Clinical Trial of Roger Adaptive Digital Technology

Remote Microphone Candidacy Study

NCT03897634

Final IRB Revision: 2.14.2020

ClinicalTrials.gov upload 2.24.2021

PROTOCOL TITLE:

Remote Microphone Candidacy Study

PRINCIPAL INVESTIGATOR:

Pamela Souza
Communication Sciences and Disorders
Number: 847-491-2433
p-souza@northwestern.edu

CO-INVESTIGATOR:

N/A

STUDENT INVESTIGATOR:

N/A

VERSION DATE:

2/14/2020

1.0 Study Summary

Investigational Agent(s) (Drugs or Devices)	Roger Select (Remote microphone manufactured by Phonak, subsidiary of Sonova)
IND / IDE / HDE #	IDE Exempt: This is a legally marketed device and will be used in accordance with its labeling.
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	40
Funding Source	Sonova
Indicate the type of consent to be obtained	☒ Written ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☐ No

2.0 Objectives:

Despite improvements in digital hearing aid technology, many individuals with hearing loss continue to report difficulty understanding speech in challenging listening environments. Remote microphones have been shown to provide benefit in many of the most common challenging listening environments: distant speakers, background noise and reverberation. Despite demonstrated benefit, there is a low rate of remote microphone use amongst adults with hearing–impairment. One reason for low uptake may be an uncertainty amongst hearing healthcare providers and potential users regarding expected clinically relevant benefit. This clinical trial, funded by Sonova, will attempt the following:

1. To describe the range of Roger remote microphone benefit among adults with mild-to-moderate sensorineural hearing loss
2. To determine specific individual factors beyond the audiogram that are associated with greater Roger remote microphone benefit.

3.0 Background / Literature Review / Rationale for the study:

Even when wearing well-fit hearing aids, many individuals with hearing loss continue to report difficulty communicating in background noise is one of the most common

complaints of individuals with hearing loss. Directional microphones can improve speech perception in noise, but often fail to provide benefit in cases where the talker is distant from the listener, where there are multiple or moving noise sources, or in reverberation. Digital noise reduction may reduce listening effort and improve listening comfort but has minimal effect on speech perception.

Placing the microphone in close proximity to the talker reduces the effective distance between speaker and listener, compensating for the effects of background noise and reverberation on the target signal. Use of a remote microphone can significantly improve signal-to-noise ratio (SNR), thereby improving speech perception in noise and at a distance. Recent studies demonstrated that remote-microphone devices that utilize adaptive digital technology (i.e., Roger) provide significantly more benefit for speech understanding in noise than non-adaptive remote microphones. Those advantages are likely related to the adaptive nature of the device, whereby the microphone gain varies according to the level of noise in the environment. In addition, interference is reduced via transmission of short digital bursts (160 μs) across a range of channels (2.4-2.4835 GHz). Further, the ability to utilize the hearing aids' onboard directional microphones in conjunction with a remote microphone gives listeners the benefits of remote microphone use without sacrificing nearfield intelligibility. The Roger system has also been shown to improve cell phone communication amongst cochlear implant patients.
Despite demonstrated advantages, use of remote microphone assistive devices among adults is low. In a recent study of listeners with severe hearing loss—a group which has substantial difficulty communicating in background noise and is likely to receive significant benefits from remote-microphone devices—less than 10% reported use of a remote microphone. While cost may be a barrier for some users, even when such systems are available for free (as in the Veterans Administration), use is still low. *One reason may be uncertainty among both providers and potential users as to expected benefit for a given listener.* For example, Wolfe et al. 2015 found significant improvements in objective speech recognition on average, but with a wide range of benefit (from 10% to 60% improvement across individual participants). That study also suggested that individual factors may affect remote microphone benefit, in that the magnitude of improved recognition was correlated with the ability to use spatial cues to improve recognition.

4.0 Study Endpoints

Primary Endpoint: Benefit from use of a remote microphone.

1. Abbreviated Profile of Hearing Aid Benefit (APHAB): This is a measure of hearing aid benefit that is standard in clinical practice. Participants will complete this questionnaire to compare perceived aided benefit with hearing aid alone vs hearing aid+ remote microphone.

Secondary Endpoints: In order to build a better profile of patients who may benefit from a remote microphone, several measures of hearing ability, manual dexterity, personality, and social activity are included.

2. Audiometric evaluation including hearing and health history, air and bone condition testing, measurement of loudness discomfort level and real-ear assessment of current hearing aids. These are all standard clinical assessments.
3. MoCA test: The Montreal Cognitive assessment is a cognitive screening test designed to detect mild cognitive impairment. It requires approximately 10 minutes and assesses short-term recall, visuospatial abilities, executive function, attention, working memory, language, and orientation to time and place.
4. Practical Hearing Aid Skills Test-Revised (PHAST-R)- will be used to ensure participants are able to use the trial devices
5. Unaided and Aided speech in noise testing: This is a standard clinical measure of an individual's ability to hearing and understand speech in background noise.
6. Speech, Spatial, and Quality of Hearing Scale (SSQ) pre- and post- Roger use: Evaluates an individual's perceptions of their hearing abilities in a variety of every day scenarios.
7. Acceptable Noise Level (ANL): This test has been shown to be correlated with successful hearing aid use.
8. LiSN-S: Spatial auditory information assessment. This test has been shown to correlate with successful assistive listening device use.
9. Level of social activity, using the HRS Activities and Time Use subscale
10. Personality, using the Positive and Negative Affectivity Scale (PANAS) and International Personality Item Pool (IPIP). Personality has been shown to be related to successful hearing aid use.
11. Self-efficacy, using the Generalized Self-Efficacy Scale. Self-efficacy is an individual's belief in his/her ability to achieve a goal and has been linked with hearing device satisfaction.
12. Working memory will be measured via the short version of the Reading Span Test. Working memory is the ability to rapidly process and store information and has been associated with speech-in-noise recognition. In addition, listeners with low working memory are thought to expend greater listening effort to understand speech. It has been suggested that listeners with low working memory will receive greater benefit from remote microphone technology.
13. Nine-hole peg test will be used to evaluate participants' dexterity.

5.0 Study Investigational Agent

The Roger Select is a remote microphone manufactured by Phonak, a subsidiary of Sonova (the funding group). To minimize confounding factors, participants will also be fit the same model and make of hearing aids (Phonak Marvel 90) for the duration of the trial. Both the Roger Select and the hearing aids are legally marketed devices currently available to consumers and and will be used in this trial accordance with its labeling, making this an IDE exempt regulation (21 CFR 812).

Only current hearing aid users will be recruited for this trial and a licensed audiologist will fit the hearing aids and remote microphones. Devices will be programmed to standard clinical targets and verified using real ear measures, a standard clinical procedure.

Devices are being provided by the manufacturer, Phonak. All hearing aids and their accessories come with unique serial numbers. Upon receiving the devices, they will be evaluated for good function and serial numbers will be noted in the device log. We will note in the log when and to whom (using participant ID number) each individual device is dispensed. When a participant returns a device this will be tracked in the log, as well as when we return to the manufacture.

6.0 Procedures Involved:

Approach: The trial will use a within-subjects design consisting: 1)Baseline assessments (see assessments), 2) Being fit with trial hearing aids for a two week adjustment period, 3) Roger connect fitting appointment, 3) Approximately four-week trial period of Roger use in the participant's everyday environment(s), 4) Final visit with outcome measures.

Participants whose hearing loss qualifies them for a dome mold fitting (non-custom) will start their trial the same day as their eligibility assessment. Participants whose hearing loss or ear structure requires a custom mold fitting will have earmold impressions taken at their eligibility assessment and then be fit with the trial devices after the custom earmold has arrived back in the lab, usually about one to two weeks later. During an earmold impression the ear is visually inspected with an otoscope (magnifying scope with light). A cotton or foam block and soft impression material are placed in the ear and sets for approximately 3 minutes. The resulting impression is used to order an earmold for later testing. This is a standard clinical procedure.

A licensed clinical audiologist will perform the assessments, fitting and counseling of hearing aids and Roger system, and conduct the outcome measures. To ensure appropriate fit and use by the participants, there will be a follow-up one week after receiving the Roger. During this appointment participants will be evaluated, and their hearing aid logging will be checked for compliance.

Hearing aid/Roger fitting: Trial hearing aids and clinically-appropriate earmolds or domes will be provided by Sonova at no charge to the participants for the duration of the trial. The Marvel 90 hearing aids are Phonak's advanced technology level and to provide datalogging via 7 base programs. Aids will be set to NAL-NL2 targets using probe microphone measurements. Directional microphones will be enabled and verified via probe-microphone testing. Roger will be verified via probe-microphone testing, following clinical best practice. Appropriate hearing aid adjustments (as judged by the study audiologist) will be permitted to provide acceptable sound quality and loudness. Final REARs will be recorded. Participants will be fit with the trial hearing aids and wear them for two weeks prior to receiving the Roger device. This is to allow participants to adjust to the sound quality of a new pair of hearing aids and ensure that measured differences are due to Roger use and not the newer hearing aids. The study audiologist will instruct participants regarding hearing aid and Roger device use. PHAST-R and a Roger competency questionnaire (to be developed with input from Phonak) will be used to document understanding of device function at the fitting and one-week follow-up appointments. Participants will then wear the hearing aids and use the Roger system for 1

month in their everyday listening environments. At the completion of the trial, participants will return to the lab for outcome assessments and to provide spontaneous feedback regarding their experiences. Hearing aids will be returned to the study site following completion of the trial.

7.0 Sharing Results with Participants

An audiologist will share and review the hearing test results with participants. They will also be given a copy of the test results if they so choose.

8.0 Study Timelines

Individual Participant Timeline: Active study time for participants will be about 6 weeks, during which they will visit the lab at least four times: baseline+fitting of hearing aids, fitting of Roger, one-week follow-up, and final visit. Participants who require an earmold will require a two separate visits for baseline and hearing aid fitting. For these participants, there will be a one to two-week delay between their baseline and hearing aid fitting appointment while the earmold is manufactured. Visits will typically take 1-2 hours. Some participants who require more counseling or breaks than is typical may find their visit durations last longer. Other participants may need to visit the lab for more appointments to ensure good physical and acoustic fit. Appointments will also be scheduled at participant's convenience, so the duration of study stages (e.g. adjustment period) may vary slightly to accommodate an individual's scheduling needs.

Overall Study Timeline: Once enrollment begins, we hope to enroll approximately 2-3 participants a week. Enrollment should be reached in 10 to 14 weeks. Study activities should then complete 6-8 weeks after that. Estimated data collection period will be 16-20 weeks, with the possibility of an extension should recruitment prove slower than anticipated. Primary data analyses will take place immediately on completion of data collection.

9.0 Inclusion and Exclusion Criteria:

Inclusion criteria:

1. Adults age 18+years
2. Speak English as their primary language
3. Normal or corrected-to-normal vision
4. Sensorineural hearing loss with pure-tone thresholds 20-85 dB HL at octave frequencies between 500 and 3000 Hz

Current hearing aid wearer with at least 3 months of experience

Exclusion criteria:

1. Clinically significant unstable or progressive medical conditions, or conditions which, in the opinion of the investigator places the participant at unacceptable risk if he or she were to participate in the study
2. Participants who do not pass a cognitive screening test (e.g., MoCA, MMSE or DRS-2)

3. Significant history of otologic or neurologic disorders
4. Conductive hearing loss pathology or fluctuating hearing loss

   No special populations will be enrolled in the study (e.g.: Adults unable to consent, minors, pregnant women or prisoners).

10.0 Sample Size:

Northwestern plans to enroll 40 total participants.

11.0 Research Locations:

All study tasks will take place in the Hearing Aid Lab, Northwestern's Center for Audiology, Speech, Language and Learning, or the School of Communications office suite in Abbot Hall located on Northwestern's downtown campus.

When testing in the Hearing Aid Lab, Frances Searle building room 1-451, we will either use the sound booth or lab space. All hearing related tasks take place in a sound booth which is a sound treated 8'x 8' room within the larger lab space. When taking histories or cognitive measures we will use the office space located within the lab or an additional nearby (i.e. same building) testing room. The additional test room is only used if participant confidentiality can be maintained (i.e. conversation is not audible to those outside the room). When using the Center for Audiology, Speech, Language and Learning all tasks will take place in a sound proof booth, in a clinical Hearing Aid fit room, or the virtual sound environment (ViSoR). ViSoR is a 16' by 14' by 9' space capable of simulating the acoustics and background noise properties of any environment by using an array of speakers. When using the Abbot Hall location, testing will take place in the testing suite #1700 which has been sound treated and is currently in use for clinical studies. Participants will be given the option to schedule appointments at the location of their choosing except for the final appointment. The final appointment must take place at the Evanston location due to equipment requirements.

12.0 Multiple sites:

N/A

13.0 Reliance Agreements/Single IRB:

N/A

14.0 Incomplete Disclosure or Deception:

N/A

15.0 Recruitment Methods:

Participants will be recruited from a variety of sources.

1. A within-laboratory participant pool of prospective participants aged 18 to 96 years has been established by the PI.
2. Flyers posted around Northwestern University's campus, off-campus community bulletin boards, and relevant online communities/message boards.
3. Northwestern University Audiology Clinic. We plan to recruit older listeners with hearing loss who seek clinical care to obtain new hearing aids. Clinicians will receive a set of participant criteria. All patients seen for clinic appointments that meet the criteria and plan to be fit with one of the hearing aids predetermined to be of relevance to this study will be offered participation in the study.
4. Local senior centers, and local chapters of the Hearing Loss Association (HLAA).
5. Communication Research Registry: The Communication Research Registry is a confidential database for individuals and families who would like to continue participating in research housed within Northwestern University's School of Communication. These individuals sign up with the intention of being contacted for various research studies centered on human communication and development.
6. Local newspaper advertisements.

16.0 Consent Process:

Prior to enrollment, potential participants will have a hearing and cognitive test with authorization by a screening consent form. These tests will allow us to exclude potential participants from enrolling in the study who are ineligible based upon their hearing or cognitive status. These 45-minute tests are built into the study design of visit 1 tasks and do not require additional visits. If a participant is not eligible to participate based upon the screening consent, they can authorize future contact with the consent's optional element and authorize the lab to retain the screening audiogram. If participant is eligible based upon their screening results, they will be enrolled in the study with separate consent. Some participants recruited from our participant database may have already passed the eligibility screening assessments and indicated their wish to be considered for other studies may be contacted. Should these participants decide this study is of interest to them, they will not need to repeat these measures and will proceed to the full consent form. All participants will provide their consent to study procedures to the investigator or her research assistants. This process will take place in the Hearing Aid Laboratory, prior to any research procedure taking place. All consent forms are stored in a locked file cabinet drawer within the Hearing Aid lab (a locked laboratory). An unlimited amount of time will be provided to the participant to ensure they have adequately reviewed the consent form and all questions have been addressed by study staff. Following the participant's opportunity to read the consent document, study staff will review each section with participant to clarify the study or any procedure and ensure understanding. Additionally, consent forms may be provided to a potential research participant before a study visit is scheduled so they may take extra time to review before committing to participation. All participants will receive a copy of their signed consent form. We will give participants the option of being audio and/or video recorded during this experiment (for both screening and data collection). The objective of this recording is to be able to have internal lab staff reliability discussions to ensure test reliability and accuracy. When recorded, participant anonymity will be maintained (i.e. name is not being said, face is not recorded, hands are being recorded if possible). Participants will

document on the consent forms whether or not they agree to being recorded, or if recording is not applicable for a specific experiment. Recordings will be kept and used for lab staff only and will be destroyed once data analysis is complete.

17.0 Financial Compensation:

Upon completion of study tasks, participants will be paid an hourly rate for participation ($15/hr). Payment will be made in cash at the conclusion of each study visit. If a subject decides to withdraw from the study before its completion, s/he will still be paid $15 per hour for the time spent. In the event that a participant is removed from the study without their consent, compensation will be pro-rated based upon the duration the participant remained compliant with study tasks and procedures. Participants who remain enrolled through the entire duration of the study will receive a $50 completion bonus.

18.0 Audio/Video Recording/Photography

We will give participants the option of declining to being audio recorded during this experiment (for data collection). The objective of this audio recording is to be able to have internal lab staff reliability discussions to ensure test reliability and accuracy. When recorded, participant anonymity will be maintained (i.e. name is not being said, filename is de-identified). Participants will document on the consent forms whether or not they agree to being recorded, or if recording is not applicable for a specific experiment. Recordings will be kept and used for lab staff only and will be destroyed once data analysis is complete.

19.0 Potential Benefits to Participants:

Although participants in this study may not directly benefit from participation, many people are attracted to hearing aid research as an opportunity to learn about their hearing and ask questions about hearing aids and assistive listening devices (such as a remote microphone) without sales pressure. Participants who had been unaware of remote microphones or unsure if they would benefit may find the study helps them determine if it is something they would like to pursue with their hearing health provider. All participants in the study will have the opportunity to receive counseling at the end of the study, done by the investigator, including listening recommendations tailored to their individual speech understanding, memory and attention. They will have a chance to ask questions and receive information about options for their hearing loss (outside of the study).

20.0 Risks to Participants:

All study procedures pose minimal risk to study participants. Some of the study tasks can be boring, or repetitive. If a participant wishes to discontinue testing at any point they may choose to do so without any consequence. Additionally, listeners who receive poor scores on the attention and memory tests may be disappointed to learn of their performance. There is a possibility that some people may find some of the questionnaires uncomfortable. Participants will be told they do not need to answer any question or questions that make them uncomfortable. Participants will not be removed from the study

for declining to answer part of all of the questionnaires. Some participants may find the hearing aid settings used in this study to be loud or sharp in comparison to their own hearing aid settings. These are all normal and expected consequences of new hearing aids.

If an earmold impression is taken, participants may experience some temporary discomfort or a ticklish feeling as the cotton or foam block is placed into the ear canal. Participants may also notice that the impression material is slightly cold, or experience a feeling of pressure while the impression material is in your ear. Rarely, there can be some minor abrasions to the skin of the ear canal. These procedures are routinely used when fitting hearing aids or creating custom earplugs and the risks in this study are no higher than the risks that would be experienced in an audiology clinic.

If the investigator determines participation in the study places a subject at an unacceptable level of risk, enrollment or study tasks will not proceed.

If a research participant decides to withdraw or discontinue study procedures all data collected up to that point can be used by the investigator unless the participant indicates they would like to have their data removed from the study. Once a participant is unable to continue with the study, compensation will end.

21.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

During the consent process a lab member will explain that their identifiable information will not be used. Each participant will receive a study code that will be used for all study data. The only link between identifiable data and a study code will be on a password protected HIPAA-approved server with server security managed by Northwestern School of Communication computer staff. Any physical data containing identifiable participant information (i.e. consent documents) are kept under lock and key accessible only by study staff.

22.0 Data Monitoring Plan to Ensure the Safety of Participants:

N/A

23.0 Data, and if applicable, Specimen Banking:

N/A

24.0 Data Sharing:

This project is funded by Sonova and data may be shared with their research staff for the purposes of developing better fitting protocols for remote microphones. Any data shared will be de-identified. Physical files in our lab are kept in a locked filing cabinet. Any data stored electronically is de-identified.

25.0 Qualifications of Research Team to Conduct the Research:

The Principle Investigator, Pamela Souza, PhD, CCC-A, FAAA, is a licensed audiologist and an experienced researcher at Northwestern University. Kendra Marks, Au.D., is a licensed audiologist with clinical and research experience.