Factors associated with successful setup of a self-fitting hearing aid and the need for personalized support

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ABSTRACT

Objectives: Self-fitting hearing aids have the potential to increase the accessibility of hearing health care. The aims of this study were to: (1) identify factors that are associated with the ability to successfully set up a pair of commercially available self-fitting hearing aids; 2) identify factors that are associated with the need for knowledgeable, personalized support in performing the self-fitting procedure; and (3) evaluate performance of the individual steps in the self-fitting procedure.

Design: Sixty adults with hearing loss between the ages of 51 and 85 took part in the study. Half of the participants were current users of bilateral hearing aids; the other half had no previous hearing aid experience. At the first appointment, participants underwent assessments of health locus of control, hearing aid self-efficacy, cognitive status, problem-solving skills, demographic characteristics, and hearing thresholds. At the second appointment, participants followed a set of computer-based instructions accompanied by video clips to self-fit the hearing aids. The self-fitting procedure required participants to customize the physical fit of the hearing aids, insert the hearing aids into the ear, perform self-directed *in situ* audiometry, and adjust the resultant settings according to their preference. Participants had access to support with the self-fitting procedure from a trained clinical assistant (CA) at all times.

Results: Forty-one (68%) of the participants achieved a successful self-fitting. Participants who self-fit successfully were significantly more likely than those who were unsuccessful to have had previous experience with hearing aids and to own a mobile device (when controlling for four potential covariates). Of the 41 successful self-fitters, 15 (37%) performed the procedure independently and 26 (63%) sought support from the CA. The successful self-fitters who sought CA support were more likely than those who self-fit independently to have a health locus of control that is externally oriented toward powerful others. Success rates on the individual steps in the self-fitting procedure were relatively high. No one step was more problematic than any other, nor was there a systematic tendency for particular participants to make more errors than others. Steps that required use of the hearing aids in conjunction with the self-fitting app on the participant's mobile device had the highest rates of support use.

Conclusions: The findings of this study suggest that non-audiologic factors should be considered when selecting suitable candidates for the self-fitting hearing aids evaluated in this study. Although computer-based instructions and video clips were shown to improve self-fitting skill acquisition relative to past studies in which printed instruction booklets were used, the majority of people are still likely to require access to support from trained personnel while carrying out the self-fitting procedure, especially when this requires the use of an app.

INTRODUCTION

Improving access to affordable, efficacious care is a key priority of the hearing health care system (Donahue et al. 2010; NASEM 2016) and of health care more generally (World Health Organization 2015). As such, there has been growing interest in interventions that can be self-directed by the patient with minimal clinician involvement. Self-fitting hearing aids have the potential to be a cost-effective, accessible intervention that confers a high level of independence and control on the user (NASEM 2016). Self-fitting hearing aids are personal amplification devices that are intended to be set up and managed primarily by the user, a process that typically encompasses four steps. First, the user may have to select, connect, and adjust appropriately sized hearing aid components, such as ear tips and tubing, to ensure a comfortable physical fit. Second, the user performs self-directed *in situ* audiometry (i.e. a measurement of hearing thresholds through the hearing aid itself). Third, the hearing aid automatically applies a prescriptive fitting rationale to the measured thresholds to determine the baseline gain/frequency response. Fourth, the user optionally fine-tunes or trains the hearing aid settings in his or her own everyday listening environments (Convery et al. 2011a; Keidser & Convery 2016). The critical distinction between self-fitting and conventional hearing aids lies in the degree of responsibility the user must assume for the tasks associated with the device. While users of both hearing aid types are responsible for the tasks involved with ongoing use and management in everyday life, only users of self-fitting hearing aids must first set up and prepare the devices for use. Given that the achievement of a successful self-fitting relies on the ability of a layperson, rather than a professional, to perform these tasks, it is of critical importance to determine what enables a successful self-fitting.

The influence of non-audiologic personal factors on hearing aid use and management has been well-explored in the literature. Associations have been reported between successful hearing aid use and intact cognitive status in a sample of older Icelandic females (Fisher et al. 2015), higher self-efficacy for basic (Meyer et al. 2014) and advanced (Hickson et al. 2014) hearing aid handling skills among older Australian adults, and a more internal locus of control in both all-female (Garstecki & Erler 1998) and combined male and female (Cox et al. 2005) groups of older adults. The ability to carry out day-to-day hearing aid management tasks has been linked to better manual dexterity among older users of behind-the-ear hearing aids (Kumar et al. 2000) and older adults with no previous hearing aid experience (Caposecco et al. 2016). In the Caposecco et al. (2016) study, higher levels of health literacy were also associated with successful performance of hearing aid management tasks.

The personal factors associated with the successful setup of a self-fitting hearing aid, however, are not yet fully understood. In the only study to date that has investigated this relationship, 40 older adults with hearing loss followed a set of written, illustrated instructions to self-fit a pair of commercially available self-fitting hearing aids in conjunction with a software application (app) on a tablet (Convery et al. 2016). Prior to performing the self-fitting procedure, standardized measures of cognitive status, health literacy, locus of control, hearing aid self-efficacy, and manual dexterity were administered. None of these factors were found to be significantly associated with self-fitting performance, an outcome that may have occurred for a number of reasons. First, the sample size may have been too small to demonstrate any significant effects. Second, the study participants performed the self-fitting procedure with help from a lay partner, and the predictor variables were averaged across each participant-partner dyad in order to account for their combined contributions. However, there was considerable variation in the extent to which the partners were involved in the procedure, and the relative contributions of each member of the dyad were not weighted to reflect their individual influence on the outcome.

Studies investigating isolated components of the self-fitting procedure have identified several personal factors that are associated with successful performance. In two separate studies, participants with better cognitive status were significantly more likely than those with poorer cognitive status to assemble a dome, tube, and body of a receiver-in-canal (RIC) hearing aid to achieve an appropriate physical fit (Convery et al. 2013) and to accurately follow step-by-step instructions to perform self-directed automatic *in situ* audiometry (Convery et al. 2015). In the latter study, locus of control was additionally found to be significantly associated with the outcome. Participants with a more internally oriented locus of control – those who believe the outcome of events results predominantly from their own actions (Levenson 1981) – were significantly more likely than those with a more externally oriented locus of control to follow the instructions for performing *in situ* audiometry accurately (Convery et al. 2015).

Both cognitive status and locus of control are examples of factors that are intrinsic to the individual and whose effects cannot necessarily be ameliorated by making hearing aid-related tasks easier to perform. Other personal factors, however, may exert a lesser or greater effect on task performance depending on the difficulty of the task and the quality of the accompanying instructional materials. Previous self-fitting research suggests that health literacy is one such factor. In Convery et al. (2011b), 80 older adults were asked to assemble and insert a RIC hearing aid. Twenty-five percent of the participants performed the task accurately; higher levels of health literacy were associated with an increased likelihood of accurate performance. These findings suggested that there was scope for improving the accompanying instructional materials in order to make self-fitting tasks more accessible to people with a wider range of abilities. The instructions for performing the task were revised to target the aspects of the procedure that were most difficult for the participants in the Convery et al. (2011b) study. In a subsequent study, a new group of 40 participants were given the revised instructions and asked to perform the same assembly and insertion task (Convery et al. 2013). Sixty-three percent of the participants performed the task accurately and health literacy was not significantly associated with the outcome. Notably, these participants demonstrated better task performance despite possessing significantly lower levels of health literacy than the participants in the earlier study (Convery et al. 2011b; $t_{118} = 4.48$, $p < 0.0001$). This outcome suggests that when health instructional materials are appropriately designed, low levels of health literacy are not necessarily a barrier to their successful use, echoing the findings of Caposecco et al. (2016) with conventional hearing aids.

The role of lay support in achieving a successful outcome has been investigated in all of the self-fitting studies discussed thus far. Participants in all studies were encouraged to attend the study appointment with a partner (a family member or friend) who would be present to offer assistance with the self-fitting task as needed. In Convery et al. (2011b), only 29% of the partners became involved in the task. In Convery et al. (2015), in which 53% of the participants successfully performed self-directed automatic *in situ* audiometry, 20% of the partners contributed to this outcome. In both of these studies, partners were instructed to provide assistance only when explicitly requested by the participant; the low rate of partner involvement was thus thought to be partly related to the constraints placed on how participants and their partners could interact. In Convery et al. 2016, in which participants were asked to perform the full self-fitting procedure with a commercially available self-fitting hearing aid, these constraints were lifted and participants and their partners were allowed to interact naturally. The proportion of partners who became involved in the task increased to 92%, as expected, but this did not result in a concomitant increase in the success rate, which was only 55%. This was likely due to the fact that the partners did not possess greater knowledge about the procedure than did the participants; both members of the pair had access only to the written instructions for performing the self-fitting task. Further, the majority of partners did not have hearing loss or wear hearing aids themselves, suggesting that in most cases, the partners had less hearing-related knowledge than did the participants. Based on these findings, it is hypothesized that knowledgeable support – something the lay partners were unqualified to provide – would enable more people to complete the self-fitting hearing aid setup procedure accurately and thus increase the success rate.

In summary, while the influence of non-audiologic personal factors on successful hearing aid use is well-established, and while previous studies have identified an association between a number of these factors and accurate performance of individual components of the self-fitting procedure, there is insufficient evidence at present to make a statement about factors that are associated with performance of the self-fitting procedure as a whole. Further, support with self-fitting has been provided by untrained laypeople in all previous self-fitting studies. The extent to which a trained layperson could assist in achieving a successful self-fitting, and the factors associated with an individual's decision to seek such support, have yet to be explored.

The primary aims of this study were therefore to: (1) identify factors that are associated with the ability to successfully set up a pair of commercially available self-fitting hearing aids; and (2) identify factors associated with the need for knowledgeable, personalized support in performing the self-fitting procedure. The following factors were investigated because of previous evidence of their association with hearing aid use and management: cognitive status, locus of control, hearing aid self-efficacy, and problem-solving skills. Cognitive status and locus of control have been linked to management of both self-fitting (Convery et al. 2013; Convery et al. 2015) and conventional hearing aid tasks (Fisher et al. 2015; Garstecki & Erler 1998; Cox et al. 2005). While no relationship has been established to date between hearing aid self-efficacy and self-fitting hearing aid management, hearing aid self-efficacy has emerged as an important factor predicting conventional hearing aid use in past studies (Meyer et al. 2014; Hickson et al. 2014) and was thus deemed important to consider in the present study. Problem-solving skills have not been formally investigated in the context of hearing aid management. However, this factor was selected for investigation due to the unique nature of the self-fitting process. Setting up and preparing self-fitting hearing aids for use is a relatively complex process and requires that the user, rather than a hearing health care professional, take the initiative in understanding, performing, and troubleshooting these tasks.

A secondary aim of the study was to evaluate performance of the individual steps in the self-fitting procedure. To guide the participants through the self-fitting process in the present study, they had access to instructions with embedded videos and personalized support from a trained clinical assistant (CA).

MATERIALS AND METHODS

Participants

Sample size determination was based on the first research question, which aimed to identify which factors predict whether a participant will be successful or unsuccessful at self-fitting a pair of hearing aids. A successful self-fitter was defined as a person who: (1) accurately completed all steps in the self-fitting procedure independently; or (2) sought help in order to accurately complete all steps in the self-fitting procedure. An unsuccessful self-fitter was defined as a person who made at least one unresolved error that prevented completion of the self-fitting procedure. The baseline probability of success was set to 50% (i.e. an equal chance of being successful or unsuccessful). Cognitive status, as measured by the Montreal Cognitive Assessment (MoCA; Nasreddine et al. 2005), was used in the power calculations, based on previous studies suggesting that it was an important contributor to successful performance of self-fitting tasks (Convery et al. 2013; Convery et al. 2015). A 2-point change in MoCA score is considered a significant difference (Krishnan et al. 2017; Tan et al. 2017). We hypothesized that a 2-point increase in MoCA score would be minimally sufficient to increase the probability of success to 65% (i.e. an odds ratio of 1.85). The required sample size to detect an odds ratio of 1.85 with 80% power at an alpha level of 0.05 was 74. However, available resources prevented the recruitment of 74 participants meeting the inclusion criteria within a reasonable time frame. The final sample size of 60 was sufficient to detect an odds ratio of 1.85 with 70% power.

The 60 participants were recruited from a database of research volunteers maintained by the National Acoustic Laboratories, local hearing health care providers, an advertisement in a community newspaper, and word of mouth. The inclusion criteria were: (1) between 50 and 85 years of age; (2) a four-frequency pure-tone average (PTA4; average of pure-tone hearing thresholds at 0.5, 1, 2, and 4 kHz across ears) between 25 and 65 dB HL to ensure the participant’s thresholds were within the fitting range of the study hearing aids; and (3) user of bilateral hearing aids for ≥1 year OR no previous hearing aid experience. The exclusion criteria were: (1) presence of active ear disease; (2) non-English speaking; and (3) additional disabilities (e.g. dementia that had been formally diagnosed by a physician) that would preclude participation in the present research study. Twenty-one participants were female and 39 were male. The higher proportion of males in the study sample approximates the gender distribution of the adult hearing-impaired population from which the sample was drawn (Access Economics 2006). Participants ranged in age from 51 to 85 years, with a median age of 73 years. The mean PTA4 was 43 dB HL and ranged from 25 to 65 dB HL. Participants were divided into two equal groups on the basis of their prior experience with hearing aids. Thirty participants wore bilateral hearing aids and had done so for between 1.5 and 37 years (median = 7.5 years); these participants were classified as "Experienced". The other 30 participants, who had no previous experience with amplification, were classified as "New".

Equipment

Each study participant was provided with a pair of SoundWorld Solutions (Park Ridge, IL) Companion self-fitting hearing aids. The Companion is a RIC hearing aid with 16-channel compression, noise reduction, feedback cancellation, a directional microphone, and an internal rechargeable power source. Users can customize the physical fit by selecting from a choice of three closed silicone ear tips of different sizes and adjusting the length of the tubing to suit the size of their ears. The tubing can be lengthened by pulling the tube out of the ear hook or shortened by allowing the tube to retract into the hook.

Users undertake the self-fitting procedure by establishing a Bluetooth connection between the hearing aids and a mobile device, thus enabling access to SoundWorld Solutions' CS Customizer app. Within the app, the user can self-administer an *in situ* measurement of pure-tone hearing thresholds, to which the app automatically applies SoundWorld Solutions' proprietary fitting formula to generate an initial gain/frequency response. The hearing test measures a minimum of three frequencies (0.5, 1, and 4 kHz), with additional frequencies (0.25, 2, and 6 kHz) tested if the user's thresholds meet particular criteria. 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 ≥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 ≥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 ≥15 dB.

The initial gain/frequency response that is derived from the results of the *in situ* hearing test is called the Personal Profile. The Personal Profile includes three listening programs designed for different acoustic environments: the Baseline Profile, which applies a proprietary prescriptive formula 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 settings in any of these programs from the app's Equalizer mode, which allows adjustments to be made to the overall gain as well as to gain in the low-, mid-, and high-frequency bands.

Materials

Cognitive status • Overall cognitive status was assessed with the MoCA (Nasreddine et al. 2005). The MoCA is designed as a screening instrument for detecting cognitive impairment in the domains of visuospatial and executive function, memory, attention, language, abstraction, delayed recall, and orientation to time and place. The maximum score that can be obtained on the MoCA is 30, with scores ≥ 26 indicating normal cognitive status and scores < 26 suggestive of varying degrees of cognitive impairment. The MoCA's developers reported a Cronbach's alpha of 0.83, suggesting good internal consistency (Nasreddine et al. 2005). The MoCA was chosen for use in the present study for two reasons. First, the MoCA was used in past self-fitting studies in which significant associations were found between cognitive status and the self-fitting task under investigation (Convery et al. 2013; Convery et al. 2015). Second, the MoCA is sensitive to mild cognitive impairment, which is common among older adults. Item analysis has shown that the test can reliably distinguish adults with mild cognitive impairment from adults with confirmed Alzheimer's dementia as well as from normal controls (Nasreddine et al. 2005).

Health locus of control • The Multidimensional Health Locus of Control (MHLC) scale (Wallston et al. 1978) was used to measure the extent to which individuals believe they can influence events that occur in their lives in a health context. Three six-item subscales each reflect a different dimension of locus of control beliefs: internality, powerful others, and chance externality. Respondents were asked to read each item (e.g. *If I become sick, I have the power to make myself well again*) and to provide a rating on a scale from 1 (strongly disagree) to 6 (strongly agree). Separate scores are reported for each of the three subscales. The developers of the MHLC scales report a Cronbach's alpha for the three subscales ranged from 0.67 to 0.77, suggesting acceptable internal consistency (Wallston 2005). Previous conventional and self-fitting hearing aid studies have employed other, more general, measures of locus of control, such as the Adult Nowicki-Strickland Internal-External Control Scale (Nowicki & Duke 1974) used in Convery et al. (2015). The MHLC was chosen for the present study due to its focus on beliefs as they apply specifically to health, and there is evidence that these beliefs impact health behaviors (Wallston 2005).

Hearing aid self-efficacy • The Measure of Audiologic Rehabilitation Self-Efficacy for Hearing Aids (MARS-HA; West & Smith 2007) is a questionnaire-style measure of 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 cope with a particular listening situation or perform a hearing aid-related skill (e.g. *I can insert a battery into a hearing aid with ease*). The MARS-HA is composed of four subscales: Basic Handling, Advanced Handling, Adjustment, and Aided Listening. Each subscale has good internal consistency, with Cronbach's alpha values ranging from 0.77 to 0.93 for new hearing aid users (i.e. those with less than 6 months of hearing aid experience) and 0.67 to 0.91 for experienced hearing aid users (West & Smith 2007). Correlation analysis confirms that while the individual subscales measure related constructs (all correlation coefficients were significant at $p = 0.01$), these constructs are independent and do not overlap with each other to a significant degree (West & Smith 2007). Test-retest reliability was high for both user groups, for the total scale, and for each individual subscale (West & Smith 2007). The MARS-HA was chosen for use in the present study because it was used in previous studies that demonstrated a link between self-efficacy and conventional hearing aid management (Hickson et al. 2014; Meyer et al. 2014).

Problem-solving skills • The ability to plan and problem-solve was measured using the Twenty Questions subtest of the Delis-Kaplan Executive Function System (D-KEFS; Delis et al. 2001). Individuals are shown a set of 30 images laid out in a 5 x 6 grid; each image shows a picture of a common, everyday object. The test-taker is instructed to determine which of the 30 pictures the experimenter has in mind by asking as few yes/no questions as possible, to a maximum of 20 questions. The test is scored by calculating the total number of questions required to identify the target picture on four presentations of the task and standardizing this number according to age decile. Higher standardized scores reflect better problem-solving skills and more flexible executive function relative to others in the same age range. The D-KEFS was standardized on 1,750 American participants ranging from 8 to 89 years of age who were selected to be representative of the wider American population in terms of gender, ethnicity, educational attainment, and geographic location. Internal consistency of the Twenty Questions Test within this normative population was moderate to high (Delis et al. 2001). The Twenty Questions Test was selected for the present study because it emphasizes the visual attentiveness and deliberation components of problem-solving (Swanson 2005), two domains of executive function that we hypothesized would be relevant to setting up a self-fitting hearing aid.

Demographic data • Information about gender, age, mobile device ownership, and previous hearing aid experience was gathered with a questionnaire.

Hearing thresholds • Participants underwent masked pure-tone air- and bone-conduction audiometry using ER-3A (Etymotic Research, Elk Grove Village, IL) insert earphones and an Interacoustics (Middelfart, Denmark) AC40 clinical audiometer. Air-conduction thresholds were measured at 0.25, 0.5, 1, 2, 3, 4, 6, and 8 kHz and bone-conduction thresholds were measured at 0.5, 1, 2, and 4 kHz. Threshold-seeking was performed according to the modified Hughson-Westlake procedure (Carhart & Jerger 1959).

Procedure

Data were collected over two appointments. At the first appointment, which took approximately 1.5 hours, health locus of control, hearing aid self-efficacy, cognitive status, problem-solving skills, demographic data, and hearing thresholds were measured.

At the second appointment, participants followed a set of step-by-step instructions to self-fit the hearing aids. Since the task was entirely self-directed, the length of the appointment varied from 30 minutes to 2 hours. The instructions were presented as a self-paced Microsoft (Redmond, WA) PowerPoint slide deck on a laptop that participants could page through with the forward and back arrow keys. An overview of each section and how it contributed to the fitting as a whole was provided before the step-by-step procedure began. The nine steps were: (1) pair the hearing aids via Bluetooth to a mobile device; (2) identify the left and right hearing aids; (3) select the correct ear tip size; (4) adjust the length of the tubing; (5) insert the hearing aids into the ear; (6) ensure the fitting app has correctly identified the left and right hearing aids; (7) use the app to perform automatic *in situ* audiometry; (8) adjust the settings; and (9) learn how to clean and care for the hearing aids. The raw text of the instructions 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 suggested that the instructions were written at a reading level of grade 5.8, consistent with recommendations that instructional materials for use in a health context be written at a level between grades 3 and 6 (Doak et al. 1996; Osborne 2005). Captioned video clips demonstrating steps 1, 3, 4, 5, 8, and 9 were embedded in the PowerPoint presentation. Participants were able to play and pause the video clips as many times as they wished during the appointment.

Participants were seated in a quiet room with a telephone they could use to call the CA, who was positioned in an office down the corridor. The CA was a non-clinician who had been trained by the first author (EC) to respond to participant questions about the self-fitting procedure and to assist participants with carrying out the self-fitting tasks upon request. Using a series of three training modules presented in Microsoft (Redmond, WA) PowerPoint format, the CA was taught to distinguish between traditional and self-fitting hearing aids, set up the self-fitting hearing aids used in the study, respond to questions from participants while they are performing the self-fitting procedure, and troubleshoot the difficulties that participants encounter. The modules used a variety of learning strategies, including reading, self-reflection, observation, hands-on activities, and discussions with the first author (Allery 2009; Buscombe 2013). Skill acquisition was assessed by the first author using teach-back and role-playing techniques. Four individuals acted in the CA role at different times: three non-clinical staff members from the National Acoustic Laboratories (two administrative staff and one software developer) and a Macquarie University student who had completed undergraduate studies in audio engineering and was about to commence a graduate program in audiology. Each was available for approximately the same number of participants.

While the participants were performing the self-fitting procedure, the experimenter monitored them audiovisually via a webcam and headphones in an office down the corridor from the test booth and rated their performance on each step with “yes” or “no” along two dimensions: accuracy and independence. *Accuracy* was defined as performance of the step in a way that achieved the intended outcome, regardless of whether this was accomplished by the participant alone or as a result of help from the CA as initiated by the participant. In the case of step 7 (use the app to perform automatic *in situ* audiometry), the assessment of accuracy was based on whether the participant initiated the test on the app and responded to the pure tones reliably enough that a full audiogram was measured, not on the validity of the measured thresholds. *Independence* was defined as performance of the step by the participant alone (i.e. without seeking help from the CA), regardless of whether the step was performed accurately or not. The experimenter did not intervene in the self-fitting process except in cases where the participant made an unresolved error that prevented completion of the full procedure. In these cases, the experimenter sent the CA into the test booth to identify the source of the error(s) and to assist the participant in completing the self-fitting procedure. Based on the accuracy and independence ratings, participants were deemed successful or unsuccessful. Successful self-fitters were those who: (1) accurately completed all steps in the self-fitting procedure independently; or (2) sought help from the CA in order to accurately complete all steps in the self-fitting procedure. Unsuccessful self-fitters were those who made at least one unresolved error that prevented completion of the self-fitting procedure.

Upon completion of the study, participants were offered a choice between a cash payment of AUD$100 (approximately USD$75) to offset their travel expenses or the opportunity to purchase the study hearing aids at the wholesale price of AUD$300 (approximately USD$225). The treatment of participants was approved by the Australian Hearing Human Research Ethics Committee (AHHREC2016-4; AHHREC2016-10) and the University of Queensland Medical Research Ethics Committee (2016000447) 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).

Data Analysis

All statistical analysis was performed using IBM (International Business Machines, Armonk, NY) SPSS Statistics version 24. Two binomial logistic regression models were fitted to the data to determine which independent variables predicted whether: (1) participants were successful with the self-fitting procedure; and (2) participants who self-fit successfully did so independently or with CA support. The continuous independent variables were all linearly related to the logit of the dependent variable as per the results of the Bonferroni-corrected Box-Tidwell procedure, confirming that the data were suitable to be analyzed with binomial logistic regression (Tabachnick & Fidell 2013). Prior to undertaking the analyses, skewness and kurtosis z-scores were calculated for each independent variable to assess normality of distribution (Tabachnick & Fidell 2013). Two variables were not normally distributed. Due to the number of participants with no HA experience, years of HA experience was strongly negatively skewed with a leptokurtic distribution. This variable was converted to a dichotomous categorical variable (experience/no experience). The other variable, cognitive status, was negatively skewed due to many participants obtaining maximum, or close to maximum, scores, and thus was transformed using a reflect and square root transformation (Osborne 2002). Each of the four subscales on the MARS-HA was significantly correlated with the other subscales ($r = 0.28$-0.77, $p < 0.05$), so only the total score was used to represent hearing aid self-efficacy. Univariate logistic regression analysis was performed on each of the independent variables with the aim of identifying those that made significant ($p < 0.1$) individual contributions to the model (Bursac et al. 2008). Among the significant variables, calculation of the variable inflation factor statistic suggested that there was no evidence of multicollinearity (O'Brien 2007). Correlation analysis (Pearson's, point-biserial, or chi-square, as appropriate to the type of variable) was performed to ensure those variables selected for entry into the final regression model were not strongly ($r \geq 0.4$) correlated with each other.

RESULTS

Table 1 shows the means and standard deviations (or ratios, for dichotomous categorical variables) for each independent variable. Relative to participants in the New group, participants in the Experienced group had a significantly greater degree of hearing loss ($t = -2.42$, $p = 0.02$), the only independent variable on which the two groups differed significantly.

Successful versus unsuccessful self-fitting

Forty-one participants (68%) self-fit successfully and 19 participants (32%) were unsuccessful. Of the eleven independent variables, seven were significantly associated with self-fitting success in the univariate analyses: health locus of control (powerful others), hearing aid self-efficacy, cognitive status, problem-solving skills, age, hearing aid experience, and mobile device ownership (Table 1). Problem-solving skills and cognitive status were significantly correlated ($r = 0.43$, $p = 0.001$). To increase the ratio of observations to independent variables, these two variables were represented by one measure. Cognitive status was selected as the representative variable because it spans a greater range of cognitive domains and its method of measurement (the MoCA) is easier and quicker to administer in a clinical setting than the Twenty Questions test. Binomial logistic regression was performed on the remaining six variables to determine the extent to which they predicted whether the participants would achieve a successful fitting. A significant model ($\chi^2 = 28.90$, $p < 0.0001$) containing all six variables was produced (Table 2). According to the Nagelkerke R^2 statistic, the model explained 54% of the variance in setup performance and correctly classified 80% of the participants as successful or unsuccessful self-fitters. A cutoff value of 0.5 was chosen, meaning that if the predicted probability was > 0.5, the model predicted that the participant would be successful with self-fitting. Sensitivity was 95% and specificity was 47%. The results of the Hosmer-Lemeshow goodness of fit test were not significant, indicating that the model fit the data well (χ^2 = 6.02, p = 0.65). There were two studentized residuals with values of 2.13 and -2.01, respectively, which were kept in the analysis. Of the six independent variables, two made individually significant contributions to the model: hearing aid experience (p = 0.016) and mobile device ownership (p = 0.023). Together, these two variables explained 42% of the variance in the outcome. Successful self-fitters were significantly more likely to have had previous experience with hearing aids and to own a mobile device when controlling for health locus of control, hearing aid self-efficacy, cognitive status, and age.

Independent versus supported fitting

Of the 41 participants who were able to self-fit successfully, 15 (37%) did so independently and 26 (63%) sought CA support. Of the eleven independent variables, two were significantly associated with the achievement of an independent or a supported fitting in the univariate analyses: health locus of control (powerful others) and problem-solving skills (Table 1). Both variables were entered into a binomial logistic regression model to determine whether they predicted whether the participants who had successfully self-fit did so independently or with CA support. A significant model (χ^2 = 6.58, p = 0.037) containing both variables was produced (Table 3). According to the Nagelkerke R^2 statistic, the model explained 20% of the variance in support needs and correctly classified 68% of the participants as achieving either an independent or a supported fitting. A cutoff value of 0.5 was chosen, meaning that if the predicted probability was > 0.5, the model predicted that the participant would self-fit independently. Sensitivity was 81% and specificity was 47%. The results of the Hosmer-Lemeshow goodness of fit test were not significant, indicating that the model fit the data well ($\chi^2 = 4.58$, $p = 0.80$). The data set contained one studentized residual with a value of 2.40, which was kept in the analysis. Only the variable health locus of control made a significant individual contribution to the model ($p = 0.047$). Alone, this variable explained 11% of the variance in the outcome. Those who required support with the setup procedure were significantly more likely than those who completed the procedure independently to have a health locus of control that was externally oriented toward powerful others when controlling for problem-solving skills.

Performance on the self-fitting steps

Figure 1 shows a breakdown of the performance on each step in the self-fitting procedure by all 60 participants. For each step, the proportion of participants who performed it correctly was relatively high, with no one component of the procedure standing out as more difficult than the others. With the exception of one participant who was unable to complete any step in the self-fitting procedure, there was no systematic tendency for particular participants to make more errors than others, even for steps that were similar in nature. For example, there was no overlap between the participants who were unable to pair the hearing aids with their mobile device and those who were unable to perform automatic *in situ* audiometry, both of which were steps that required use of the self-fitting app.

Figure 2 shows, for each step in the self-fitting procedure, the proportion of the 41 successful self-fitters who performed the step independently and those who did so with CA support.

Participants requested support more frequently for steps requiring use of their mobile devices compared to steps in which the hearing aids were handled or manipulated in isolation.

DISCUSSION

Achievement of a successful self-fitting arises from the interaction between the personal characteristics of the user and the resources that are available to support performance of the task. The results suggest that previous experience with hearing aids and previous experience with mobile devices, such as smartphones and tablets, were the two most important personal factors that influenced the likelihood of a successful self-fitting. The effect of hearing aid experience appears sensible given the overlap between the skills needed to set up a self-fitting hearing aid and those that are employed when managing a conventional hearing aid of the same style, such as inserting the device into the ear. Likewise, the significance of mobile device experience also seems sensible, and could be related to the major role the app played in the self-fitting process. However, the importance of mobile device experience in the larger context of hearing rehabilitation should not be overlooked. The majority of hearing technology manufacturers now enable wireless communication between their products and mobile devices (e.g. Hallenbeck 2016); it is thus probable that smartphones will become the primary method for interacting with hearing aids and personal sound amplification products in the near future. However, it must be borne in mind that smartphone penetration among older adults – arguably the prime demographic for hearing aid use – lags behind that of other age groups. The Pew Research Center reports that only 30% of American adults over the age of 65 own a smartphone, compared to 83% of adults between the ages of 30 and 49 and 68% of all Americans over the age of 18 (Pew Research Center 2016). Age has also been identified as a barrier to technology adoption more generally. In a recent investigation into technology use among adults with hearing loss, Stieglitz Ham et al. (2014) found that older age was associated with lower use of both “everyday” (e.g. DVD player, answering machine) and “advanced” (e.g. mobile device app, Bluetooth) technologies. Within the older population, the presence of hearing loss and the use of hearing aids has also been found to influence the use of technology. Gonsalves and Pichora-Fuller (2008) reported that the use of information and communication technologies, such as email and the internet, was significantly lower among older adults with hearing loss who had not adopted hearing aids compared to age-matched peers with normal hearing. The findings of Stieglitz Ham et al. (2014) and Gonsalves and Pichora-Fuller (2008), combined with our observation that support with self-fitting was sought most frequently for those steps that required use of the self-fitting app, underscores the need for manufacturers to ensure that a lack of previous experience with mobile devices and apps does not become an unintended barrier to the use of their products by older adults with hearing loss. While it could be argued that this problem will diminish in the future as those who are currently familiar with smartphones grow older, it is very likely that subsequent introduction of newer technology will continue to challenge the older population.

Participants whose health locus of control was more externally oriented toward powerful others were more likely to seek help with one or more steps in the self-fitting procedure. Two recent studies have suggested that locus of control also plays an important role in hearing aid management more generally. Kelly-Campbell and Allan (2016) found that when current and former hearing aid users were asked to describe their experience of hearing loss, the former hearing aid users made a significantly greater number of statements consistent with an externally oriented locus of control (e.g. “I was just never able to keep my hearing aids from whistling”). The authors suggest that discontinuation of hearing aid use may be linked to a lack of perceived control over any hearing aid problems that may arise and a belief that these problems cannot be resolved. Similarly, in a study by Bennett et al. (2018), a discrepancy was noted between hearing aid users and clinicians regarding which group should assume responsibility for identifying and solving hearing aid problems. While the consensus among the hearing aid user group was that clinicians should be primarily responsible for these tasks – a belief that could be interpreted as reflecting an external locus of control oriented toward powerful others – the clinicians believed that hearing aid users should take greater personal responsibility for hearing aid problem-solving. Both Kelly-Campbell and Allan (2016) and Bennett et al. (2018) suggested that adopting a more patient-centered approach to hearing health care would empower hearing aid users to take a more proactive approach to hearing aid management and stave off the possibility of discontinuing hearing aid use. While this is a feasible strategy within a traditional model of hearing health care, it may present a greater challenge to a direct-to-consumer or over-the-counter model, the channel through which most self-fitting hearing aids are likely to be provided in future. The roles and responsibilities of hearing aid users and providers within such a model, particularly with respect to ensuring continued hearing aid use, are important considerations for self-fitting hearing aids and remain to be fully explored.

A number of factors investigated in the present study were not found to be significant predictors of the outcome. Although cognitive status and problem-solving skills were significantly associated with successful self-fitting in the univariate analyses, the predictive value of cognitive status was diminished when controlling for other factors such as hearing aid experience and mobile device ownership. Similarly, the predictive value of problem-solving skills was diminished when it was entered into the regression analysis in place of cognitive status. While it is likely that problem-solving skills and cognitive status have some bearing on the ability to self-fit and the decision to seek help with the procedure, it is possible that the specific instruments we chose to measure these two factors, the MoCA and the Twenty Questions test, were not sufficiently sensitive to identify the extent of their impact. An additional contributor to this outcome may also be the fact that many participants scored at or near ceiling on the MoCA. An association between hearing aid self-efficacy and conventional hearing aid use has been demonstrated in previous studies (Hickson et al. 2014; Meyer et al. 2014). However, this was not the case in the present study. This may have occurred because the MARS-HA, the questionnaire we used to assess hearing aid self-efficacy, was designed to represent the skills needed to use and manage a conventional hearing aid (West & Smith 2007). Skills that are necessary for successful self-fitting of the hearing aids used in the present study, such as pairing the hearing aids to a mobile device via Bluetooth and performing self-directed *in situ* audiometry with an app, are not covered by the MARS-HA. It is possible that an association between self-efficacy and self-fitting success may have been identified if an instrument that tapped into specific self-fitting skills had been used, since self-efficacy is domain-specific: high self-efficacy for one task does not necessarily imply high self-efficacy for another, even if the two tasks are related (Pajares 1997).

Usability of a product is not only determined by the physical attributes of the product itself, but can be influenced by the accompanying instructional materials (Stork et al. 2008). In the present study, the self-fitting instructions were designed in accordance with best-practice health literacy principles and high rates of accuracy were observed on each step in the self-fitting procedure. Our findings support those of Caposecco et al. (2016), who found that hearing aid management was influenced by the quality of hearing aid user guides. Novice hearing aid users who were given a user guide that was modified to conform to best-practice health literacy principles performed significantly better than those who had received a standard guide on a test of hearing aid management skills. Further, participants in that study who had the modified guide required significantly less prompting to perform several of the tasks on the skills test, including hearing aid insertion, volume and program adjustments, use of the telephone in conjunction with the hearing aid, and cleaning.

While not a specific aim of the study, we hypothesized that the use of video clips to illustrate key steps in the self-fitting procedure would improve participant performance, particularly on historically challenging components of the procedure like insertion of the hearing aid into the ear. Our findings support this hypothesis, with 78% of all participants in the present study inserting both hearing aids correctly without assistance, compared with rates of 46-64% observed in past self-fitting studies (Convery et al. 2011b; Convery et al. 2015). These findings are also in line with studies demonstrating that access to video demonstrations significantly improves knowledge and skill acquisition, both in the context of hearing aid use (Ferguson et al. 2016) and for other health-related skills more generally (Bloch & Bloch 2013; Renton-Harper et al. 1999; Schnellinger et al. 2010). Although the instructional videos used in the present study were presented to participants on a laptop, a review of available hearing health care apps conducted by Paglialonga et al. (2015) suggests the feasibility of incorporating these videos directly into the self-fitting app. Streamlining the self-fitting support materials in this way could potentially facilitate skill acquisition and motivate users to troubleshoot independently, since all resources would be easily accessible from a single location.

While the quality of the instructional materials plays an important role in self-fitting success, access to personalized knowledgeable support during self-fitting is critical, as highlighted by our finding that the majority of participants who achieved a successful fitting did so with help from the CA, rather than independently. This outcome has at least two implications. First, any service delivery model designed to offer self-fitting products should also incorporate access to trained support personnel. In our study, the CAs initially responded to participant requests for support via telephone. The CAs then used their own judgement to decide whether they could resolve the problem over the telephone or whether they needed to enter the test booth and provide the necessary support in person. At the conclusion of the study, three of the CAs reported that they found providing telephone support very challenging because they could not see the problem, the participants were not always able to adequately describe the difficulties they had encountered, and the participants with more severe hearing loss were not always able to hear their advice over the telephone, since they almost invariably sought support before the self-fitting hearing aids had been properly inserted and programmed. The fourth CA, who had extensive professional experience providing remote technical support for computer software and hardware, was more at ease providing telephone support in the present study. However, he commented that the challenges cited by the other three CAs made the task more difficult and often more protracted. All CAs suggested that remote troubleshooting would have been easier if a videoconferencing platform such as Skype (Luxembourg City, Luxembourg) had been used, since the addition of a video connection would have enabled them to inspect the placement of the hearing aid in the participant's ear, view any error messages in the self-fitting app on the participant's mobile device, and provide visual cues to assist participants in understanding their speech. It is worth noting that both currently operating manufacturers of self-fitting hearing aids, SoundWorld Solutions (Park Ridge, IL) and iHear Medical (San Leandro, CA), offer on-demand customer support via email, telephone, or live webchat. It is unknown to what extent the different channels impact upon the effectiveness of problem resolution and customer satisfaction, but it is likely that these two outcomes could be enhanced with the addition of a videoconferencing option.

Second, personalized support does not necessarily need to be provided by an audiologist. None of the four individuals who acted in the CA role possessed formal clinical qualifications; they were trained specifically by the first author to assist participants with the self-fitting procedure. While introducing an audiologist as a source of knowledgeable support might seem an attractive option, it would be contrary to one of the purposes of introducing self-fitting hearing aids in the first place, namely to reduce the burden on an already limited pool of clinical resources (Clark et al. 2014; Dillon 2006). Despite varying levels of previous experience performing similar tasks and the challenges the CAs encountered in providing support over the telephone, all CAs were equally effective at providing support to the participants in the present study. This finding suggests that any trained individual, or at least anyone trained and evaluated using the training modules that we developed specifically for the test device, could ostensibly fulfill this role, a conclusion that has important implications for improving the affordability and accessibility of hearing health care.

Upon completion of the study, 22 of the participants chose to purchase the self-fitting hearing aids and the remaining 38 opted to receive the cash gratuity. There was no significant relationship between purchasing the hearing aids and whether the participant had self-fit successfully ($\chi^2(1) = 0.31$, $p = 0.58$), or, among the successful participants, whether self-fitting had been undertaken independently or with support (χ^2 $(1) = 0.32$, $p = 0.57$). While the reasons for purchasing the hearing aids were not formally investigated as part of this study, many individual participants informally discussed their decision with the first author (EC) at their final study appointment. As reported by the participants, the factors that influenced their choice to purchase the self-fitting hearing aids included an inability to afford conventional hearing aids, the desire for an inexpensive pair of backup hearing aids in the event that their conventional hearing aids needed to be sent away for repair, or the view that the study hearing aids could serve as a “starter” device that could be used as long as their perceived hearing handicap remained relatively mild. Interestingly, no participant cited the fact that the study hearing aids were self-fitting as a reason for their purchase.

The results of this study should be considered in the context of several limitations. First, although the regression model for successful versus unsuccessful self-fitting correctly classified 80% of the participants, it should be noted that this was due primarily to a high sensitivity value (95%); specificity was only 47%. In other words, the factors included in the model were very good at predicting a successful outcome, but relatively poor at predicting an unsuccessful outcome. While caution should be exercised in applying these results to a clinical context, the overprediction of successful outcomes suggests that one future possibility could be to provide additional up-front support with the goal of increasing the likelihood of a successful self-fitting. Another potential avenue would be to improve the predictive value of the model by conducting a study in which a range of different independent variables are measured, such as specific domains of cognitive function or self-efficacy for performing tasks specific to self-fitting. Second, the regression model for predicting independent versus supported self-fitting, although statistically significant, was not very strong. The two predictors included in the model, health locus of control (powerful others) and problem-solving skills, explained only 20% of the variance in outcome. In addition, the model correctly classified only 68% of the participants as achieving either an independent or a supported fitting. The classification accuracy of the model is not much higher than the actual proportion of participants (63%) who achieved a supported fitting. This finding suggests that the need for support is influenced by factors not measured in the present study; future research should aim to identify those factors so that support can be targeted effectively and efficiently to those who truly require it. Third, this study was conducted with only one implementation of a self-fitting hearing aid. Characteristics of the hearing aid and the usability of its associated self-fitting app may have influenced the success rates of our participants in ways that would not occur with a different implementation. Fourth, the statistical analysis of the factorial models included both significant and non-significant predictors. An alternative approach would have been to consider only the significant predictors, but this was rejected on the basis that there was an *a priori* hypothesis as to which predictors would likely be significant based on outcomes of our previous self-fitting research. Future studies should focus on replicating these results with different self-fitting products in a more diverse sample of adults with hearing loss in order to confirm the applicability of the present findings. More importantly, future research should investigate the short- and long-term fitting outcomes achieved with self-fitting hearing aids, particularly in comparison to those obtained with conventional, audiologist-fit hearing aids.

CONCLUSION

This study demonstrated that previous experience with hearing aids, mobile device ownership, and health locus of control are all important factors underpinning successful self-fitting with the hearing aids used in this study and the means by which this is achieved. These findings, along with those indicating that the majority of successful self-fitters required support to complete the procedure, have important implications for any service delivery model that supports self-fitting hearing aids. To be viable, a delivery model would need to ensure that relevant predictive factors – which may not be part of the standard audiologic test battery – are appropriately assessed, and that access to trained personnel is available to provide on-demand support to patients at every stage of the self-fitting procedure.

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FIGURES

Figure 1. The proportion of participants (N = 60) who completed each step in the self-fitting procedure accurately (gray bars) and with errors (black bars).

Figure 2. The proportion of participants who successfully self-fit (N = 41) who completed each step in the self-fitting procedure independently (gray bars) and with CA support (black bars).