Date of submission: March 8, 2016

Title: Evaluation of the self-fitting process with a commercially available hearing aid

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ACKNOWLEDGEMENTS

The authors would like to thank Shawn Stahmer and Stavros Basseas of SoundWorld

Solutions for providing the hearing aids, tablet, and app used in this study and for their

ongoing support during data collection. The authors acknowledge the financial support of the

HEARing Cooperative Research Centre, established and supported by the Australian

Commonwealth Government's Department of Industry and Science, and the Australian

Commonwealth Government through the Department of Health.

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ABSTRACT

Background: Hearing aids and personal sound amplification products (PSAPs) that are designed to be self-fitted by the user at home are becoming increasingly available in the online marketplace. While these devices are often marketed as a low-cost alternative to traditional hearing health care, little is known about people's ability to successfully use and manage them. Previous research into individual components of a simulated self-fitting procedure has been undertaken, but no study has evaluated performance of the procedure as a whole using a commercial product.

Purpose: To evaluate the ability of a group of adults with a hearing loss to set up a pair of commercially available self-fitting hearing aids for their own use and to investigate factors associated with a successful outcome.

Research Design: An interventional study that used regression analysis to identify potential contributors to the outcome.

Study Sample: Forty adults with mild to moderately severe hearing loss participated in the study: 20 current hearing aid users (the "experienced" group) and 20 with no previous amplification experience (the "new" group). Twenty-four participants attended with partners, who were present to offer assistance with the study task as needed.

Data Collection and Analysis: Participants followed a set of written, illustrated instructions to perform a multi-step self-fitting procedure with a commercially available self-fitting hearing aid, with optional assistance from a lay partner. Standardized measures of cognitive function,

health literacy, locus of control, hearing aid self-efficacy, and manual dexterity were collected. Statistical analysis examined the proportion of participants in each group who successfully performed the self-fitting procedure, factors that predicted successful completion of the task, and the contributions of partners to the outcome.

Results: Fifty-five percent of participants were able to successfully perform the self-fitting procedure. Although the same success rate was observed for both experienced and new participants, the majority of the errors relating to the hearing test and the fine-tuning tasks were made by the experienced participants, while all of the errors associated with physically customizing the hearing aids and most of the insertion errors were made by the new participants. Although the majority of partners became involved in the self-fitting task, their contributions did not significantly influence the outcome. Further, no characteristic or combination of characteristics reliably predicted which participants would be successful at the self-fitting task.

Conclusions: Although the majority of participants were able to complete the self-fitting task without error, the provision of knowledgeable support by trained personnel, rather than a fellow layperson, would most certainly increase the proportion of users who are able to achieve success. Refinements to the instructions and the physical design of the hearing aid may also serve to improve the success rate. Further evaluation of the range of self-fitting hearing aids that are now on the market should be undertaken.

KEY WORDS

amplification, hearing aids, personal sound amplification products, self-fitting hearing aids

ABBREVIATIONS

ANOVA = analysis of variance; ANSIE = Adult Nowicki-Strickland Internal-External Control Scale; BTE = behind the ear; GNI = gross national income; GPT = Grooved Pegboard Test; MARS-HA = Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids; MoCA = Montreal Cognitive Assessment; PSAP = personal sound amplification product; PTA4 = average of pure-tone hearing thresholds at 0.5, 1, 2, and 4 kHz; RIC = receiver in canal; S-TOFHLA = Short Test of Functional Health Literacy in Adults, WHO = World Health Organization

INTRODUCTION

Improving access to high-quality, affordable hearing care is a major public health concern. The World Health Organization (WHO) estimates that 636 million people over the age of 15 years, or 15% of the world's adult population, have some degree of hearing loss (Mathers et al., 2008; World Health Organization, 2014). In the United States, 30 million Americans over the age of 12 years are estimated to have bilateral hearing thresholds of 25 dB HL or greater (Lin et al., 2011). The consequences of untreated hearing loss extend throughout the lifespan, and can include impaired speech and language acquisition (Davis et al., 1986; Blamey et al., 2001); diminished vocational prospects and earning power (Kochkin, 2005); and avoidance of, or withdrawal from, family and social life (Arlinger, 2003; Ciorba et al., 2012). The economic impact, too, is considerable. Communication disorders are estimated to cost the United States economy the equivalent of 3% of the gross national product (Ruben, 2000). In spite of this, reliable access to hearing health care services remains elusive for a significant proportion of the world's population.

One of the primary factors restricting access to hearing health care is cost. The WHO has established global guidelines suggesting that the cost of a single hearing aid should not exceed 3% of a country's per capita gross national income (GNI), thus relating hearing aid cost to the average income of a single local household. In the United States, which has a per capita GNI of US\$53,470, application of these guidelines would mean that hearing aids should be sold for no more than US\$1,600 each (World Bank, 2014). By way of comparison, the cost of a single digital hearing aid in the United States averaged US\$1,500 in 2010, with many devices ranging from US\$3,000-\$5,000 (National Institutes of Health, 2010). Cost has also emerged as one of the most-cited reasons people do not take up hearing aids in surveys

conducted in the United States (Kochkin, 2007), as well as in Australia (Access Economics, 2006), Germany, the United Kingdom, and France (Hougaard and Ruf, 2011).

A further barrier that prevents access to hearing rehabilitation is the scarcity of skilled hearing health care professionals (Brouillette, 2008). An international survey of professional organizations representing hearing health care providers revealed that of the 62 countries surveyed, 86% reported an insufficient number of audiologists to meet the needs of the populations they serve (Goulios and Patuzzi, 2008). Although the impact is greatest in developing countries, many high-income nations will soon be facing an increased demand for hearing health care due to an aging population, in which there is a higher incidence of hearing loss. In the United States, for example, there are more audiologists retiring from active practice than there are new graduates entering the profession (Gallagher, 2006; Freeman, 2009).

An obstacle specific to hearing aid uptake is the perception among many people with hearing loss that these devices provide insufficient benefit. Despite significant advancements in signal processing technology and miniaturization over the past two decades, there has not been a concomitant increase in hearing aid fitting rates during the same time period. Repeated surveys of American adults who self-identify as having a hearing loss have revealed that between 1989 and 2008, the proportion of hearing aid owners has increased only marginally, from 22.9% to 24.6% (Kochkin, 2009). Although the fitting rate is slightly higher in Europe, survey respondents in Germany, the United Kingdom, and France reported the same reasons for non-adoption of hearing aids as did their American counterparts. In addition to the prohibitive cost, the most commonly cited reasons in both the American and European surveys were the perceived lack of benefit in noise, the belief that they hear "well enough" in

most situations to remain unaided, and the expectation that hearing aids will be physically uncomfortable to wear (Kochkin, 2009; Hougaard and Ruf, 2011). Even if these initial barriers are overcome to the extent that an individual goes ahead with obtaining hearing aids, the same factors will often emerge as reasons why ongoing use is subsequently discontinued (Kochkin, 2000; McCormack and Fortnum, 2012).

Dissatisfaction with, and lack of access to, traditional hearing health care has given rise to a parallel market in which hearing aids and personal sound amplification products (PSAPs), are becoming increasingly available. While amplification devices that have been granted Food and Drug Administration (FDA) approval to be marketed as "hearing aids" can be legally purchased online and used by Americans with a hearing loss, the same authorization does not extend to PSAPs. Despite the risks associated with using a PSAP to compensate for impaired hearing without first consulting with a trained professional, a growing number of "selffitting" amplification devices with a range of capabilities can now be purchased online, ranging from those with a choice of preset gain/frequency responses to devices incorporating an automatic hearing test and the option to self-program and fine-tune the settings (e.g. HearSource, SoundWorld Solutions). Several of these products employ an accompanying software application ("app") with which the user can access these features, thus taking advantage of the user's pre-existing ownership of a smartphone or tablet. Most companies emphasize low cost, independence, and technological innovation as points of difference that set their products apart from those provided by audiologists in a traditional clinical setting. Little evidence exists, however, regarding the ability of potential users to successfully manage such devices.

Previous research investigating aspects of the self-fitting concept has reported that both new and experienced hearing aid users are able to customize the physical fit of a device to suit their own ears, provided they are presented with simple, well-designed instructions for the task (Convery et al., 2011; Convery et al., 2013), and that an automatic, self-directed, *in situ* hearing test yields reliable and valid audiometric results (Convery et al., 2015). These studies were based on an "ideal" vision of a self-fitting hearing aid as a physically customizable device that could administer a self-directed, automatic, *in situ* hearing threshold measurement, then be fine-tuned by the user to suit real-life listening preferences, all without supplementary equipment or direct clinician input. These studies, however, investigated only isolated elements of the self-fitting procedure, using either conventional hearing aid components or offline, computer-based simulations. The extent to which individuals can manage the procedure as a whole with a fully featured, commercially available device has never been evaluated.

This study aimed to determine whether a group of adults with a hearing loss can successfully follow a set of written, illustrated instructions to set up a pair of commercially available self-fitting hearing aids, with access only to a lay partner as an additional resource. The rationale for this request was to simulate conditions in real life, as hearing aid users undertaking activities associated with a self-fitting hearing aid would likely turn to a fellow member of the household or other layperson for assistance if they encountered any difficulties. The influence of a variety of personal and sociodemographic factors on task success was also investigated.

METHOD

Participants

Forty adults with a hearing loss participated in the study: 20 current users of hearing aids (the "experienced" group) and 20 with a diagnosed hearing loss but no previous amplification experience (the "new" group). Members of the experienced group ranged in age from 66 to 88 years, with a median age of 77 years. The mean four-frequency pure-tone average (PTA4; average of pure-tone hearing thresholds at 0.5, 1, 2, and 4 kHz) of the experienced participants was 47 dB HL and ranged from 31 to 62 dB HL. Participants in the new group had a median age of 69 years (range = 50-79 years) and a mean PTA4 of 30 dB HL (range = 20-55 dB HL).

Participants were asked to attend the study appointment with an adult partner, if possible. Although partner attendance was strongly encouraged, not all participants were able to locate a suitable person to act in this capacity; a compromise was made to ensure steady participant recruitment. Twenty-four participants attended with a partner, 11 in the experienced group and 13 in the new group. Partners ranged in age from 20 to 82 years, with a median age of 71 years. Three partners had personal experience wearing hearing aids, two of whom accompanied new participants and one of whom attended with an experienced participant.

Participants were paid a small cash gratuity to offset the cost of travelling to the laboratory. The treatment of participants was approved by the Australian Hearing Human Research Ethics Committee and conformed in all respects to the Australian government's National Statement on Ethical Conduct in Human Research (National Health and Medical Research Council, 2007).

Test Device

The test device was a pre-production unit of the SoundWorld Solutions HD100 Personal Sound Amplifier. The HD100 is a behind-the-ear (BTE), receiver-in-canal (RIC) hearing aid with 16-channel compression, noise reduction, feedback cancellation, and a directional microphone. The hearing aid is made up of a body, which contains the signal processing components and the power source; a retractable tube; and an instant-fit ear tip. The length of the hearing aid's tubing can be increased by pulling the tube out of the ear hook or decreased by allowing the tube to retract back into the hook. All participants were provided with two hearing aids for a bilateral fit.

To self-fit the hearing aids, the user must first select the appropriate instant-fit ear tips from a range of three sizes and adjust the tubing length to allow the hearing aids to sit comfortably over the pinna. The hearing aids are then paired via Bluetooth with a tablet or smartphone so that users can access the SoundWorld Solutions app. The app enables users to self-administer a brief pure-tone hearing test. Users are tested at a minimum of three frequencies (0.5, 1, and 4 kHz); three additional frequencies (0.25, 2, and 6 kHz) are presented if the user's thresholds meet certain requirements. Tones are first presented at 1 and 0.5 kHz for all users. If the 1 kHz threshold exceeds the 0.5 kHz threshold by \geq 15 dB, and the 0.5 kHz threshold exceeds 12 dB, the user is tested at 0.25 kHz. All users are then tested at 4 kHz. If the absolute difference between the 1 and 4 kHz thresholds is \geq 15 dB, then 2 kHz is tested. The user is tested at 6 kHz if 2 kHz was tested and if the absolute difference between the 2 and 4 kHz thresholds is \geq 15 dB.

The results of the automatic hearing test are used to generate a customized gain/frequency response called the Personal Profile. The Personal Profile contains three programs designed for different acoustic environments: the Baseline Profile, which is derived by applying a prescriptive formula designed to equalize intelligibility to the measured hearing thresholds; Restaurant Mode, which is the Baseline Profile with the directional microphone activated; and Entertainment Mode, which is the Baseline Profile with a low-frequency boost. Users may further fine-tune the hearing aid's settings in any of these programs with the app's equalizers, which allow adjustments to be made to the overall gain as well as to gain in the low-, mid-, and high-frequency bands. In this study, however, fine-tuning activities were confined to the Baseline Profile for the sake of simplicity.

Procedure

Participants (and their partners, if available) attended the laboratory for one appointment of approximately two hours. Both members of the pair completed the Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA; West and Smith, 2010). The MARS-HA is a 24-item questionnaire probing hearing aid self-efficacy, or the degree of confidence an individual has regarding his or her ability to successfully use and manage hearing aids. Respondents are instructed to report how certain they are that they would be able to perform a hearing aid-related skill or cope with a particular listening situation. The total score is calculated as the unweighted average of the four subscales (basic handling, advanced handling, adjustment to hearing aids, and aided listening skills) and is expressed as a percentage.

Participants were then given a pair of HD100 hearing aids; three instant-fit tips of different sizes for each ear, the smallest of which were already attached to the hearing aids; a Samsung Galaxy tablet preloaded with the SoundWorld Solutions app; and a set of written, illustrated instructions for performing the self-fitting task. Since the hearing aid used in this study was not commercially available at the time of data collection, an instructional booklet of the sort that accompanies other SoundWorld Solutions products was not yet available. A description of the HD100's capabilities was provided to the experimenters by a SoundWorld Solutions representative as an unformatted, text-only Microsoft Word document, along with photographs of the hearing aid and its components. The contents of this document and the photographs were used by the first author (EC) to design a set of instructions for the selffitting task in accordance with best-practice health literacy principles, which specify appropriate typography, illustration, layout, and readability characteristics (Caposecco et al., 2011). The authors also drew on their experiences designing instructions for previous selffitting tasks, including those intended for culturally and linguistically diverse participant groups with low literacy (Convery et al., 2011; Convery et al., 2013), as well as the feedback received from the 250 participants in past self-fitting studies with respect to phrasing and simplicity. The text of the instructions intended for use in the current study was evaluated for readability using three methods: the Flesch Reading Ease test, the Flesch-Kincaid Grade Level formula, and the Gunning Fog Index (Kincaid et al., 1975). The results of these tests suggest that the instructions were written at approximately a fifth-grade reading level, consistent with recommendations that instructional materials for use in a health context be written at a level between the third and sixth grades (Doak et al., 1996; Osborne, 2005). Feedback regarding quality and ease of use of the instructions was solicited from the pilot participants; they had no suggestions for further improvements.

The instructions outlined a step-by-step procedure for (1) identifying the left and right hearing aids, (2) selecting the ear tips, (3) adjusting the tubing length, (4) switching on the hearing aids, (5) inserting the hearing aids into the ears, (6) pairing the hearing aids with the tablet via Bluetooth, (7) launching the app, (8) assigning the hearing aids to the left and right ears within the app, (9) performing the automatic hearing test, and (10) fine-tuning the settings with the app's equalizers. Participants were asked to follow these steps to complete the self-fitting task, calling on their partners for assistance whenever necessary. Participants (and their partners, if available) were left alone in the test room and were monitored by the experimenter from outside via headphones and a webcam.

Users of other SoundWorld Solutions devices have the option of using the app on a desktop or laptop computer, a tablet, or a smartphone. Although our preference was for a computer-based app, a platform we anticipated the majority of our participants would have previous experience with, the hearing aids used in this study could only be fine-tuned with a tablet- or smartphone-based app. We chose to use a tablet to offset any visual or manual handling difficulties our participants may encounter with a smaller device. To compensate for the unfamiliarity of the tablet, we allowed participants to request assistance from the experimenter with steps 6-8 of the self-fitting task. We decided that since these steps related more to the general operation of a tablet than to hearing aid management, success with the self-fitting procedure should be evaluated only on the basis of performance on steps 1-5 and 9-10 (the "hearing aid" steps), and that performance on steps 6-8 (the "tablet" steps) should be considered separately.

The Adult Nowicki-Strickland Internal-External Control Scale (ANSIE; Nowicki and Duke, 1974), the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005), the Grooved

Pegboard Test (GPT; Trites, 1977), the Australian version of the Short Test of Functional Health Literacy in Adults (S-TOFHLA; Parker et al., 1995; Barber et al., 2009), and a demographic questionnaire were administered to all participants and to those partners who had become involved in the self-fitting task. The ANSIE is a 40-item yes/no questionnaire that measures locus of control, a psychological construct that describes the extent to which individuals feel they are in control of events that affect their lives (Rotter, 1966). Those who believe that the outcome of events result predominantly from their own actions are considered to have an internal locus of control, while those who believe that life events are primarily in the hands of luck, fate, or "powerful others" have an external locus of control. Scores of 0 to 8 indicate a locus of control that is highly internal, while scores of 17 to 40 are interpreted to mean the respondent is highly external. Scores between 9 and 16 are considered "average," neither highly internal nor highly external.

The MoCA assesses visuospatial and executive function, memory, attention, language, abstraction, delayed recall, and orientation to time and place, with a maximum attainable score of 30. Scores \geq 26 indicate normal cognitive function and scores < 26 are suggestive of varying degrees of cognitive impairment. Version C of the MoCA was used due to the high proportion of participants who were familiar with Versions A and B from past studies.

The GPT measures manual dexterity by requiring the individual to place small metal pegs into a 5 X 5 board of 25 keyhole-shaped holes. Each hole is angled slightly differently, thus requiring the test-taker to use fine motor skills to manipulate each peg to its correct orientation. The test is completed twice, first with the dominant hand and again with the non-dominant hand. The GPT is scored on the basis of the time taken, in seconds, to complete the task for each hand, with lower scores indicative of better performance.

Health literacy – defined by the WHO as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand, and use information in ways which promote and maintain good health" (Nutbeam, 1998) – was assessed with the Australian version of the S-TOFHLA. The test-taker is presented with several paragraphs of health-related text from which key words have been deleted. The task of the participant is to choose the correct word from a list of four choices to fill in the blanks. Scores of 23 to 36 indicate adequate health literacy, while scores of 17 to 22 and 0 to 16 are interpreted as marginal and inadequate levels of health literacy, respectively.

The demographic questionnaire was designed specifically for this study and elicited information about age, gender, level of formal education, current or previous occupation, previous hearing aid experience, and previous experience using a tablet or smartphone.

Pure-tone air and masked bone conduction audiometry was performed on participants whose audiometric records were more than six months old to ensure their thresholds were within the dynamic range of the self-fitting hearing aids

RESULTS

Success with the self-fitting procedure was judged on the basis of participants' performance on the seven "hearing aid" steps. Participants who completed these steps correctly, regardless of the extent of partner involvement, were classified as successful. Participants who made at least one error were categorized as unsuccessful. On this basis, 55% of the overall participant group performed the self-fitting task successfully. Identical success rates were observed for

both the new and experienced groups, meaning that performance accuracy was not significantly associated with group membership according to a chi-square test with Yates' correction ($\chi^2_{(1,N=40)} = 0.10$, p = 0.75). The success rate among participants whose partners assisted with the task was 64%; among participants who performed the procedure independently, it was 44%. This difference was not statistically significant ($\chi^2_{(1,N=40)} = 0.30$, p = 0.58). Previous experience with a tablet or smartphone did not play a statistically significant role in the outcome either; 61% of those with tablet experience performed the self-fitting task accurately and 42% of those without experience did so ($\chi^2_{(1,N=40)} = 0.58$, p = 0.45). Table 1 provides an overview of the number of participants who made errors on each of the hearing aid steps, along with the nature of those errors.

While there was no difference in the error rate between the experienced and new participants, there was a difference in the nature of the errors made by members of each group. These differences were not all statistically significant, however. Five members of the new group made errors physically customizing the hearing aids: three selected inappropriate ear tip sizes and two did not adjust the tubing length correctly. Eleven participants made errors relating to the insertion of the hearing aid, nine of whom were members of the new group. This was the only significant difference according to a chi-square test with Yates' correction ($\chi^2_{(1,N=40)} = 4.51$, p = 0.03). In contrast, experienced participants made the majority of the errors that occurred with the hearing test and the fine-tuning steps. Twelve participants performed the hearing test incorrectly, eight of whom were part of the experienced group. Nine participants made errors in fine-tuning; five of these were experienced, while four were new. No participant made an error identifying the left and right hearing aids or switching them on.

Table 2 lists the independent variables measured on the experienced participants, the new participants, and the partners who became involved in the self-fitting task. The values shown are the median for age, the mode for level of education and occupation, and the mean for the remaining variables, with standard deviations shown in parentheses where appropriate. The experienced group was significantly older than the new group ($t_{38} = 3.76$, p < 0.001), with a greater degree of hearing loss ($t_{37} = 5.74$, p < 0.001) and a higher level of hearing aid self-efficacy ($t_{38} = 2.15$, p = 0.04).

To investigate effects of the independent variables on task success, controlling for the effects of the other independent variables, logistic regression was performed. The dependent variable was task success (successful or unsuccessful), and the independent (predictor) variables were locus of control, hearing aid self-efficacy, cognitive function, health literacy, manual dexterity, age, gender, previous hearing aid experience, level of education, and occupation. For the 22 participants whose partners became involved in the task, the "better" of the two scores on each of the independent variables, with the exception of gender, was selected so that each participant-partner pair was represented by a single value on each measure. In the case of the ANSIE, whose scores cannot be judged along a continuum of better to worse, the lower of the two scores was chosen. Lower scores on the ANSIE indicate a more internal locus of control, a trait that was associated with an increased likelihood of success with self-directed *in situ* audiometry in a previous study (Convery et al., 2015).

Because the sample size was small compared with the number of available predictor variables, we fitted the logistic regression model using the lasso method (Tibshirani, 1996), with the value of the regularization parameter chosen to minimize the cross-validation deviance (Friedman et al., 2010). The lasso is a variable selection method, meaning that it

may omit some of the predictor variables from the fitted model. When the lasso was used to fit the model for task success, all predictor variables were omitted from the model, suggesting that no variable or combination of variables measured was useful in predicting which participants or participant/partner pairs were likely to be successful at the self-fitting task in this data set. This was consistent with the result of using the conventional fitting method (maximum likelihood estimation), which produced a model in which no variable had a statistically significant effect. It should, however, be noted that the omission and non-significance of all variables was likely to have been at least partially due to the relatively small sample size.

The three "tablet" steps of the self-fitting task – pairing the hearing hearing aids with the tablet, launching the self-fitting app, and assigning the hearing aids to the left and right ears within the app – differed from the hearing aid steps in that the experimenter was permitted to assist participants with this component of the procedure. Assistance was provided either in response to a request from the participant, or because the experimenter observed that the participant was having difficulty or making an error. Twenty-one participants were able to successfully pair the hearing hearing aids to the tablet (16 independently and five with their partner's help), while 19 required the experimenter's intervention. Launching the app, a step that involved simply tapping an icon on the tablet screen, was performed correctly by 38 participants, 33 of whom did so independently and five with assistance from their partner. Two participants required the experimenter's help to complete this step. Twenty-two participants assigned the hearing aids to the correct ears within the app, 17 independently and five with their partner's help. Eighteen participants made an error on this step, 17 of whom were corrected by the experimenter and one of whom moved on to the next step too quickly for the experimenter to intervene. Interestingly, there was no statistically significant effect of

previous experience with a tablet or smartphone on the ability to launch the app ($\chi^2_{(1,N=40)}$ = 0.03, p = 0.87) or to assign the hearing aids to the correct ears ($\chi^2_{(1,N=40)}$ = 0.00, p = 0.94), but the relationship between tablet experience and the ability to pair the hearing aids with the tablet almost reached statistical significance ($\chi^2_{(1,N=40)}$ = 3.74, p = 0.05), with a trend for participants with previous tablet experience to be more likely to perform the pairing step correctly.

DISCUSSION

A group of 40 adults performed a multi-step procedure to set up a pair of self-fitting hearing hearing aids for their own use. Fifty-five percent of participants were able to do so – either independently or with the assistance of a layperson – without error. The success rate observed in the current study is similar to that reported for a self-directed *in situ* audiometry task (Convery et al., 2015) and better than was achieved on a hearing aid self-assembly task by comparable populations (Convery et al., 2011). Unlike previous studies, in which locus of control (Convery et al., 2015), cognitive function (Convery et al., 2011; Convery et al., 2013; Convery et al., 2015), and health literacy (Convery et al., 2011) were found to variously influence success with self-fitting tasks, no factor or combination of factors was found to predict success in the current study. It is possible that the small sample size, coupled with the experience we gained developing appropriate instructional materials in previous studies, have reduced the effect of such factors. On the other hand, the self-fitting procedure that we asked participants to perform in this study was more complex than previous tasks, and it is possible that factors not measured here, such as problem-solving ability, may have been stronger contributors to the outcome. Future studies should aim to reduce the number of independent

variables and increase the number of participants in order to ensure they are appropriately powered.

Insertion of the physically customized hearing aid is a key step in the self-fitting procedure. Past self-fitting studies that have included an insertion component all resulted in a significant proportion of participants failing to do so correctly, with success rates of 58% reported in Convery et al. (2011) and 77% in Convery et al. (2015). Even as the quality of the instructions has evolved and improved over time, correct insertion technique remains elusive for a substantial proportion of participants: only 73% of participants in the current study were able to successfully insert both hearing aids. In all three studies, the primary insertion error was shallow placement in the ear canal. Insertion of a hearing aid into the ear canal is a difficult action to describe in words without using anatomical language. The insertion process is also difficult to capture in a static, two-dimensional line drawing, especially since the ear tip, once inserted, is no longer visible outside the confines of the ear canal. Even when provided with a mirror, it is not easy to visually evaluate the placement of a hearing aid in one's own ear. The use of a RIC hearing aid is likely to have compounded the problem, since it is not immediately obvious – as it is with a traditional BTE hearing aid coupled to an earmold – when the hearing aid is fully and correctly inserted. Based on the results of the current study, insertion errors are likely to disproportionately affect self-fitting hearing aid users who are new to amplification, which may lay the groundwork for subsequent inaccuracies in the hearing test results and fine-tuning strategies. This finding suggests that the instructions for performing the self-fitting procedure could be tailored according to previous hearing aid experience, with more emphasis and explanation given for the steps the user is likely to have difficulty with. Presenting the instructions in video format may also

better illustrate such components of the self-fitting process as hearing aid placement, thus increasing the chances of a successful outcome.

We expected that partner involvement in the self-fitting procedure would benefit our participants. Collaboration on problem-solving tasks has been shown to improve outcomes for older adults (e.g. Berg et al., 2007; Kimbler and Margrett, 2009) due to presumed compensatory effects on the cognitive declines associated with aging (Dixon, 1996; Dixon and Gould, 1996). Participants in all previous self-fitting studies were encouraged to attend with a partner, but constraints were placed on how they could interact (Convery et al., 2011; Convery et al., 2015). Participants were instructed to request help from their partners only after an initial attempt at performing each step of the procedure had been made, and partners were told they could not intervene in the task on their own initiative. As a result, few partners - 29% in Convery et al., 2011 and 20% in Convery et al., 2015 – became involved in the task. We hypothesized that allowing participants and partners to interact more naturally would lead to a larger number of participant-partner collaborations, which would then, in turn, lead to a higher proportion of successful outcomes. Although 92% of partners became involved in the task in the current study, their participation did not lead to the expected increase in successful outcomes. This was likely due to the fact that the partners did not know any more about the procedure than did the participants; both members of the pair had access only to the written instructions that were provided to them by the experimenter. Further, the majority of people who acted as partners in these studies did not have hearing loss or wear hearing aids themselves, suggesting that in most cases, the partners had even less relevant knowledge to draw on than did the participants.

Although lay support made little difference to the outcome in this study, support from a person who is knowledgeable about the task's requirements would very likely mean the difference between a successful and an unsuccessful fitting. This conclusion is strengthened by the observation that in the majority of cases, errors made by participants were not recognized as such, either by their partners or by the participants themselves, and thus no action was taken to correct them. The consequences of errors also seemed to be poorly understood. For example, many participants did not make the link between the accuracy of the hearing test results and the effectiveness of the initial settings. One participant commented that he did not see the need to fine-tune at all "because the computer just gave me a hearing test," thereby demonstrating his lack of understanding of the procedure as a whole and his role in the success of the outcome. The inability to self-identify errors has been observed repeatedly in past self-fitting studies (Convery et al., 2011; Convery et al., 2013; Convery et al., 2015) and presents a major concern for clinical procedures that are designed to be undertaken independently, without professional supervision. As a first step, the instructions could be modified – either in content or form – to provide more information about how each step contributes to the overall outcome. More importantly, if no robust solution can be found to frequently encountered problems, such as hearing aid insertion, our observations point to the desirability of professional or paraprofessional support for users attempting a self-fitting procedure.

When evaluating performance on the self-fitting task, three steps of the procedure – pairing the hearing aids with the tablet, launching the self-fitting app, and assigning the hearing aids to the left and right ears within the app – were not taken into account. The rationale was that this component of the procedure would not reflect participants' ability to manage a hearing aid, but would instead demonstrate only their expertise with smartphone and tablet

technology. A growing number of amplification products available online, however, require the use of tablet- or smartphone-based apps in order for the user to access the full range of hearing aid features. Disregarding performance on the tablet steps may therefore have obscured some of the potential difficulties individuals could have with these products, given that they form an integral component of many amplification systems. Smartphone and tablet ownership among older adults – arguably the primary market for online amplification products – lags behind the general population, suggesting that app-based hearing devices may present a particular problem for this demographic. While 55% of Americans report smartphone ownership, only 18% of seniors do so. Smartphone penetration drops even lower with increasing age, with 10% of adults in the United States between the ages of 75 and 79 years reporting smartphone ownership and 5% of those 80 years of age and older (Pew Research Center, 2014). The rates of smartphone ownership in Australia, where this study was conducted, are comparable: only 15% of Australian adults over the age of 65 years own a smartphone and 8% own a tablet (Australian Communications and Media Authority, 2013). Although 70% of participants in the current study reported previous tablet or smartphone usage – a rate far greater than is typically reported for either Americans or Australians in this age range – this factor did not exert a significant influence on success with the self-fitting task. Additionally, participants experienced more difficulties with the tablet-based steps than with any other step in the procedure. This could be linked to the fact that none of the participants had ever used a Samsung Galaxy, the tablet that was used in the study. Several participants explicitly identified this as a reason for their difficulty navigating the tablet steps, reporting that their tablet experience had been gained with a different make or model.

Hearing aids that are intended to be self-fitted by the user at home are gaining ground in the hearing health care arena. It is therefore critical that these devices be rigorously evaluated for

quality, benefit, safety, and ease of use. Future investigations should focus on identifying factors that predict success with self-fitting hearing aids, with an eye toward determining candidacy for these sorts of devices. The role of support, particularly who should provide it, how it should be provided, and how this could work in the context of hearing aids that are largely purchased online, should be a further research priority. An investigation of the fitting outcomes yielded by a variety of self-fitting hearing aid implementations, particularly in comparison to those obtained with hearing aids fitted by an audiologist, is another important avenue for future exploration.

CONCLUSION

Data from this study emphasize the dual importance of quality instructional materials and knowledgeable support for hearing aid users undertaking a self-fitting procedure. While previous experience with traditional hearing aids did not affect the success rate in this study, this factor does appear to influence the parts of the procedure with which individuals are most likely to have difficulty. This finding suggests that the instructions or type of support could be tailored according to previous hearing aid experience. The rate of successful outcomes with these hearing aids may further be enhanced as a result of physical modifications to the style of the device.

REFERENCES

- Access Economics (2006). Listen Hear! The Economic Impact and Cost of Hearing Loss in Australia, Access Economics.
- Arlinger S. (2003) Negative consequences of uncorrected hearing loss: a review.

 *International Journal of Audiology 42: S17-S20.
- Australian Communications and Media Authority. (2013) Communications report 2011-12 series, Report 3 Smartphones and tablets: Take-up and use in Australia. Canberra, ACT: Commonwealth of Australia.
- Barber M, Staples M, Osborne R, et al. (2009) Up to a quarter of the Australian population may have suboptimal health literacy depending upon the measurement tool: results from a population-based survey. *Health Promotion International* 24: 252-261.
- Blamey PJ, Sarant JZ, Paatsch LE, et al. (2001) Relationships among speech perception, production, language, hearing loss, and age in children with impaired hearing. *Journal of Speech, Language, and Hearing Research* 44: 264-285.
- Brouillette R. (2008) Rehabilitation of hearing loss: challenges and opportunities in developing countries. In: McPherson B and Brouillette R (eds) *Audiology in Developing Countries*. New York: Nova Science Publishers, Inc., 141-154.
- Caposecco A, Hickson L and Meyer C. (2011) Assembly and insertion of a self-fitting hearing aid: design of effective instruction materials. *Trends in Amplification* 15: 184-195.

- Ciorba A, Bianchini C, Pelucchi S, et al. (2012) The impact of hearing loss on the quality of life of elderly adults. *Clinical Interventions in Aging* 7: 159-163.
- Convery E, Keidser G, Caposecco A, et al. (2013) Hearing aid assembly management among adults from culturally and linguistically diverse backgrounds: toward the feasibility of self-fitting hearing aids. *International Journal of Audiology* 52: 385-393.
- Convery E, Keidser G, Hartley L, et al. (2011) Management of hearing aid assembly by urban-dwelling hearing-impaired adults in a developed country: implications for a self-fitting hearing aid. *Trends in Amplification* 15: 196-208.
- Convery E, Keidser G, Seeto M, et al. (2015) Factors affecting reliability and validity of self-directed automatic in situ audiometry: implications for self-fitting hearing aids.

 **Journal of the American Academy of Audiology 26: 5-18.
- Davis JM, Elfenbein J, Schum R, et al. (1986) Effects of mild and moderate hearing impairments on language, educational, and psychosocial behavior of children. *Journal of Speech and Hearing Disorders* 51: 53-62.
- Dixon RA. (1996) Collaborative memory and aging. In: Herrmann D, Johnson M, McEvoy
 C, et al. (eds) *Basic and Applied Memory: Theory in Context*. Mahwah, NJ: Erlbaum,
 359-383.
- Dixon RA and Gould ON. (1996) Adults telling and retelling stories collaboratively. In:

 Baltes P and Staudinger U (eds) *Interactive Minds: Lifespan Perspectives on the*Social Foundation of Cognition. New York, NY: Cambridge University Press, 221241.

- Doak C, Doak L and Root J. (1996) *Teaching Patients with Low Literacy Skills*, Philadelphia, PA: JB Lippincott.
- Freeman BA. (2009) The coming crisis in audiology. *Audiology Today* 21: 46-53.
- Friedman J, Hastie T and Tibshirani R. (2010) Regularization paths for generalized linear models via coordinate descent. *Journal of Statistical Software* 33(1): 1-22.
- Gallagher TM. (2006) US doctoral education: critical shortages and plans for reshaping the future. *Folia phoniatrica et logopaedica* 58: 32-35.
- Goulios H and Patuzzi R. (2008) Audiology education and practice from an international perspective. *International Journal of Audiology* 47: 647-664.
- Holube I, Fredelake S, Vlaming M, et al. (2010) Development and analysis of an International Speech Test Signal (ISTS). *International Journal of Audiology* 49: 891-903.
- Hougaard S and Ruf S. (2011) EuroTrak I: A consumer survey about hearing aids in Germany, France and the UK. *Hearing Review* 18: 12-28.
- Kincaid J, Fishburne R, Rogers R, et al. (1975) Derivation of new readability formulas

 (Automated Readability Index, Fog Count and Flesch Reading Ease Formula) for

 Navy enlisted personnel. Research Branch Report 8-75. Millington, TN: Naval

 Technical Training, US Naval Air Station, Memphis, TN.
- Kochkin S. (2000) MarkeTrak V: "Why my hearing aids are in the drawer": The consumers' perspective. *Hearing Journal* 53: 34,36,39-41.

- Kochkin S. (2005) The Impact of Untreated Hearing Loss on Household Income. Better Hearing Institute.
- Kochkin S. (2007) MarkeTrak VII: Obstacles to adult non-user adoption of hearing aids. Hearing Journal 60: 24,26,28,31-34,36-41,44,46,48,50.
- Kochkin S. (2009) MarkeTrak VIII: 25-year trends in the hearing health market. *Hearing Review* 16: 12,14,16,18-20,22-24,26,28,30-31.
- Lin F, Niparko J and Ferrucci L. (2011) Hearing loss prevalence in the United States.

 *Archives of Internal Medicine 171: 1851-1853.
- Mathers C, Boerma T and Ma Fat D. (2008) The global burden of disease: 2004 update.

 Geneva: World Health Organization.
- McCormack A and Fortnum H. (2012) Why do people fitted with hearing aids not wear them? *International Journal of Audiology* 52: 360-368.
- Nasreddine ZS, Phillips NA, Bédirian V, et al. (2005) The Montreal Cognitive Assessment (MoCA): a brief screening tool for mild cognitive impairment. *Journal of the American Geriatrics Society* 53: 695-699.
- National Health and Medical Research Council. (2007) National Statement on Ethical Conduct in Human Research. Canberra, ACT: Commonwealth of Australia.
- National Institutes of Health. (2010) NIH Fact Sheet: Hearing Aids.
- Nowicki S and Duke M. (1974) A locus of control scale for noncollege as well as college adults. *Journal of Personality Assessment* 38: 136-137.
- Nutbeam D. (1998) Health promotion glossary. Health Promotion International 13: 349-364.

Osborne H. (2005) Health Literacy from A to Z, Boston, MA: Jones and Bartlett.

Parker RM, Parker RM, Baker DW, et al. (1995) The test of functional health literacy in adults: a new instrument for measuring patients' health literacy skills. *Journal of General Internal Medicine* 10: 537-541.

Pew Research Center. (2014) Older adults and technology use. Washington, DC.

Rotter JB. (1966) Generalized expectancies for internal versus external control of reinforcement. *Psychological Monographs* 80: 1-28.

Ruben RJ. (2000) Redefining the survival of the fittest: communication disorders in the 21st century. *The Laryngoscope* 110: 241-245.

Tibshirani R. (1996) Regression shrinkage and selection via the lasso. *Journal of the Royal Statistical Society Series B: Methodological* 58(1): 267-288.

Trites R. (1977) Neuropsychological Test Manual, Ottawa, ON: Royal Ottawa Hospital.

West RL and Smith SL. (2007) Development of a hearing aid self-efficacy questionnaire.

International Journal of Audiology 46: 759-771.

World Bank. (2014) GNI per capita, Atlas method (current US\$).

World Health Organization. (2014) World health statistics 2014.