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Factors Related to Self-Identification of Candidacy, Device Selection, and Self-Fitting of Over-The-Counter Hearing Aids

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Abstract

Purpose: The Over-The-Counter (OTC) Hearing Aid Act was introduced in an effort to make hearing aids more accessible and affordable. Implementation of this law will go into effect in 2020. It is assumed that the average consumer will be able to self-navigate an OTC hearing aid fitting. In the OTC hearing aid model consumers are expected to self-diagnose, self-treat, and self manage their hearing loss. The purpose of the present study was to assess how well the average consumer can perform each step in the OTC hearing aid model, and identify factors related to self-identification of candidacy, device selection, and self-fitting of an OTC hearing aid.

Method*:* Participants included 52 adults who were 40 years of age and older, self-reported having trouble hearing and were interested in trying an OTC hearing aid. They had to have owned a smartphone and had no prior hearing aid experience. Data was collected over two tests sessions. During the first session all participants were asked to report their degree of hearing loss, identify if they thought they were at risk for having ear disease, and completed questionnaires related to demographics, health literacy, hearing aid self-efficacy, health locus of control, and technology commitment and usage. Also, participants completed three cognitive tasks and were given a hearing test and administered three cognitive measures: the Reading-SPAN, Digit Symbol Substitution Task, and the Simon task. During the second test session participants were asked to browse three different OTC hearing aids online and select the device they preferred. They were asked to complete a questionnaire regarding potential reasons for why they selected a particular device. The OTC hearing aid they selected was given in its original packaging, and participants were asked to set the device up without any assistance. The Practical Hearing Aid Skills Test- Revised (PHAST-R) along with three questions related to Bluetooth connectivity was used to evaluate the participants' hearing aid handling skills. Real-ear verification was performed to assess how closely the participant's settings were to NAL-NL2 prescriptive targets. Last, participants completed the Consumer Ear Disease Risk Assessment (CEDRA) to determine if participants correctly self-identified the risk for ear-disease.

Results: Only 38% of participants were able to correctly classify their hearing status in both ears, with pure tone average being a significant predictor of correct hearing status classification. A majority of the participants who misclassified their hearing status had normal hearing, but self-reported they had a hearing loss. Eighty-eight percent of the participants who were identified for being at risk for ear disease misclassified their risk for ear disease. Years of education was inversely related to correctly self-identifying risk for ear disease. Sixty percent of the participants who were flagged by the CEDRA and 30% of normal-hearing participants indicated that they would purchase an OTC hearing aid at the end of the study. Participants' scores ranged from 45-100% on the PHAST-R and Bluetooth connectivity assessment. The type of the manufacturer's instructional material was significantly associated with participants' hearing aid and Bluetooth connectivity skills. For the normal-hearing participants all of the OTC devices attenuated speech, and none of the devices met NAL-NL2 targets in the high frequencies for the hearing-impaired participants. Income status and technology commitment was not predictive of OTC hearing aid device selection and all participants ranked 'easy to read descriptions' and 'website appearance' as the main factors that influenced their decision to select a device.

***Conclusions*:** Most participants were unable to successfully navigate all of the steps in the OTC hearing aid model. Some of the participants who had normal hearing but self-reported a hearing loss and the participants who were at risk for ear disease said they would purchase an OTC hearing aid as a treatment option. Unfortunately, both groups are not the intended user of an

OTC hearing aid. Manufacturer instructional material can impact set up and programming of an OTC device. However, users may still run into fitting and programming challenges that will require the assistance of a hearing health care professional.

FACTORS RELATED TO SELF-IDENTIFICATION OF CANDIDACY, DEVICE SELECTION, AND SELF-FITTING OF OVER-THE-COUNTER HEARING AIDS

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LITERATURE REVIEW

It is estimated that 37.5 million adults in the United States have some degree of hearing difficulty (Blackwell, Lucas, & Clark, 2014). Of these adults, 25% who are between 65 and 74 years old, and 50% of those who are 75 years and older, have a disabling hearing loss (NIDCD, 2016). With this large prevalence in the population, hearing impairment is an important public health issue that requires appropriate diagnosis and treatment. Age related hearing loss (ARHL), also known as presbycusis, is the gradual deterioration of the auditory system over an individual's lifetime. It typically results in a permanent high frequency hearing loss. Although ARHL is commonly accepted as a normal part of aging, untreated ARHL has been shown to impact cognitive function, balance, quality of life and unemployment (Amieva et al., 2015; Gurgel et al., 2014; Jiam, Li, & Agrawal, 2014; Mick, Kawachi, & Lin, 2014; Hjalte, Brannstrom, & Gerdtham, 2012; Jung & Bhattacharyya, 2012; Lin & Ferrucci, 2012; Kochkin, 2010; Lin et al., 2011; Gopinath et al., 2009; Arlinger, 2003; Lin, 2001; NCOA, 1999)

It is predicted that by 2026, 30% of the population will be above the age of 55, and 18% of the population will be above the age of 65 (Donahue, Dubno, & Beck, 2010). Given that age is one of the strongest predictors of hearing impairment in adults aged 20 to 69 years old (NIDCD, 2016), this shift in the US population's demographic suggests that there will be a greater number of adults who will suffer from hearing loss. In fact, it is predicted that the number of individuals suffering from hearing loss will double by 2060 (Goman, Reed, & Lin, Addressing Estimated Hearing Loss in Adults in 2060, 2017).

Despite the large number of individuals who have hearing loss, hearing aid uptake remains low. It is estimated that only 30% of hearing aid candidates purchase hearing devices, and only 76% of hearing aid owners actually use them (Nash et al, 2013; Hartley et al., 2010).

Also, it takes approximately 10 years for an individual with hearing loss to seek professional help. The average age of a person with hearing loss seeks help at a hearing clinic for the first-time is approximately 70 years of age (Davis et al, 2007).

The Over-the-Counter Hearing Aid Act

In 2017, the Over-the-Counter (OTC) Hearing aid Act was passed to make a new category of hearing devices that would be available for consumer purchase. The purpose was to make hearing aids more accessible and affordable to the public. The OTC Hearing Aid Act will allow adults 18 years of age and older, and who have a mild-to-moderate hearing loss to purchase OTC hearing aids, also sometimes referred to as self-fitting hearing aids. Individuals will be able to purchase OTC hearing aids without being seen by a hearing health care professional. By the year 2020, the Food and Drug Administration (FDA) is to establish standardized requirements for OTC hearing aids that are consistent with other medical devices (i.e. labeling, safety, and manufacturer protection). Until then it is illegal to sell hearing devices labeled as an OTC hearing aid.

The primary treatment used for people with hearing loss is a hearing aid. Currently, hearing aids are classified as medical devices by the FDA, and can only be purchased through a licensed hearing aid dispenser or audiologist. Audiologists and hearing aid dispensers customize digital hearing aids to compensate for the individual’s specific degree and configuration of hearing loss. In addition, clinicians can create hearing aid programs to meet the patient’s specific communication needs. Hearing aids are not the only technology available to the hearing impaired population to help improve their hearing. These devices are often referred to as Personal Sound Amplification Products (PSAPS). PSAPS are considered non-medical devices that are advertised to help consumers hear sounds that are at a low volume or at a distance (FDA, 2018). These devices come in a wide range of amplification capabilities. Basic level PSAP devices can include pre-set programs with each successive program increasing amplification, while high end PSAPs can include an automatic hearing test that is utilized to create personalized fittings (Convery, 2017). In 2009, the FDA provided guidelines to consumers to help differentiate between approved medical hearing devices (i.e. hearing aids) and PSAPs. The guidelines indicate that only hearing aids are designed to help compensate for hearing loss, while PSAPs are intended for normal hearing individuals who require sounds to be amplified for various reasons (i.e. hunting, bird watching). Given this definition, it is confusing why some PSAPS include advance-fitting features like an automatic hearing test, and also function similarly to digital hearing aids that are purchased through a hearing healthcare provider.

With the new OTC legislation, it is anticipated that much of the current PSAP technology will be integrated into the new category of OTC hearing aids. Hearing devices with OTC labeling will be able to advertise that they are intended to correct for hearing impairment, much like hearing aids dispensed through a hearing healthcare provider (Hearing Care Associations, 2018; President's Council of Advisory on Science and Technology [PCAST], 2015; Strom, 2018). OTC hearing aids will be available for purchase online, in stores, or by mail order. The goal of the new OTC legislation is to increase the low use of hearing aids, and therefore decrease the negative impact of untreated hearing loss (PCAST, 2015). The challenge will be for the average consumer to be able to select and fit an OTC hearing aid on their own, which the FDA assumes they will be able to do. The new OTC legislation has the potential to improve hearing healthcare by making hearing aids more accessible.

Factors that Limit Hearing Aid Adoption

Reasons for non-adoption of hearing aids are quite extensive, with the literature suggesting that a lack of technological experience, geographical limitations, the current cost of hearing aids, and milder degrees of hearing loss can prevent individuals from seeking traditional hearing aids (Tahden et al., 2018; Barnett et al., 2017; Chan et al., 2017; Goman & Lin, 2016; McCormack & Fortnum, 2013; Baernholdt et al., 2012; Jenstad & Moon, 2011; Gonsalves and Pichora-Fuller, 2008; Kochkin, 2007).

Technology

Although there have been great advancements in hearing aid technology, there is research to suggest that non-users do not necessarily take advantage of the communication technologies offered to them. Particularly, older adults may not be able to adapt easily to technological changes, even though this is the population who will likely benefit the most from them (Czaja, 2006). In a study completed by Gonsalves and Pichora-Fuller (2008), the authors investigated how hearing loss, and hearing aid status was related to being able to use common communication technologies. In this study, communication technologies are any piece of technology that allows for communication (i.e. telephone, pager, fax, radio, computer, email, internet). The authors included 135 adults, who were over the age of 65 years old. In their study 82 participants had normal hearing, 28 had corrected hearing loss, and 25 had uncorrected hearing loss. The results showed that hearing aid non-users did not use newer communication technologies (i.e. computers, cellphones, e-mail) as much as those with normal hearing or corrected hearing loss (Gonsalves & Pichora-Fuller, 2008). These findings suggest that there may be some difficulty encouraging individuals with uncorrected hearing loss to pursue new and more advanced communication technologies.

Tahden et al., (2018) reported similar findings of lower technology use among hearing aid non-users. The authors investigated how hearing aid users and non-users differed on measures of hearing, cognition, health status, economic status, and technological commitment. Their second objective was to determine if these variables predicted hearing aid status (user or non-users). They included 595 participants who were over the age of 60 years old from the Horzentrum Oldenburg GmbH database in Germany. All participants were matched for age, sex and pure-tone average. Results showed that the hearing aid non-users self-reported better hearing, had a poorer technology commitment score, and had a lower socioeconomic status compared to the hearing aid users (Tahden et al., 2018). Furthermore, self-reported hearing status, technology commitment scores, and socioeconomic status were also the best predictors for determining hearing aid use status (Tahden et al., 2018).

Rural Populations

Geographical limitations imposed on individuals who live in rural America can act as a barrier to hearing healthcare access. Approximately 20% of the US population lives in rural America (United States Census Bureau, 2016), where there is a recognized shortage of hearing health care specialist available (Barnett et al., 2017). Also, patients living in Rural America are more likely to be poorer, older, and in poorer health compared to those who live in urban areas (Barnett et al., 2017; Rural Health Information Hub, 2019). In fact, individuals living in rural America are twice as likely to have hearing loss and are more likely to be socially isolated than those who live in more populated areas (Barnett et al., 2017; Chan et al., 2017; Baernholdt et al., 2012). In a systematic review completed by Barnett et al., (2017), the authors noted that patients in rural America reported a number of barriers to obtaining hearing health care, some of which included: issues with transportation, limited hearing health care supply, lack of quality of care, and financial challenges.

In a study by Chan et al. (2017), the authors investigated if there was a difference in hearing aid acquisition time for individuals who lived in rural versus urban areas. The authors surveyed 336 participants over a four-year period. The survey included questions about demographic information, socioeconomic status, hearing aid status, and self-reported information about hearing aid acquisition. They found that the onset time between hearing loss diagnosis and hearing aid acquisition was significantly longer for those who lived in rural areas (time = 10.9 years) versus those who lived in urban areas (time = 7.9 years) (Chan et al., 2017). Furthermore, the authors also investigated if those who lived in rural areas had longer driving times to their closest hearing specialist. The results showed that those who lived in rural areas had to drive significantly longer (mean= 68 minutes) to their closest hearing specialist, compared to those in urban areas (mean= 32 minutes) (2017). They also reported a positive correlation between hearing aid acquisition time and distance to their closest audiologist (2017). These findings suggest OTC hearing aids could improve some of the barriers for accessing hearing health care in rural areas.

Cost

Financial limitations have been reported in several studies as a major barrier to hearing aid access (Barnett et al., 2017; McCormack & Fortnum, 2013; Jenstad & Moon, 2011; Kochkin, 2007). It is estimated that hearing aids can cost a patient anywhere from $1,800 to $6,800 for a pair of hearing aids, which is typically a bundled cost that includes: the device, hearing specialists' services such as fitting and follow-up appointments, repairs, and warranty coverage

(Blustein & Weinstein, 2016; PCAST, 2015). Hearing aids on average have a life span of 5-7 years, with the recommendation to change devices when there are significant advancements in technology or a significant change in hearing loss or hearing needs. The average hearing aid user will most likely obtain two to three sets of hearing aids over their lifetime, which can add up to a significant cost for many patients.

The MarkeTrak VII report, which is a tracking survey of the hearing impaired population and the hearing aid market, surveyed 80,000 household to determine the primary reasons for the non-adoption of hearing aids (Kochkin, 2007). Based on the survey it was determined that 64% of participants could not afford hearing aids. Few insurance companies cover the cost of hearing aids, leaving patients to pay for these devices out of pocket (Blustein & Weinstein, 2016; PCAST, 2015). With 46 million Americas being uninsured and the median household income at $61,372 most families have limited disposable income (U.S. Census Bureau, 2017). As previously stated, if an individual purchases an average of three sets of hearing aids over their lifetime, many adults cannot prioritize the purchase of a hearing aid over other basic needs (i.e.. housing, food, medical bills).

Cost has been identified as a major barrier to hearing health care access in the USA, but interestingly there has been research to suggest that hearing aid uptake remains low even in countries with subsidized hearing health care (Laplante-Levesque, Hickson, & Worrald, 2012; Hartley et al, 2010). For example, Australia currently subsidizes the cost of hearing aids for its citizens. In a population-based survey completed by Hartley et al. (2010), the authors investigated the prevalence of hearing loss and usage of hearing aids in the Australian elderly population. The authors sampled 2,956 participants from the Blue Mountains Hearing Survey, who were between the ages of 49 and 99 years old. The results showed that 33% of the population surveyed had some form of hearing loss, with only 11% pursuing amplification. Of this 11%, 24% never used their hearing aid(s). Similarly, in the United Kingdom there is a subsidiary program for hearing aids coverage. In a cross-sectional study Sawyer et al. (2019), assessed hearing aid use among participants in the United Kingdom Biobank. Participants who were 40 to 69 years old with a hearing impairment (n= 18,730) were included in this study. The authors found that only 9.25% (n= 1732) of participants with hearing loss used their hearing aid(s) most of the time. Even among Americans who can afford hearing aids, continued use remains low. In a prospective cohort study completed by Nash et al. (2013), the authors investigated the prevalence of hearing aid use among participants in the Beaver Dam Offspring Study (Cruickshank & University of Wisconsin School of Medicine and Public Health, 2004). The study included a sample size of 3130 participants. Results showed that 12.8% of the participants reported they owned a hearing aid, but 41.3% of them did not use a hearing aid regularly. These findings speak to the complex nature of hearing aid uptake and use.

Mild Hearing Loss

Mild hearing loss is the most prevalent degree of hearing loss. Although individuals with mild hearing losses can benefit from a hearing aid (Ferguson et al., 2017), the challenge is that not all mild hearing loss patients want or believe they need hearing aids (Moller & Jespersen, 2013). For example, it is estimated that only 10% of patients with a mild hearing loss use a hearing aid (Hearing Industries Association, 2017; Kochkin, 2010). This is partially due to the fact that many hearing-impaired patients do not perceive themselves as having a hearing loss (Moller & Jespersen, 2013). In a cross-sectional analysis completed by Goman & Lin (2016), the authors utilized the National Health and Nutrition Examination Survey to estimate the severity-specific prevalence of hearing loss across different age groups (Goman & Lin, 2016). Data from 9684 participants, ages 12 and older, was used from the database between 2001 and 2004. In their study mild hearing loss was defined as 25 to 40 dB HL and moderate hearing loss was defined as 40 through 60 dB HL (World Health Organization, 2019). The results showed that mild hearing loss was the most prevalent degree of hearing loss in adults aged 12 to 79 years old, with moderate hearing loss being the most prevalent degree of hearing loss in older adults aged 80 years and older (Goman & Lin, 2016).

Another potential reason for the lack of hearing aid uptake for those with mild hearing loss is due to misinformation given by health care-professionals. The MarkeTrak VIII (2010) Report investigated factors related to purchasing a hearing aid. The authors sent a screening questionnaire to over 80,000 participants, and an additional 4,325 non-hearing aid users were given a detailed survey. The results showed that those with mild or moderate hearing loss were more likely to speak with their family doctors about their hearing issues, rather than an Otolaryngologists (ENT) or an audiologist. Furthermore, family doctors, ENTs, and audiologists were more likely to not recommend hearing aids for individuals with a mild hearing loss. That is, 31% of family doctors, 38% of ENTS, and 43% of audiologists recommended that their patient with mild hearing loss should wait or re-test their hearing in a year or more. Thus, some patients may be putting off their communication concerns because of the advice given by their healthcare providers.

Rationale for OTC Hearing Aid

The President's Council of Advisors on Science and Technology (PCAST) in 2015 identified cost as the biggest barrier to hearing aid technology adoption. The PCAST committee also highlighted that the current distribution channel of hearing loss treatment, which is purchasing a hearing aid through a licensed hearing aid dispenser, is a barrier to access (PCAST, 2015). Specifically, the council highlighted that the current practice of bundling the costs of both the hearing aid itself and professional services limits the ability for consumers to shop around for a product that they feel is worth the price (PCAST, 2015). Based on the results from this committee's investigations they recommended a classification of over-the-counter (OTC) hearing device that could be easily accessible by consumers (PCAST, 2015).

The PCAST rationale was to open the market for companies to develop an OTC-hearing aid designed for mild to moderate hearing losses, consistent with age-related changes in hearing. This would drive the overall cost of products down and allow for consumers to shop around for an OTC hearing aid that best fits their needs. The assumption being that the lower cost will result in an increase in hearing aid use (PCAST, 2015). To prevent barriers in accessing this new category of OTC devices, the committee also recommended that the FDA remove the required medical evaluation, or signed medical waiver of that evaluation, prior to obtaining hearing aids. Currently between 60 to 85% of patients forgo a medical evaluation and sign the medical waiver (PCSAT, 2015).

OTC Hearing Aid Model vs. Audiology Best Practice Model

The OTC hearing aid model assumes that the intended consumer of OTC hearing aids will be able to self-diagnose, self-treat, and self-manage their hearing loss (PCAST, 2015). The model begins with an individual who perceives a hearing loss and will need to decide which treatment approach is the most appropriate for their needs (i.e. working with an audiologist, physician, or searching online). If based on their own assessment they self-identify as an OTC hearing aid candidate, one of the avenues consumers may choose is to receive treatment is online. Their online search of products will require the individual to make an assessment about which device is the most suitable for them given their listening needs. After purchasing their self-selected device, they will then need to set up and program the device on their own. Figure 1 provides a summary of the OTC hearing aid model.

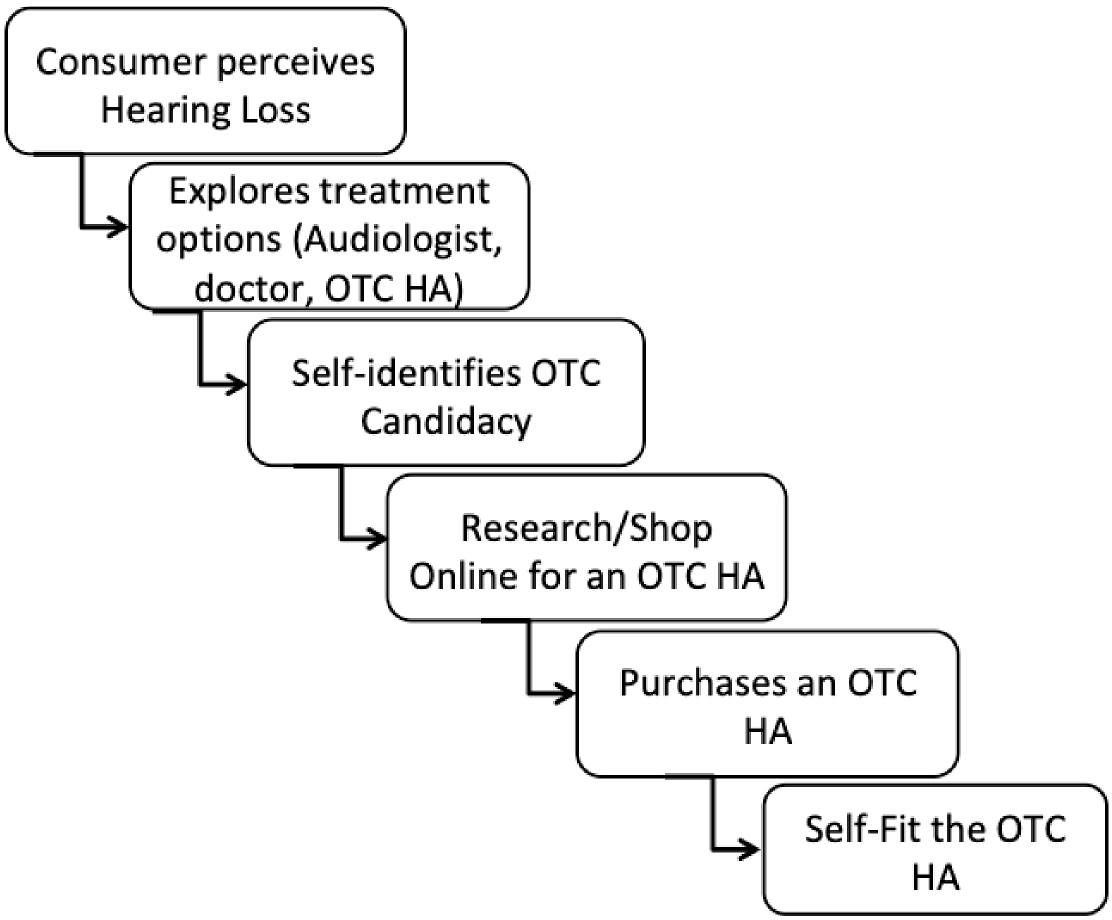


Figure 2: OTC Hearing Aid Model

Although the OTC hearing aid model is predicted to improve accessibility and affordability for individuals with hearing loss, there is limited evidence exploring whether or not this model ensures comprehensive care and treatment for those with hearing impairment. In contrast, the audiology best-practice model was developed and continues to evolve based on scientific evidence that has been published in peer-reviewed journals.

Evidence based practice is necessary for comprehensive care and treatment (American Academy of Audiology, 2015). The audiology best-practice model requires patients with suspected hearing loss to first have a diagnostic hearing evaluation. A diagnostic evaluation includes: a case history, otoscopy, tympanometry, air and bone pure tone audiometry, and audiometric speech testing. Once the evaluation is complete, patients are counseled on the results (type, configuration, degree, impact of hearing loss on everyday communication settings etc.) and a treatment plan is recommended. Patients are recommended a device based on the audiologist's clinical expertise, which requires an understanding of the differences in hearing aid style, output, and models to recommend a hearing aid that is most appropriate for the patient's hearing loss and communication needs. The recommended hearing aid(s) is fit based on the patient's audiogram and feedback provided by the patient. Hearing aid fittings are typically verified using a real-ear verification system, which measures the hearing aid gain in the ear canal. This critical measurement ensures that the hearing aids are fit accurately for the patient's hearing loss. Furthermore, audiologists counsel their patients on how to use and care for their devices. The audiology best-practice model also includes a 45-day trial period. During that trial period, both the audiologist and patient meet several times to discuss the patient's challenges and successes with their hearing aids. Programming adjustments are made by the clinician feels as needed. At the end of the trial period patients can choose to: purchase the device(s), trial another model of hearing aid, or return the device(s) all together.

Recently, Humes et al. (2017) investigated if an OTC hearing aid delivery model is as efficacious as current best-practice hearing aid fitting by a hearing healthcare specialist. They completed a randomized double-blind placebo-controlled study that investigated hearing aid outcomes based on two service delivery models: (1) audiology best practice hearing health care, and (2) OTC consumer decided model. One hundred and seventy three participants pre-screened for a mild to moderate hearing loss participated in this study. Participants were randomly assigned to one of the following intervention groups: audiology based (AB) best practice intervention, OTC consumer decide (CD) intervention, or a placebo intervention. Participants assigned to the CD intervention group were provided with three options of 'OTC-like' hearing aids, which were pre-programmed high-end hearing aids and were set to have output prescriptions that matched the three most common patterns of hearing loss. Participants in this group selected their desired hearing aid output, and were provided with an instructional video to assemble the hearing aid. Participants wore the hearing aids for approximately six weeks. Participants in the AB intervention group had significantly higher hearing aid benefit scores compared to both the CD and placebo intervention group. Also, participants in the AB intervention group had significantly better hearing aid satisfaction scores compared to both the CD and placebo intervention groups. These results suggest that the self-navigating OTC hearing aid model may not lead to optimal hearing aid outcomes.

OTC Hearing Aid Candidacy

The language in the OTC Hearing Aid Act recommends this category of devices for individuals who *perceive* their hearing loss to be mild-to-moderate in severity. Yet, previous research has demonstrated that individuals with hearing impairment are not good at self-identifying the degree of their hearing loss, and there have been several studies that have demonstrated discordance between self-perceived hearing difficulty and gold standard audiometric testing (Kamil et al, 2015; Kiely et al, 2011; Kim et al, 2017; Nondahl et al, 1998). It is estimated that concordance rates between self-reported hearing loss status and pure tone audiometric thresholds ranges from 43-81% (Kamil et al, 2015; Kiely et al, 2011; Kim et al, 2017; Nondahl et al, 1998). For example, Kamil et al., (2015) investigated if demographic factors were associated with the accuracy of self-reported hearing loss in older adults. They used the National Health and Nutrition Examination Survey (NHANES) cycles 1999-2006 and 2009-10, and examined audiometric thresholds for 3,557 participants (Pure tone average of 0.5, 1.0, 2.0, and 4.0 kHz), self-reported hearing status (i.e. excellent, good, a little trouble, a lot of trouble, and deaf), and demographic factors (i.e. age, gender, race, and education). They found that older adults (80 years old and older) were significantly less accurate in predicting their hearing loss status compared to younger adults (ages 50-59). Participants with higher education were significantly more accurate at predicting their degree of hearing loss. Interestingly, younger men and women were more likely to overestimate their hearing impairment, while older men and women were more likely to underestimate their hearing impairment.

Kim et al., (2017) investigated if participants could accurately predict their degree of hearing loss severity. The study utilized data of 19,642 participants from the Korea National Health and Nutrition Examination Survey (KNHANES) database. Participants of the KHANES database were asked to categorize their hearing loss status as one of the following: ‘I feel no difficulty’, ‘I feel some difficulty’, ‘I feel much difficulty’, and ‘I cannot hear’. For the purposes of the study, ‘I feel much difficulty’ and ‘I cannot hear’ were combined to form one group. The authors then equated the previously stated, self-reported hearing loss categories, to specific degrees of hearing loss, which were pure tone averages (PTA) of: < 25 dB HL, ≥25 dB HL and <40 dB HL, and ≥40 dB HL respectively. Results were described based on three categories:

concordance, over-estimation, and under-estimation. Concordance was defined as participants who accurately predicted their PTA, over-estimation was when participants self-reported hearing loss was higher than their PTA, and underestimation was defined as participants whose self-reported hearing loss was lower than their PTA. Results from the Kim et. al (2017) study indicates that of the participants with mild hearing loss 28.1% were in concordance, 5.8% of participants overestimated their hearing loss, and 66.1% underestimated their hearing loss. For participants with moderate-to-severe hearing loss 27.4% were in concordance and 72.5% underestimated their hearing loss (no one with moderate-to-severe hearing loss over-estimated their hearing loss).

In a follow-up study evaluating the efficacy of the OTC hearing aid delivery model (Humes, Kinney, Main, & Rogers, 2019), the authors assessed how not pre-screening their participants for age-related, mild-to-moderate hearing loss impacted their sample population. The authors found that 30% of the participants enrolled in their study had either too mild of a hearing loss, too severe of a hearing loss, or had a significant asymmetry. The findings from these studies suggest that the average consumer is not able to consistently self-identify the severity of their hearing loss. This could potentially result in those with greater degrees of hearing loss, or even those with normal hearing to purchase OTC hearing aids. Currently there is little known about consumers' ability to accurately self-report monaural versus binaural hearing loss.

These previous studies suggest that people are making an evaluation of their hearing status based on their perceived hearing difficulty in everyday situations. This is of concern as there has been research to suggest poor concordance between hearing threshold's and perceived hearing handicap. The International Classification of Impairment, Disabilities, and Handicaps, established by the World Health Organization, considers hearing handicap to be a combination of measurable dysfunction, and the auditory and non-auditory effects experienced by individuals in their everyday life (Granberg et al., 2014). Previous studies have shown that there is a weak correlation (approximately 0.3) between pure tone thresholds and hearing handicap scores (Newman et. al, 1990; Brainerd & Frankel, 1985).

More recent examples of this discordance between hearing thresholds and hearing handicap level are studies completed by Singh & Doherty (2020), and Alicea & Doherty (2017). Singh & Doherty (2020) reported that individuals who have normal hearing, but self-reported difficulty hearing in background noise, had significantly higher levels of hearing handicap compared to a group of clinically normal hearing, age-matched individuals who did not self-report having difficulty hearing in background noise. In another study, Alicea & Doherty (2017) found that individuals who had normal hearing, and self-reported difficulty hearing in background noise had hearing handicap levels that were equal to individuals who had a mild-to-moderate sensorineural hearing loss. Thus, an individual’s perception of how much they struggle in their everyday communication settings influences their self-reported degree of hearing loss. As a result, some people with normal hearing may purchase OTC hearing aids because they perceive they have a hearing loss.

The American Speech Language and Hearing Association (ASHA) defines a mild hearing loss as a range from 26 to 40 dB HL, and moderate hearing loss as a range from 41 to 50 dB HL (ASHA, 2019). Mild hearing losses typically result in reduced speech understanding in background noise, reduced audibility, and increased listening fatigue, while those with a moderate to severe hearing loss experience an added layer of difficulty due to decreased frequency and temporal resolution (Hearing Care Associations, 2018). With moderate degrees of hearing loss or higher, communication needs are more complex and individuals may need counseling and not just amplification alone (2018).

Last, the average consumer purchasing an OTC hearing aid may overlook an underlying medical reason that is the cause of his/her hearing loss (Hearing Care Associations, 2018; Adams, 1995). For example, impacted cerumen can obstruct the ear canal resulting in hearing loss. Lewis-Cullinan & Janken (1990) assessed the prevalence of cerumen impaction in an elderly population of 226 participants who were hospitalized. Thirty-five percent of the participants presented with impacted cerumen (1990). Patients with impacted cerumen may purchase OTC hearing aids without recognizing that their hearing issues could be alleviated or reduced with cerumen removal. There are other medical conditions such as an acoustic neuroma, which could be overlooked when purchasing an OTC hearing aid. However, it should be noted that proponents of OTC hearing aids suggest that due to the multiple symptoms typically associated with an acoustic neuroma it is expected that patients would know to seek out medical care under these circumstances (PCAST, 2015).

In an attempt to protect consumers from overlooking potential medical reasons for their hearing loss the Consumer Questionnaire to Detect Disease Risk Before Hearing Aid Purchase (CEDRA) was developed by , Kleindienst, Zapla, & Nielson (2017). The CEDRA is a 15-item questionnaire, with a yes/no response to each question. The questionnaire is designed to detect the presence of ear disease, with a score of 4 or greater recommending that the consumer see a physician. This assessment tool was tested on 307 patients at the Mayo Clinic with ear disease, and has been shown to have 90% sensitivity, and 75% specificity for ear disease detection. Kleindienst et al., (2017) suggest that prior to buying an OTC hearing aid, consumers should complete the CEDRA.

Self-Fitting Hearing Devices

The viability of consumers being able to self-fit a hearing device without the help of a hearing aid specialist has been previously evaluated. For example, Convery et al., (2011), investigated the management of hearing aid assembly among a group of elderly individuals with hearing loss. They included 80 participants, of which 62 had previous hearing aid experience, and required all participants to bring a partner in case they needed assistance in the assembly of the hearing aid. They reported that 99% of the participants were able to complete the hearing aid assembly tasks either on their own or with the help of a partner. However, the hearing aid assembly included very basic hearing aid handling skills, and participants were not required to demonstrate advance hearing aid skills (i.e. using an app to program the device). They also found that higher health literacy, and gender strongly influenced performance on the assembly task. These results indicate that older adults can complete basic hearing aid assembly tasks, if they are provided with the device and given detailed instructions.

Convery et al., (2017) investigated if adults with hearing loss can successfully fit a commercially available self-fitting hearing aid programmed via a smartphone app, when provided with well-written instructions. Forty adults were recruited for their study, 20 of which had previous hearing aid experience. Results showed that only 55% of participants were able to successfully complete the self-fitting OTC task and no specific factors were identified to predict successful self-fitting. The percent of individuals who were successful in completing the self-fitting task with this commercial product (55%) was much lower than the percent of individuals who were successful in completing the basic hearing aid handling tasks (99%) in Convery et al (2011). Furthermore, the instructions provided to participants in the Convery et al., (2017) study were written by the investigators, and were easy to follow. These results suggest that the self-fitting of more complex devices (i.e. Bluetooth, in situ hearing test via an app) that require familiarity with smartphone technology, could be difficult for many consumers. Perhaps with the more advanced devices a trained professional will need to provide support during the self-fitting process.

In their next study, Convery et al., (2018) investigated the factors associated with the need for personalized support for the successful fitting of a commercially available OTC hearing aid. A sample of 60 participants with hearing loss was recruited, with 30 participants having previous hearing aid experience. Participants were evaluated on their accuracy of completing each step of the fitting, regardless of whether or not they requested help. Standardized questionnaires related to cognitive function, locus of control, health literacy, problem solving skills and hearing aid self-efficacy were also administered. Results showed that 68% of participants were able to complete the self-fitting of the hearing aid successfully with and without additional support from a trained professional. Those who were successful in the hearing aid fitting were significantly more likely to have previous hearing aid and smartphone technology experience. The result of all these Convery et al. studies (Convery et al., 2011; Convery et al., 2017; Convery et al., 2019) suggest that depending on the complexity of the device, consumers may require additional support to successfully set up their hearing aid.

As previously discussed, Humes et al., (2017, 2019) investigated the efficacy of the OTC hearing aid model, and randomly assigned participants into three treatment intervention groups: audiology based (AB) best practice intervention, OTC consumer decide (CD) intervention, or a placebo intervention. They found that participants in the CD intervention group were more likely to select a hearing aid with less gain than required for their hearing loss, and they were also less likely to purchase their hearing aids after the six-week trial. Participants in the ‘OTC like’ group were provided with top of the line hearing devices with pre-selected programs, and were not required to perform any advanced hearing aid handling skills, such as pairing the devices to a smartphone. These limitations make it difficult to generalize the findings from this study to a true OTC hearing aid model.

PURPOSE OF THE STUDY

Although the FDA has set a 2020 deadline to develop guidelines for OTC hearing aids, there are already a growing number of hearing devices that are available for purchase online. Interestingly, many of these devices advertise being able to compensate for hearing loss and can be purchased today without seeing a hearing health care specialist, regardless of the fact that FDA guidelines have yet to be released for the sale of OTC hearing aids. Devices can be behind-the-ear or in-the-ear style fit with pre-set programs or paired with a smartphone to perform an in situ hearing test, which can then be used to prescribe gain. There are currently no estimates on how many companies are entering the OTC hearing aids market, however a quick Google search provides a plethora of potential devices that are already available for purchase.

Currently, there is no evidence identifying how well consumers will be able to navigate the online OTC market, and which factors they will use to base their device selection decision on. Furthermore, there is limited information about if the average consumer will be able to correctly self-identify if he/she is a candidate for OTC hearing aids, and be able to self-fit and use an OTC hearing aid. In the present study, self-identification for OTC hearing aid candidacy is operationally defined as an individual being able to correctly self-identify two basic candidacy factors: the presence of a hearing loss, and identifying the risk for ear disease. Self-fitting is operationally defined in the present study as an individual’s ability to assemble the hearing device (select correct dome venting, dome size, place battery in door etc.), as well as device usage (i.e. being able to toggle through pre-set programs or use an in-app hearing test to program the device).

The purpose of the proposed study is to 1) identify factors associated with successful self-identification of OTC hearing aid candidacy, which includes predicting hearing loss and ear disease status, 2) identify factors associated with OTC hearing aid use and handling skills, and 3) identify differences between fit and prescribed gain to determine deviations from prescriptive targets across devices. The following hypotheses were tested:

- *Hypothesis 1:* Higher levels of cognitive function, locus of control, health literacy, and/or education will increase an individual's ability to correctly identify hearing loss status.
- *Hypothesis 2:* Higher levels of cognitive function, locus of control, health literacy, and/or education will increase an individual's ability to correctly identify ear disease status.
- *Hypothesis 3*: Individuals with higher levels of cognitive function, locus of control, hearing aid self-efficacy, and/or technology commitment will have better OTC hearing aid use and handling skills
- *Hypothesis 4:* OTC hearing aids that have greater fitting flexibility will have smaller RMS deviations between aided and prescriptive gain.

In addition factors that might influence OTC hearing aid selection when purchasing a device online were explored.

EXPERIMENTAL DESIGN AND METHODS

Participants

Adults 40 years old and older, who are proficient in English, and had no prior hearing aid experience were eligible to participate in this study. All participants had normal finger dexterity function and vision, as determined by the 9-hole peg test (Grice et al., 2013) and the SLOAN Near Vision Acuity task, respectively. Last, all participants were owners of a smartphone, and used their personal device, if necessary, during the study.

Participants were recruited through an advertisement in Syracuse University's electronic newsletter and flyers posted around Syracuse University's Campus, local churches, libraries, and community centers. All participants responded to an advertisement that asked, "Do you have difficulty hearing? For example in group settings, restaurants, talking with friends etc. Over-the-Counter (OTC) Hearing Aids were recently approved by congress. We are looking for participants 40 years old and older who have trouble hearing to participate in a research study designed to determine how the average consumer obtains and self-fits OTCs." All participants were paid for their time. The study and recruitment materials were approved by the Syracuse University's Institutional Review Board.

A statistical power analysis was performed and generated a sample size estimation of 71 participants. This sample size was based on *a priori* power analysis for logistic regression with a significance level of α= 0.05, a power requirement of 80%, and an odds ratio of 2.124, which was the calculated odd ratio for the Montreal Cognitive Assessment in the study completed by Convery et al. (2018). However, all data collection had to stop due to the COVID-19 pandemic. As a result, a total of 52 participants were included in this study, but only 49 participants were able to complete both sessions of the study before we had to close the lab. Therefore, a post-hoc power analysis was performed using the results from hypothesis 3 with a sample size of 49 participants, three predictors, a sample size of 49, and an R-squared value of 23.2%, and revealed an observed power of 86.1%.

Participants included in the study were between 45 to 77 years old, with a mean age of 64.4 (SD = 7.50). Thirty-two participants were female and 20 were male. For the purposes of this study, each ear (right/left) was categorized as ‘normal-hearing’ or ‘hearing impaired’ based on a pure-tone average (PTA) at 1, 2, and 4 kHz. If the participant had a 20 dB difference in threshold between 4 and 8 kHz then the 6 kHz threshold was included in the PTA calculation. The inclusion of 6 kHz in the PTA has been shown to be more sensitive to high frequency hearing impairment compared to the traditional three-frequency pure tone average of 0.5, 1, and 2 kHz (Huh et al., 2019). A PTA better than or equal to 25 dB HL was considered normal-hearing for the purposes of this study. Of the 104 ears that were tested, 62 were classified as normal. In an effort to show the range of thresholds for the participants who were categorized as having either normal hearing or hearing loss, the thresholds are plotted separately. Mean audiometric hearing thresholds are shown in Figure 2. The audiometric PTA for all participants ranged from 0 to 55 dB HL, nine ears (six participants) had occluding cerumen, and two ears (2 participants) had a conductive hearing loss. The CEDRA flagged 15 participants who were at risk for ear disease.

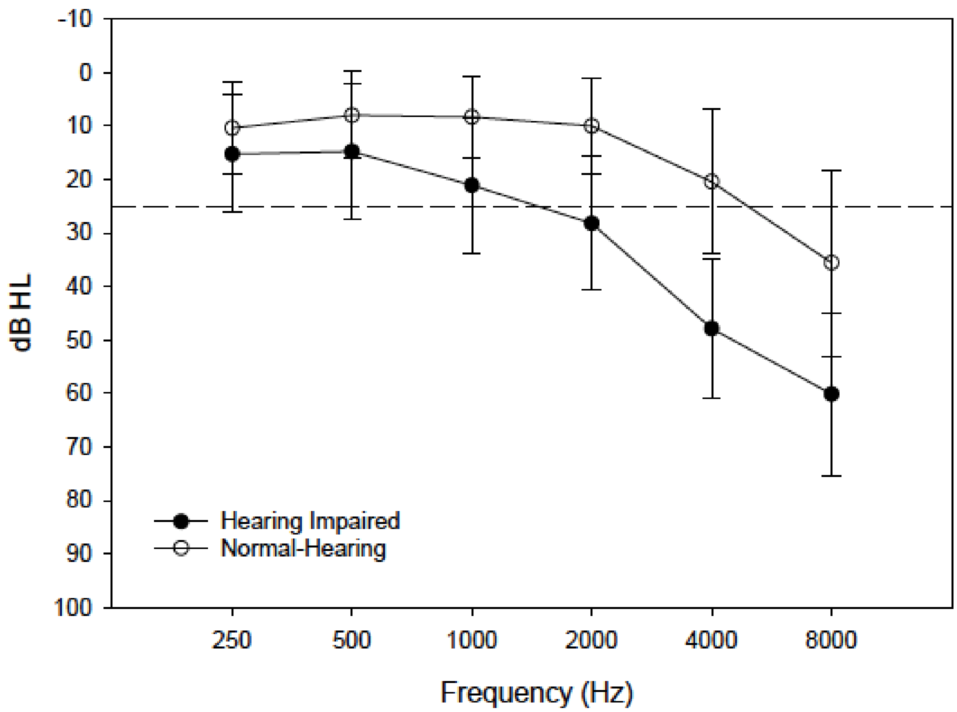


Figure 2: Mean audiometric thresholds for hearing impaired and normal-hearing ears. Error bars shown depict the standard deviation for each threshold.

Procedure

Participants were encouraged to complete this study over two sessions, however some participants completed the entire study in one session when they had scheduling conflicts. During the first session participants completed two screening tests, six questionnaires, three cognitive tasks, and an audiometric evaluation. This took approximately 90 minutes. During the second test session participants were asked to browse through three OTC hearing aid websites, and to decide which OTC hearing aid they would like to purchase. Participants were given that device, and asked to assemble and set it up. In addition, an evaluation of their hearing aid handling skills, real ear measurements and a final questionnaire on risk of ear disease was completed in session two. This session took approximately two and a half hours to complete. See Figure 3 for a flowchart of the study protocol.

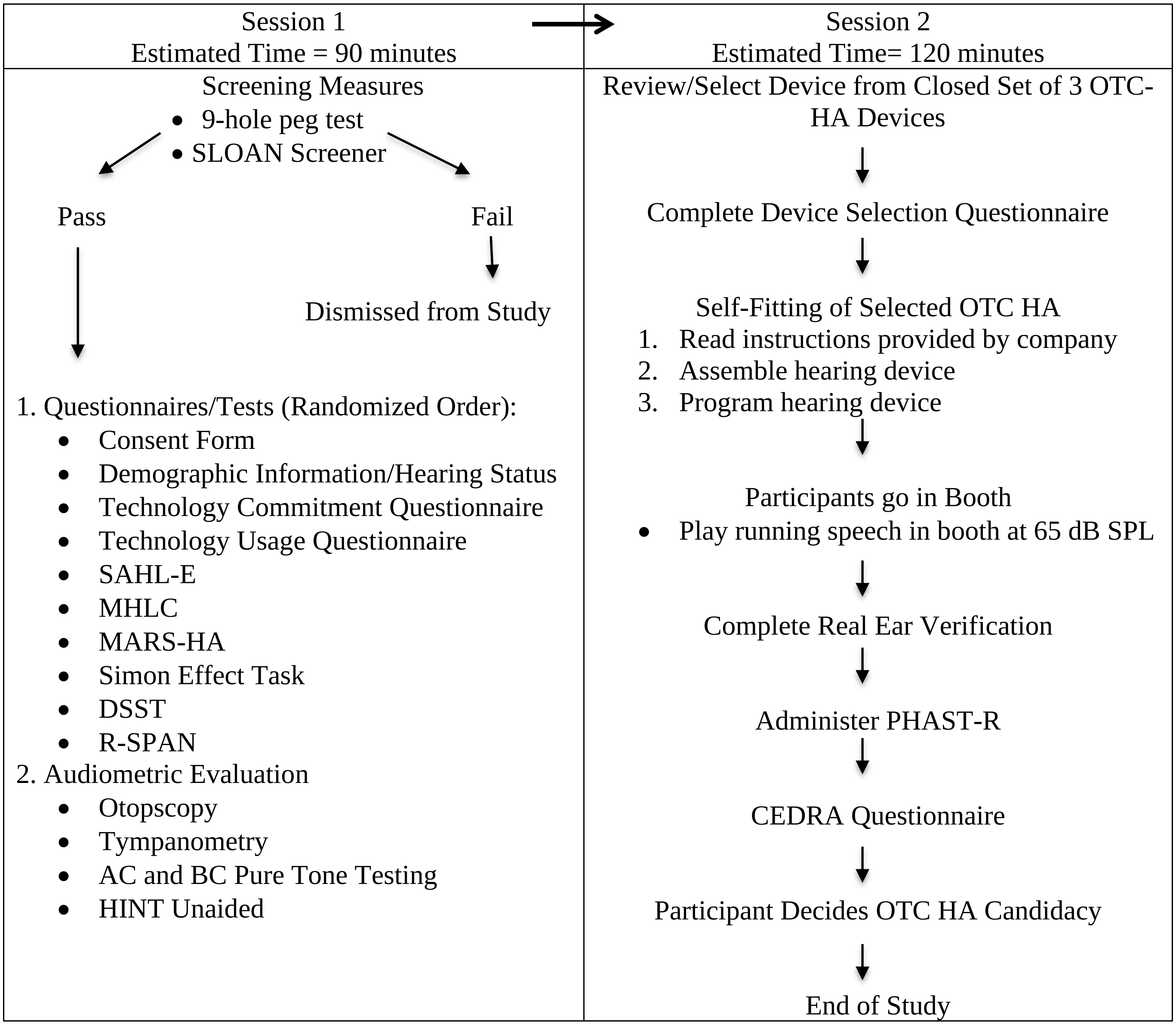


Figure 3: Study Protocol

SESSION ONE:

Screening Measures

All participants were administered the 9-hole peg test to screen for normal finger dexterity (Grice et al., 2013). The 9-hole peg test is a brief measure of upper extremity function, and participants who score 2 standard deviations below their age and gender mean-normed score were not eligible to participate in the study. Participants were also asked to read the SLOAN Near Vision Card for normal near vision acuity (Holladay, 2004). The SLOAN Near Vision Card is read at 40 cm from the participant's face. Individuals who were unable to read the letters, with or without corrective lenses, on line 20/40 for either the left or right eye were not eligible to participate. All participants passed both screeners, and then completed several questionnaires and cognitive tasks.

Questionnaires

Questionnaires were used to determine demographic information, participant technology usage, health literacy, locus of control, and hearing aid efficacy. See appendices A through E for samples of the questionnaires. The order of the questionnaires was randomly presented to the participants.

Demographic Information/Hearing Status Questionnaire

A questionnaire was developed in the lab to obtain information about the participants' age, gender, and education level. In addition, participants were asked to self-report if they had a hearing loss, if the loss was in one or both ears, and how long they suspected having hearing loss. They were also asked if they thought there was an underlying medical reason for their hearing loss, and if they would plan to see a doctor prior to purchasing hearing aids.

Technology Commitment and Usage Questionnaires

The level of participants' technology commitment was measured using the Technology Commitment Questionnaire (TCQ) (Neyer et al., 2012). The TCQ is a 12-item self-report questionnaire that evaluates an individual's technology competence, acceptance and control, as well as provides an overall score, which is referred to as technology commitment. Examples of a technology competence, acceptance, and control statement are, "I often feel overstrained with dealing with new technological developments", "I am very curious about new technological developments", and "Success in dealing with modern technology depends on me", respectively. For each statement, there are five response options: (1) Strongly Disagree, (2) Disagree, (3) Partly Disagree, (4) Agree, and (5) Strongly Agree. Scores are tallied for each subscale, and then an overall score is determined as a global measurement of technology commitment.

Technology usage was measured with a subset of questions from a media usage questionnaire (Tahden et al., 2018). A subset of questions related to how often an individual uses a computer, the Internet, a smartphone, and shops online were specifically selected from this media usage survey. These were selected because they represent media interactions consumers will experience when purchasing and setting up OTC hearing aids online. For each statement, there are five response options: (1) No usage, (2) Less than once a month, (3) At least once a month, (4) At least once a week, and (5) At least once a day. A *usage habit total score* was calculated by totaling the answers from all of these questions.

Health Literacy

Health literacy was measured by the Short Assessment of Health Literacy- English questionnaire (SAHL-E; Lee et al., 2010). To administer the SAHL-E participants were asked to read out loud 18 medical terms, with each medical term being presented with a key word and distractor word. For example, the medical term 'Kidney' is presented with 'Urine' and 'Fever', as the key and distractor words respectively. The participant was asked to identify which of the two words (i.e. urine or fever), had the closer association or meaning to the medical word (i.e. kidney). Once completed, a total number of correct associations were tallied and a total score of less than 14 is considered low health literacy. The maximum score is 18.

Locus of Control

The Multidimensional Health Locus of Control (MHLC) was administered to measure participants' locus of control (Wallston et al., 1978). Locus of control is the degree to which individuals believe that they are in control of the outcomes to life events, rather than external forces (Wallston et al., 1978). The MHLC is an 18-item questionnaire that evaluates participant's locus of control based on three subscales: Internal, Chance, and Powerful of Others. An example of an 'Internal' statement is, "If I get sick, it is my own behavior which determines how soon I get well again"; an example of a "Chance" statement is, "No matter what I do, if I am going to get sick, I will get sick"; and an example of a 'Powerful of Others' statement is, "Having regular contact with my physician is the best way for me to avoid illness". For each statement there are 6-response options: (1) Strongly Disagree, (2) Moderately Disagree, (3) Slightly Disagree, (4) Slightly Agree, (5) Moderately Agree, and (6) Strongly Agree. Scores are tallied and can range from 6 to 36 for each of the three subscales.

Hearing Aid Self-Efficacy

Hearing aid self-efficacy was determined by using the Measurement of Audiologic Rehabilitation Self-Efficacy for Hearing Aids questionnaire (MARS-HA; West & Smith, 2007). Hearing aid self-efficacy is the degree of confidence a participant has regarding his/her ability to use and care for their hearing device. The MARS-HA has been validated for both new and experienced hearing aid users, and can be used to identify a mismatch between a patient's perceived and actual hearing aid handling abilities (West & Smith, 2007). The MARS-HA is comprised of 20 questions that evaluates four components of hearing aid self-efficacy or hearing aid handling: (1) basic handling, (2) advanced handling, (3) adjustments to hearing aids, and (4) aided listening skills. An example of a 'basic handling' statement is, "I can insert a battery into a hearing aid with ease."; an example of an 'advanced handling' statement is, "I can operate all the controls on a particular hearing aid (i.e. knobs, switches, and/or remote control) appropriately."; an example of an 'adjustment to hearing aids' statement is, "I could get used to the sound quality of a hearing aid."; and an example of an 'aided listening skills' statement is, "I could understand a one-on-one conversation in a quiet place if I wore hearing aids". For each statement participants are to select a percentage of how certain they are that they can do each task statement (i.e. 0%= cannot do this at all; 100%= I am certain I can do this).

Cognitive Tasks

Working Memory

Working Memory was evaluated by using a computerized version of the Reading(R)-SPAN task (Loboda, 2012; Daneman & Carpenter, 1980), which is a reliable measure of working memory capacity (Conway et al., 2005). Working memory capacity is responsible for the active maintenance of information with ongoing cognitive processing (can be useful or distracting). The R-SPAN task consists of two interleaved tasks: the memorization of a series of letters (F, H, J, K, L, N, P, Q, R, S, T, or Y), and judging English sentences to be semantically correct or incorrect. An example of a semantically correct sentence is, "The host greeted all the guests and asked them to sit at the table", and an incorrect sentence is, "John never liked chocolate and this is why he lives in the country." Each trial varied the number of letter and sentence presentations from 2 (i.e. 2-span) to 7 (i.e. 7-span). At the end of each trial, participants were asked to recall the letters presented. Participants completed 18 trials, 3 trials for each set size between 2 and 7 (set sizes were randomized). For each trial, the proportion of correctly recalled letters was calculated and the participant's final score was the average of scores from all 18 trials (Conway et al., 2005).

Processing Speed

The Digit Symbol Substitution Task (DSST) was used to measure participants processing speed (Wechsler, 2981). The DSST has also been shown to be sensitive to cognitive dysfunction and correlates well with real world function outcomes (Jaeger, 2018). Participants were given a piece of paper with a symbol legend. The legend consisted of numbers 1 through 9, with each digit paired with a unique, easy to draw symbol. Below the legend were rows of double boxes, with a number provided in the top box (1-9) and nothing in the bottom box. Participants were directed to go in order and draw the associated symbol for each digit in the empty boxes. They were given 120 seconds to fill as many boxes as possible. The number of correctly drawn symbols was the participant's score for this task.

Selective Attention and Inhibition

Selective attention and cognitive inhibition were measured using the computerized version of the Simon Task (PsyToolKit, 2017; PsyToolKit, 2010; Simon & Rudell, 1967). The Simon Task is a measurement of behavioral inhibition, specifically of irrelevant information.

Behavioral inhibition is necessary to carry out goal-directed behavior (Cheung, Mitsis, & Halperin, 2010; Barkley, 1997). The words ‘left’ or ‘right’ were shown randomly on either the left or right side of the computer screen. Participants were instructed to press the letter ‘q’ when they saw the word ‘left’ or to press the letter ‘p’ when they saw the word ‘right’. Compatible conditions were categorized as trials that showed the key word on the same side of the screen as the key word (i.e. the key word ‘right’ is shown on the right side of the computer screen). Incompatible conditions were categorized as trials that showed the key word on the opposite side of the screen as the key word (i.e. the key word ‘right’ is shown on the left side of the computer screen). The Simon Effect was the difference between the response time for incompatible and compatible conditions. Only trials with correct responses were included in the tabulation of the Simon Effect.

Hearing Test

After completing the questionnaires and cognitive tasks, participants underwent a standard audiometric exam consisting of otoscopy, tympanometry, and air and bone conduction testing. The computerized version of the Hearing in Noise Test (HINT), a standardized sentence in noise test was also administered in the sound field at 0 degrees azimuth (Nilsson, Soli, & Sulivan; 1994). The HINT is an adaptive test comprised of 250 sentences, which are divided into 25 lists. The test is adaptive in that the signal to noise ratio (SNR) is adjusted based on the participant’s performance. For each sentence that is correctly identified the presentation level of the following sentence is decreased, while for each sentence that is incorrectly identified the presentation level of the following sentence is increased. The background noise is presented at a constant level of 65 dBA throughout all testing. The objective of the test is to find the SNR that results in a 50% correct response rate. All testing was completed in a double-walled sound-attenuating booth with a clinically calibrated GSI 61 audiometer (ANSI, 2010). The HINT was administered in the unaided condition only.

SESSION TWO:

OTC Hearing Aid Selection

There are several "OTC-like" hearing aids currently available for purchase online. For the present study, three devices were selected. These three devices were specifically selected to provide a range of fitting flexibility, instructional material, and price. All three devices were behind-the-ear/receiver-in-the ear style hearing aids. None of the devices selected falsely advertised that they are OTC hearing aids, however these devices are likely to represent the type of technology that will be available for purchase once OTC labeling is approved by the FDA. The three devices were labeled OTC Hearing Aid 1, 2, and 3, with OTC hearing aid 1 having the least fitting flexibility and OTC hearing aid 3 having the greatest. OTC hearing aid 1 had four pre-set programs, OTC hearing aid 2 allowed for gain adjustments to be made to the frequency response using six frequency bands (1 low frequency band, 3 mid frequency bands, and 2 high frequency bands), and OTC hearing aid 3 used the results from an in-app hearing test to prescribe gain. These features and cost of each of the three devices, as advertised on each company's website are summarized in Table 1. In order to utilize the websites of each OTC hearing aid company, participants could not be blinded to the name of the OTC hearing aid. However, none of these devices are well known brands and was unlikely to influence the participants' hearing aid selection. Participants were given as much time as needed to make their selection.

Table 1: Summary of features and cost of each OTC device based off of what is advertised on each company's website.

Company	1	2	3
Style	Behind-the-ear with slim tube	Behind-the-ear with slim tube	Receiver-in the ear
Fitting Flexibility	4 pre-programmed settings	Gross adjustments to specific frequency bands via an app	In situ hearing test via an app
Number of Programs	4	18	4
Feedback Cancellation	+	+	+
WDRC	+	-	-
Noise Cancellation	+	+	+
Directionality	-	+	+
T-Coil	+	+	-
Cleaning Tools	+	+	+
Batteries	+	+	+
Advertised Hearing Loss Severity	Mild to Severe	Mild to Moderately-Severe	Mild to Moderately-Severe
Instructional Material	Written Manual	Written Manual and step-by-step in app instruction	Step-by-step in app instruction with illustrations
Cost	$399/HA	$699/HA	$799/HA

+ Device has feature advertised online
- Device does not have feature advertised online

The investigator pulled up the website links for each of the three OTC hearing aids on a desktop PC computer. The investigator showed to the participants the three separate links to ensure that the participants knew how to toggle back and forth between the three different websites. Participants were asked to browse through each of the websites, and decide which of the three OTC hearing aids they would want to purchase.

Once the participant was done browsing through all three websites, the investigator asked the participant, "Given what you read on these websites, at this point in time would you purchase an Over-The-Counter Hearing Aid?" The participant's response was recorded as either 'yes' or 'no'. Regardless of their response, all participants were asked to identify which device they would purchase, and then were given the hearing aid selection questionnaire that was developed for this study. The questionnaire asked participants which OTC hearing aid they selected, if for one or both ears, and a checklist of potential reasons for why they selected that particular device (See Appendix F for the selection questionnaire).

Hearing Aid Self-Fitting

Each participant was then given the OTC hearing aid that they selected in its the original packaging. They were asked to use the instructions provided by the company to assemble the OTC hearing aid, familiarize themselves with the different features of the device, and then place the device(s) on their ear(s). For OTC hearing aids 2 and 3, participants were required to program their aids using a smartphone.

Real Ear Measurements

Participants were asked to insert and set up their selected OTC device(s) while being presented with running speech at 65 dB SPL in the sound field. They were asked to adjust the gain of the aid to a comfortable level and if they already found sounds to be at a comfortable level then they made no changes to the gain. Once the participant was satisfied with the level of the sound, real-ear verification was completed. Real ear verification was performed using the AudioScan Verifit VF-2 real ear system (Dorchester, ON, Canada) and NAL-NL2 targets at three input levels (50, 65, and 75 dB SPL).

Assessment of OTC Hearing Aid Use Skills

In order to evaluate participants' use of their devices, the 'use' tasks on the Practical Hearing Aid Skills Test-Revised (PHAST-R) was administered, as well as the addition of one task related to hearing aid assembly, and three tasks related to Bluetooth connectivity and use of an OTC app. The PHAST-R is an objective measure that evaluates how well hearing aid users are able to use and care for their hearing aids (Doherty & Desjardins, 2012). The investigator rated the participant's performance on the PHAST-R 'use' tasks, plus the additional tasks. For example one hearing aid handling task is, 'Please take out your hearing aid'; an example of Bluetooth connectivity task is, 'Please show me how you connect your hearing aid to your phone'; and an example of an assembly task is, 'Please connect your hearing aid to the tube and dome you selected'. The investigator rated the participants' performance on a scale of 0 to 2, with 0 for when a participant was unable to perform the task, and 2 for when the participant accurately performs the task. A score of 1 was given when the participant performed the task, but through deviant means or needs re-instruction. The overall PHAST-R score can range from 0-100%. Participants were encouraged to use the instruction booklet provided by the hearing aid company during the PHAST-R assessment. Please refer to Appendix 'G' for a list of the use tasks.

CEDRA

Participants were asked to complete an ear disease risk assessment questionnaire called the CEDRA (Klyan et al., 2019). Participants responded to 15 questions related to hearing, balance, general health, and non-otological symptoms. Participants who achieve a score of 4 or higher were flagged for being at risk for ear disease. An example of a question related to hearing is, “Did the hearing loss in either of your ears develop suddenly?”; an example a question related to balance is, “How often do you have dizziness?”; an example of a question related to general health, “Overall, how would you rate your health?”; and an example of a question related to non-otological symptoms, ““Have you ever had a rapid change in vision in one or both eyes?” This questionnaire was administered last to prevent biasing the participant about their eligibility for an OTC hearing aid. At the end of the study, participants were asked again if they would purchase an over-the-counter hearing aid at that point in time. Thus, a comparison before and after they were exposed to an OTC hearing aid could be included. Please refer to Appendix H for the CEDRA questionnaire.

STATISTICAL ANALYSIS

Data analysis was completed using SPSS v. 26 (IBM Corp, 2019) and SAS Software 9.4 (SAS Institute Inc., 2020). For hypotheses 1 and 2 the following 10 independent variables were used in the regression model: RSPAN, DSST, Simon Effect, Internal Locus of Control, PTA, health literacy, previous hearing test status, and demographic factors (i.e. gender, age, education). Specifically to test hypothesis 1, participants were categorized as being ‘correct’ or ‘incorrect’ in their ability to identify their hearing status in each ear. That is, they identified their hearing as being normal or impaired in each ear. Participants’ self-predicted hearing status in each ear was compared to their measured PTA to determine if they were correct or incorrect in their assessment of their hearing. The categorization of these participants as ‘correct’ or ‘incorrect’ was used as the dependent variable for logistic regression modeling. An exploratory analysis was completed first by performing a univariate logistic regression for each of the 10 independent variables separately. All statistically significant independent variables identified from these individual models were eligible for inclusion in the final logistic model. All models were performed using a 50% cutoff value (i.e. a predicted probability greater than 50% would indicate that the participant would be classified as correct).

To test hypothesis 2, participants were categorized as either ‘correct’ or ‘incorrect’ in their ability to determine their risk for ear disease. All participants were asked if they suspected an underlying medical reason for their hearing loss. Their response to this question was compared to their results on the CEDRA. The categorization of participants as ‘correct’ or ‘incorrect’ was used as the dependent variable for the logistic regression modeling. An exploratory analysis was completed first by performing a univariate logistic regression for each of the 10 independent variables separately. All significant variables were put into the final logistic regression model. All models were performed using a 50% cutoff value.

For hypothesis 3, a one-way ANOVA was performed to evaluate the effect of device type on PHAST-R scores. Post-hoc multiple comparisons were completed using Bonferroni adjustments. Furthermore, a linear regression was completed using the RSPAN, DSST, TQ Overall, Internal Locus of Control, MARS Basic subscale as the independent variables and PHAST-R scores as the dependent variable. For hypotheses 1, 2, and 3, all significant independent variables were evaluated for multicollinearity. Multicollinearity is suspected when the tolerance value is < 0.2 and the variance inflation factor is above 10 (Hair, Anderson, Tatham, & Black, 1995).

To test hypothesis 4, normal-hearing (62 ears) and hearing-impaired (42 ears) ears were analyzed separately. OTC hearing aids 1, 2, and 3 were defined as having varying levels of fitting flexibility, with OTC hearing aid 1 having the least fitting flexibility, and OTC hearing aid 3 having the greatest fitting flexibility. For the ears that were classified as being ‘normal-hearing’ an average overall hearing aid output level (dB SPL) was calculated by taking the average of the output levels at all test frequencies (0.25, 0.5, 0.75, 1.0, 1.5, 2.0, 3.0, and 4.0 kHz). This was calculated for three input levels (50, 65, or 75 dB SPL). Average overall gain was determined by subtracting the input level (i.e. 50, 65, or 75 dB SPL) from the previously calculated averaged overall output level. A two-way Repeated Measures (RM)- Analysis of Variance (ANOVA) was performed with OTC device and the input levels (50, 65, and 75 dB SPL) as the independent variables, and average overall gain as the dependent variable. Post-hoc multiple comparisons were completed using Bonferroni adjustments.

The root mean square (RMS) deviations between the OTC hearing aid gain and NAL-NL2 targets were calculated for each input level. That is, the gain differences between the NAL-NL2 targets and the output measurements (i.e. real ear measurement) at each test frequency were squared and then averaged. The square root was taken of that value to then determine the RMS deviation. A two-way RM-ANOVA was performed with OTC device and input level (50, 65, and 75 dB SPL) as the independent variables, and RMS deviations from NAL-NL2 target being the dependent variable. Post-hoc multiple comparisons were completed using Bonferroni adjustments.

Last, descriptive statistics were used to explore which factors may have influenced the participants' OTC hearing aid selection. The most common reasons for device choice was determined based on the participants' response on the device selection questionnaire. In addition, a Likelihood-Ratio Chi Square Test was performed to assess the association between income level and device selection, and a one-way ANOVA was performed to assess the relationship between technology commitment and device selection.

RESULTS

Factors Associated with Correctly Identifying Hearing Status

Participants were asked to self-report the presence or absence of a hearing loss for their left and right ear. Hearing loss was defined as a PTA greater than 25 dB HL. Thirty-eight percent (20/52) of the participants correctly identified their hearing status in both ears. Approximately 72% (23/32) of the participants incorrectly categorized themselves as having a hearing loss when they had a PTA of 25 dB HL or better in both ears. Interestingly 78% (18/23) of these participants were female.

Ten predictor variables were analyzed for their association with the binary categorization of participants correctly or incorrectly identifying their hearing loss status, and their mean scores (or ratios for dichotomous variables) are summarized in table 2. Logistic regression results for each independent variable in a single variable model revealed that the RSPAN, Gender, and PTA were significantly associated with hearing status classification (p-values are shown in table 2 for each independent variable). Using these significant predictors, a logistic regression was performed to determine the association between each independent variable and its impact on classification outcome.

Table 2: Mean scores (or % for categorical variables) for each predictor variable based on classification for hearing status. Standard deviations indicated in the brackets. Odds ratios and P-values provided for single predictor logistic regressions.

	Classification		
Variable	**Correct (n= 20)**	**Incorrect (n=32)**	**Odds Ratio (p-values)**
R-SPAN	0.61 (0.20)	0.72 (0.19)	0.05 (0.04)*
DSST	64.6 (12.5)	70.6 (11.0)	0.96 (0.08)
Simon Effect (seconds)	-77 (259)	-54.1 (264)	1.00 (0.76)
Internal Locus of Control	25.5 (4.31)	26.8 (4.82)	0.94 (0.29)
Health Literacy	17.5 (0.69)	17.6 (0.84)	0.86 (0.67)
Gender (% male)	60.0	31.3	0.30 (0.04)*
Age (Yrs)	66.1 (8.14)	63.4 (7.01)	1.05 (0.22)
Previous Hearing Test (% Yes)	25%	34.4	0.64 (0.48)
Education (Yrs)	16.3 (2.68)	16.4 (2.64)	0.98 (0.85)
PTA (dB HL)	30.5 (12.)	18.7 (9.49)	1.10 (<0.00)*

* indicates a significant ($p < 0.05$) logistic regression model.

The logistic regression showed a significant model (χ^2= 15.8, d.f. = 1.00, p = 0.001), containing all three variables as shown in table 3. The Nagelkerke R^2 value accounted for 35.7% of the variation in hearing loss classification, with the cross tabulation showing that the model correctly classified 80.8% of the participants as either correct or incorrect. However, the model had 90.6% sensitivity and 65.0% specificity, using a cut-off value of 0.5 (i.e. a predicted probability greater than 50% would indicate that the participant would be classified as correct). The Hosmer-Lemeshow goodness of fit test was not significant (χ^2= 4.08 d.f. = 8.00, p > 0.05), indicating that the model fit the data. Of the three variables in the model, only PTA was found to be a significant ($p < 0.001$), but it was a weak predictor of the model. Participants who successfully classified their hearing loss status were 1.09 times more likely to have a greater PTA, when controlling for gender and working memory.

Table 3: Logistic regression model predicting classification of correct versus incorrect prediction of hearing status using the statistically significant predictor variables from Table 2.

Variable	B	S.E.	Wald	d.f.	P-Value	Odds Ratio	95% Confidence Interval
PTA*	0.09	0.03	7.21	1	<0.001	1.09	1.024 – 1.166
Gender (male)	0.64	0.69	0.87	1	0.35	1.90	0.493- 7.315
RSPAN	-1.95	1.72	1.28	1	0.26	0.14	0.005 - 4.148

Factors Associated with Correctly Identifying Ear Disease Risk

In response to the closed-set question, "Do you think there is an underlying medical reason for your hearing loss?" twenty-nine, two, and twenty-one participants responded 'no', 'yes', and 'I don't know', respectively. The 31 participants who responded 'yes' or 'no' were included in the exact logistic regression modeling, and eight of these participants were flagged for ear disease risk based on their CEDRA score. A score of four or higher on the CEDRA indicates that an individual should seek medical care prior to purchasing a hearing aid. The participants' results on the CEDRA were compared to their self-reported risk for ear disease in order to classify them as correct or incorrect in self-identifying risk for ear disease. Overall, 26% (8/31) of the participants incorrectly classified their ear disease risk status, and 88% (7/8) of these participants in this group were flagged for being at risk for ear disease based on the CEDRA. Table 4 shows the mean and standard deviations (ratios for dichotomous variables) for the 10-predictor variables using the binary categorization of participants being either correct or incorrect. Logistic regression analysis using each independent variable in a separate model fit revealed that only education (χ^2= 5.40, d.f. = 1, p = 0.03, OR = 0.64, 95% C.I.= 0.37 to 0.97) was significantly associated with correct ear disease status classification.

Table 4: Mean scores (or % for categorical variables) for each predictor variable based on classification for ear disease risk. Standard deviations indicated in the brackets. Odds ratios and P-values provided for single predictor logistic regressions.

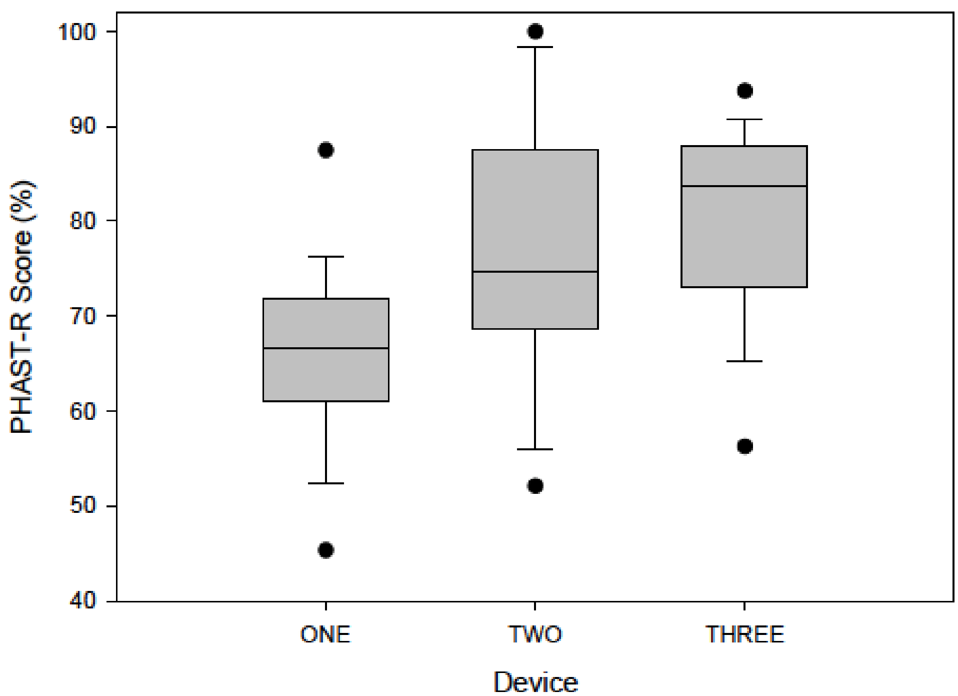
	Classification		
Variable	**Correct (n= 23)**	**Incorrect (n=8)**	**Odds Ratio (p-values)**
R-SPAN	0.69 (0.20)	0.74 (0.14)	0.19 (0.49)
DSST	67.8 (12.3)	71.9 (11.9)	0.97 (0.45)
Simon Effect (seconds)	-2.04 (244)	-49.9 (198)	1.00 (0.62)
Internal Locus of Control	26.1 (4.26)	22.8 (5.32)	1.20 (0.09)
Health Literacy	17.6 (0.66)	17.6 (0.52)	0.96 (1.00)
Gender (% male)	52.2%	25%	0.31 (0.24)
Age (Yrs)	67.1 (6.10)	61.8 (8.53)	1.12 (0.07)
Previous Hearing Test (% Yes)	78%	50%	1.05 (0.18)
Education (Yrs)	16.1 (2.38)	18.37 (2.39)	0.63 (0.03)*
PTA (dB HL)	25.1 (11.5)	19.2 (13.1)	0.28 (0.23)

The Nagelkerke R^2 value accounts for 23.5% of the variation in ear disease status classification, with the cross tabulation showing that the model correctly classified 80.6% of the participants as either correct or incorrect. However, the model had 95.7% sensitivity and 37.5% specificity when using a cut-off value of 0.5 (i.e. a predicted probability greater than 50% would indicate that the participant would be classified as correct). The Hosmer-Lemeshow goodness of fit test was not significant (χ^2= 6.46, d.f. = 5, p > 0.05), indicating that the model fit the data. These results suggest that for each additional year in education, participants were 1.58 times more likely to incorrectly classify their ear disease status.

Factors Related to OTC Hearing Aid Use and Handling Skills

The distribution of the PHAST-R scores for the three different OTC hearing aids are shown in Figure 4. Ninety-eight percent of participants needed to be reinstructed on at least one PHAST-R item. Fifty-three percent (26/49) of participants required reinstruction on the PHAST-R item that evaluated if the individual could correctly place the device(s) in their ear(s). Approximately 83% (14/17) of participants who selected OTC Hearing Aid I required reinstruction on the PHAST-R item that evaluated if the individual could change the volume on their device. For participants who selected OTC hearing aid 2 and 3, only 7% (1/15) and 29% (5/17), respectively, required re-instruction on the volume control item, respectively. OTC Hearing Aid 1 required participants to chose the dome vent and size and 75% of them selected a closed dome, which was only appropriate for one participant.

Figure 4: Box and whisker plots of PHAST-R scores for each OTC Hearing Aid.



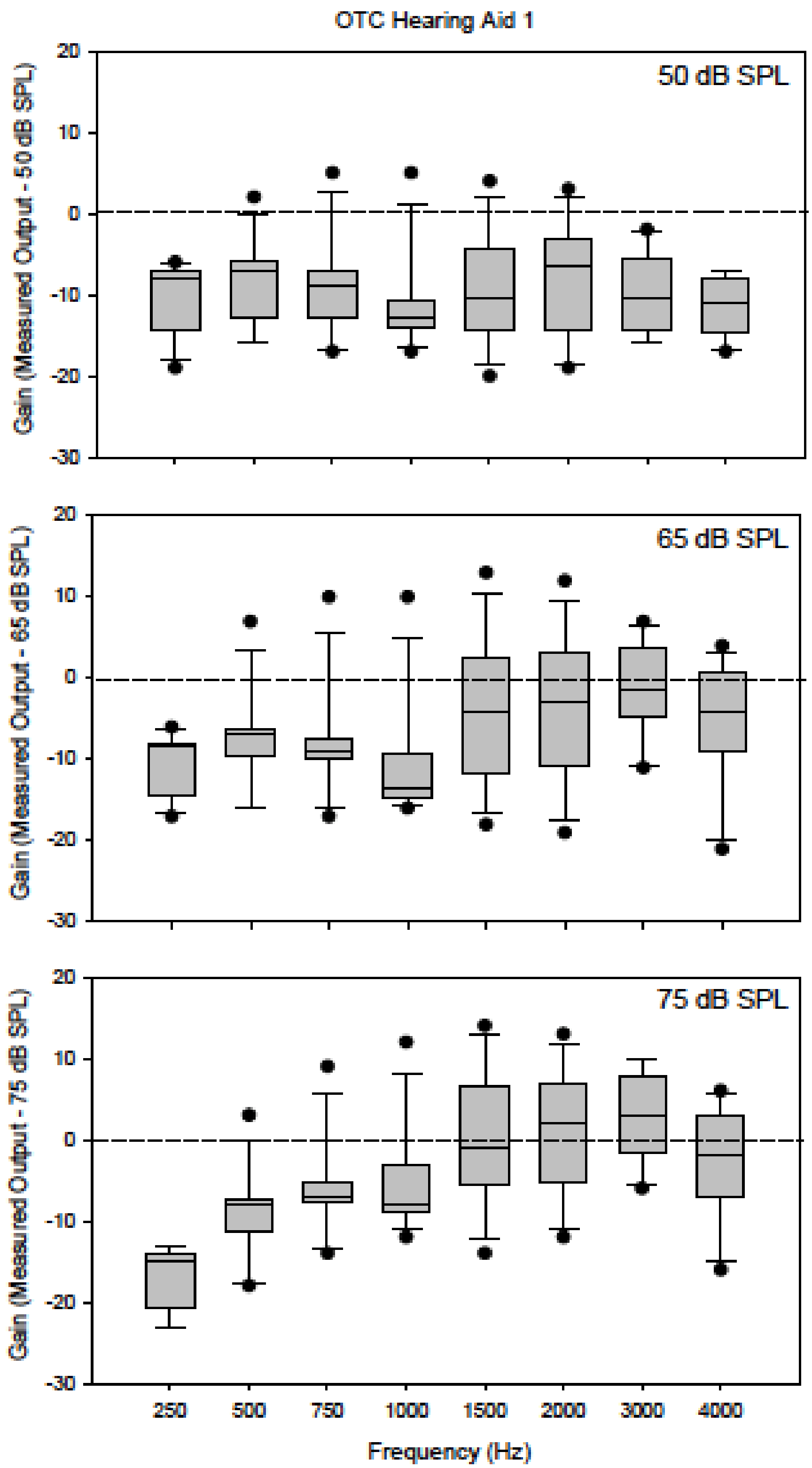
The one-way ANOVA revealed a significant effect of device type (F(2, 48) = 8.52, $p < 0.01$, n_p^2= 0. 264) with the participants who selected OTC hearing aid 1 (mean = 66.0%, SD = 9.20%) performing significantly worse on the PHAST-R compared to those who chose OTC hearing aid 2 (mean = 77.0 %, S.D.= 13.3% ; p = 0.02) or 3 (mean = 80.1%, S.D.= 9.98% ; p = 0.001). There was no difference in PHAST-R scores between the participants who chose OTC hearing aid 2 and OTC hearing aid 3 ($p > 0.05$). The linear regression, which evaluated the relationship between PHAST-R scores and several independent variables revealed an insignificant model (F (8,48) = 0.642, $p > 0.05$) with an adjusted R-square value of -6.3%.

OTC Hearing Aid Fitting Flexibility and Measured Outputs

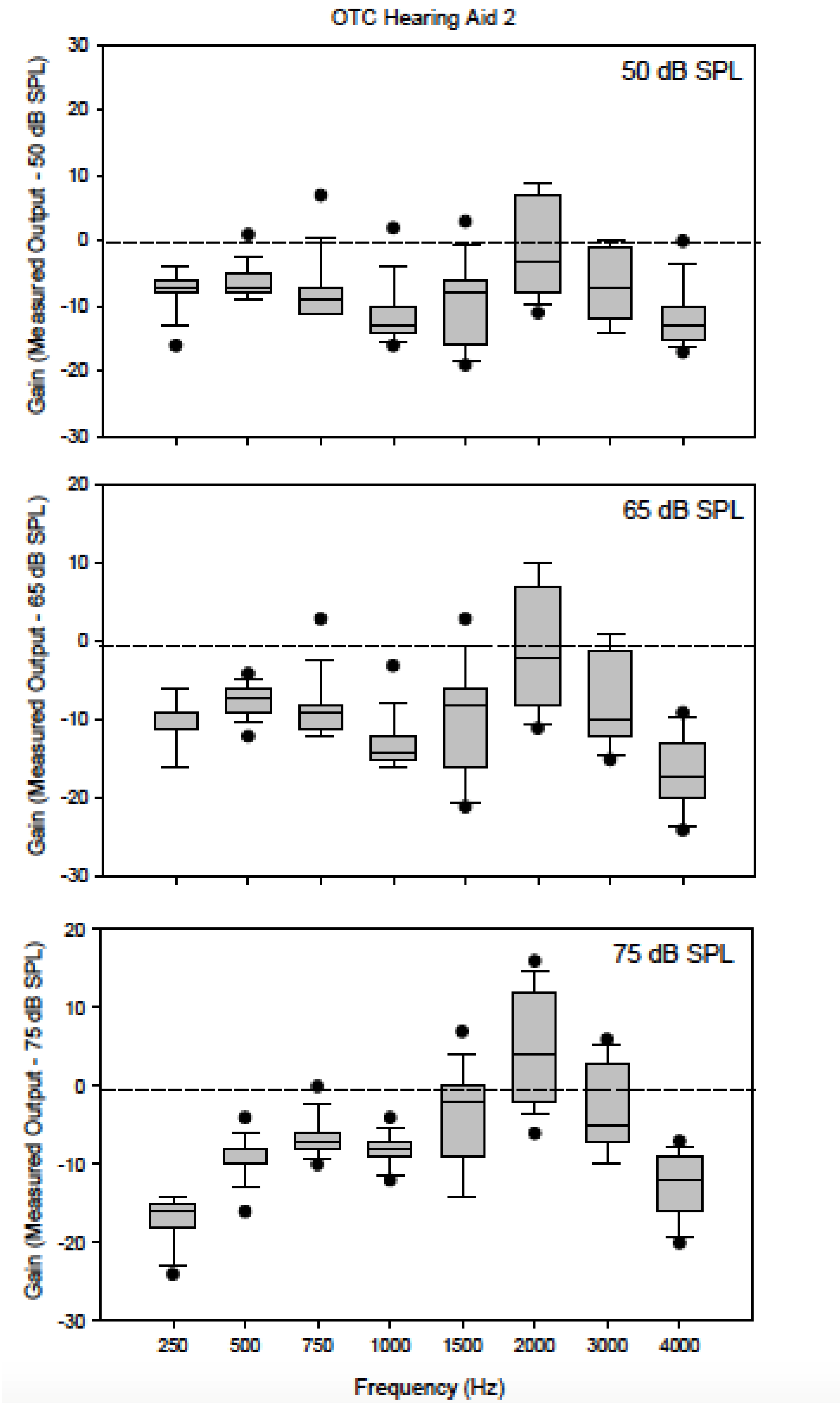
Of the 49 participants who completed the second session of the study, 16 chose a unilateral fit and 33 chose a bilateral fit. The 16 participants who chose a unilateral fit had a mean PTA of 24.4 (SD = 11.9) in the ear they chose to aid and a mean PTA of 17.9 (SD = 14.0) dB HL in the ear they chose to not aid. Nine of the 82 OTC hearing aid self-fittings were omitted from the real ear measures due to cerumen blockage. In 42 ears the hearing was normal and in 31 ears had hearing loss. For the participants who had normal-hearing, figures 5a-c show the hearing aid gain for each OTC hearing device at the three input levels 50, 65, and 75 dB SPL, respectively. Any value below the dotted line indicates that the device attenuated the input signal. For these participants all three devices attenuated the input signals for the low frequencies and varied in the amount of attenuation in the higher frequencies. OTC hearing aid 3 had attenuated the input at all frequencies and at all three input levels. The mean gain at each input level for each device is shown in table 5.

Figure 5 a-c: Box and whisker plots of hearing aid gain at each test frequency. Gain = Measured Output – Input.

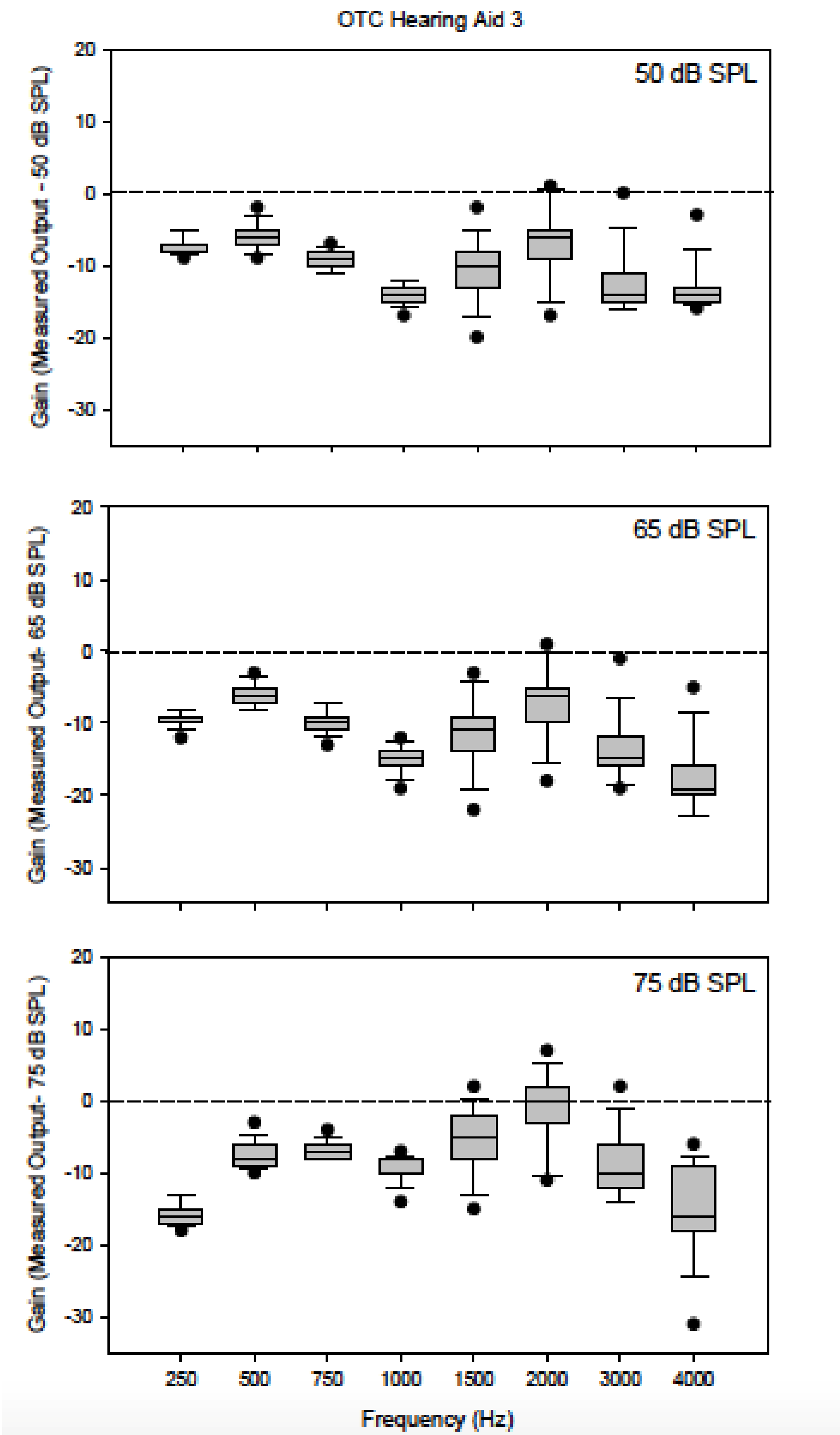
a)



b)


OTC Hearing Aid 2
50 dB SPL
65 dB SPL
75 dB SPL
Gain (Measured Output - 50 dB SPL)
Gain (Measured Output - 65 dB SPL)
Gain (Measured Output - 75 dB SPL)
30
20
10
0
-10
-20
-30
250
500
750
1000
1500
2000
3000
4000
Frequency (Hz)

c)


OTC Hearing Aid 3
50 dB SPL
65 dB SPL
75 dB SPL
Gain (Measured Output - 50 dB SPL)
Gain (Measured Output- 65 dB SPL)
Gain (Measured Output- 75 dB SPL)
20
10
0
-10
-20
-30
250
500
750
1000
1500
2000
3000
4000
Frequency (Hz)

The two-way RM-ANOVA revealed a significant interaction between input level and device (F (4,78)= 40.1, p< 0.001, n_p^2= 0.67). Bonferroni corrected post-hoc multiple comparisons showed that the mean attenuation levels for all three devices at the 50 dB SPL input level were not statistically different from one another (p > 0.05). However, OTC hearing aid 1 had statistically less attenuation compared to OTC hearing aid 3 at the 65 (p =0.001) and 75 dB SPL (p= 0.001) input levels. The attenuation of OTC hearing aids 1 and 2, and OTC hearing aids 2 and 3 were not statistically different (p >0.05) from one another at input levels of 65 and 75 dB SPL.

For OTC hearing aid 1, the device attenuated the 50 dB SPL input level significantly more than the 65 (p <0.001) and 75 (p < 0.001) input levels. Furthermore, OTC hearing aid 1 attenuated the 65 dB SPL input significantly (p <0.001) more than it attenuated the 75 dB SPL input. In contrast, the OTC hearing aid 2 device attenuated the 50 dB SPL input signal statistically less than the 65 dB SPL input signal (p< 0.001), but statistically more than the 75 dB SPL input signal (p = 0.004). At 65 dB SPL OTC hearing aid 2 attenuated the signal statistically more than the 75 dB SPL signal (p<0.001). Similarly, OTC hearing aid 3 attenuated the 50 dB SPL input statistically less than the 65 dB SPL input signal (p <0.001), but provided more attenuation compared to the 75 dB SPL input (p= 0.02). Finally, OTC hearing aid 3 attenuated the 65 dB SPL input significantly more than the 75 dB SPL input (p <0.001).

Table 5: Mean gain values for each OTC hearing aid at 50, 65, and 75 dB SPL. Standard deviations are indicated in the brackets.

	Input Level (dB SPL)		
OTC Device	**50**	**65**	**75**
1	-9.57 (3.61)	-6.31 (4.70)	-4.42 (3.91)
2	-7.71 (3.30)	-9.17 (3.25)	-6.77 (2.90)
3	-9.90 (1.60)	-11.3 (1.66)	-8.77 (1.97)

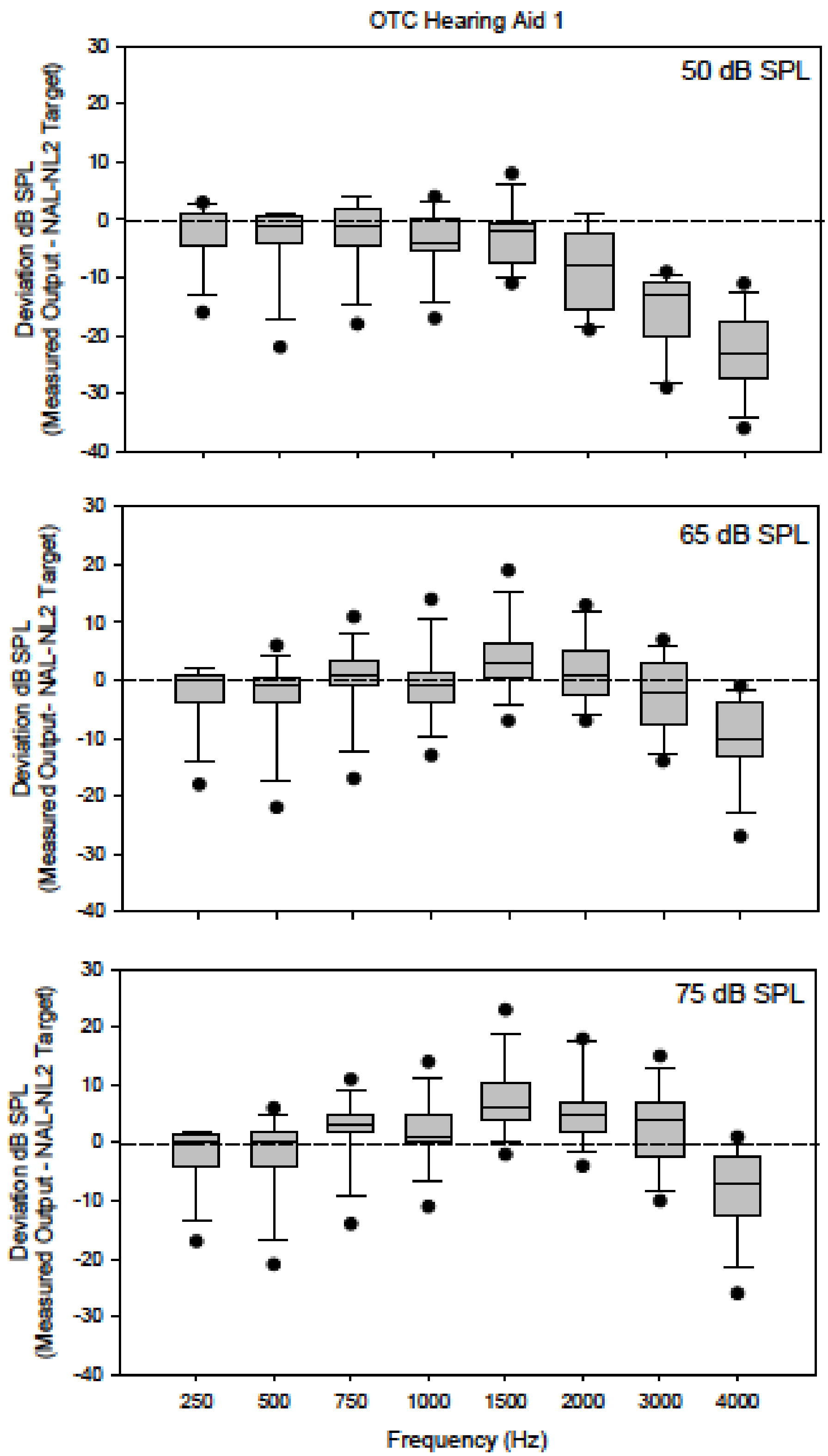
For the ears with hearing loss measured hearing aid output levels for each input level were compared to NAL-NL2 target outputs at each test frequency. Figures 6a-c shows the deviation between the NAL-NL2 targets and the measured OTC hearing aid output at each test frequency for the three input levels. Any value below the dotted line indicates that the device provided less gain than NAL-NL2 prescribed target gains. In general, all three devices tended to under fit at 3-4 kHz for all three input levels. Mean RMS deviations, for each OTC hearing aid, at each input level is shown in table 6. The RM-ANOVA revealed a significant interaction between device and input level (F (3.27, 47.5)= 3.21, p = 0.03, n_{p}^{2}= 0.18). Bonferroni corrected post-hoc multiple comparisons showed that at 50, 65, and 75 dB SPL none of the devices' RMS deviations were statistically different from one another (p > 0.05).

For OTC hearing aid 1, RMS deviations were statistically greater at 50 dB SPL compared to 65 (p < 0.001) and 75 (p <0.001) dB SPL, with no statistical differences between RMS deviations at 65 and 75 dB SPL (p >0.05). For OTC hearing aid 2, RMS deviations were statistically greater at 50 dB SPL compared to 65 (p < 0.006) and 75 (p <0.001) dB SPL, and RMS deviations at 65 dB SPL were statistically greater than 75 dB SPL (p = 0.002). Finally for OTC hearing aid 3, RMS deviations were statistically greater at 50 dB SPL compared to 65 (p < 0.001) and 75 (p <0.001) dB SPL, with no statistical differences between RMS deviations at 65 and 75 dB SPL (p >0.05).

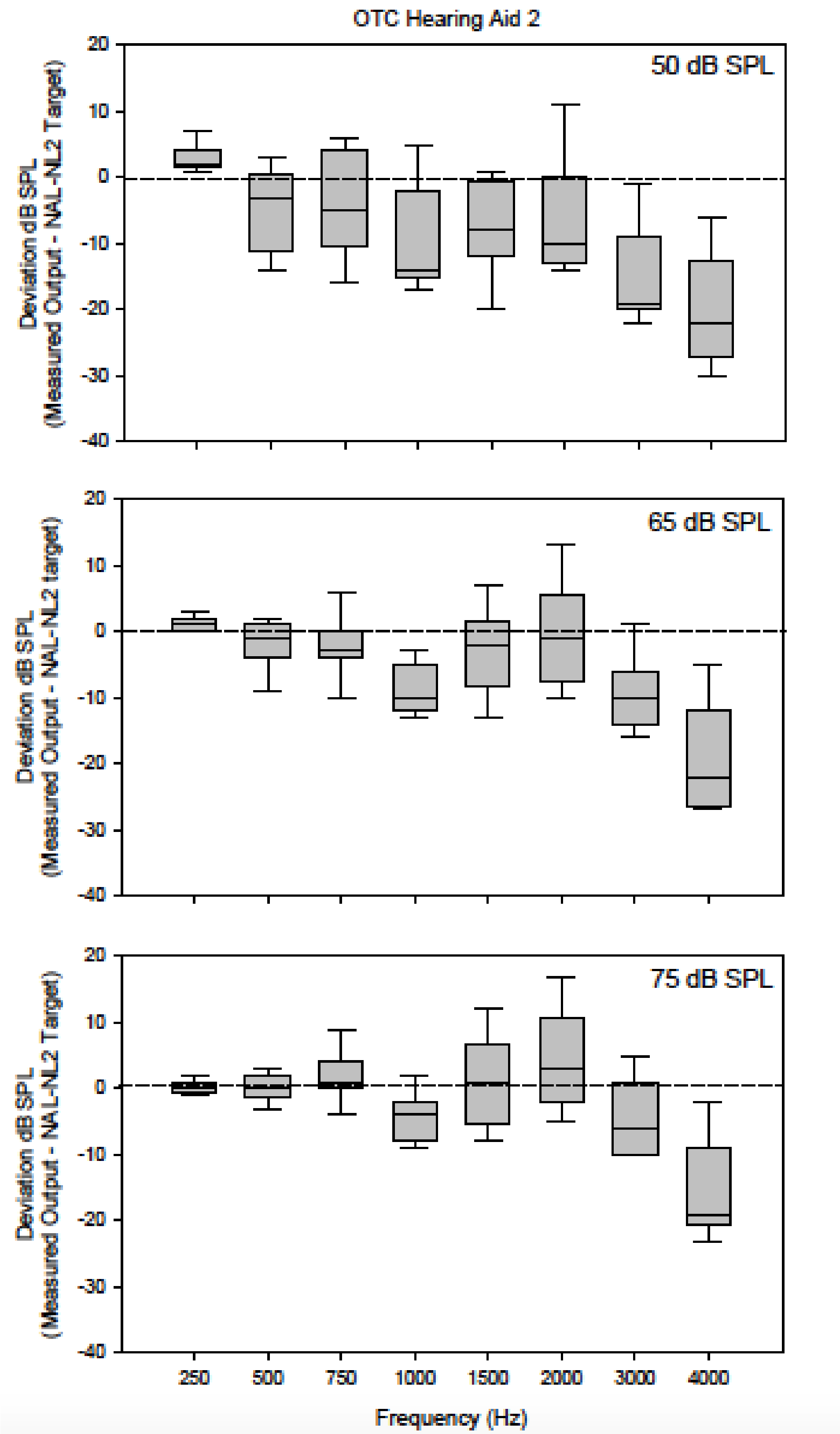
Table 6: Mean RMS deviations for each OTC hearing aid at 50, 65, and 75 dB SPL. Standard deviations are indicated in the brackets.

	Input Level (dB SPL)		
OTC Device	**50**	**65**	**75**
1	11.4 (4.16)	6.31 (3.79)	7.02 (3.39)
2	12.0 (3.82)	9.68 (2.32)	7.57 (1.84)
3	12.6 (3.57)	9.28 (3.33)	8.29 (1.86)

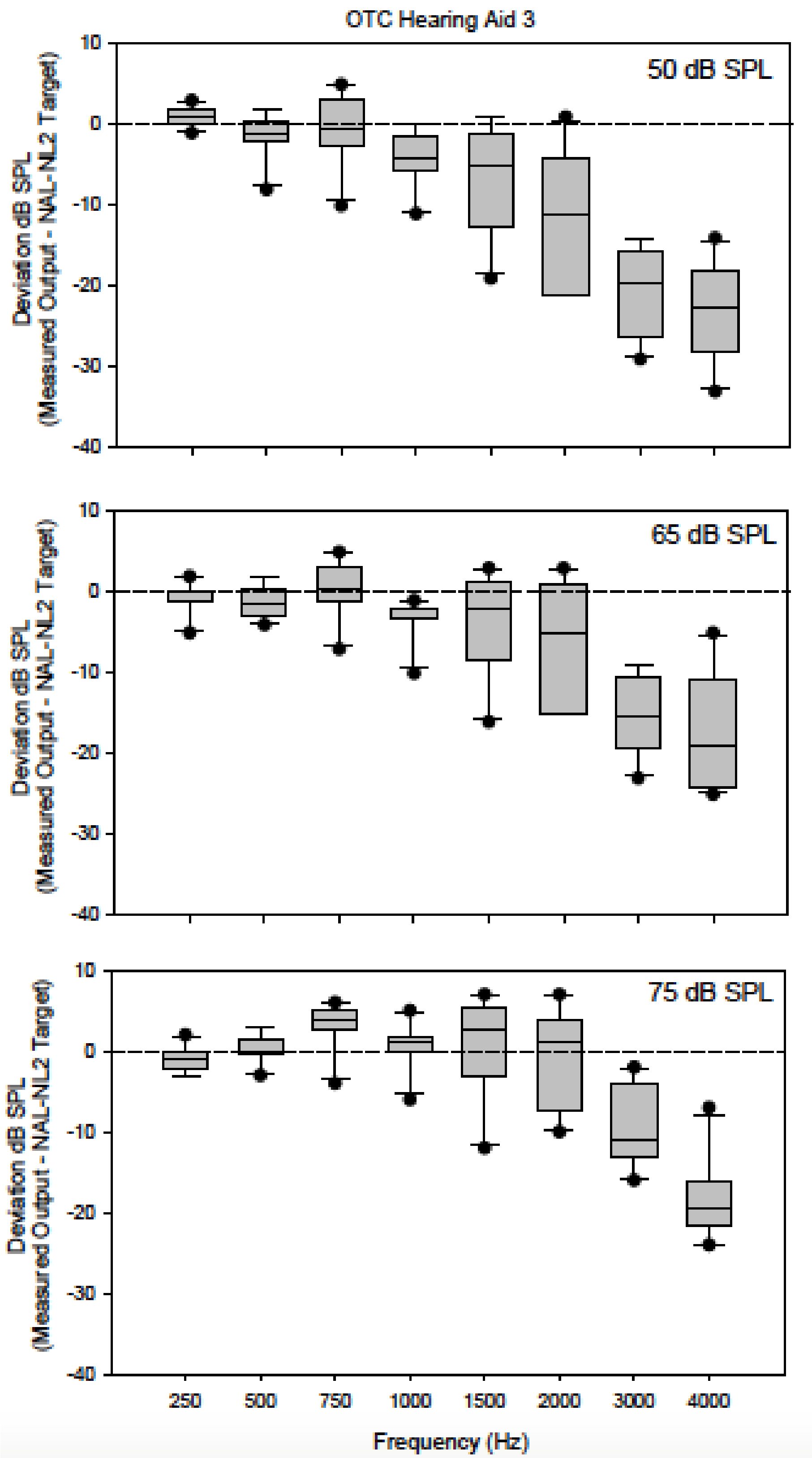
Figure 6 a-c: Box and whisker plots of each OTC hearing aid's deviation from NAL-NL2 target at each test frequency. Deviation= Measured Output – NAL –NL2 Target.
a)



b)


OTC Hearing Aid 2
50 dB SPL
65 dB SPL
75 dB SPL
Deviation dB SPL
(Measured Output - NAL-NL2 Target)
20
10
0
-10
-20
-30
-40
250
500
750
1000
1500
2000
3000
4000
Frequency (Hz)

c)


OTC Hearing Aid 3
50 dB SPL
65 dB SPL
75 dB SPL
Deviation dB SPL
(Measured Output - NAL-NL2 Target)
10
0
-10
-20
-30
-40
250
500
750
1000
1500
2000
3000
4000
Frequency (Hz)

Factors Related to OTC Hearing Aid Selection and Purchasing Questions

Participants were asked to indicate from a closed-set list of 14 factors, what influenced their decision to select the OTC device they wanted to purchase. Table 7 provides the top five factors for each device, and how many participants selected each factor. Clear website and easy to read descriptions were ranked as the top three and five factors, respectively, that influenced participants OTC hearing aid selection. For participants who selected OTC hearing aid 1 price and size were their top two factors and interestingly this device was the smallest and cheapest of the three OTC hearing aids. For participants who selected OTC hearing aids 2 and 3, smartphone compatibility was one of their top three factors. These two devices did offer hearing aid control via an app.

Table 7: Top five factors in descending order that influenced participants for each OTC hearing device.

Device	Factor	Percentage of Participants Who Selected Response
One (n= 17)	Size	82
	Price	76
	Clear Website	65
	Reviews	59
	Easy to Read Descriptions	53
Two (n = 15)	Clear Website	80
	Easy to Read Description	73
	Smartphone Compatibility	60
	Warranty	53
	Price	47
Three (n =17)	Smartphone Compatibility	88
	Easy to Read Description	76
	Clear Website	64
	Size	53
	Reviews	47

The distributions of participants' income levels for each device are shown in . To evaluate if income level was associated with device selection a Likelihood-Ratio Chi Square Test was performed. One subject was not included in this analysis, as they declined reporting their income level. The results showed that there was no significant association between income level and selected device (X^2 (8,48) = 12.7, p > 0.05).

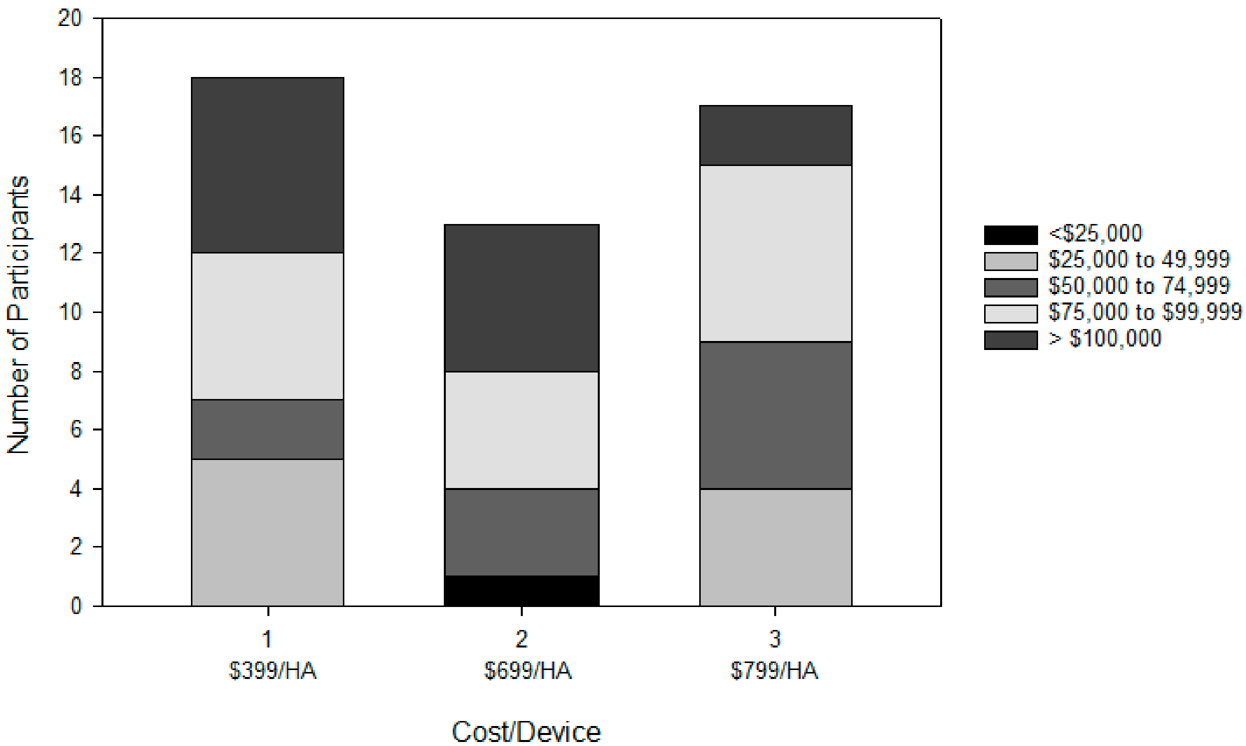


Figure 7: Distribution of participants' income status for each OTC hearing aid.

Participants' mean overall technology commitment scores for each OTC device are shown in table 8. A one-way ANOVA revealed no significant differences between OTC devices and technology commitment scores (F (3,48)= 0.005, p > 0.05).

Table 8: Mean scores for technology commitment for each OTC device. Standard deviations indicated in the brackets.

	OTC Hearing Aid 1	**OTC Hearing Aid 2**	**OTC Hearing Aid 3**
Overall Technology Commitment	44.4 (5.91)	44.5 (6.54)	44.6 (6.77)

After participants reviewed the OTC hearing aid devices' websites, but before they were given the device(s) they were asked if they would purchase an OTC hearing aid. Sixty-one percent of the 49 participants indicated that they would purchase an OTC hearing aid, and 53% (16/30) of these participants had normal PTAs in both ears and 47% (14/30) had a hearing loss in at least one ear. After completing the study, participants were asked again if they would purchase an OTC hearing aid. There was a 16% decrease in the number of participants who said they would purchase an OTC hearing aid, and 60% (15/25) of these participants were classified as having normal hearing in both ears.

Of the 15 participants flagged based on their CEDRA score for being at risk for ear disease, 60% (8/15) of these participants said that they would purchase an OTC hearing aid at the end of the study. Nine of the 15 participants indicated they would see a doctor a prior to purchasing an OTC hearing aid, but the other six participants would not have sought medical consultation before purchasing an OTC hearing aid.

DISCUSSION

The purpose of the present study was to determine if the average consumer is able to successfully navigate an OTC hearing aid model. The OTC hearing aid model requires an individual to self-identify if they are a candidate for an OTC hearing aid, self-select a device that is appropriate for their needs, and then self-fit and program the device. In addition, factors associated with successful self-identification of OTC hearing aid candidacy and the ability to self-fit a consumer selected device were assessed. The difference between a prescriptive target gain and the OTC hearing aid gain was measured for each device. Last, the factors that may have influenced an individual's device selection were investigated.

Factors Associated with Correctly Identifying OTC Hearing Aid Candidacy

In the OTC Hearing Aid Act (2017) it states that OTC hearing aids are intended for individuals with age-related (i.e. sensorineural), *perceived* mild-to-moderate hearing loss. This assumes individuals are able to correctly determine their degree and type of hearing loss. The participants in the present study responded to a flyer stating that we were seeking individuals who had difficulty hearing and were interested in trying an OTC hearing aid. They were not pre-screened for eligibility based on their audiometric thresholds. Interestingly, the participants had no greater than a moderate degree of hearing loss (i.e. a PTA > 55 dB HL), which is consistent with the criteria for the intended OTC hearing aid population. Perhaps individuals who have more severe degrees of hearing loss did not feel that an OTC hearing aid was an appropriate treatment option for them. Unfortunately, 48% (25/52) of the participants did not meet the OTC hearing aid candidacy requirement based on their hearing evaluation. That is, two participants had a conductive hearing loss in one ear and 23 participants had normal-hearing in both ears even though they self-reported a hearing loss. These findings are similar to those reported by Humes et al. (2019), where 30% of their participants who were interested in trying a direct-to-consumer hearing aid were excluded from the study because they did not meet the audiometric pre-screening criteria, and 66% of those who were excluded had a hearing loss that was too mild, which is similar to the high percent of individuals who had normal hearing in the present study.

Participants in the present study were asked to self-report the presence of a hearing loss in each ear. Only 20 of the 52 participants were able to correctly perform this task. Individuals who had a greater degree of hearing loss were more likely to correctly predict the presence of a hearing loss, which is not surprising given individuals who have greater degree of loss have more difficulties hearing (ASHA, 2019). However, the magnitude of the odds ratio related to this predictor variable in the present study was small. Several previous studies have also reported that there is discordance between self-predicted hearing loss and measured hearing loss (Kamil et al, 2015; Kiely et al, 2011; Kim et al, 2017; Nondahl et al, 1998), with self-reported hearing loss being more consistent with perceived hearing disability than an estimate of measured degree of hearing loss (Kiley et al., 2011). The concordance rate for the present study was 38%, which is slightly lower than the rates (43-81%) previously reported in other studies (Kamil et al, 2015; Kiely et al, 2011; Kim et al, 2017; Nondahl et al, 1998). This may be because participants in the previous studies were classified as being concordant based on an overall self-report of their hearing status, while the participants in the present study had to correctly identify their hearing status in *both* ears.

The variables gender and working memory have been reported to be predictive of discordance between self-predicted and measured hearing loss (Kim et al., 2017; Zekveld, George, Houtgast, & Kramer, 2013). For example, males have been shown to be more likely than females to underestimate their hearing loss (Kim et al., 2017), and better working memory has been found to be associated with more self-reported problems with speech perception in noise, which was independent of the individual's PTA (Zekveld, George, Houtgast, & Kramer, 2013). In the present study, the majority of participants who misclassified their hearing status were normal-hearing women who had higher levels of working memory. It should be noted that gender and working memory were found to be significant predictors of correctly categorizing hearing status in the exploratory analysis in the present study, but were not significant in the final logistic model. This is likely because univariate analyses are unable to identify covariate relationships between multiple predictors (Wang et al., 2017). Thus, the covariate relationship between working memory, gender, and PTA resulted in only PTA being a significant predictor in the final model. This suggests that there is an interaction between these three predictors, which diminished the predictive value of working memory and gender.

Little is known about the relationship between working memory and self-reported hearing status. Working memory has been shown to play an important role in a wide range of complex cognitive behaviors such as comprehension, decision-making, judgment, and problem solving (Missier et al., 2014; Conway et al., 2005). However, working memory was not shown to be a significant predictor in the final logistic model may be because of the test that was used to measure working memory capacity in the present study. For example, the R-SPAN evaluates how an individual keeps relevant information active and accessible during complex cognitive tasks (Conway et al., 2005; Baddeley and Hitch, 1974), but these two processes involved may not be directly related to the cognitive processes required to correctly self-report their hearing status. Although, working memory was not significantly related to correctly classifying hearing status it should be evaluated in future studies with different cognitive measures.

The majority of participants who stated that they would purchase an OTC hearing aid at the end of the present study were those individuals who had clinically normal-hearing thresholds. Previous studies have identified a clinical population of individuals who have clinically normal audiometric thresholds but self-report trouble hearing (Singh & Doherty, 2020; Alicea & Doherty, 2019; Roup, Post, & Lewis, 2018; Tremblay et al., 2015; Saunders & Haggard, 1989). Thus, these individuals experience significant hearing difficulties regardless of their normal-hearing thresholds. For example, Alicea & Doherty (2019) reported that the average hearing handicap level for a group of individuals who had normal-hearing, but self-reported difficulty hearing, was similar to a group of individuals who had a mild-to-moderate sensorineural hearing loss. This could be problematic because the guidelines of the OTC Hearing Aid Act indicate that

OTC hearing aids are intended for those who *perceive* a mild-to-moderate hearing loss. The purpose was likely to exclude the need for involvement by a hearing health care professional. However, the results from the present study suggest that clinically normal-hearing adults who *perceive* trouble hearing would be considered to meet the current candidacy guidelines.

Unfortunately, previous studies have shown that even high-end hearing aids that are fit by an audiologist using best practice methods are not the best treatment option for this population who have clinically normal-hearing (Singh & Doherty, 2020; Roup et al., 2018). Specifically, Singh & Doherty (2020) assessed the use of a mild-gain by two groups of middle-aged normal-hearing adults; one group self-reported trouble hearing in background noise and the other did not self-report trouble hearing in background noise. After a two-week trial with hearings aids the participants who self-reported having trouble hearing in background noise showed a decrease in hearing handicap levels. However, the decrease was not enough to motivate these individuals to want to actively address their hearing problems, as indicated by the University of Rhode Island Change Assessment. Also, only 20% of these participants stated they would consider purchasing a hearing aid. Perhaps such a low percent of participants were interested in purchasing a hearing aid because their hearing handicap levels were still significantly higher than the individuals who did not self-report trouble hearing in background noise. At the end of the present study, 60% of participants who stated they would purchase an OTC hearing aid had normal-hearing thresholds. However, this higher percentage of participants may reflect the fact that the participants in the present study did not have a trial period with their OTC hearing aids. Perhaps if they did have a trial, fewer of the normal-hearing participants would state they would purchase an OTC hearing aid, as Singh & Doherty (2020) found that normal-hearing adults who self-reported trouble hearing received little benefit from a hearing aid.

Another group of unintended users of OTC hearing aids are individuals who have ear disease. There were 53% (8/15) of the participants in the present study who were identified as being at risk for ear disease based on their CEDRA scores and said they would purchase an OTC hearing aid. In addition, 40% of these participants stated they would not see a medical doctor prior to purchasing OTC hearing aids. Although the majority of the participants in the present study were able to correctly classify their risk for ear disease, this small group of participants who were not able to was mostly comprised of individuals who were flagged by the CEDRA. This suggests that the CEDRA may play a useful role in the OTC hearing aid model.

It was assumed that higher education would be related to correctly classifying one's own ear disease status. However, this was not the case, but it should be noted that the predictive model had only 35% specificity, indicating that the model had a high rate of misclassifying participants who were incorrectly classifying their risk for ear disease as correct. Thus, the relationship between years of education and the classification of ear disease status should be tempered. None of the other independent variables assessed in this study were able to predict ear disease classification for these individuals. These results challenge the PCAST's (2015) assumption that the average consumer will be able to rule out the presence of ear disease. This can be a problem for consumers who may choose to purchase an OTC hearing aid without seeking medical consultation, and could result in negative consequences such as cholesteatoma. tympanic membrane perforation, benign tumors etc. which otherwise could be corrected for with medical or surgical intervention (ASHA, 2020). Furthermore, consumers may delay seeking critical medical care for changes in their hearing because they assume they are typical age-related changes (ASHA, 2017) .

Factors Associated with the Self-Fitting, Selection, and Programming of OTC Hearing Aids

Hearing aid handling skills have been shown to impact hearing aid success (Bennett et al., 2015). In the present study, one of the primary factors associated with participants' hearing aid handling skills was the type of OTC device they selected. No other factors were predictive of the participants' hearing aid handling and Bluetooth connectivity skills. Similar findings were reported in previous studies (Convery et al., 2018; Convery et al, 2017). For example, Convery et al. (2018) found that only previous hearing aid and smartphone experience were significant predictors of successful hearing aid assembly. In the present study, factors such as more of an internally focused locus of control, higher cognition, and better hearing aid self-efficacy were hypothesized to be related to better hearing aid and Bluetooth connectivity skills, but no significant relationship was observed. These negative findings may have been due to the inclusion criteria that was used in this study. That is, participants were required to be an owner of a smartphone/tablet, which meant all participants had some level of experience with technology prior to enrolling into the study. Previous studies have shown that individuals who use technology (i.e. smartphone or tablet) are more likely to have an internally focused locus of control (Abay, Blalock, & Berhane, 2017; Wishart, 2006), higher level of cognitive function (Tun & Lachman, 2010; Van Der Wardt, Bandelow, Hogervost, 2010), and higher level of technology self-efficacy (McCoy, 2010). Thus, there was not enough variation in performance across individuals on these measures for significant relationships because most of them had a more internally focused locus of control, and higher levels of cognitive function and technology self-efficacy compared to the general population.

The requirements that participants had to own a smartphone/tablet may also explain why the technology commitment scores did not differ between participants for a given device.

Previous studies have shown that users of technology have higher levels of technology commitment. For example, Taheden et al., (2018) reported that technology commitment scores and technology usage habits were significantly higher in hearing aid users compared to non-users. The technology commitment scores in the present study were relatively high. Scores ranged from 38 to 50, with the mean score on the questionnaire being 44 for each device. Thus, this may explain why technology commitment was not a factor that predicted OTC device selection.

In the present study an OTC device selection questionnaire was administered to participants to identify factors that influenced the individuals to select a specific device. Results from the questionnaire highlighted how both website design and content are important factors the participants used to select an OTC device. The usefulness of a web page is based on the information provided, the usability of the site, and the impression given to the user (Schenkman & Jonsson, 2000). Studies have shown that the aesthetics is the main factor of a webpage that provides the first overall impression, however people self-report that their first impression is based on the website's content (Thielsch, Blotenberg & Jaron, 2014). The findings from the present study are consistent with those reported in previous studies as the majority of participants ranked 'website appearance' and 'easy to read descriptions' as important factors that influenced their device selection. One of the limitations of the exploratory analysis is that it is difficult to know what specifically about each of the OTC website's appearance and content appealed to each participant. It is possible that participants were making their device decisions based on features they understood (i.e. price, size, smartphone compatibility), rather than features related to improving the function of the sound quality of the hearing aid. For example, the majority of the participants who selected OTC hearing aid 2 articulated that they did not know what the advantages were of t-coil technology, and therefore did not select it as a main factor that influenced their device selection.

Although income status was not found to be a predictor of device selection in the present study, participants who selected the least expensive OTC hearing aid did indicate that price influenced their decision. In contrast, participants who selected the other two OTC hearing aids did not identify price as being one of the main factors that influenced their device selection. Perhaps the participants who selected the least expensive OTC hearing aid had reservations about financially investing in OTC hearing aids because they did not think their hearing problems were significant enough to spend more money or they were hesitant to spend a lot of money on an online device that they were not fully confident would work for them. One of the reasons the PCAST (2015) recommended the development of an OTC hearing aid was to allow for consumers to easily shop around for a hearing aid that would provide them with the best value. Regardless of the device that a consumer chooses, the success with the device will be dependent upon the individual’s ability to self-fit the device and correctly use it during everyday listening situations.

Self-fitting an OTC devices will rely heavily on how well the manufacturer guides the consumer through the self-fitting process. This is typically done through instructional materials such as written guides, images, and videos provided by the manufacturer. The importance of good instructional materials for successful hearing aid use has been highlighted in previous studies (Convery et al., 2018; Caposecco, Hickson, Meyer, and Khan, 2015; Caposecco, Hickson, and Meyer, 2012). For example Caposecco et al. (2015) reported that the type of hearing aid user manual significantly influenced an individual’s performance on hearing aid handling skills tests. In their study they found individuals who were provided a modified manual (i.e. formatting content to follow best practice guidelines, enlarging graphics and including captions, adjusting content to be at a fourth grade reading level) obtained 3 points higher on the hearing aid management (HAM) task, which ranged from 0-14, than those who used the original version of the manual (Caposecco et al., 2015). Hearing aid management skills have also been shown to impact hearing aid uptake (McCormack & Fortnum, 2013). In the present study, although participants were encouraged to refer to the manufacturer manuals throughout the assessment, those who selected OTC hearing aids 2 or 3 performed significantly better on the PHAST-R compared to participants who selected OTC hearing aid 1. The individuals who selected OTC hearing aid 1 relied primarily on a written manual, which consisted of one, front and back, letter size paper with all of the instructions for use and assembly (See Appendix I for example). OTC hearing aid 1 did provide additional YouTube videos/links, but only one participant used the links when assembling their hearing aid. In contrast, OTC hearing aids 2 and 3 provided consumers with written guides, but individuals were required to set up the device by systematically moving through each stage of the fitting process and hearing aid programming using guided text and/or pictures on their smartphone application (See Appendix J and K for examples).

The majority of the participants who selected OTC hearing aid 1 did not know how to manipulate the volume control on the device. This may be because the instructions for how to change the volume versus programs was on the last page of the manual, and many participants likely did not read the manual in its entirety. Many of these participants also chose to incorrectly fit themselves with a closed dome. This was likely because the manual began with, "Use only closed-dome tip to start", then further down on the page it recommends, "Feeling too plugged? Try a vented tip", and participants did not read the second prompt. The vented dome was the best fit for the majority of the participants in the present study. Another possibility is the participants did not have enough of an opportunity during the study to establish if they felt plugged.

Regardless of the device the majority of participants had difficulty correctly inserting their OTC hearing aid(s). This suggests that both the hard copy and systematic instructions were inadequate to explain how to properly insert hearing aid(s). The insertion of these devices requires practice and the consumer is left to self-evaluate if they have correctly performed this task. Participants who selected OTC hearing aids 2 or 3 had the most difficulty with the pre-selected tip being too large for their ear(s). Alicea (2018) found that first time hearing aid users in their study obtained a mean score of 87.6% on the PHAST-R after being provided with targeted re-instruction at their initial hearing aid fitting. This is in contrast to the first-time hearing aid users in the present study who obtained an average score of 77.6% on the PHAST-R. These findings suggest that first-time hearing aid users who choose to pursue OTC hearing aids may have more difficulty with the handling and use of their hearing aids compared to those who obtain hearing aids from a hearing health care provider.

However, even with these fitting issues 45% of the participants in this study, which included both hearing impaired and normal hearing participants, said they would purchase an OTC hearing aid at the end of the study. This is consistent with previous studies that have shown that individuals are satisfied with their hearing aids, even if they are not working appropriately (Doherty & Desjardins, 2009). Thus, the average OTC hearing aid consumer may be satisfied with their devices even if they are poorly fit, which can compromise the function of the hearing aid.

It was assumed that the amount of fitting flexibility in a device would be related to better hearing aid programming. However, devices that provided more flexibility to fine-tune gain did not provide gain that was closer to prescriptive targets across frequencies than the OTC hearing aids with less fitting flexibility. For participants who had normal-hearing thresholds, all three devices attenuated the incoming signal at most of the test frequencies. This is concerning as these individuals would have spent several hundred dollars for a device that they thought would be providing them with amplification, but rather was plugging up their ears and attenuating sound. All three OTC devices for the hearing-impaired individuals in the present study did not provide adequate gain in the high frequencies. This is a problem given the importance of high frequency information for speech recognition. This under amplification in the higher frequencies may have been due to the poor physical fit of these devices. In general, the fit of a hearing aid has been shown to impact the broad acoustic characteristics of the sound (both high and low frequencies) being transferred from the hearing aid (Dillon, 2012). Several participants experienced feedback, which was also likely due to the poor fit. In an effort to reduce the feedback participants decreased the hearing aid gain. Also, with many participants choosing a closed dome for OTC hearing aid 1, it is possible that the participants programmed their hearing aids to be softer overall in an effort to reduce the occlusion effect. It is also possible that participants in this study chose to under-fit themselves for their initial fit, which would be consistent with the findings reported in previous studies (Humes et al., 2019; Humes et al., 2017; Mueller, Hornsby, & Weber, 2008).

Limitations in the current OTC hearing aid model were identified in the present study, which could have a negative impact on the success of OTC hearing aids for some individuals. For example, consumers will not be able to assess if they are good candidates for an OTC hearing aid or know how to correctly self-fit the OTC hearing aid. These individuals will think they have appropriately addressed their hearing problems, when in fact they are receiving inappropriate gain and in some cases or even worse gain with a hearing aid in their ear than without.

Although the OTC hearing aid model is designed to not include a hearing health care provider, there are measures that can be implemented to ensure that consumers of OTC hearing aids are protected. The American Academy of Audiology (2017) and the American Speech-Language- Hearing Association (2017) both recommend that OTC hearing aid labeling should state that better hearing aid outcomes are likely to be achieved if consumers receive a comprehensive audiological examination that is coupled with a rehabilitation program. This would encourage consumers who are struggling with their OTC hearing aid to seek help from a trained professional, who can then guide them through hearing aid self-fitting and programming process (Strom, 2019). At a minimum, consumers should be required to complete the CEDRA prior to the sale of an OTC hearing aid to identify if they are at risk for ear disease. This would reduce the potential risk of consumers overlooking an underlying medical condition that could be causing their hearing loss.

Audiologists should educate themselves in knowing the current direct-to-consumer hearing devices such as OTC hearing aids and PSAPS to be better prepared to provide hearing-impaired patients with entry-level options for those who are not ready to purchase higher end hearing aids (Strom, 2019). Furthermore, clinicians can counsel patients who are seeking more help with their OTC devices on how to use their hearing aids in different listening situations. As the hearing healthcare experts, it is important for audiologists to be able to be a part of the OTC hearing aid process as much or as little as needed by their patients.

Study Strengths and Limitations

The present study was the first to evaluate how well a consumer can navigate all of the stages of the OTC hearing aid model. Participants had to self-diagnose their hearing loss and risk for ear disease, self-select an OTC device, and fit and program the device using only the manufacturer's instructions. Previous studies that have evaluated the OTC hearing aid model only looked at specific stages of the model and/or lacked ecological validity. For example, Humes et al. (2017) did not require participants to self-determine OTC hearing aid candidacy, and pre-screened participants to include only people who had a mild-to-moderate hearing loss. Furthermore, participants in both the Humes et al., (2017) and Humes et al., (2019) studies were given pre-selected, high-end hearing aids that were pre-programmed to provide various amounts of high frequency gain. Participants were also provided with video-based assembly instructions that were designed by the researchers (Humes et al., 2019; Humes et al., 2017). A similar limitation was observed in the series of studies by Convery et al. (2018, 2017) where participants were provided with instructional material designed by the researchers, and were not required to self-program the hearing aids (Convery et al., 2018; Convery et al., 2017). Thus, a strength of the present study was participants performed all stages of the OTC hearing aid model. It was also the first study to explore factors that may influence a consumer when selecting a OTC hearing aid online. is the first to look at the OTC hearing aid model in its entirety.

One limitation of the present study was that participants were not required to complete a field trial with their self-selected OTC hearing aids. Thus, it is difficult to know if participants' hearing aid handling skills, and programming of their devices would have changed over time. All of the devices used in the present study were advertised to include at least a 30-day money back guarantee, which would have given the OTC hearing aid users a chance to adjust the fit of their device (e.g. change dome) and make programming changes based on their everyday listening situations. In the present study, participants were required to program their device while listening to running speech via a speaker in the sound booth at fixed 65 dB SPL level. Also, they were required to demonstrate their hearing aid handling skills only once, immediately after they programmed their device. A field trial would have provided participants a chance to practice using and learning more about their device, as well as to potentially make program changes.

The final limitation of the present study is related to the diversity of the participants. All but one participant was white, and 58% of the participants in the present study had a household income level that was greater than $75,000, which is above the current median income ($63,179) in the U.S. (U.S. Census, 2018). Race and socioeconomic disparities have been shown to impact hearing aid uptake, and the introduction of OTC hearing aids was to improve hearing aid use among these populations (Nieman, Marrone, Szanton, Thorpe, & Lin, 2016; PCAST, 2015). Furthermore, the participants in the present study were likely more technologically competent compared to the average consumer. Thus, it is difficult to know if the results from the present study are generalizable to the general population. Furthermore, all participants were screened for both vision and dexterity issues. Both poor vision and dexterity have been shown to negatively impact hearing aid manipulation (Singh, 2009; Kricos, 2007). If individuals with vision and/or dexterity issues were included in the present study, it would have likely impacted the findings related to hearing aid use and handling. However, none of the participants in the present study were excluded based on these types of screening measures. Therefore, results from the present study cannot be generalized to these populations. It is likely that individuals with poorer vision and/or dexterity would require more support if they were to pursue OTC hearing aids

Future Directions

Future studies should implement a field trial with these self-selected devices to learn about how consumer adjust to using OTC hearing aids and asses if they are more positive or less positive about the hearing aids after trying them for a longer period of time. Specifically if these individuals would experience a reduction in their hearing handicap and perceive benefit from their self-fit devices they would be more likely to wear them. It would also be interesting to see if a field trial would impact OTC hearing aid programming. Mueller et al., (2008) found that individuals who were under fit, preferred gain that was below prescriptive target. Thus, would be useful to learn how OTC hearing aid consumers adjust the programming of their hearing aids over time, and if they are able to reach prescriptive targets or stay under amplified as was seen in the present study.

Another area of interest would be to investigate how OTC hearing aid consumers are making device selection decisions. Focus groups could be used to evaluate how different advertised hearing aid features influence a novice hearing aid users' decision to select a specific device. Collaborating with a marketing researcher would be valuable when conducting such a study. It would be interesting to understand what about the OTC hearing aid model influenced an individual to change their perception of OTC hearing aids and motivation to change them.

CONCLUSION

The primary goal of the present study was to assess how well consumers could navigate each stage of the OTC hearing aid model (i.e., self-diagnose, self-treat, and self-manage their hearing loss). No participant was able to successfully perform all of the stages. OTC hearing aids are intended for adults with age-related mild-to-moderate hearing loss. However, in the present study the CEDRA identified 15 participants who were at risk for ear disease, and 60% of these individuals said they would purchase an OTC hearing aid. Also, 53% of the normal-hearing participants who self-reported that they had a hearing loss said they would purchase an OTC hearing aid. Thus, it is likely that there will be consumers who will inaccurately think that they are candidates for an OTC hearing aid. This does not support the PCAST's (2015) assumption that consumers will be able to self-determine OTC hearing aid candidacy. Furthermore, successful set up and use of an OTC hearing aid was dependent on the instructional materials provided by the OTC hearing aid manufacturer, but the majority of participants had difficulty correctly inserting their device. This will have a negative impact on how consumers program their OTC device and this type of poor fitting could limit the benefit a person receives from their OTC hearing aid. Last, participants selected the OTC hearing aid device based on factors such as price, size, and smartphone capabilities rather than features that were designed to improve sound quality.

Appendices

Appendix A: Demographic Questionnaire

Subject ID: _________

Date of Birth: ___________________________

Gender: _____________

Years of education completed: _______

Occupation: _________________________

Household Income (please circle one):

Less than $25,000	$25,000 to $49,999	$50,000 to $74,999	$75,000 to $99,999	$100,000 +

Do you have a hearing loss (please circle one):

YES NO

Which ears do you perceive a hearing loss:

RIGHT ONLY LEFT ONLY BOTH NONE

How would you describe your degree of hearing loss in both ears, if any?

	RIGHT	LEFT
NORMAL	____	____
MILD	____	____
MODERATE	____	____
MODERATELY- SEVERE	____	____
SEVERE	____	____
PROFOUND	____	____

How long have you had a hearing loss? (Please circle one)

< 1 YEAR	1-3 YEARS	3-5 YEARS	5-10 YEARS	11-20 YEARS	>20 YEARS

Do you think there is a medical condition that could be causing your hearing loss?

YES NO I DON'T KNOW

If yes, what? ____

Do you currently have health insurance?

YES NO

Do you currently have a primary care physician?

YES NO

Would you see your doctor before buying an over-the-counter hearing aid?

YES NO

Appendix B: Technology Questionnaire and Usage Questionnaire

TECHNOLOGY QUESTIONNAIRE

1. I often feel overstrained with dealing with new technological developments

Strongly Disagree | Disagree | Partly Disagree | Agree | Strongly Agree

2. Dealing with new technology is difficulty for me- I'm unable most of the times.

Strongly Disagree | Disagree | Partly Disagree | Agree | Strongly Agree

3. I'm often afraid when dealing with modern technology.

Strongly Disagree | Disagree | Partly Disagree | Agree | Strongly Agree

4. I'm rather afraid of breaking new technological developments instead of using them

Strongly Disagree | Disagree | Partly Disagree | Agree | Strongly Agree

5. I am very curious about new technological developments

Strongly Disagree | Disagree | Partly Disagree | Agree | Strongly Agree

6. I'm always interested in using the newest technical devices

Strongly Disagree | Disagree | Partly Disagree | Agree | Strongly Agree

7. I would use technological products more often if I had the opportunity

Strongly Disagree	Disagree	Partly Disagree	Agree	Strongly Agree

8. I quickly take to new technological developments

Strongly Disagree	Disagree	Partly Disagree	Agree	Strongly Agree

9. It is in my hands whether the use of new technological developments succeeds

Strongly Disagree	Disagree	Partly Disagree	Agree	Strongly Agree

10. Solving difficulties in dealing with technology depends on me

Strongly Disagree	Disagree	Partly Disagree	Agree	Strongly Agree

11. It is in my control what happens when I work with new technological developments.

Strongly Disagree	Disagree	Partly Disagree	Agree	Strongly Agree

12. Success in dealing with modern technology depends on me

Strongly Disagree	Disagree	Partly Disagree	Agree	Strongly Agree

TECHNOLOGY USAGE

Please circle one answer for each of the following questions:

1. Do you use a computer? If so, how often?

No Usage	Less than once a month	At least once a month	At least once a week	At least once a day

2. Do you use the internet? If so, how often?

No Usage	Less than once a month	At least once a month	At least once a week	At least once a day

3. Do you shop online? If so, how often?

No Usage	Less than once a month	At least once a month	At least once a week	At least once a day

4. How often do you use your smartphone?

No Usage	Less than once a month	At least once a month	At least once a week	At least once a day

Appendix C: Health Literacy Assessment

Instruction for Administering SAHL-E: Short Assessment of Health Literacy English (SAHL-E)

Interviewer's Instruction:

The *Short Assessment of Health Literacy-English*, or *SAHL-E*, contains 18 test items designed to assess an English-speaking adult's ability to read and understand common medical terms. The test could help health professionals estimate the adult's health literacy level. Administration of the test could facilitated by using laminated 4"×5" flash cards, with each card containing a medical term printed in boldface on the top and the two association words—i.e., the key and the distracter—at the bottom.

Directions to the Interviewer:
1. Before the test, the interviewer should say to the examinee:

"Im going to show you cards with 3 words on them. First, I'd like you to read the top word our loud, Next, I'll read the two words underneath and I'd like you to tell me which of the two words is more similar to or has a closer association with the top word. If you don't know, please say 'I don't know'. Don't guess."

2. Show the examinee the first card.

3. The interviewer should say to the examinee:
"Now, please, read the top word out loud"

4. The interviewer should have a clipboard with a score sheet to record the examinee's answers. The clipboard should be held such that the examinee cannot see or be distracted by the scoring procedure.

5. The interviewer will then read the key and distracter (the two words at the bottom of the card) and then say:
"Which of the two words is most similar to the top word? If you don't know the answer, please say 'I don't know'."

6. The interviewer may repeat the instructions so that the examinee feels comfortable with the procedure.

7. Continue the test with the rest of the cards.

8. A correct answer for each test item is determined by both correct pronunciation and accurate association. Each correct answer gets one point. Once the test is completed, the interviewer should tally the total points to generate the *SAHL-E* score.

9. A score between 0 and 14 suggests the examinee has low health literacy.

The 18 items of SAHL-E ordered according to item difficulty (keys and distracters are listed in the same random order as in field interview)

Stem	Key or Distractor		
1.kidney	__urine	__fever	__don't know
2.occupation	__work	__education	__don't know
3.medication	__instrument	__treatment	__don't know
4.nutrition	__healthy	__soda	__don't know
5.miscarriage	__loss	__marriage	__don't know
6.infection	__plant	__virus	__don't know
7.alcoholism	__addiction	__recreation	__don't know
8.pregnancy	__birth	__childhood	__don't know
9.seizure	__dizzy	__calm	__don't know
10.dose	__sleep	__amount	__don't know
11.hormones	__growth	__harmony	__don't know
12.abnormal	__different	__similar	__don't know
13.directed	__instruction	__decision	__don't know
14.nerves	__bored	__anxiety	__don't know

15.constipation	__blocked	__loose	__don't know
16.diagnosis	__evaluation	__recovery	__don't know
17.hemorrhoids	__veins	__heart	__don't know
18.syphilis	__contraception	__condom	__don't know

Appendix D: Locus of Control Assessment

Form A

Instructions: Each item below is a belief statement about your medical condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer EVERY ITEM and that you circle ONLY ONE number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

1=STRONGLY DISAGREE (SD)
2=MODERATELY DISAGREE (MD)
3=SLIGHTLY DISAGREE (D)
4=SLIGHTLY AGREE (A)
5=MODERATELY AGREE (MA)
6=STRONGLY AGREE (SA)

Number	Question	SD	MD	D	A	MA	SA
1	If I get sick, it is my own behavior which determines how soon I get well again.	1	2	3	4	5	6
2	No matter what I do, if I am going to get sick, I will get sick.	1	2	3	4	5	6
3	Having regular contact with my physician is the best way for me to avoid illness	1	2	3	4	5	6
4	Most things that affect my health happen to me by accident.	1	2	3	4	5	6

5	Whenever I don't feel well, I should consult a medically trained professional.	1	2	3	4	5	6
6	I am in control of my health.	1	2	3	4	5	6
7	My family has a lot to do with my becoming sick or staying healthy.	1	2	3	4	5	6
8	When I get sick, I am to blame.	1	2	3	4	5	6
9	Luck plays a big part in determining how soon I will recover from an illness.	1	2	3	4	5	6
10	Health professionals control my health.	1	2	3	4	5	6
11	My good health is largely a matter of good fortune.	1	2	3	4	5	6
12	The main thing which affects my health is what I myself do.	1	2	3	4	5	6
13	If I take care of myself, I can avoid illness.	1	2	3	4	5	6
14	Whenever I recover from an illness, it's usually because other people (for example, doctors, nurses, family, friends) have been taking good care of me.	1	2	3	4	5	6

15	No matter what I do, I 'm likely to get sick.	1	2	3	4	5	6
16	If it's meant to be, I will stay healthy.	1	2	3	4	5	6
17	If I take the right actions, I can stay healthy.	1	2	3	4	5	6
18	Regarding my health, I can only do what my doctor tells me to do.	1	2	3	4	5	6

Appendix E: Hearing aid Self Efficacy Questionnaire

These questions ask about your ability to do certain activities with a hearing aid, and they also ask about your ability to hear in certain situations. If you have never been in these situations, then make your best guess about how well you could do. Given what you know right now, indicate how confident you are that you could do the things described here.

Sample question:

a. I can lift a 10-pound object with ease.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

1. I can insert a battery into a hearing aid with ease.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

2. I can remove a battery from a hearing aid with ease.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

3. I can tell a right hearing aid from a left hearing aid.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

4. I can insert hearing aids into my ears accurately.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

5. I can remove hearing aids from my ears with ease.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

6. I can identify the different components of a particular hearing aid (i.e. microphone, battery door, vent etc.)

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

7. I can operate all the controls on a particular hearing aid (i.e. knobs, switches, and/or remote control) appropriately.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

8. I can stop a hearing aid from squealing.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

9. I can troubleshoot a hearing aid when it stops working.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%

Cannot do this at all	Moderately Certain can do	I am certain I can do this

10. I can clean and care for a hearing aid regularly.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

11. I can name the make or model of a particular hearing aid.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

12. I can name the battery size needed for a specific hearing aid.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

13. I could get used to the sound quality of a hearing aid.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

14. I could get used to how a hearing aid feels in my ear.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

15. I could get used to the sound of my own voice if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

16. I could understand a one-on-one conversation in a quiet place if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

17. I could understand conversation in a small group in a quiet place if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

18. I could understand conversation on a standard telephone if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

19. I could understand television if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

20. I could understand the speaker/lecturer at a meeting or presentation if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

21. I could understand a one-on-one conversation in a noisy place if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

22. I could understand conversation in a small group while in a noisy place if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

23. I could understand a public service announcement over the loudspeaker in a public building if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

24. I could understand conversation in a car if I wore hearing aids.

How certain are you that you can do this? (circle percentage)

0%	10	20	30	40	50	60	70	80	90	100%
Cannot do this at all					Moderately Certain can do					I am certain I can do this

Appendix F: OTC selection questionnaire

OTC SELECTION QUESTIONNAIRE

Device Selected: ________________________

Number of Devices Purchased: ____________

Which of the following influenced your decision to select the OTC hearing aid you chose:

Clear/Easy to Navigate Website	____
Price	____
Size of device	____
Color of Device	____
Reviews on device	____
Provides a hearing test	____
Warranty	____
Company Name	____
T-Coil Technology	____
Smartphone Compatibility	____
Battery life	____
Discounts	____
Website Appearance	____
Clear Descriptions and Explanations	____

Other:
____
____
____
____

Appendix G: Hearing aid Use Tasks Tool

Hearing Aid Use Skills Tasks

Instructions:
Place the following items in front of the participant: A telephone, and different size batteries (10, 312, 13 etc.). Also disassemble the hearing aid prior to starting the hearing aid use skills tasks.
Scoring:
2= Performs the task without any problems
1= Performs the task using 'deviant' means (e.g. takes aid out to adjust VC), needs some re-instruction
0= Cannot perform the task

1. Ask the participant, "Show me how to put the hearing aid together"				
a. Can he/she attach the dome to the tube?	0	1	2	N/A
b. Can he/she attach the tube to the hearing aid?	0	1	2	N/A
2. Ask the participant, "Open up the batter door."				
a. Can he/she locate the door on the first try?	0	1	2	N/A
b. Can he/she open the door without difficulty?	0	1	2	N/A
3. Ask the participant, "Please show me how you change your hearing aid battery."				
a. Can he/she remove the old battery?	0	1	2	N/A
b. Did he/she choose correct battery size?	0	1	2	N/A
c. Can he/she remove battery tab?	0	1	2	N/A
d. Can he/she correctly place new battery in battery compartment?	0	1	2	N/A
4. Ask the participant, "Please put your hearing aid back in your ear."				
a. Can he/she grasp aid?	0	1	2	N/A
b. Can he/she place the aid properly in the ear?	0	1	2	N/A
c. Can he/she distinguish between left and right hearing aid?	0	1	2	N/A
5. Ask the participant, "Turn up the volume of your hearing aid"				
a. Can he/she correctly manipulate the VC?	0	1	2	N/A
6. Ask the participant, "Show me how you use the telephone with your HA. (Hand phone to patient)				
a. Can he/she choose correct program/t-coil?	0	1	2	N/A
b. Can he/she correctly place the phone in relation to the aid?	0	1	2	N/A
7. Ask the participant, "Show me how you would adjust your hearing aid when you are in a noisy environment."				
a. Can he/she use correct program?	0	1	2	N/A
8. Ask the participant, "Show me how you download the app for your hearing aid."				
	0	1	2	N/A

a. Does he/she have the correct application selected on their phone?	0	1	2	N/A
b. Can he/she install the application to their phone?				
9. Ask the participant, “Show me how you connect your hearing aid to your phone.”				
a. Can he/she turn on Bluetooth on their phone?	0	1	2	N/A
b. Can he/she pair the device to their phone?	0	1	2	N/A
10. Ask the participant, “Show me how you use the app to set the programs of your hearing aid.”				
a. Can he/she change programs using the app?	0	1	2	N/A
11. Ask the participant, “Please take out your hearing aid.”				
a. Can he/she grasp the aid?	0	1	2	N/A
b. Can he/she remove aid properly?	0	1	2	N/A

Appendix H: CEDRA questionnaire

This questionnaire is designed to help you decide if you need to see a doctor before obtaining a hearing device. If you have any medical questions or concerns about your hearing, you should see a doctor no matter what your score is on this questionnaire.

Questions about your Ears and Hearing

Circle "Yes" or "No"

1. When talking on a telephone, do you understand what people say better in one ear than the other?	Yes	No
2. Did the hearing loss in either of your ears develop suddenly?	Yes	No
3. Have you ever had a sudden permanent change in your hearing?	Yes	No
4. Do you have hearing loss in only one ear?	Yes	No
5. Do you hear better in one ear than the other?	Yes	No
6. Does your hearing change from day to day?	Yes	No
7. As an adult, have you ever had more than one infection in the same ear during one year?	Yes	No
8. Have you ever noticed pus, blood or other active fluid discharge from your ear?	Yes	No
9. Have you ever been told by a physician that you have Meniere's disease?	Yes	No

10. Overall, how would you rate your health?

☐ Very good

☐Good

☐Poor

☐ Very poor

11. How often do you have dizziness?

☐Never

☐Occasionally

☐Frequently

☐Always

12. How would you rate your balance?

☐ Very good

☐Good

☐Poor

☐ Very poor

13. Do you have tinnitus, such as ringing, roaring, or cricket-like sounds in your ears? Yes No

If you answered "No", skip to <u>question 14</u>.

13a. If yes to 13, do you have tinnitus in (check one):

- ☐ Right Ear
- ☐ Left Ear
- ☐ Both Ears
- ☐ Unsure

13b. If yes to 13a, do you have any of the following symptoms with your tinnitus?

Dizziness	Yes	No
Pressure in the ear	Yes	No
Fullness in the ear	Yes	No
Plugged feeling in the ear	Yes	No

14. Have you ever had any of the following symptoms lasting longer than 10 minutes?

Sudden drop in hearing in one or both ears	Yes	No
A rapid change in vision in one or both eyes	Yes	No

15. In the past 3 months, have you had any of the following symptoms?

Any persistent discharge from either ear	Yes	No
Pus or blood in your ears	Yes	No
Any persistent pain in or around either ear	Yes	No
A change in hearing in one or both ears	Yes	No
A head cold or sinus problem that made your hearing worse	Yes	No
Dizziness	Yes	No
Fell because of poor balance	Yes	No
A persistent or recurring headache	Yes	No
Recurring fever, night sweats, chills	Yes	No

Score Sheet

Please proceed with scoring only if you have finished answering all questions on pages 1 and 2. Check on pages 1 and 2 to ensure you have answered all 15 questions before you calculate your score.

For the following questions count the number of times you have responded "yes":

Question #	1	2	3	4	5	6	7	8	9
Number of "yes"									
	Add the numbers in the boxes above [A]								

Question #		Points
10	**One** point if "Poor" or "Very Poor" is checked	
11	**One** point if "Frequently" or "Always" is checked	
12	**One** point if "Poor" or "Very Poor" is checked	
13	**No points** for this question.	0
13a	**One** point if **either** "Right ear" OR "Left Ear" is checked, **Zero** if **both** are checked	
13b	**Number of "yes"** responses	
14	**Number of "yes"** responses	
15	**Number of "yes"** responses	
	Add points above [B]	

Add scores from above: [A] + [B] = CEDRA score

If your score is 4 or higher, you should talk to a doctor about your symptoms.

Appendix I: OTC Hearing Aid 1 Instructions

iHEARmax™

5 Optimizing your Sound Profile Volume

Now that you have selected your sound profile, you can adjust the volume in 2-steps for better clarity.

With the device(s) out of your ear(s) TURN ON the TV & ADJUST the volume until the speech level is **very soft**. RE-INSERT your device(s) LISTEN to the news or your favorite talk show for approximately 10 minutes.

If you experience problems understanding soft speech level, boost your Sound Profile Volume by pressing the button for 2 seconds (long press) until you hear a high frequency tone. Repeat the volume boost for improved loudness and intelligibility. You have a maximum of 2 level boosts. You will hear 3 tones when maximum volume is reached. To return to default volume boost setting, you must open and close the battery door.

ACTION	FUNCTION
SHORT PRESS	Change sound profile (1-4)
LONG PRESS (2 sec)	Boost Volume

CIRCLE YOUR BOOST LEVEL

L	0 [NO BOOST]	1	2	R	0 [NO BOOST]	1	2

Left and right may have a different boost levels due to different listening preferences.

Customizing your device

You may customize your iHEAR device(s) with the Programming Kit or with the Pre-Programming Service option. Please visit www.ihearmedical.com/ihearmax or contact Customer Support at 1-844-443-2744 for more information on customization options.

⚠ **USE ONLY iHEAR TIPS - *DO NOT USE*** other manufacturer tips as they are ***NOT COMPATIBLE*** with the iHEARmax.

Tip needs to be replaced after 30 days of use for optimal performance and hygiene.

iHEAR batteries, Cleaning Wipes and Tip replacements are available through our on-line store at www.ihearmedical.com or through customer support at 1 (844) IHEAR44 (1-844-443-2744).

iHEARmax — Easy Setup GUIDE

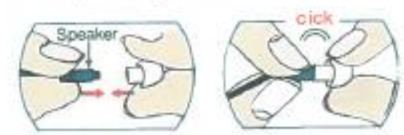
IMPORTANT INFORMATION - PLEASE READ

1 Selecting the correct Tip size

Watch video https://www.ihearmedical.com/max-video-1

Determine your Tip size by using the Closed Tip - *use only Closed Tip to start.*

⚠ Start with the Tip already attached to your device(s).



⚠ Tip(s) should be attached securely to the Speaker.

2 Inserting the Tip into your ear canal

Watch video https://www.ihearmedical.com/max-video-3

a. Gently **INSERT** the Tip (attached to the device) into your ear (**blue** - left | **red** - right).
b. **TUCK** the device behind your ear.
c. Gently **PUSH** the Tip into your ear to ensure it fits in securely.

- *Too tight? Go down a size. Too loose? Go up a size*
- *Correct Tip size should feel snug but comfortable in the ear.*
- *Each ear canal may require different Tip sizes.*
- *Feeling too plugged up? Try a Vented Tip.*

iHEARmax™

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Now that you have selected your sound profile, you can adjust the volume in 2-steps for better clarity.

With the device(s) out of your ear(s) TURN ON the TV & ADJUST the volume until the speech level is **very soft.** RE-INSERT your device(s) LISTEN to the news or your favorite talk show for approximately 10 minutes.

If you experience problems understanding soft speech level, boost your Sound Profile Volume by pressing the button for 2 seconds (long press) until you hear a high frequency tone. Repeat the volume boost for improved loudness and intelligibility. You have a maximum of 2 level boosts. You will hear 3 tones when maximum volume is reached. To return to default volume boost setting, you must open and close the battery door.

ACTION	FUNCTION
SHORT PRESS	Change sound profile (1-4)
LONG PRESS (2 sec)	Boost Volume

CIRCLE YOUR BOOST LEVEL

L	0 [NO BOOST]	1	2	R	0 [NO BOOST]	1	2

Left and right may have a different boost levels due to different listening preferences.

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You may customize your iHEAR device(s) with the Programming Kit or with the Pre-Programming Service option. Please visit www.ihearmedical.com/ihearmax or contact Customer Support at 1-844-443-2744 for more information on customization options.

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iHEARmax Easy Setup GUIDE

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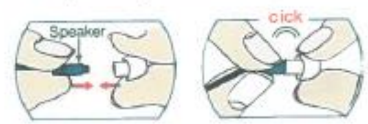


⚠ Tip(s) should be attached securely to the Speaker.

2 Inserting the Tip into your ear canal

Watch video https://www.ihearmedical.com/max-video-3

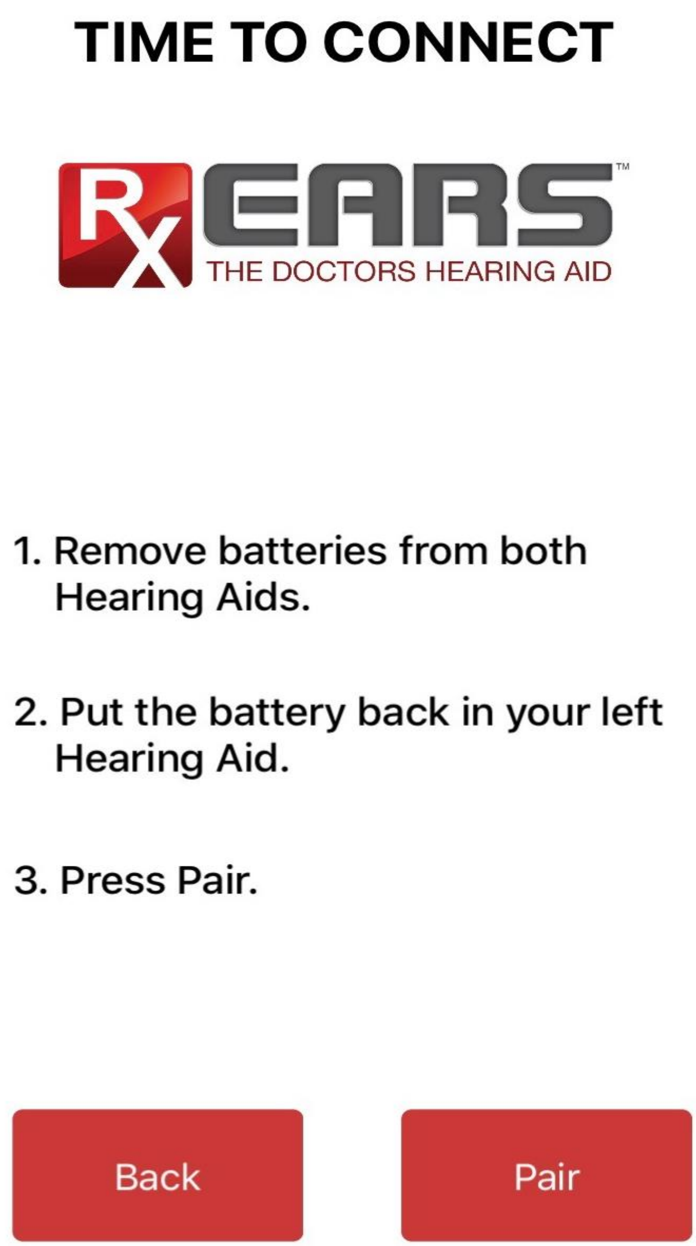
a. Gently **INSERT** the Tip (attached to the device) into your ear (**blue** - left | **red** - right).

b. **TUCK** the device behind your ear.

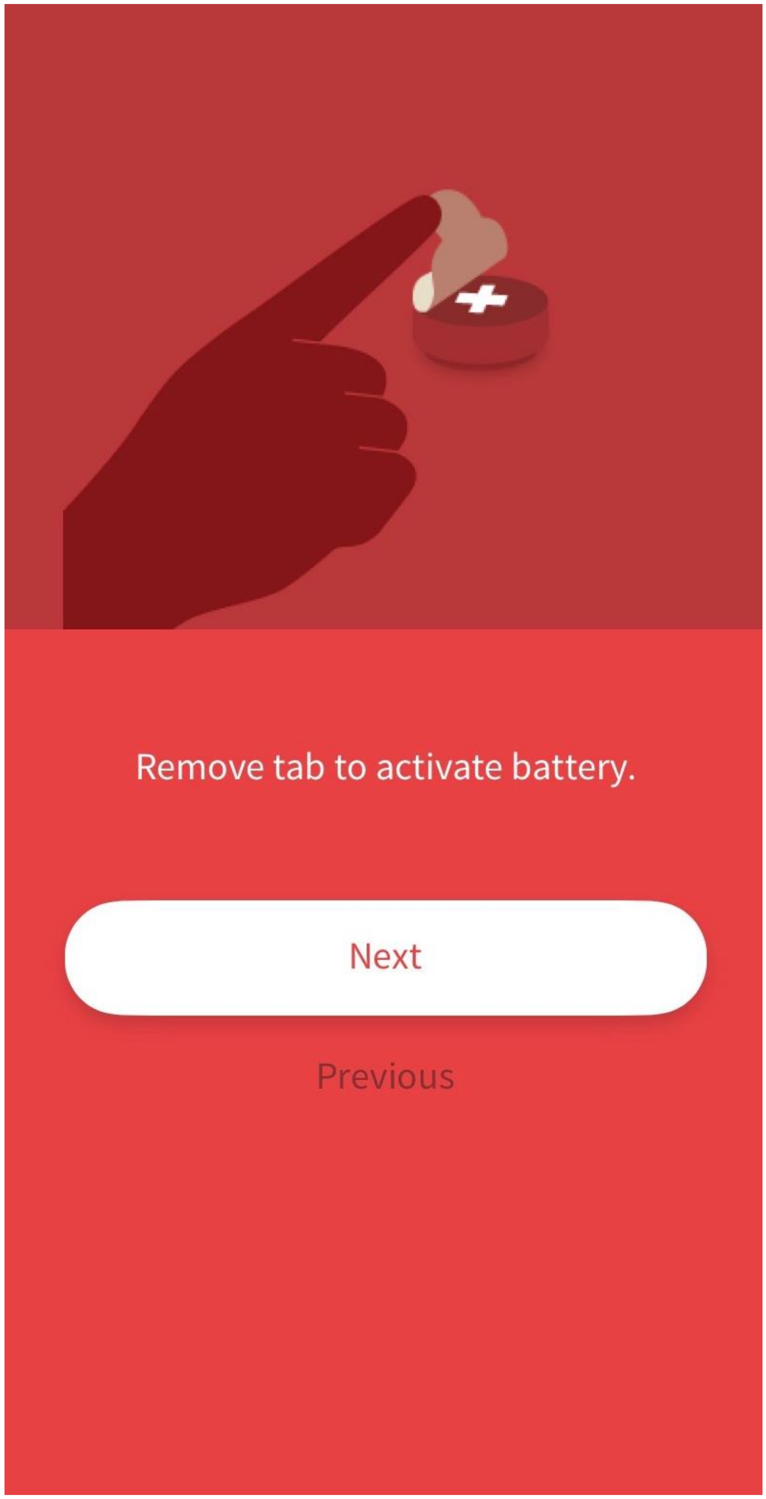
c. Gently **PUSH** the Tip into your ear to ensure it fits in securely.

- *Too tight? Go down a size. Too loose? Go up a size*
- *Correct Tip size should feel snug but comfortable in the ear.*
- *Each ear canal may require different Tip sizes.*
- *Feeling too plugged up? Try a Vented Tip.*

Appendix J: Sample of systematic instructions given through OTC Hearing Aid 2's app



Appendix K: Sample of systematic instructions given through OTC Hearing Aid 3's app



Appendix L: Pairwise correlation between predictors for objective 1

Self-identification of Hearing Status:

Correlation between working memory and PTA

- $r = -0.26$, p-value > 0.05

References

Abay, K. A., Blalock, G., & Berhane, G. (2017). Locus of control and technology adoption in developing country agriculture: Evidence from Ethiopia. *Journal of Economic Behavior & Organiation* , *143*, 98-115.

Adams, S. (1995). Who Will Hear? An Examination of the Regulation of Hearing Aids. *Journal of Contemporary Health Law & Policy* , *11* (2).

Alicea, C. C. (2018) Targeted Re-Instruction for Hearing Aid Use and Care Skills. *Dissertations - ALL*. 951.

Alicea, C. C., & Doherty, K. A. (2017). Motivation to Address Self-Reported Hearing Problems in Adults With Normal Hearing Thresholds. *Journal of Speech Language and Hearing Research* , *60* (12), 3642-3655.

American Academy of Audiology. (2017). *Over-the-Counter (OTC) Hearing Devices: Issue Statement from the American Academy of Audiology*.

American Speech Language Hearing Association. (2020). *Hearing Loss- Beyond Early Childhood*. Retrieved from American Speech Language Hearing Association: https://www.asha.org/Practice-Portal/Clinical-Topics/Hearing-Loss/

American Speech Language Hearing Asssociation. (2016). *ASHA: Professional Counseling and Access Go Together When It Comes to Hearing Aids*. Retrieved June 2019, from American Speech Language Hearing Asssociation: https://www.asha.org/About/news/Press-Releases/2016/Professional-Counseling-and-Access-Go-Together-When-It-Comes-to-Hearing-Aids/

American Speech-Language-Hearing Association. (2017). *Statement for the Record for the Health Subcommittee of the Energy and Commerce Committee Regarding Over-the-Counter Hearing Aids (H.R. 1652).* Rockville: American Speech-Language-Hearing Association.

Amieva , H., Ouvrard, C., Giulioli , C., Meillon , C., Rullier , L., & Dartigues , J. (2015). Self-Reported Hearing Loss, Hearing Aids, and Cognitive Decline in Elderly Adults: A 25-Year Study. *Journal of the American Geriatrics Society* .

Arlinger, S. (2003). Negative consequences of uncorrected hearing loss - A review. *International Journal of Audiology* .

Baddeley, A. D., & Hitch, G. (1974). Working Memory. *Psychology of Learning and Motivation*, 47-89.

Barnett, M., Hixon, B., Okwiri, N., Irungu, C., Ayugi, J., Thompson, R., et al. (2017). Factors Involved in Access and Utilization of Adult Hearing Healthcare: A Systematic Review . *Laryngoscope* , *127* (5), 1187-1194.

Bennett, R. J., Taljaard, D. S., Brennan-Jones, C., Tegg-Quinn, S., & Eikelboom, R. H. (2015). Evaluating hearing aid handling skills: A systematic and descriptive review. *International Journal of Audiology* , 765-776.

Blustein, J., & Weinstein, B. E. (2016). Opening the Market for Lower Cost Hearing Aids: Regulatory Change Can Improve the Health of Older Americans. *American Journal of Public Health* , *106* (6), 1032-1035.

Brainerd, S. H., & Frankel, B. G. (1985). The Relationship between Audiometric and Self-Report Measures of Hearing Handicap. *6* (2), 89-92.

California Ear Institute. (2019). *Acoustic Neuroma / Vestibular Schwannoma*. Retrieved May 2019, from California Ear Institute: http://www.californiaearinstitute.com/ear-disorders-acoustic-neuroma-california-ear-institute-bay-area.php

Caposecco, A., Hickson, L., & Meyer, C. (2011). Assembly and Insertion of a Self-Fitting Hearing Aid: Design of Effective Instruction Materials. *Trends in Amplification , 15* (4), 184-195.

Caposecco, A., Hickson, L., & Meyer, C. (2014). Hearing aid user guides: Suitability for older adults. *International Journal of Audiology , 53* (S1).

Carlson, M., Habermann, E., Wagie, A., Driscoll, C., Van Gompel, J., Jacob, J., et al. (2015). The Changing Landscape of Vestibular Schwannoma Management in the United States—A Shift Toward Conservatism. *Otolaryngology– Head and Neck Surgery , 152* (3), 440–446.

Center for Disease Control and Prevention. (2018, October 13). *HRQOL Concepts*. Retrieved 2019, from Center for Disease Control and Prevention: https://www.cdc.gov/hrqol/concept.htm

Chan, S., Hixon, B., Adkins, M., Shinn, J. B., & Bush, M. L. (2017). Rurality and Determinants of Hearing Healthcare in Adult hearing Aid Recipients. *The Laryngoscope , 127* (10), 2362-2367.

Chisolm, T., Johnson, C. E., Danhauer, J. L., Portz, L. J., Abrams, H. B., Lesner, S., et al. (2007). A Systematic Review of Health-Related Quality of Life and Hearing Aids: Final Report of the American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults. *Journal of the American Academy of Audiology , 18*, 151-183.

Convery, E., Keidser, G., Hickson, L., & Meyer, C. (2018). Factors Associated With Successful Setup of a Self-Fitting Hearing Aid and the Need for Personalized Support. *Ear & Hearing* .

Convery, E., Keidser, G., Seeto, M., & McLelland, M. (2017). Evaluation of the Self-Fitting Process with a Commercially Available Hearing Aid . *Journal of the American Academy of Audiology , 28*, 109-118.

Convery, E., Kiedser, G., Hartley, L., Caposecco, A., Hickson, L., & Meyer, C. (2011). Management of Hearing Aid Assembly by Urban-Dwelling Hearing-Impaired Adults in a Developed Country. *Trends in Amplification , 15* (4), 196–208.

Czaja, S. (2006). Factors Predicting the Use of Technology: Findings From the Center for Research and Education on Aging and Technology Enhancement (CREATE). *Psychology and Aging , 21* (2), 333-352.

Davis, A., Smith, P., Ferguson, M., Stephens, D., & Gianopoulos, I. (2007). Acceptability, benefit and costs of early screening for hearing disability: a study of potential screening tests and models. *Health Technology Assessment* .

Dillon, H. (2012). Hearing Aid Earmolds, Ear Shells, and Coupling Systems. In *Hearing Aids, Second Edition* (pp. 127-169). New York: Thieme Publishers.

Doherty, K. A., & Desjardins, J. L. (2009). Do Experienced Hearing Aid Users Know How to Use Their Hearing Aids Correctly? *American Journal of Audiology , 18* (1), 69-76.

Doherty, K. A., & Desjardins, J. L. (2015). The benefit of amplification on auditory working memory function in middle-aged and young-older hearing impaired adults. *Frontiers* .

Doherty, K. A., & Desjardins, J. L. (2012). The Practical Hearing Aids Skills Test-Revised. *American Journal of Audiology , 21* (1), 100-105.

Donhue, A., Dubno, J. R., & Beck, L. (2010). Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss. *Ear and Hearing , 31* (3), 2-6.

Ferguson, M. A., Kitterick, P. T., Chong, L. Y., Edmondson-Jones, M., Barker, F., & Hoare, D. J. (2017). Hearing aids for mild to moderate hearing loss in adults. *Cochrane Library* .

Goman, A., & Lin, F. R. (2016). Prevalence of Hearing Loss by Severity in the United State. *American Journal of Public Health , 106* (10), 1820–1822.

Goman, A., Reed, N. S., & Lin, F. R. (2017). Addressing Estimated Hearing Loss in Adults in 2060. *JAMA Otolaryngol Head Neck Surg , 143* (7), 733-734.

Gonsalves, C., & Pichora-Fuller, K. M. (2008). The effect of hearing loss and hearing aids on the use of information and communication technologies by community-living older adults. *Canadian Journal of Aging , 27* (2), 145-157.

Gopinath, B., Wang, J. J., Schneider, J., Burlutsky, G., Snowdon, J., McMahon, C. M., et al. (2009). Depressive Symptoms in Older Adults with Hearing Impairments: The Blue Mountains Study. *Journal of the American Geriatrics Society , 57* (7), 1306-1308.

Govender, N. G., Maistry, N., Soomar, N., & Paken, J. (2014). Hearing loss within a marriage: perceptions of the spouse with normal hearing. *South African Family Practice* , 50-56.

Granberg, S., Swanepoel, E., Moller, C., & Danermark, B. (2014). The ICF core sets for hearing loss project: International expert survey on functioning and disability of adults with hearing loss using the international classification of functioning, disability, and health (ICF). *International Journal of Audiology , 53* (8), 497-506.

Gurgel, R. K., Ward, D., Schwartz, S., Norton, M. C., Foster, N., & Tschanz, J. T. (2014). Relationship of Hearing loss and Dementia: a Prospective, Population-based Study. *Otology & Neurotology* , 775–781.

Hair, J. F. Jr., Anderson, R. E., Tatham, R. L. & Black, W. C. (1995). Multivariate Data Analysis (3rd ed). New York: Macmillan.

Hartley, D., Rochtchina, E., Newall, P., Maryanne, G., & Mitchell, P. (2010). Use of Hearing Aids and Assistive Listening Devices in an Older Australian Population. *Journal of the American Academy of Audiology* , 642-653.

Hearing Care Associations. (2018). *Regulatory Recommendations for OTC Hearing Aids: Safety and Effectiveness. Consensus Paper from Hearing Care Associations.*

Hearing Industries Association . (2017). HIA Comments on FTC “Now Hear This” Workshop and OTC Hearing Aids. *The Hearing Review* .

Hjalte, F., Brannstrom, J., & Gerdtham, U. (2012). Societal Cost of Hearing Disorders: A Systematic and Critical Review of Literature. *International Journal of Audiology , 51* (9), 655-662.

Holladay, J. (2004). Visual acuity measurements. . *The Journal of Cataract & Refractive Surgery, 30*, 287–290.

Humes, L. E., Kinney, D. L., Main, A., & Roberts, S. E. (2019). A Follow-Up Clinical Trial Evaluating the Consumer-Decides Service Delivery Model. *America Journal of Audiology , 28* (1), 69-84.

Humes, L., Rogers, S., Quigley, T., Main, A., Kinney, D., & Herring, C. (2017). The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double- Blind Placebo-Controlled Clinical Trial. *American Journal of Audiology , 26*, 53-79.

IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.

Jenstad, L., & Moon, J. (2011). Systematic Review of Barriers and Facilitators to Hearing Aid Uptake in Older Adults. . *Audiology Research , 10* (1), e25.

Jiam, N. T., Li , C., & Agrawal , Y. (2016). Hearing loss and falls: A systematic review and meta-analysis. *The Laryngoscope* , 2587-2596.

Jung, D., & Bhattacharyya, N. (2012). Association of Hearing Loss with Decreased Employment and Income Amongst Adults in the United States. *Annals of Otology, Rhinology, & Laryngology , 121* (12), 771-775.

Kamil, R. J., Genther, D. J., & Lin, F. R. (2015). Factors Associated with the Accuracy of Subjective Assessments of Hearing Impairment. *Ear and Hearing* , 164-167.

Kim, S. Y., Kim, H. J., K, M., Park, B., Kim, J., & Choi, H. G. (2017). Discrepancy between self-assessed hearing status and measured audiometric evaluation. *Public Library of Science , 12* (8).

Kleindienst, S. J., Zapala, D. A., & Nielson, D. W. (2017). Development and Initial Validation of a Consumer Questionnaire to Predict the Presence of Ear Disease. *JAMA Otolaryngology, Head & Neck Surgery , 143* (10), 983-989.

Kricos, P. B. (2007). Hearing Assistive Technology Considerations for Older Individuals With Dual Sensory Loss. *Trends in Amplification, 11*(4), 273-279. doi:10.1177/1084713807304363

Kochkin, S. (2010). MarkeTrak VII: Consumer satisfaction with hearing aids is slowly increasing. *The Hearing Journal* .

Kochkin, S. (2010). MarkeTrak VIII: The efficacy of hearing aids in achieving compensation equity in the workplace. *The Hearing Journal* , 19-24,26,28.

LaPierre, T. A., Ferguson, S. H., & Jirenga, M. C. (2012). Hearing Loss in Later Life: How Couples Cope. *JARA* .

Laplante-Levesque, A., Hickson, L., & Worrall, L. (2012). What makes adults with hearing impairment take up hearing AIDS or communication programs and achieve successful outcomes? *Ear and Hearing , 33* (1), 79-93.

Lee, S., Stucky, B. D., Lee, J. Y., Rozier, R. G., & Bender, D. (2010). Short Assessment of Health Literacy—Spanish and English: A Comparable Test of Health Literacy for Spanish and English Speakers. *Health Services Research , 45* (4), 1105–1120.

Lehane, C. M., Dammeyer, J. D., & Elsass, P. (2017). Sensory loss and its consequences for couples' psychosocial and relational wellbeing: an integrative review. *Aging and Mental Health* , 337-347.

Lewis-Cullinan, C., & Janken, J. K. (1990). Effect of cerumen removal on the hearing ability of geriatric patients. *Journal of Advanced Nursing , 15* (5), 594-600.

Lin, F. R. (2011). Hearing loss and cognition among older adults in the United States. *The Journals of Gerontology , 66A* (10), 1131–1136.

Lin, F. R., & Ferrucci, L. (2012). Hearing Loss and Falls Among Older Adults in the United States. *JAMA Internal Medicine* , 369–371.

Lin, F. R., Metter, J. E., O'Brien, R. J., Resnick, S. M., Zonderman, A. B., & Ferrucci, L. (2011). Hearing Loss and Incident Dementia. *JAMA Neurology , 68* (2), 214-220.

Maharani, A., Dawes, P., Nazroo, J., Tampubolon, G., & Pendleton, N. (2018). Longitudinal Relationship Between Hearing Aid Use and Cognitive Function in Older Americans. *Journal of the American Geriatrics Society , 66* (6), 1130-1136.

Maharani, A., Dawes, P., Nazroo, J., Tampubolon, G., & Pendleton, N. (2018). Longitudinal Relationship Between Hearing Aid Use and Cognitive Function in Older Americans. *Journal of the American Geriatrics Society , 66* (6), 1130-1136.

McCormack, A., & Fortnum, H. (2013). Why do people fitted with hearing aids not wear them? *International Journal of Audiology* , 360-368.

McCoy, C. (2010). Perceived self-efficacy and technology proficiency in undergraduate college students. *Computers & Education , 55* (4), 1614-1617.

Mick, P., Kawachi, I., & Lin, F. R. (2014). The Association between Hearing Loss and Social Isolation in Older Adults. *Otolaryngology–Head and Neck Surgery* .

Missier, F. D., Mantyla, T., Hansson, P., Bruine de Bruin, W., Parker, A. M., & Nilsson, L. (2014). The Multifold Relationship Between Memory and Decision Making: An Individual-differences Study. *J Exp Psychol Learn Mem Cogn. , 39* (5), 1344-1364.

Moller, K. M., & Jespersen, C. T. (2013). What are Some Common Misconceptions of Mild Hearing Loss?

Monzani, D., Galeazzi, G. M., Genovese, E., & Marrara, A. (2008). Psychological profile and social behaviour of working adults with mild or moderate hearing loss. *Acta Otorhinolaryngologica Italica* , 61-66.

Mueller, G. H., Hornsby, B., & Weber, J. (2008). Using Trainable Hearing Aids to Examine Real-World Preferred Gain. *Journal of the American Academy of Audiology , 19* (10), 758-773.

Nash, S. D., Cruickshanks, K. J., Huang, G. H., Klein, B. E., Klein, R., Nieto, F. J., et al. (2013). Unmet Hearing Health Care Needs: The Beaver Dam Offspring Study. *American Journal of Public Health , 103* (6).

Nasreddine, Z. S., Phillips, N. A., Bedirian, V., Charbonneau, S., Whitehead, V., Collin, I., et al. (2005). The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *Journal of the American Geriatrics Society , 53* (4), 695-699.

National Institute on Deafness and Other Communication Disorders. (2016, December 15). *Quick Statistics About Hearing*. Retrieved from National Institute on Deafness and Other Communication Disorders: https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing

Newman, C. W., Weinstein, B. E., Jacobson, G. P., & Hug, G. A. (1990). The Hearing Handicap Inventory for Adults: Psychometric Adequacy and Audiometric Correlates. *Ear and Hearing , 11* (6), 430-433.

Neyer , F. J., Felber, J., & Gebhardt , C. (2012). Entwicklung und Validierung einer Kurzskala zur Erfassung von Technikbereitschaft. . *Diagnostica , 58*, 87-99.

Nondahl, D. M., Cruickshank, K. J., Wiley, T. L., Tweed, S. L., Klein, R., & Klein, B. E. (1998). Accuracy of self-reported hearing loss. *Audiology , 37* (5), 295-301.

PCAST. (2016). *, Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*, . The White House President Barak Obama.

Pham, M. T., Andrijana, R., Greig, J., Sargeant, M., Papadopoulos, A., & McEwena, S. A. (2014). A scoping review of scoping reviews: advancing the approach and enhancing the consistency. *Research Synthesis Methods* , 371-385.

Pronk, M., Deeg, D., & Karmer, S. E. (2013). Hearing status in older persons: a significant determinant of depression and loneliness? Results from the longitudinal aging study Amsterdam. *American Journal of Audiology* .

Roup, C. M., Post, E., & Lewis, J. (2018). Mild-Gain Hearing Aids as a Treatment for Adults With Self-Reported Hearing Difficulties. *Journal of the American Academy of Audiology , 29* (6), 477-494.

Rural Health Information Hub. (2019). *Rural Health Disparities*. Retrieved from Rural Health Information Hub: https://www.ruralhealthinfo.org/topics/rural-health-disparities

SAS Institute Inc. Released 2014. SAS Software for Windows, Version 9.4. North Carolina: SAS Institute Inc.

Saunders, G. H., & Haggard, M. P. (1989). The Clinical Assessment of Obscure Auditory dysfunction--1. Auditory and Psychological Factors. *Ear and Hearing , 10* (3), 200-208.

Sawyer, C. S., Armitage, C. J., Munro, K. J., Singh, G., & Dawes, P. D. (2019). Correlates of Hearing Aid Use in UK Adults: Self-Reported Hearing Difficulties, Social Participation, Living Situation, Health, and Demographics. *Ear and Hearing* .

Schenkman, B. N., & Jönsson, F. U. (2010). Aesthetics and Preferences of a Web Page. *Behaviour & Information Technology , 19* (5), 367-377.

Seniors Research Group. (1999). The Consequences of Untreated Hearing Loss in Older Persons. *The National Council on the Aging* .

Sieving, P. C. (2007). What is a Cochrane Review? *ORL Head Neck Nurses , 25* (4), 15.

Singh, G. (2009). The Aging Hand and Handling of Hearing Aids: A Review. In International Conference Hearing care for adults (2009: Chicago, Ill.), *Hearing care for adults 2009: The challenge of aging: Proceedings of the second international adult conference* (pp. 265-277). Place of publication not identified, Illinois: Phonak AG.

Singh, J., & Doherty, K. A. (2020). Use of a Mild-Gain Hearing Aid by Middle-Age Normal-Hearing Adults Who Do and Do Not Self-Report Trouble Hearing in Background Noise. *American Journal of Audiology* https://doi.org/10.1044/2020_AJA-19-00051

Strom, K. E. (2019). Preparing for OTC hearing aids. *Hearing Review , 26* (7), 6.

Strom, K. (2018). OTC Hearing Aid Consensus Statement Published by AAA, ADA, IHS, and ASHA. *Hearing Review* .

Tahden, M. A., Gielser, A., Meis, M., Wagener, K. C., & Colonius, H. (2018). What Keeps Older Adults With Hearing Impairment From Adopting Hearing Aids? *Trends in Hearing, 22*.

Thielsch, M. T., Haines, R., & Flacke, L. (2019). Experimental investigation on the effects of website aesthetics on user performance in different virtual tasks. *PeerJ* (7), e6516.

Tremblay, K. L., Pinto, A., Fischer, M. E., Klein, B. E., Klein, R., Levy, S., et al. (2015). Self-Reported Hearing Difficulties Among Adults With Normal Audiograms: The Beaver Dam Offspring Study. *Ear and Hearing , 36* (6), e290-e299.

Tun, P. A., & Lachman, M. E. (2010). The Association Between Computer Use and Cognition Across Adulthood: Use it so You Won't Lose it? *Psychology and Aging , 25* (3), 560-568.

United States Census Bureau. (2016, December 08). *New Census Data Show Differences Between Urban and Rural Populations*. Retrieved 2019, from United States Census Bureau: https://www.census.gov/newsroom/press-releases/2016/cb16-210.html

Van Der Wardt, V., Bandelow, S., & Hogervost, E. (2010). The relationship between cognitive abilities, well-being and use of new technologies in older people. *Proceedings of the 28th Annual European Conference on Cognitive Ergonomics* (pp. 333-334). European Conference on Cognitive Ergonomics.

Wallston, K. W. (1978). Development of the multidimensional health locus of control (MHLC) scales. . *Health Education Monographs , 6* (2), 160-170.

Wang, H., Peng, J., Wang, B., Lu, X., Zheng, J. Z., Wang, K., et al. (2017). Inconsistency Between Univariate and Multiple Logistic Regressions. *Shanghai Archives of Psychiatry, 29* (2), 124-128.

Weinstein, B. E., Sirow, L., & Moser, S. (2016). Relating Hearing Aid Use to Social and Emotional Loneliness in Older Adults. *American Journal of Audiology* , 54-61.

West, R. L., & Smith, S. L. (2007). Development of a hearing aid self-efficacy questionnaire. *International Journal of Audiology , 45,* 759-771.

Wishart, J. (2006). Initial teacher training students' attitudes to use of information technology and individual locus of control. *Journal of Information Technology for Teacher Education, 6* (3), 1997.

Zekveld, A. A., George, E. L., Houtgast, T., & Kramer, S. E. (2-13). Cognitive abilities relate to self-reported hearing disability. *Journal of Speech, Language, and Hearing Research , 56* (5), 1365-1372.

Vita

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EDUCATION

Syracuse University September 2014- Present
Doctor of Philosophy
Department of Communication Sciences and Disorders

Syracuse University September 2013- August 2018
Doctor of Audiology
Department of Communication Sciences and Disorders

McMaster University September 2009- April 2013
Honors Bachelor of Life Sciences
Department of Life Sciences

PROFESSIONAL EXPERIENCE

Fourth Year Audiology Extern August 2017- August 2018
National Technical Institute for the Deaf,
Rochester, NY

Graduate Research Assistant September 2017- August 2018
Hearing Science Laboratory
PI: Joseph Bochner
Dept. of Culture and Creative Studies
Rochester Institute of Technology, Rochester, NY

Project Title: *Auditory Experience, Critical Periods and the Development of Categorical Perception in Cochlear Implant Users: A Preliminary Investigation*.

Graduate Research Assistant September 2013- May 2014
Hearing Science Laboratory

PI: Karen A. Doherty
Dept. of Communication Sciences & Disorders
Syracuse University, Syracuse, NY

Project Title: *The benefit of amplification on auditory working memory function in middle-aged and young-older hearing-impaired adults.*

TEACHING EXPERIENCE

Guest Lecturer Fall, 2019
Introduction to Sensation and Perception (PSY 321)

Adjunct Professor Spring, 2019
Hearing Science (CSD 325)
Syracuse University, Syracuse, NY

Laboratory Instructor Fall, 2018
Hearing Aids I (CSD 673)
Syracuse University, Syracuse, NY

Laboratory Instructor Fall, 2018
Instrumentation (CSD 637)
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Guest Lecturer Spring, 2017
Anatomy and Physiology in Speech (CSD 315)
Syracuse University, Syracuse, NY

Publications

Singh, J., & Doherty, K.A. (2020) Use of a mild Gain Hearing Aid by Middle-Aged Normal-Hearing Adults Who Do and Do Not Self-report Trouble Hearing in Background noise. *American Journal of Audiology*. https://doi.org/10.1044/2020_AJA-19-00051

AWARDS AND HONORS

Summer Dissertation Fellowship 2020

Syracuse University Graduate Student Organization Travel Award 2020

Poster Blitz Award: Best Poster Presentation 2019

Research Excellence Doctoral Funding Fellowship 2019

Syracuse University Graduate Assistantship Award 2018

Canadian Institute of Health (CIHR) Research Travel Award 2018

Best-Lay Abstract Award: CIHR Institute of Aging- Summer Program in Aging 2018

CIHR Institute of Aging- Summer Program in Aging, Trainee 2018

New York State Speech-Language-Hearing Association Graduate Student Scholarship 2018

American Speech-Language-Hearing Association Audiology/Hearing Science Research Travel Award 2017

Syracuse University Graduate Student Organization Travel Award 2017

American Academy of Audiology Fellows-in-Training Travel (FITT) Grant 2016

Syracuse University Graduate Fellowship Award 2015 & 2016

PRESENTATIONS

Singh, J., & Doherty, K.A. (March, 2020) Can the average consumer navigate the over-the-counter hearing aid model? Poster Presentation at the American Auditory Society Conference. Scottsdale, AZ.

Singh, J., & Doherty, K.A. (October, 2019) Use of a Mild Gain Hearing Aid for Normal Hearing Adults. Poster Presentation at the Canadian Academy of Audiology Conference. Halifax, NS

Singh, J., & Doherty, K.A. (September, 2018) Use of Amplification for Normal Hearing Adults in Background Noise, Poster Presentation at the Academy of Rehabilitative Audiology Conference. Pittsburgh, PA.

Singh, J., & Doherty, K.A. (April, 2018) Benefits of Amplification for Normal Hearing Adults with Trouble in Background Noise, Poster Presentation at the New York State Speech Language Hearing Association Conference. Rochester, NY.

Singh, J., & Doherty, K.A. (March, 2017) Mild Gain Hearing Aid for Normal Hearing Adults. Poster Presentation at the American Auditory Society Conference. Scottsdale, AZ

Moldanado, C.C., **Singh, J.,** & Doherty, K.A. (November, 2016) Variation in & Accuracy of Hearing Aid Adjustments Prescribed by Four Manufacturers' Troubleshooting Software. Poster Presentation at the American Speech Language Hearing Association Annual Conference. Philadelphia, PA.

Singh, J., & Moldanado, C.C., & Doherty, K.A. (April, 2016) Inaccuracy of Hearing Aid Software Adjustments. Poster Presentation at Audiology Now Conference. Phoenix, AZ.

PROFESSIONAL AFFILIAITONS

National Student Speech-Language-Hearing Association
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PROFESSIONAL DEVELOPMENT

WISE Future Professionals Program, Trainee 2018-2019
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