Protocol 00041124: Assessment of e-Audiology for providing clinical services and support

Background and Rationale

Hearing loss is a chronic disability and a major public health concern. As the U.S. population ages, hearing loss prevalence rates are expected to nearly double by 2060 (Goman, Reed et al. 2017). Given this projection and the negative, costly impacts of untreated hearing loss on health outcomes, there is a national emphasis on increasing access and affordability of hearing healthcare (HHC) (President's Council of Advisors on Science and Technology 2015, National Academies of Sciences 2016). Two significant factors hinder the achievement of successful HHC outcomes: First, US adults face structural barriers to accessing HHC including high cost, and limited, inflexible points of entry into the system (National Academies of Sciences 2016). Second, hearing aids are often the sole intervention offered. While hearing aids improve speech understanding in quiet, difficulties understanding speech in challenging listening environments remain. Many of these difficulties can be addressed by including hearing assistive technology [HAT] options in the intervention plan. Unfortunately, hearing aid uptake is low for adults with hearing loss, and HAT usage is reported among only a fraction of those who use hearing aids (Southall, Gagné et al. 2009, Hartley, Rochtchina et al. 2010, Chien and Lin 2012, Bainbridge and Ramachandran 2014). Technological advances in hearing aids and telecommunications, including the widespread availability of "e-Audiology" applications, have the potential to expand both access and affordability of HHC by allowing for greater flexibility, lower costs, and personalized intervention plans that take into account the listening and lifestyle needs of the individual. There is a lack of evidence, however, as to how e-Audiology and patient acceptance for e-Audiology impact HHC outcomes. There is an urgent need to understand the efficacy of accessible, patient-centered, and comprehensive HHC alternative delivery models, like e-Audiology, without which the critical public health problem of untreated hearing loss in adults will likely worsen.

With the long-term goal of enhancing decision-making by patients and providers and improving outcomes, the pilot data collected in this proposal will be used for an upcoming R01 submission which will be responsive to the NIDCD's call for research comparing different HHC delivery models and the utilization of new technologies to improve care. The overall objectives of this work are twofold. First, we will evaluate outcomes from an e-Audiology service delivery model. Second, we will determine the impact of patient preferences for delivery model on outcomes. The rationale of the proposed study is that the results will enhance the evidence-base for the use of e-Audiology as a mechanism for increasing HHC access for diverse adult populations. Results obtained will be submitted as pilot data in an upcoming R01 grant application

Research Objectives, Questions, and Hypotheses

The primary research questions, objectives, and associated hypotheses of this research are as follows:

- Research Question: For older adults who receive hearing aid services via an e-Audiology delivery model, what are the hearing-related outcomes in terms of real ear aided responses, speech understanding in noise, average hours of daily use, and self-perceived hearing handicap? Objective #1. Assess outcomes for adults who receive hearing aid related services and support via an e-Audiology delivery model. The working hypothesis is that both subjective self-report and objective outcomes will be similar to published norms.

- Research Question: What are the preferences for audiology service delivery among older adults and what is the patient's satisfaction with an e-Audiology model for hearing aid-related services? Objective #2. Assess patient satisfaction and preferences related to e-Audiology service delivery. The working hypothesis is that preference will impact outcomes, with those who prefer an e-Audiology model having better outcomes than those who prefer an in-office model.

Study Design

This study is designed as a pilot. We plan to use a quasi-experimental, single-group, pre/post design to assess outcomes before the initial hearing aid fitting and after the 6-week study period.

Sample size

The anticipated number of older adults evaluated for participation in the study is 20 with the goal of 10 participants completing the study. It is anticipated that some participants who are enrolled will not meet the audiometric inclusion criteria.

Study Population

Inclusion criteria are as follows:

- Aged 70 years or older
- Community-dwelling
- Can speak and read English fluently, assessed by self-report
- Mild to severe sloping hearing loss, as determined by a 4-frequency pure-tone average (0.5 to 4.0 kHz) of > 30 dB HL in the better ear and no greater than 90 dB at any frequency
- Cognitively intact, as determined by a Mini-Mental State Exam (MMSE) score ≥ 23 for individuals with high-school degree or less; Mini-Mental State Exam (MMSE) score ≥ 25 for individuals with some college or more
- Regular access to computer, tablet, or "smart device" capable of delivering the e-Audiology platform (Phonak's Remote Support)

Exclusion criteria are as follows:

- Bilateral conductive hearing loss, defined as a > 10 dB air-bone gap at 2 or more frequencies
- Corrected vision no worse than 20/40, assessed by the MN Read Acuity vision screening card
- Unwillingness to use hearing aids on a daily basis, determined by self-report

The Expected Results of the Research

The results of this research will be submitted as pilot data in an upcoming R01 grant application.

Principle Investigator

The PI of this pilot study is:

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Potential Risks to the Participants

Potential risks to participants in this study are minimal. There is a slight risk of boredom, anxiety, or fatigue associated with complete the questionnaires, hearing testing, hearing aid fitting, and/or follow-up hearing aid e-Audiology sessions. These risks will be offset by offering breaks between tasks as needed. All of the test measures in this study are used routinely in clinical practice by audiologists and psychologists for assessing the hearing and cognitive status of clinical and research participants.

Sounds presented to participants are not harmful and are used routinely in clinical evaluations. The hearing aid device evaluation and fitting procedures are standard protocols used routinely by the staff research audiologists. All hearing evaluations involve an otoscopic examination which involves the use of an otoscope (i.e., ear flash light) with a disposable speculum that is inserted partially into the ear canal for visual inspection. All hearing aids will be behind-the-ear models fitted with small, non-custom plastic tips that are inserted into the ear canal while the device is being worn. The hearing aids are digital devices that will be programmed to the audibility needs of each participant, according to standard clinical practice procedures.

Study Procedures

- Measures
    - *Mini Mental State Exam (MMSE*) : The MMSE is a brief cognitive screening tool that will be used to determine whether participants are cognitively-intact according to the inclusion criteria.
    - *Vision assessment*. The University of Minnesota Read Acuity (MN Read) Card will be used to assess visual acuity in conditions of high contrast and luminance. The MN Read will be used to determine whether participants meet inclusion criteria for corrected vision.
    - *Demographic Characteristics*: A simple questionnaire will be used to obtain participants' demographic information
    - *Degree of hearing impairment.* All participants will undergo an audiometric evaluation consisting of measurement of pure tone sensitivity using American Speech-Language-Hearing Association (2018) guidelines. Understanding of speech in noise will also be assessed using the Quick Speech in Noise (QuickSIN; Killion, Niquette et al. (2003) in which participants repeat sentences presented at six signal-to-noise ratios (SNRs) and the 'SNR loss' is computed. The SNR loss is the dB SNR relative to the SNR required for normal hearing individuals to repeat back 50% of the key words correctly.
    - *Self-reported hearing difficulties*. The Hearing Handicap Inventory for the Elderly Screening (HHIE-S) (Ventry and Weinstein 1982, Newman and Weinstein 1988) will be used to measure self-reported hearing difficulties.
    - *International Outcome Inventory for Hearing Aids and Other Interventions (ioi-HA).* The IOI-HA is a brief, 7-item measure that will be used to measure hearing aid benefits following a sustained period of use (6 weeks or more).

- *Real-ear acoustic responses (REAR) of hearing aid performance*: REARs will be measured using the AudioScan Verifit II hearing aid analyzer to determine how close responses are to NAL-NL2 prescriptive targets
- *Telehealth Acceptance Questionnaire (TAQ)*. (Wade, Cartwright et al. 2012). The TAQ is based on the Technology Acceptance Model, and will be used to assess participants' attitudes about telehealth as well as their beliefs regarding self-efficacy for telehealth use.
- *Client-oriented Scale of Improvement (COSI)* (Dillon, James et al. 1997) – The COSI is a self-report tool used to determine effectiveness of hearing aid intervention based on the user's own goals.
- *Average hourly hearing aid and HAT use*: Annual device usage will be tracked using the hearing device data logging software.
- *Patient satisfaction with service delivery*: Patient satisfaction with service delivery will be assessed after each e-Audiology session using the Visit Specific Satisfaction Instrument (VSQ-9) (Association AMG).
- *Semi-structured interview.* Participants will take part in a semi-structured interview at the end of the study. We will be asking questions regarding: (1) the participant's perceptions regarding e-Audiology services (2) Preferences for in-office vs. telehealth appointments in general

- Intervention. Participants will receive bilateral, behind-the-ear hearing aids as part of this study. The intervention will involve e-Audiology sessions following the initial hearing aid fitting and orientation. E-Audiology sessions will consist of hearing aid follow-up programming, troubleshooting, HAT assistance, and general help with hearing devices. E-Audiology sessions will take place over the course of approximately 6 weeks.
- Study Visits
  - Baseline visit: At the time of the baseline visit, participants will undergo the informed consent process and complete measures to determine whether they meet inclusion criteria (MoCA, SKILL, unaided HHIE-S, Audiometric assessment, demographic intake). For those who continue onto enrollment, the next step will be to complete hearing aid fitting, device orientation and use counseling, and completion of the COSI.
  - Follow-Up visits (e-Audiology sessions): Follow-up visits will take place at regularly-scheduled, 2-week intervals following the baseline visit over the course of 6 weeks, or as needed by the participant. E-Audiology sessions will consist of hearing aid follow-up programming, troubleshooting, and general help with hearing devices. Data logging and VSQ-9 data will be collected after each e-Audiology session.
  - Outcomes assessment visit: Participants will return to the laboratory setting to complete the outcomes assessment visit approximately 6 weeks following the baseline visit. Outcomes assessments will include: REARs, average hourly hearing aid use, aided QuickSIN testing, COSI outcomes, aided HHIE-S outcomes, and the semi-structured exit interview.
- Data Analysis. As this is a pilot study, the majority of results will be analyzed descriptively. When possible, non-parametric analyses will be conducted to determine differences pre/post baseline hearing aid fitting for the HHIE-S, QuickSIN, and COSI.

Potential Benefits to Participants

The protocol offers several benefits to participants, including a comprehensive audiometric evaluation, state-of-the-art hearing technology, and communication strategies training free of charge. Participants will be informed of the results of evaluations and will have the opportunity to ask questions about those results. Participants will be referred to other professionals for additional evaluation or treatment as necessary. Ultimately, this study may also benefit the public at large by helping to determine efficient delivery of hearing rehabilitative intervention that leads to improved communication abilities for hearing-impaired older adults.

Human Subjects Considerations

- Informed Consent Process: Written consent will be obtained from all participants. Participants who express an interest in participating will be provided a copy of the consent form prior to the first visit, either by U.S. mail or in person, and instructed to carefully review the consent form before the study visit. Upon arrival at the study visit, the investigator will describe the purpose of the informed consent and will ask if there are any questions about informed consent. The investigator will then briefly review information contained in the informed consent form and the voluntary nature of participation will be explained and emphasized. The investigator will ask the potential participant several questions such as naming potential risks of participating in the study, the number of visits in the study, and what the patient should do if they experience any problems during the study. The participant must be alert, able to communicate, able to understand information about the research, make a decision based upon the information, and give informed consent. If there is any indication that the participant does not comprehend the consent information following any clarification that has been made, participation will not be allowed. Following review, the investigator will ask if there are any other questions and will allow the subject to sign the informed consent if they so choose. No participants considered to be Vulnerable Subjects will be enrolled.
- Privacy and confidentiality: All participants will have a participant number assigned at the time of their initial laboratory participation. All data for each participant will be coded with this number. Patient intake forms with PHI will be stored separately from the participant files with the signed informed consent documents. Any original results in paper form will be stored in a file folder marked with the subject participation number on the outside. All data will be stored within that folder, including the results from the audiometric evaluation and score sheets from speech and non-speech auditory perceptual tasks. Subject folders will be stored in a locked file cabinet in the laboratory, PCD 1003, 4202 E. Fowler Ave., University of South Florida. Access to the data will be restricted to laboratory staff approved by this IRB. All electronic data will be stored on a secure server at USF. The research team will make every effort to protect participant information and guard against any loss of privacy.
    - COVID-19 contingency plan: Participants with remaining remote sessions scheduled will be seen using the same telehealth technology. An ARCT lab member who is IRB approved will conduct these sessions using a USF laptop in a private room of their own home. Participants will be notified of these changes via written correspondence (can be seen in "Other Site Documents" section of the IRB application), and will be allowed to suspend their final remote visit until the risk of COVID-19 is significantly reduced. In the event a participant opts to suspend their final visit, an RNI Smartform for protocol deviation will be submitted to the IRB within 5 business days of the event.

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> Hearing impairment in older adults is associated with psychological and social difficulties. The goal of hearing aid fitting is to reduce the perceived handicap resulting from the hearing loss. Measures of self-perceived handicap are being increasingly incorporated into the clinicians armamentarium as an objective measure of the outcome of intervention. Eighteen elderly hearing-impaired males and their spouses responded to the Hearing Handicap Inventory for the Elderly (HHIE) prior to and following 1 year of hearing aid provision. Our findings revealed a significant reduction in the perceived emotional and social effects of hearing impairment following 1 year of hearing aid use. The reduction in perceived handicap, as measured using the

HHIE, was greater for the hearing aid users than for their spouses. The findings attest to the construct validity of the HHIE as a measure of hearing aid benefit.

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