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Research Article

Comparing Hearing Aid Outcomes in Adults Using Over-the-Counter and Hearing Care Professional Service Delivery Models

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ABSTRACT

Purpose: More affordable hearing aids are now available due to over-the-counter (OTC) hearing aid regulations. Although laboratory studies have validated many OTC hearing technologies, there are limited real-world benefit studies. This study compared hearing aid outcomes reported by clients from OTC and conventional hearing care professional (HCP) service delivery models.

Method: An ecological, cross-sectional survey design was employed. An online survey was sent to the Hearing Tracker user and OTC Lexie hearing aid user databases. Moreover, 656 hearing aid users completed the survey—406 through conventional HCP services (M_{age} = 66.7 ± 13.0 years) and 250 through the OTC model (M_{age} = 63.7 ± 12.2 years). Self-reported hearing aid benefit and satisfaction were measured with the International Outcome Inventory for Hearing Aids outcome tool.

Results: No significant difference for overall hearing aid outcomes between HCP and OTC users was evident using regression analyses, controlling for age, gender, duration of hearing loss, duration before hearing aid purchase, self-reported hearing difficulty, and unilateral versus bilateral fitting. For the "daily use" domain, HCP clients reported significantly longer hours of daily use. For the "residual activity limitations" domain, OTC hearing aid users reported significantly less difficulty hearing in situations where they most wanted to hear better.

Conclusions: OTC hearing aid outcomes could complement and provide similar satisfaction and benefit to HCP models for adults. Service delivery aspects such as self-fitting, acclimatization programs, remote support, behavioral incentivization, and payment options should be investigated for their potential role in OTC hearing aid outcomes.

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An aging population is the leading cause of hearing loss, affecting 48 million Americans (Lin et al., 2011). The most common treatment for hearing loss is hearing aids (HAs), but unfortunately, only 17% of people needing HAs globally use them (Orji et al., 2020). Even in high-income countries like the United States, HA adoption rates have been reported to be less than 20% for clinically significant hearing loss (Chien & Lin, 2012). This is particularly disconcerting

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since untreated hearing loss is associated with less social interaction and, consequently, higher levels of loneliness and isolation (Bott & Saunders, 2021; Sung et al., 2016) and even a greater probability of anxiety in older adults (Contrera et al., 2016). Moreover, HA use in older adults has been associated with improvements in psychosocial and physical functioning (Wells et al., 2020). Various factors have contributed to the low adoption of hearing interventions, including insufficient advocacy and awareness, limited hearing care professionals (HCPs), and the expense associated with traditional models of hearing care and HA technology (Mamo et al., 2016; Wilson et al., 2017). Persons from low-income communities are particularly vulnerable, with the lowest adoption rates (Mamo et al., 2016).

The traditional hearing care model involves the pathway that people with hearing difficulties follow for assessing and treating their hearing loss. Specialized clinical services are delivered by HCPs (audiologists or hearing instrument specialists, the latter with less formal training) and include a diagnostic hearing evaluation, the selection of appropriate HAs in collaboration with the patient based on the patient's individual needs, programming and verification of the HAs by means of specialized software, education on handling and care of the hearing aids, follow-up visits for further training, fine-tuning of the acoustic settings, and provision of rehabilitative care (e.g., adaptation to hearing aids, communication strategies). The high cost of HAs, which is typical of traditional hearing care models, combined with limited insurance coverage, necessitating out-of-pocket payments, is an important driver of alternative HA delivery models directed at consumers (McNeal, 2016; Willink et al., 2019). Unsurprisingly, there has been increasing emphasis on service delivery models that promote more accessible and affordable hearing care (Borg et al., 2018; Ratanjee-Vanmali et al., 2020; Swanepoel, 2020). New adaptations of traditional hearing care service delivery models employing community-based approaches, telehealth, or hybrid combinations demonstrate the potential to increase access and efficiency (Borg et al., 2018; Ratanjee-Vanmali et al., 2020; Yong et al., 2019). Another rapidly developing trend is HA delivery models directed at consumers.

Direct-to-consumer (DTC) hearing devices can be purchased without consulting a hearing health professional and can fall into a variety of categories, including (a) personal sound amplification products (PSAPs; i.e., wearable consumer electronic products, unregulated by the Food and Drug Administration [FDA], intended for people without hearing loss to amplify sounds in certain environments such as recreational activities) and (b) over-the-counter (OTC) HAs (Manchaiah et al., 2017). Each of these DTC categories may represent a range of consumer journeys across acquisition, fitting, and support components. In the United States, the Over-the-Counter Hearing Aid Act of 2017 tasked the FDA to define regulatory standards for the OTC sale of HAs for mild-to-moderate hearing loss (FDA, 2022). This was in response to the President's Council of Advisors on Science and Technology report calling for more accessible and affordable HAs. The final OTC regulations, published in August 2022 and which went live across the United States on October 17, 2022, established a new category of HAs intended for adults with perceived mild-to-moderate hearing loss (FDA, 2022). In short, the OTC service delivery model allows people with hearing difficulties to self-select, set up, and use OTC hearing devices without the supervision or involvement of an HCP.

Outcomes research for OTC hearing devices and associated service delivery models has been limited to date (Almufarrij et al., 2019; Manchaiah et al., 2017). A small-scale, single-group study (N = 31) by Sacco et al. (2016) reported OTC hearing device (i.e., TEO First) outcomes in older adults, showing improvements in hearing in quiet and noisy situations as well as a decrease in perceived hearing difficulties, but acceptability was low to moderate. In a study on another OTC hearing device (i.e., by Sound World Solutions; N = 52), Keidser and Convery (2018) reported no significant difference in speech recognition scores compared to a conventional HA but with a lower rating on some aspects such as physical appearance. Manchaiah et al. (2019) explored the benefits and shortcomings of OTC hearing devices by analyzing Amazon customer reviews (N = 11,258) using qualitative and quantitative methods. Sound quality, cost, and customer service were identified as primary considerations in the adoption and acceptance of HAs in this category.

The efficacy of an OTC service delivery model for older adults was investigated by Humes et al. (2017) using a randomized, double-blind, placebo-controlled trial employing preprogrammed, self-select HAs compared to audiology best practice control and placebo conditions. The outcomes of the two models were similar on most 6-week post-fit measures, with only slightly poorer OTC outcomes overall. There were significantly lower satisfaction and percentage of those likely to buy HAs after the trial in the OTC group. A follow-up trial (Humes et al., 2019) using less front-end screening of users and employing a wider frequency gain on the HAs replicated the positive findings of the first study (Humes et al., 2017). Neither of these trials, however, included post-fitting support such as HA acclimatization and troubleshooting guidance or remote adjustments. A lack of support (e.g., during self-fitting and post-fitting of OTC HAs) and limited access to technology or insufficient technology literacy or skills might be barriers to using the OTC type of hearing devices (Blustein et al., 2022). Moreover, the Humes et al. (2017) study was a well-controlled study that was designed with internal validity in mind but lacked external validity due to its study design.

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OTC HA service delivery models are emerging rapidly. The reduced cost associated with this service delivery model will result in improved financial access to HA ownership, yet certain aspects related to support provided before, during, and after fitting of OTC hearing devices are critical to consider, especially for older adults, as they may impact the benefit obtained from these devices (Blustein et al., 2022). Some of these aspects include support in terms of choices with regard to the appearance of functions of the hearing devices; support during self-fitting of the devices; and education and support after fitting to improve the use, care, and management of the devices (Blustein et al., 2022). A number of FDA-approved OTC HA models are now available online, in pharmacies and big-box retailers in the United States. Some of these OTC self-fitting HA models include post-fitting support services and app-based adjustments (Williams & Leppla, 2021). Lexie Hearing, for example, includes an app-based acclimatization program that also informs users about adjustment strategies, HA troubleshooting, and care (Williams & Leppla, 2021). Self-fitting OTC devices that include smartphone customizers have previously demonstrated better electroacoustic (e.g., maximum power output, gain, distortion) and match-to-target gain and slope performance (i.e., matching prescription targets for gain across the frequency range; Almufarrij et al., 2019). The addition of remote support and app-based acclimatization services, however, has not been evaluated in OTC service delivery models.

The OTC HA regulations in the United States and its potential spillover to other global markets and the way in which services are provided should be supported by more evidence in regard to drivers of benefit and satisfaction. Although laboratory research has validated many OTC hearing technologies, there is a need for real-world benefit studies (Reed, 2019). This study, therefore, compared HA outcomes for users of a select OTC model to a conventional HCP model.

Method

An ecological, cross-sectional survey design was employed to compare self-reported HA outcomes of two pools of users from a select OTC model and a conventional HCP model. A Consensus-Based Checklist for Reporting of Survey Studies (Sharma et al., 2021; see Supplemental Material S1) was followed. Ethical approval (IRB-FY21-248) was obtained from the institutional review board at Lamar University, Beaumont, Texas.

Participants

Participants included members of the Hearing Tracker (http://www.hearingtracker.com) mailing list and the Lexie Hearing (http://www.lexiehearing.com) U.S. user database. An online survey was sent out using the Qualtrics platform in October and November 2021 through the Hearing Tracker website to their U.S. database and to Lexie HA users in the United States as an e-mail with an in-message link. The link led to a participant information sheet and a consent form that had to be signed electronically before the survey could be completed anonymously. In both instances, the link was sent to unselected groups of users based on being an active HA user registered on the platforms. Confidentiality of user databases and the number of registered users precluded response rate calculations. Six hundred fifty-six HA users completed the entire survey, of which 406 reported using hearing aids received through the conventional HCP service delivery model and 250 used Lexie HAs through the OTC model.

Conventional HCP HA Users

The Hearing Tracker website is an online consumer forum that collects unsolicited reviews on HAs by members of the public, wherein users describe their personal opinions and experiences with HAs. Participants from the Hearing Tracker community were HA users who used a conventional, in-person service delivery model for hearing care that was delivered by HCPs (assessment, HA fitting, follow-up appointments), for example, through private HA clinics, public health services (e.g., Veterans Affairs), or discount warehouses (e.g., Costo, Sam's Club). There is no mechanism for HCPs to interact with users of the Hearing Tracker platform.

OTC HA Users

The OTC Lexie hearing care model (http://www.lexiehearing.com) entails online and in-store purchase of self-fitting, behind-the-ear (BTE) OTC HAs with an accompanying app. This study utilized the Lexie Lumen HAs (16-channel wide dynamic–range compression, Bluetooth, adaptive directionality, and noise reduction) and included users who purchased devices online (prior to the FDA OTC regulations going live for in-store purchases). The device setup entails app-based instructions, followed by an in situ pure-tone audiometry self-test (i.e., measurement of hearing thresholds at 0.5, 1, 2, and 4 kHz through the HA using the built-in sound generator and the hearing aid receiver) through Bluetooth. An autofit based on the NAL-NL2 fitting formula (an HA fitting prescription procedure from the National Acoustic Laboratories, aimed at making speech intelligible and overall loudness comfortable) is subsequently performed from the app, based on the in situ hearing thresholds (Frisby et al., 2022). The app includes user settings (volume and environmental programs), the Lexie Rewards program, and remote support via video or audio calls. The rewards program provides guidance and support on HA acclimatization, troubleshooting, and use

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through guided wearing goals, interactive learning, and feedback activities. Rewards include potential discounts on subscriptions or accessories based on the completion of wearing goals, learning activities, or feedback. Remote support includes access to troubleshooting and remote fine-tuning by the Lexie experts.

Measures

The survey examined HA experiences from adult HA users' perspectives. The survey consisted of four sections, including (a) demographic and audiological related items; (b) open-ended questions on HA experiences; (c) the International Outcome Inventory for Hearing Aids (IOI-HA; Cox & Alexander, 2002); and (d) general health, well-being, and social network items (see Supplemental Material S2). This study considered responses from Sections (a) and (c), with subsequent studies focused on Sections (b) and (d). Demographic and audiological related items inquired about age, gender, self-reported hearing difficulty (*unaided*, 1 = *hear everything*, 2 = *sometimes don't hear*, 3 = *regularly don't hear*, 4 = *almost never hear*), duration of hearing loss, duration before HAs were obtained after noticing hearing problems, monaural or binaural fitting, HA style (in-the-ear or BTE), HA brand, and service delivery model. The widely used IOI-HA (Cox & Alexander, 2002) outcome tool was included (see Supplemental Material S2) because it was considered brief enough, consisting of only seven questions that are generally applicable to evaluate different dimensions of HA outcomes, and general enough to be appropriate in different research studies (Cox & Alexander, 2002; Cox et al., 2003). Each of the seven items covers an outcome domain of everyday life that might be improved by HA use. The domain items in order are (a) daily use, (b) benefit, (c) residual activity limitations, (d) satisfaction, (e) residual participation restrictions, (f) impact on others, and (g) quality of life. Each of the seven IOI-HA questions was scored from 1 to 5, with a score of 5 indicating the best result and a score of 1 indicating the worst. Thus, a higher score on each individual question and on the total score was indicative of a better outcome (Cox & Alexander, 2002).

Statistical Analysis

Survey data were extracted from the Qualtrics platform and exported into Microsoft Excel to organize the data into one data set. Prior to analysis, data cleaning was conducted, and the following responses were excluded: participants who did not provide consent (n = 23), participants who had only an implantable device(s) (e.g., cochlear implants, bone-anchored hearing devices; n = 3), and participants who did not have a conventional type of HAs but PSAP devices (n = 14). Note that this article presents the results of the analyses of data from Sections (a) and (c) of the survey. All statistical analyses were completed in SPSS (Version 28; IBM Corporation).

IOI-HA studies have typically reported mean response scores for each question. However, a recent study examining the large-scale IOI-HA data from several countries has concluded that IOI-HA data should be analyzed using nonparametric methods as the data generated are ordinal in nature (Leijon et al., 2021). To make the data backward compatible, we report mean scores, but we also include the median, interquartile range, and total scores consistent with recent recommendations.

Most demographic variables violated the assumption of normality. Hence, the nonparametric Mann–Whitney U test or chi-square analyses were used to test for demographic and audiological differences between the two independent groups. Subsequently, eight regression models were built, with the dependent variables being IOI-HA total score (continuous variable) and IOI-HA Questions 1–7 (ordinal variables). The independent variables were age, gender, duration of hearing loss, duration before HA purchase, self-reported hearing difficulty, and unilateral versus bilateral HA fitting. After evaluating assumptions, we opted for a quantile regression model for the total IOI-HA score, as there are no distributional assumptions and it is robust to outliers. Furthermore, for these types of models, ideally, there should be a reduction in the mean absolute error (MAE) from the null model to the final model, which was the case here (null MAE = 3.435, final MAE = 3.384; percentage reduction = 1.47%). Model fit was established by comparing the final model to the null/intercept model, with the latter being the model with no predictors. For the ordinal dependent variables (IOI-HA Questions 1–7), generalized ordinal logit regression models were built as opposed to ordinal regression models, as the latter has the assumption of proportional odds, which is often violated. Generalized ordinal logit models were developed to address the issue of proportional odds by allowing the effect of each explanatory variable to vary across different cut-points of the ordinal outcome variable without data restructuring (Liu & Koirala, 2012).

Results

Table 1 provides a summary of the demographic and audiological details as well as the statistical comparison between these groups for several variables. The two groups had significant differences in terms of age, duration of hearing loss, duration before HAs were purchased, and self-reported hearing difficulty. Relative to participants who obtained HAs through the HCP model, participants from the OTC group were significantly younger, had a shorter duration of hearing loss but a longer period before HAs were obtained, and had less severe self-reported hearing difficulties.

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Table 1. Characteristics and comparison of hearing aid (HA) users' demographic and audiological variables for the hearing care professional (HCP) and over-the-counter (OTC) Lexie Hearing service delivery groups.

Variable	HCP model (n = 406)	OTC model (n = 250)	Mann–Whitney U or chi-square analysis: Z or χ^2 value; p value
Age (years), *M* (*SD*)	66.7 (13.0)	63.7 (12.2)	$Z = -3.84$; $p < .001$*
Mdn (IQR)	69.0 (13.3)	66.0 (15.3)	
Gender, *n* (%)			
Male	240 (59.1)	162 (64.8)	$\chi^2 = 2.1$; $p = .146$
Female	166 (40.9)	88 (35.2)	
Hearing loss duration (years), *M* (*SD*)	24.0 (18.6)	14.4 (14.0)	$Z = -7.50$; $p < .001$*
Mdn (IQR)	18.0 (28.0)	10.0 (15.0)	
Duration before HA purchase (years), *M* (*SD*)	7.0 (11.4)	8.5 (11.2)	$Z = 3.95$; $p < .001$*
Mdn (IQR)	2.3 (7.0)	5.0 (8.0)	
Self-reported hearing difficulty, *n* (%)			$\chi^2 = 20.43$; $p < .001$*
Almost never hear	114 (28.1)	33 (13.2)	
Regularly don't hear	193 (47.5)	145 (58.0)	
Sometimes don't hear	97 (23.6)	69 (27.6)	
Hear everything	2 (0.5)	3 (1.2)	
Unilateral vs. bilateral, *n* (%)			
Bilateral	370 (91.1)	240 (96.0)	$\chi^2 = 5.62$; $p = .018$*
Unilateral	36 (8.9)	10 (4.0)	
Hearing aid style, *n* (%)			
BTE	370 (91.1)	250 (100.0)	$\chi^2 = 23.46$; $p < .001$*
ITE	36 (8.9)		
Hearing aid brand, *n* (%)			
Lexie		250 (100.0)	$\chi^2 = 656.0$; $p < .001$*
Phonak	107 (26.4)		
Oticon	83 (20.4)		
ReSound	66 (16.3)		
Kirkland	51 (12.6)		
Starkey	26 (6.4)		
Widex	24 (5.9)		
Signia/Siemens	22 (5.4)		
Other	27 (6.6)		

Note. IQR = interquartile range; BTE = behind-the-ear; ITE = in-the-ear.
*Significant difference between HCP and OTC; $p < .05$.

HCP and OTC HA outcomes on the IOI-HA questions were compared using regression models that controlled for variables of age, duration of hearing loss, duration before HA purchase, gender, self-reported hearing difficulty, and unilateral versus bilateral HA fitting. Generalized ordinal logit regression models were built for IOI-HA Questions 1–7, with the omnibus test (which is a likelihood ratio chi-square [LR-χ^2] test of the final model vs. the null model) indicating that the models for IOI-HA Question 1 (Q1; LR-$\chi^2 = 72.026$; $p < .001$), Question 3 (Q3; LR-$\chi^2 = 110.653$; $p < .001$), Question 5 (Q5; LR-$\chi^2 = 71.241$; $p < .001$), Question 6 (Q6; LR-$\chi^2 = 37.310$; $p < .001$), and Question 7 (Q7; LR-$\chi^2 = 25.447$; $p = .003$) significantly outperformed the null model. However, the IOI-HA Question 2 (Q2; LR-$\chi^2 = 11.721$; $p = .229$) and Question 4 (Q4; LR-$\chi^2 = 16.435$; $p = .058$) models did not significantly outperform the null model. The results are shown in Table 2.

For the total IOI-HA score, a quantile regression model showed no significant differences between HCP and OTC HA service delivery outcomes when controlling for the variables mentioned previously (see Table 2). Moreover, there were no significant differences between HCP and OTC HA service delivery outcomes (see Table 2) for the IOI-HA items of benefit (Q2), satisfaction (Q4), residual participation restrictions (Q5), impact on others (Q6), and quality of life (Q7). Significant differences between HCP and OTC HA service delivery models were, however, evident for IOI-HA items of daily use (Q1) and residual activity limitations (Q3). For daily use (Q1), HCP clients reported significantly longer hours of daily HA use (see Figure 1a). For residual activity limitations (Q3), OTC HA users reported significantly less difficulty hearing in situations where they most wanted to hear better (see Figure 1b). OTC HA users were 2.5 times more likely to fall one category higher in response options (1–5), indicating less residual activity limitations (Q3) than HCP HA participants.

Discussion

This study examined HA outcomes for adults using an OTC model compared to a traditional HCP model. Overall HA outcomes based on IOI-HA total scores showed no statistically significant difference between the

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Table 2. Comparing International Outcome Inventory for Hearing Aids (IOI-HA) outcomes (1 = *poorest outcome*; 5 = *best outcome*) for the hearing care professional (HCP) and over-the-counter (OTC) Lexie Hearing service delivery groups.

IOI-HA item (*N* = 656)	HCP (*n* = 406) Mean score (*SD*) Median score (IQR)	OTC (*n* = 250) Mean score (*SD*) Median score (IQR)	*p*	ß regression coefficient [*SE*]	*OR* [95% CI]
Q1 Use	4.73 (0.75) 5.00 (0)	4.44 (1.00) 5.00 (1)	**< .001**	**–.70** **[0.21]**	**0.50** **[0.33, 0.75]**
Q2 Benefit	3.95 (1.05) 4.00 (2)	3.99 (1.00) 4.00 (1)	.338	.15 [0.16]	1.16 [0.85, 1.58]
Q3 Residual activity limitations	3.25 (1.01) 3.00 (1)	3.78 (0.92) 4.00 (1)	**< .001**	**.91** **[0.17]**	**2.50** **[1.80, 3.45]**
Q4 Satisfaction	4.29 (1.02) 5.00 (1)	4.34 (1.00) 5.00 (1)	.107	.27 [0.17]	1.32 [0.94, 1.84]
Q5 Residual participation restrictions	3.65 (1.12) 4.00 (1)	3.90 (1.13) 4.00 (2)	.152	.23 [0.16]	1.26 [0.92, 1.73]
Q6 Impact on others	3.85 (1.02) 4.00 (2)	3.96 (1.12) 4.00 (2)	.392	.14 [0.16]	1.15 [0.84, 1.58]
Q7 Quality of life	4.00 (0.97) 4.00 (2)	4.12 (0.88) 4.00 (1)	.082	.28 [0.16]	1.32 [0.96, 1.81]
Overall score	27.72 (4.61) 29.00 (6)	28.54 (4.49) 29.00 (6)	1.000	.00 [0.49]	N/A

Note. Regression models accounted for age, gender, duration of hearing loss, duration before hearing aid purchase, self-reported hearing difficulty, and unilateral versus bilateral hearing aid fitting. Significant effects are indicated by bold typeface. IQR = interquartile range; *OR* = odds ratio; CI = confidence interval; Q1–Q7 = Questions 1–7; N/A = not applicable.

OTC and conventional HCP models. Overall, both models showed outcomes for adult HA users within similar ranges compared to previous studies in the United States and other countries such as Australia, the Netherlands, and Germany (Cox & Alexander, 2002; Heuermann et al., 2005; Hickson et al., 2010; Kramer et al., 2002).

Reported hours of HA use per day exceeded the previously reported use on the IOI-HA (Cox & Alexander, 2002; Heuermann et al., 2005; Hickson et al., 2010; Houmøller et al., 2022; Kramer et al., 2002), despite the OTC HA usage (4.43) being significantly lower than the HCP model (4.73). Humes et al. (2017) did not find daily HA use impacted by the service delivery approach, comparing audiology best practice and OTC interventions. To date, there has been limited evidence linking hearing health care professionals' behaviors and HA outcomes, such as daily use, with only a few studies showing some effect but insufficient to identify specific behaviors (Ismail et al., 2019). Interactions with HCPs could potentially encourage more HA use, as the amount of use is a typical indicator of HA success in the audiologic community (Laplante-Lévesque et al., 2013). HA use time (e.g., number of hours per day) is known to correlate with HA benefit and satisfaction (Humes et al., 2017; Wong et al., 2003). However, it is important to note that the concept of optimal HA use based on the patient's hearing and communication needs might be a more appropriate HA use outcome measure relative to the absolute amount of HA use (Laplante-Lévesque et al., 2013). Some users may acquire HAs for a specific situation(s) that may require limited daily use but could still support optimal perceived benefit. This emphasizes the importance of providing patient-centered care to achieve successful outcomes.

The residual activity limitations (Q3) item score was within the range of previously reported studies, although the OTC model had significantly better scores (Cox & Alexander, 2002; Heuermann et al., 2005; Hickson et al., 2010; Kramer et al., 2002). This item, in addition to Items 5 and 7, constitutes an IOI-HA principal component factor describing residual limitations after HA fitting, described as "me and the rest of the world" (Cox & Alexander, 2002; Houmøller et al., 2022). It is not clear what factors inherent in the specific OTC model may have contributed to less residual activity limitations with HA use compared to an HCP model independent of factors such as age, gender, and severity of self-reported hearing difficulty. The specific OTC HA model allows for HA control and immediate in-app access to remote support and fine-tuning (Williams & Leppla, 2021), which may contribute to a sense of independence and control, leading to improved HA self-efficacy. Consequently, reduced activity limitations may be experienced as these HAs are increasingly integrated into the users' daily living.

Comparable overall outcomes of the OTC HA model support current initiatives for more accessible and affordable hearing care through OTC HAs (Lin et al., 2016; President's Council of Advisors on Science and Technology, 2015; Reed et al., 2018). In particular, findings indicate that optimal HA outcomes can be achieved with an OTC service delivery model as complementary to

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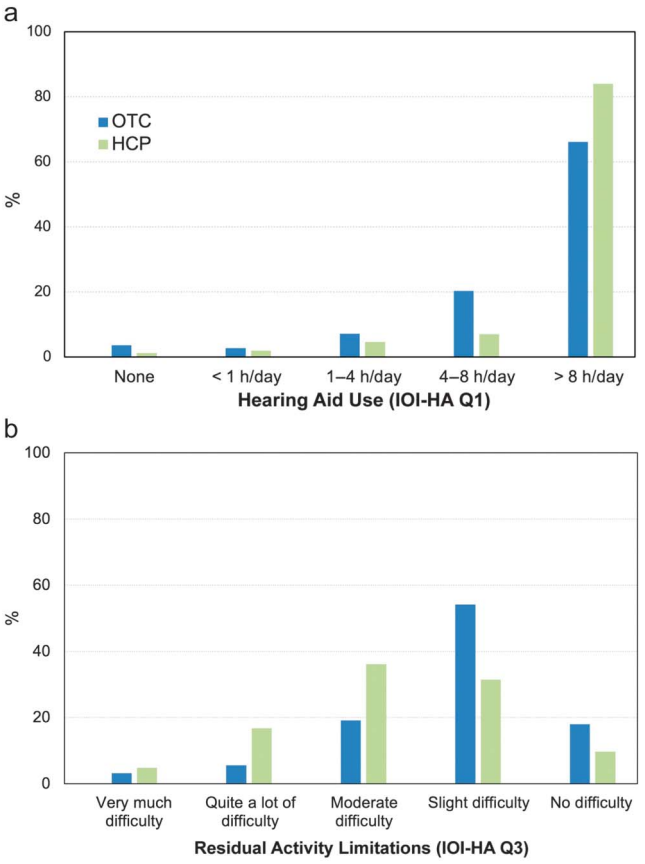
Figure 1. Distribution of International Outcome Inventory for Hearing Aids (IOI-HA) responses on items that were significantly different between over-the-counter (OTC) and hearing care professional (HCP) models. (a) IOI-HA Question 1 (Q1) for hearing aid use. (b) IOI-HA Question 3 (Q3) for residual activity limitations. h = hours.



existing HA service delivery models. However, it will be important to consider some implications of these evolving service delivery models as recently highlighted by Blustein et al. (2022), especially to improve use and benefit of OTC hearing devices for older adult populations, such as ensuring guidance and support throughout the OTC HA journey.

Study Limitations and Future Directions

This study had a few limitations that should be noted while interpreting the study results. First, drawing causal conclusions using observational study designs should be approached with care. Second, as an ecological study drawing from two source pools, results are also open to potential sampling bias. For example, users may have self-selected themselves to obtain HAs from a particular service delivery model. Third, surveying consumer databases with restricted access precluded us from sample-related controls, such as response rate calculations, and may have resulted in self-selection bias. Fourth, due to survey design, recall bias may have influenced participants' responses, as some of the IOI-HA questions requested the participants to recall a specific situation or report over a 2-week period (e.g., Q1, Q2, Q5, and Q6). Fifth, there are several unmeasured potential confounders that may have influenced the study findings. For instance, increasing hearing loss severity has been associated with improved outcomes on IOI-HA scores (Hickson et al., 2010; Houmøller et al., 2022; Thunberg Jespersen et al., 2014). This study used self-reported hearing difficulties as opposed to pure-tone audiometry as a measure of hearing loss severity, which has shown limited correlation previously (Ardeshirrouhanifard et al., 2022; Curti et al., 2019). Nevertheless, the FDA OTC regulations (FDA, 2022) stipulate that OTC HAs are to be provided based on self-perceived mild-to-moderate hearing impairment, independent of pure-tone audiometry findings. Finally, differentiating factors of persons accessing OTC versus HCP services that were not captured in this study may have potentially influenced outcomes (e.g., OTC users may be more likely to have higher technology literacy levels).

Future studies should focus on examining factors contributing to HA outcomes for users of different service delivery models (HCP vs. OTC vs. OTC with different levels of clinical support) using prospective and controlled study designs. Moreover, including objective HA outcomes, such as behavioral measures (e.g., speech in noise examined in the laboratory) and cortical changes (e.g., Glick & Sharma, 2020), may help supplement the self-reported outcomes observed in this study.

Conclusions

An OTC HA model, including app-based fitting, acclimatization, and remote support, demonstrates overall outcomes similar to users receiving HAs from HCPs. This is the first large-scale study comparing real-world HA outcomes in adults from a traditional HCP and OTC model, controlling for independent variables. Characteristics of OTC HA service delivery models, such as app-based self-fitting, acclimatization programs, remote support, behavioral incentivization, and payment options, should be considered for their potential contributions to HA benefit and satisfaction. Improved uptake and use of HAs through complementary, consumer-friendly models could potentially reduce the long-term cost and negative effects of untreated hearing loss on various associated conditions, such as cognitive decline and dementia (Livingston et al., 2020).

Data Availability Statement

The data sets generated and/or analyzed during this study are available from the corresponding author on reasonable request.

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