by fitting to prescriptive target levels such as NAL NL2 (Keidser et al 2011) has been shown to lead to improved speech quality and intelligibility while maintaining listening comfort (Bentler and Ricketts, 2016; Byrne and Cotton, 1988; Johnson et al, 2016; Moore et al, 2001). Thus clinical benefit of the hearing loss compensation provided is expected if the hearing aids can provide the gain recommended by the fitting formulas ("target"). Real ear measurements using probe microphones are considered best practice as a reliable and accurate procedure to determine how well a hearing device matches a given target while in the ear of the hearing aid user.

3.1 Background for the used measurements in the trial

To investigate speech intelligibility (SI) performance for speech at 65dB in a quiet listening situation, the **Freiburger monosyllabic speech test** is used which is still the gold standard for Hearing Care Professionals in Germany. For more details, see e.g., Hahlbrock (1953).

To investigate SI performance in a noisy listening situation, **Oldenburger Satztest (OLSA)** with speech from the front (0°) and 65 dB SPL noise (OLnoise) continuously played back from the back (180°), adapting to speech recognition threshold of 80% (STR80) is used. Oldenburger Satztest is a state-of-the-art test to investigate this. More details can be found here: https://www.hz-ol.de/de/diagnostik-olsa.html or in Wagener et al. (1999).

To investigate the satisfaction and performance in various real-life listening situation, subjects will wear test hearing aids in their daily life and answer questionnaires (**SSQ17 and IOI-HA questionnaires**, **Satisfaction questionnaire**, to give subjective ratings on absolute rating scales with respect to perceived sound quality of conversation partners, of their own voice and of surrounding sounds, speech intelligibility, localization, audible artifacts, and overall satisfaction.

To investigate the ability to reach NAL-NL2 insertion gain targets, in-situ measurements will be done with probe mics placed close to the eardrum and ISTS noise played from the front. With this it will be documented how close the insertion gain matches the postulated NAL-NL2 targets (Keidser et al 2011) after "first fit" and after "fine-tuning".

4. Study Goals: Objectives and hypotheses of clinical investigation

The overall goal of this study is to investigate speech intelligibility and satisfaction with hearing aid performance experienced by test subjects when using the test hearing aids in lab and real-life situations. For this purpose, the subjects will undergo speech tests in quiet and noise, and they will listen and rate their sound perception in in real life.

4.1 Study objectives

Primary objectives

Objective 1: Investigate whether speech intelligibility in noise is better with the study HAs than without, as measured by the OLSA test (German version).

Objective 2: Investigate whether speech intelligibility in noise with the study HAs is non-inferior (i.e. the same or better) compared to speech intelligibility in noise with the subjects' own HAs, as measured by the OLSA test (German version).

Secondary objectives

Objective 3: Investigate whether speech intelligibility in quiet is better with the study HAs than without HAs as measured by the German Freiburger test.

Objective 4: Investigate whether speech intelligibility in quiet with the study HAs is non-inferior (i.e. the same or better) compared to speech intelligibility in quiet with the subjects' own HAs as measured by the German Freiburger test.

Objective 5: Investigate how close the study hearing aids fitted with the fitting software to NAL-NL2 Targets match the postulated targets, as measured in-situ with real-ear measurements.

Objective 6: Investigate speech perception, sound localisation, satisfaction and quality of hearing perceived in real-life with the study hearing aids compared to the subjects' own hearing aids as measured by the SSQ17 questionnaire (German version)

Objective 7: Investigate outcomes and effectiveness of hearing aid usage in real-life with the study hearing aids compared to the subjects' own hearing aids as measured by the IOI-HA questionnaire (German version)

Objective 8: Investigate satisfaction in real-life with the study hearing aids compared to the subjects' own hearing aids as measured with the Satisfaction questionnaire (WSA internal questionnaire)

4.2 Hypotheses

4.2.1 Primary objectives

The **primary objectives 1 and 2** will be addressed by measuring a speech reception threshold (SRT) for each hearing aid, using an adaptive speech-in-noise test, OLSA. The SRT corresponds to the signal-to-noise ratio (SNR) where 80% of the words presented are correctly repeated by the test subject. Thus, a lower SRT value indicates better performance.

The difference between the study HAs and the subjects' own HAs or no HAs will be assessed as the mean SRT difference. The expectation is that the study HAs give an advantage over not wearing HAs so the first hypothesis is:

H_0 (Objective 1) SRT(study HA) is not significantly different from SRT without HAs

H_1(Objective 1) SRT(study HA) is significantly better than SRT without HAs

A mean difference in SRT of 1 dB measured with the Oldenburg sentence test (Wagener et al, 1999a-c), can be assumed as a typical difference in speech intelligibility to show a clinically meaningful improvement (Kollmeier et al, 2011).

In addition, the expectation is that the study HAs are not inferior to the subjects' own HAs:

H_0 (Objective 2) SRT(study HA) is significantly worse than SRT(own HAs).

H_1(Objective 2) There is no difference between SRT(study HA) and SRT(own HAs)

A significant difference means that the study HAs are inferior to own HAs, otherwise they are non-inferior. .

4.2.2 Secondary objectives

For the **secondary objectives 3 and 4**, Speech intelligibility (SI) in quiet will be assessed with the Freiburger monosyllabic speech test where the outcome measure is percent correctly repeated words. The hypotheses related to the third and fourth objectives are:

H_0 (Objective 3) SI(study HA) is not significantly different from SI without HAs

H_1(Objective 3) SI(study HA) is significantly better than SI without HAs

H_0 (Objective 4) SI(study HA) is significantly worse than SI(own HAs).

H_1(Objective 4) There is no difference between SI(study HA) and SI(own HAs)

A significant difference means that the study HAs are inferior to own HAs, otherwise they are non-inferior.

The **secondary objective 5** will be assessed by calculating the absolute differences between the NAL-NL2 Target curves (Keidser et al 2011) realised in the Otometrics/Natus Freefit and the measured REAR/REIG curves after First Fit and after Fine-Tuning, if applicable. The expectation is that the deviation from the target curves is ≤ 5dB in the frequency range 0.25-4 kHz

The **secondary objective 6** will be addressed by asking the participants to rate speech understanding, localization and quality of sound in different situations as well as listening effort after having worn the hearing aids 10-14 days in real-life on a scale from 0-10 with a shortform of the SSQ questionnaire (SSQ 17 German Version, Kiessling 2011) in different situations. Mean rating will be calculated across the participants for each HA. For each domain we will test whether the ratings are significantly worse with study HAs compared to own HAs, if they are, that indicates the study hearing aids are inferior to own HAs. Otherwise, they are non-inferior.

The **secondary objective 7** will be addressed by asking the participants to rate hearing aid outcomes after having worn the hearing aids 10-14 days in real-life on a 5-point scale with IOI-HA (Cox & Alexander 2002, German Version Cox et al 2002). Mean rating will be calculated across the participants for each HA. For each question we will test whether the ratings are significantly worse with study HAs compared to own HAs, if they are, that indicates the study hearing aids are inferior to own HAs. Otherwise, they are non-inferior.

For the **secondary objective 8**, to evaluate satisfaction, subjects are asked to rate their satisfaction with the hearing aids regarding several aspects including sound, conversations and overall satisfaction after having worn the hearing aids 10-14 days in real-life. In Marke-Trak10 survey (Picou, 2020), respondents rated their satisfaction on a 7-point scale, where 1 indicates very dissatisfied, 4 indicates neutral, and 7 indicates very satisfied. Respondents who indicated scores of 5, 6, or 7 were considered to be satisfied and satisfaction was reported as % satisfied of the study sample. In a similar manner the percentage of satisfied subjects will be calculated for the study HAs and compared to published values of (MarkeTrak10 (Picou, 2020) and EuroTrak German (2022), EuroTrak France (2022), EuroTrak Spain (2023)). For each question we will test whether the proportion of satisfied subjects is significantly lower with study HAs compared to the published values (MarkeTrak/EuroTrak), if they are, that

indicates the study hearing aids are inferior the hearing aids reported on in the MarkeTrak/EuroTrak Reports. Otherwise, they are non-inferior.

In addition, mean ratings will be calculated across the participants and will be compared for the study HAs and own HAs and for each question we will test whether the ratings are significantly worse with study HAs compared to own HAs, if they are, that indicates the study hearing aids are inferior to own HAs. Otherwise, they are non-inferior.

5. Risks and Safety as adverse events

5.1 Known potential risks

This study is conducted with CE-marked devices, so all risks identified are mitigated as low as possible and are below the risk acceptability threshold. Residual risks are presented in the user instructions (if applicable) and there is no new risk due to study-related measures.

The risk management process for the hearing aid system is performed in accordance with the requirements stated in ISO 14971. The identified risks and mitigations for the hearing aid system conducted by the Sponsor is documented in the Signia Pure C&G T IX User Guide (see Appendix 16.1) and in the Safety manual for hearing aids Master (see Appendix 16.1).

There are no new risks due to study-related measures.

In conclusion, the overall residual risk is acceptable for this PMCF study using the PURE C&G T 7IX M hearing aid and Connexx 9.11 fitting software.

5.2 Known potential benefits

Hearing aids relieve the strain of hearing, i.e., less strain and more clear hearing. It is anticipated that inexperienced wearers will experience improved ease and better speech understanding in various listening environments, e.g., watching television, conversations.

Subjects get the chance to try out state-of-the-art modern hearing aids. Subjects already fitted with hearing aids will gain experience with hearing aids.

During screening the hearing of the subjects is checked by a hearing care professional thus the subjects gain current information about the status of their hearing.

Having to participate in laboratory speech tests and filling in surveys during the study may have the benefit that subjects pay more attention to their hearing which might lead to increased perceptiveness of sound being an incentive to become more socially active. Overall, this could contribute to their emotional well-being.

5.3 Adverse Events and Serious Adverse Events

Unaffected by handling AEs and SAEs within the scope of the study, the provisions and reporting deadlines of the corresponding legal regulations (MDR, MPDG, MPMIV) apply to incidents (=Vorkommnisse") involving medical devices.

5.3.1 Definition of adverse events (AE)

Adverse event, as defined according to ISO1455, means any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device and whether anticipated or unanticipated.

Note 1: This definition includes events related to the investigational device or comparator.
Note 2: This definition includes events related to the procedures involved.
Note 3: For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators.

An Adverse event related to the use of an investigational medical device is called an Adverse Device Effect. This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. This definition includes any event resulting from use error or from intentional misuse of the investigational medical device. It also includes comparator if comparator is a medical device.

5.3.2 Definition of serious adverse events (SAE)

A Serious Adverse event is an adverse event that led to any of the following:
a) death,
b) serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:

1) a life-threatening illness or injury, or
2) a permanent impairment of a body structure or body function including chronic disease, or
3) in-patient or prolonged hospitalization, or
4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

c) fetal distress, fetal death or a congenital abnormality or birth defect including physical or mental impairment

Note: Planned hospitalization for a pre-existing condition, or a procedure required by the study, without serious deterioration in health, is not considered a SAE.

Unanticipated serious adverse device effect (USADE) is a serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current risk assessment.

Note: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.

5.3.3 Classification of an adverse event

5.3.3.1 Severity of event

For adverse events (AEs) the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the subject's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.

- **Severe** – Events interrupt a subject's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate too "serious".

5.3.3.2 Relationship to study intervention

All adverse events (AEs) must have their relationship to study intervention assessed by the clinician who examines and evaluates the subject based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

5.3.3.3 Expectedness

The Sponsor will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

5.3.4 Time period and frequency for event assessment and follow-up

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study subject presenting for medical care.

All AEs, including local and systemic reactions not meeting the criteria for SAEs, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the subject is screened will be considered as baseline and not reported as an AE. However, if the study subject's condition deteriorates at any time during the study, it will be recorded as an AE.

5.3.5 Adverse event reporting

The investigator must record non-serious adverse events and report them to the Sponsor in a timely manner after the investigator first learns of the adverse event. AEs which are non-serious and not related to the research procedures do not have to be reported to the ethics committee but will be reviewed by the Sponsor.

In case however that the event is unexpected AND more likely than not related to the research procedures it shall be reported to the ethics committee within 5 days of Investigator receiving notice of the event.

5.3.6 Serious adverse event reporting

The study investigator shall report an Unanticipated Adverse Device Effect to the study sponsor and to the reviewing ethics committee as soon as possible, but in no event later than 5 working days after the investigator first learns of the effect. The study sponsor is responsible for conducting an evaluation of an unanticipated adverse device effect and shall report the results of such evaluation to the ethic committee within 10 working days after the sponsor first receives notice of the effect.

The sponsor must immediately conduct an evaluation of any unanticipated adverse device effect.

If the sponsor determines that an unanticipated adverse device effect presents an unreasonable risk to subjects, the sponsor must terminate all investigations or parts of the investigations presenting that risk as soon as possible. Termination must occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first received notice of the effect.

Resumption of Terminated Studies:

For a nonsignificant risk device investigation, a sponsor may not resume a terminated investigation without ethics committee approval. If the nonsignificant risk study was terminated for unanticipated adverse device effects, the sponsor must also obtain ethics committee approval.

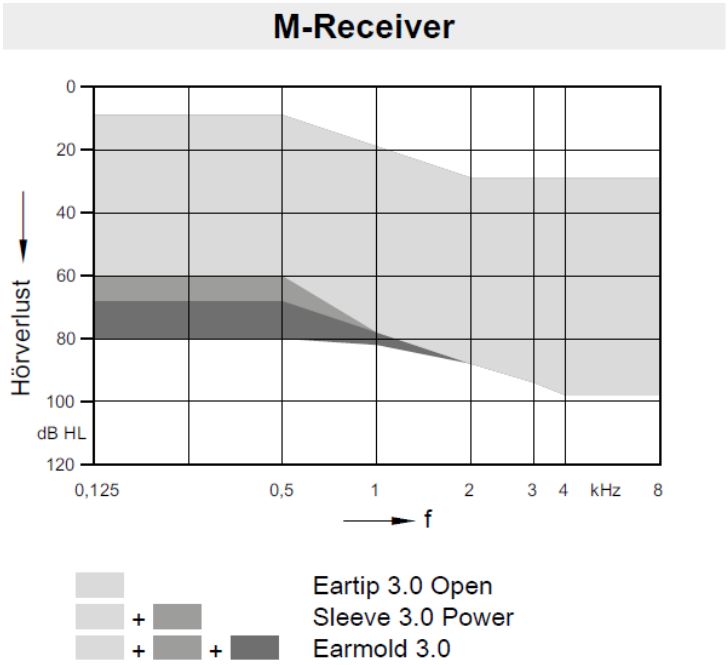
6. Design of the clinical investigation

6.1 Subjects

The test will be conducted with 20 mild to moderately hearing-impaired listeners (HIL) in the fitting range of an M-receiver.

Inclusion criteria:

- The allowed audiometric range for HIL is shown below:



- They should be experienced hearing aid users
- Air-Bone-Gap should be less or equal to 20 dB HL.
- Sensorineural HV, mild-to-moderate
- HV corresponding to the fitting range of the HA
- Healthy (outer) ear
- Older than 18 years
- German is mother tongue
- Able to understand the instructions
- Willing to participate in laboratory tests and to wear the HAs at home for 2 weeks
- Informed consent

Exclusion criteria:

- Contraindication for HA treatment
- Fluctuating or rapidly progressing hearing loss
- "Central" hearing problems
- Limited mobility
- Limited dexterity (in handling the HA)
- Known psychological problems
- They must not show any injuries or a complete perforation of the ear drum. This must be clarified prior to the beginning of the study by means of otoscopy.
- They should be quite healthy (e.g., they shall not suffer from dementia) and should not use medical treatments that might affect study results.

Any deviations from the above requirements must be noted and justified.

Additionally, both women and men should take part in the study. Also, the hearing loss of the subjects should be roughly distributed over the fitting range of the hearing aids (not covering the extremes is permitted).

6.2 Devices & Fitting

The test will be conducted with CE-marked **PURE C&G 7IX M** devices.

Study HA are first fitted according to individual hearing loss, using released fitting software Connexx 9.11. Fitting formular for REM Measurements is NAL NL2. Fine Tuning to target will be done via AutoFit Feature in Connexx. After REM Measurements First Fit will be repeated with proprietary formula IXFit. Fine-tuning should be done as required by standard-of care (best practice) before sending the subjects to the home trial. Adding extra programs is allowed if requested by the subject (best practice). In the second lab session after the home trial and before the speech tests are performed, subjects will be asked if further fine-tuning is needed.

If the subject wishes for the use of Signia App as remote control during the Home Trial, the subjects are shown how to download the Signia App and the study HAs are coupled with the subject's own smartphone to support e.g. volume control via Signia App during the home trial.

6.3 Workflow

All subjects will participate in two lab sessions as described below. Sessions should not exceed 90 min per subject. Additionally, subjects will do a home trial to rate subjective perception in relevant daily-life situations.

1st lab trial **Fit-to-Target**	**1st Home Trial** **Study HAs**	**2nd Lab Trial** **Speech tests**	**2nd Home Trial** **Own HAs**
• Audiometry & Anamnesis • Fit to NAL_NL2 • Real-Ear Measurements • ISTS @55/65/80 dB SPL • Document Match-to Target • New fitting to proprietary Rationale • Listen to HAs in quiet and conversation and fine-tune as needed	• Duration 10-14 days • Use HAs in daily life environments • Option to come back for fine-tuning if needed • At the end of home-trial fill out questionnaires: o SSQ 17 o IOI-HA o Satisfaction o Basic User Needs	• Perform fine-tuning upon request • Speech test in quiet (Freiburger @65 dB SPL) o Unaided o Study HAs o Own Has • Speech test in noise (OLSA, SRT 80%, OL noise @65 dB SPL) o Unaided o Study HAs o Own Has	• Duration 10-14 days • Use HAs in daily environments • At the end of home-trial fill out questionnaires: o SSQ-17 o IOI-HA o Satisfaction • Return questionnaires via mail

7. Statistical design and analysis

7.1 Sample size estimation

The sample size is determined by considering the primary objective 1 and the related hypothesis expecting a mean difference in SRT between the study HA and no HA of at least 1 dB.

Speech intelligibility in noise is usually determined as a speech intelligibility threshold in dB SNR, so a difference between dependent mean values is analyzed. The data for these data are expected to be normally distributed, so a t-test is used to estimate the number of cases.

A mean difference in SRT of 1 dB measured with the Oldenburg sentence test (Wagener et al, 1999a-c), can be assumed as a typical difference in speech intelligibility to show a clinically meaningful improvement (Kollmeier et al, 2011).

The interindividual standard deviation in hearing-impaired test subjects for this method with the stationary noise associated with the test is 1.3 dB (Wagener & Brand, 2005). Assuming that dependent mean values for two comparative measurements show a high correlation (0.8), this results in an average effect size for the method (effect size dz) of 0.77 and, with an α value of 0.05 and a β value of 0.2 (power = 0.8), a number of cases of n = 16, calculated using the G*Power (3.1.9.7) program of the University of Düsseldorf (Faul et al., 2007),

With an added 25% dropout risk this suggests that recruiting 20 subjects will be appropriate with respect to addressing the primary objectives and testing the related hypothesis. N = 20 subjects will provide a statistical power of 0.9 when the other parameters are kept constant.

7.2 Statistical analysis

Objectives 1 and 2 (Speech in Noise OLSA): The SRT data will be analyzed using a one-tailed paired t-test.

Objectives 3 and 4 (Speech in Quiet Freiburger): Similarly to the OLSA Test the % correct data will be analyzed using a one-tailed paired t-test.

Objective 5 (NAL-NL2 Targets): No statistical analysis will be performed, only descriptive statistics will be used.

Objectives 6-7 (Questionnaires – SSQ17, IOI-HA)

Subjective rating data from real-life questionnaires will be analyzed using one-tailed paired t-tests, comparing ratings of study HA and own HA with a significance level of 0.05 to determine significance.

In addition, descriptive statistics of the SSQ 17 scores and IOI-HA scores will be reported by Hearing Aid (study or own) for each subscale and put into perspective of published data (von Gablenz et al, 2018; Cox et al, 2013).

Objective 8 (Questionnaire – Satisfaction)

One-sided test of proportions will be done to analyze whether the proportion of satisfied hearing aid users is significantly lower with study hearing aids than reported in the literature (MarkeTrak 10, EuroTrak). A significant effect indicates that the study hearing aids are inferior, otherwise they are non-inferior.

In addition, subjective rating data from satisfaction questionnaire will be analyzed using one-tailed paired t-tests, comparing ratings of study HA and own HA with a significance level of 0.05.

8. Deviations from clinical investigation plan

A protocol deviation is any noncompliance with the clinical investigation plan. The noncompliance may be either on the part of the subject, the investigator, or the study site staff.

As a result of deviations, corrective actions are to be developed by the site and implemented promptly. Prior approval by the sponsor is required for changes in or deviations from the plan. It is the responsibility of the study partner to use continuous vigilance to identify and report deviations.

All deviations must be addressed and reported to the sponsor.

9. Device preparation/handling/storage/accountability

9.1 Acquisition and accountability

Sponsor will deliver the hearing aids to the investigation site before the first subject is enrolled in the study.

If for any reason devices need to be returned to the sponsor, investigator site will be responsible to safely send the respective devices back.

Return of all devices will be with responsibility of the investigator site to send those safely back to the sponsor site directly after the close out virtual meeting with the investigation site.

9.2 Product storage and stability

Devices should be stored in their designated jewel cases or appropriate trays or boxes. Temperature for storage should be between 10 to 40 °C (50 to 104 °F). Relative humidity should be 10 to 80% and Atmospheric pressure 700 to 1060 hPa.

9.3 Preparation

Randomization coding need to be done in advance by the designated investigational site staff.

9.4 Randomization and blinding coding

The study design does not allow for the study to be blinded. REM Measurements will only be done with the study HAs and during Home-Trial, subjects are well aware of which HA they are wearing. For the speech tests the order of study HA, own HA and unaided will be randomized.

10. Statement of compliance

This non-significant risk device study will be carried out in accordance with:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, MDR, Article 74 (1).
- BERUFSORDNUNG DER ÄRZTEKAMMER, BO ÄKN § 15

The protocol, informed consent form (ICF), privacy statement according to GDPR, recruitment materials, and all subject materials will be submitted to the medical ethics committee (Oldenburg University) for review and approval. Test persons who wish to discontinue the study before termination of the full study period can do so without retribution from Oldenburg Hörzentrum or WSA. Approval of the protocol, the consent form, and privacy statement must be obtained before any subject is enrolled.

Any amendment to the protocol will require review and approval by the medical ethics committee (Oldenburg University) before the changes are implemented to the study. In addition, all changes to the consent form or privacy statement will be approved; a determination will be made regarding whether a new consent needs to be obtained from subjects who provided consent using a previously approved consent form.

11. Informed consent process

11.1 Consent and other Informational Documents provided to subjects

The responsible investigator ensures to provide informed consent which is part of the PMCF umbrella ethic approval as well as the consent to be contacted again for further studies

11.2 Consent Procedures and Documentation

Test persons will provide informed consent and are compensated with [redacted]€ per hour for their participation. The investigator will explain the research clinical investigation to the subject and answer any questions that may arise. A verbal explanation will be provided in terms suited to the subject's comprehension of the purposes, procedures, and potential risks of the clinical investigation and of their rights as research subjects. The subject must also give their permission for representatives of the Sponsor and regulatory authorities to review their records for the purposes of source data verification.

The screening process is described in detail in 7.1 Subjects.

11.3 Study Discontinuation and Disclosure

This clinical investigation may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for clinical investigation suspension or termination, will be provided to the ethics committee. If the clinical investigation is prematurely terminated or suspended, clinical investigation subjects will promptly be informed as well as of possible changes to clinical investigation visit schedule.

11.4 Confidentiality and Privacy

Subject confidentiality and privacy are strictly held in trust by the participating investigators, their staff, and the sponsor and their interventions. Other authorized representatives of the sponsor and representatives of the ethics committee may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records for the subjects in this clinical investigation. The clinical investigation site will permit access to such records.

12. Publication policy

The data collected in the study is primarily aimed for WSA regular PMCF report but may be published in white papers and/or trade journal papers. All data are presented in a fully anonymized form. Only descriptive statistics are presented, like mean values, standard deviations and counts of participants.

13. Bibliography

Bentler, R.A.M., H.G.; Ricketts, T.A., *Modern Hearing Aids: Verification, Outcome Measures, and Follow-up*. 2016, San Diego: Plural Publishing. 748

Byrne, D. and S. Cotton, *Evaluation of the National Acoustic Laboratories' new hearing aid selection procedure.* J Speech Hear Res, 1988. **31**(2): p. 178-86.

Byrne, D. and H. Dillon, *The National Acoustic Laboratories' (NAL) new procedure for selecting the gain and frequency response of a hearing aid.* Ear Hear, 1986. **7**(4): p. 257-65.

Cox RM, & Alexander GC (2002). The International Outcome Inventory for Hearing Aids (IOI-HA): Psychometric properties of the English version. International Journal of Audiology, 41(1), 30-35. https://doi.org/10.3109/14992020209101309

Cox RM, Stephens D, Kramer SE (2002). Translations of the International Outcome Inventory for Hearing Aids (IOI-HA), Int J Audiology 41:3-26

Cox RM, Alexander GC, Beyer CM (2003). Norms for the International Outcome Inventory for Hearing Aids. *Journal of the American Academy of Audiology*, 14(8): 403-413.

EuroTrak France 2022, Results: EuroTrak_France_2022 (ehima.com)

EuroTrak Germany 2022, Results: EuroTrak_Germany_2022 (ehima.com)

EuroTrak Spain 2022, Results: EuroTrak_Spain_2023 (ehima.com)

Hahlbrock KH (1953). Über Sprachaudiometrie und neue Wörterteste. *Archiv für Ohren-, Nasen- und Kehlkopfheilkunde*, 162, 394–431.

Johnson, J.A., J. Xu, and R.M. Cox, *Impact of Hearing Aid Technology on Outcomes in Daily Life II: Speech Understanding and Listening Effort.* Ear Hear, 2016. **37**(5): p. 529-40.

Keidser G, Dillon H, Flax M, Ching T, & Brewer S (2011). The NAL-NL2 prescription procedure. *Audiology Research*, 1(1), e24. https://doi.org/10.4081/audiores.2011.e24

Keidser, G., et al. (2012) *NAL-NL2 empirical adjustments.* Trends Amplif. **16**(4): p. 211-23

Kiessling J, Grugel M, Meister H, Meis M (2011). Übertragung der Fragebögen SADL, ECHO und SSQ ins Deutsche und deren Evaluation*. Zeitschrift für Audiologie,* 50 (1) 6–1

Kollmeier, B, Lenarz, T, Winkler, A et al. Hörgeräteindikation und -überprüfung nach modernen Verfahren der Sprachaudiometrie im Deutschen. HNO 59, 1012–1021 (2011). https://doi.org/10.1007/s00106-011-2345-5

Moore, B.C., J.I. Alcantara, and J. Marriage, *Comparison of three procedures for initial fitting of compression hearing aids. I. Experienced users, fitted bilaterally.* Br J Audiol, 2001. **35**(6): p. 339-53.

Picou E M (2020). MarkeTrak 10 (MT10) Survey Results Demonstrate High Satisfaction with and Benefits from Hearing Aids. *Seminars in Hearing*, 44(1), 21-36.

Scollie, S., et al., (2005) The Desired Sensation Level multistage input/output algorithm. Trends Amplif 9(4): p. 159-97.

Von Gablenz P, Otto-Sobotka F, Holube I (2018). Adjusting Expectations: Hearing Abilities in a Population-Based Sample Using an SSQ Short Form. *Trends in Hearing*, 22: 1–21.

Wagener KC, Brand T, & Kollmeier B (1999). Entwicklung und evaluation eines satztests für die deutsche sprache I-III: design, optimierung und evaluation des oldenburger satztests. *Zeitschrift für Audiologie*, 38(1-3), 4-15.

Wagener KC, Brand T (2005). "Sentence intelligibility in noise for listeners with normal hearing and hearing impairment: Influence of measurement procedure and masking parameters." *Intern J Audiol*, 44 (3), p 144-157.

Wagener KC, Brand T, Kollmeier B (1999). "Entwicklung und Evaluation eines Satztests für die deutsche Sprache I-III: Design, Optimierung und Evaluation des Oldenburger Satztests." *Zeitschrift für Audiologie*, 38 (1-3), p 4-15 (a), 44-56 (b), 86-95 (c).