Toward the Development of an Intervention to Improve Hearing Aid Access for Older People With Dementia

A Dissertation

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Dana Patton Urbanski

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Abstract

Untreated age-related hearing loss in individuals with dementia is a critical public health issue. Among Americans older than age 80, over 80% have age-related hearing loss and one-fifth live with dementia (Plassman et al., 2007; Sharma et al., 2020). Based on prevalence alone, hearing loss and dementia often co-occur; however, growing evidence reveals that untreated hearing loss is independently associated with accelerated cognitive decline and incident dementia, (Lin et al., 2013; Loughrey et al., 2018) possibly via its impact on social engagement and/or sensory deprivation (Slade et al., 2020; Uchida et al., 2019). Of critical importance, untreated hearing loss also complicates the clinical management of neuropsychiatric dementia symptoms by exacerbating communication difficulties, (Mamo et al., 2017; Slaughter et al., 2014) thus reducing social engagement, lowering quality of life, and increasing the risk of depression (Dawes et al., 2019; Mamo et al., 2018; Resnick et al., 1997). For many individuals with dementia, hearing aid use may relieve the compounding effects of hearing loss and dementia by improving communication, increasing quality of life, reducing the risk of depression, and possibly slowing the rate of cognitive decline. (Amieva et al., 2018; Bucholc et al., 2021; Dawes et al., 2019; Lin et al., 2023; Maharani et al., 2018; Mamo et al., 2018; Ray et al., 2018). However, only 30% of people with hearing loss in a memory clinic sample reported using hearing aids, a figure consistent with overall hearing aid uptake in Americans with hearing loss. (Bainbridge & Ramachandran, 2014; Nassiri et al.,
Increasing hearing aid use in older persons with co-occurring dementia and hearing loss is thus imperative. Low hearing aid adoption among older adults, including those with dementia, is primarily attributed to the high cost of hearing aids and poor access to specialized hearing care (Coco et al., 2018; Jilla et al., 2023). To address both cost and access, the Food and Drug Administration introduced over-the-counter (OTC) hearing aids in October 2022. Lower-cost, more accessible OTC hearing aids are intended to facilitate hearing aid use by allowing adults to purchase, fit, and manage hearing aids without a licensed care provider. The resulting “do-it-yourself” approach to hearing loss has been shown to be efficacious in cognitively healthy individuals (e.g., Humes et al., 2017; Nelson et al., 2018; Urbanski et al., 2021) but, to our knowledge, no research has examined whether and how people with dementia can successfully use OTC hearing aids. Evidence from the gerontechnology literature, however, implies that older persons with dementia may face unique challenges for using OTC hearing aids effectively. It is well documented that individuals with dementia have greater difficulty using, handling, and maintaining assistive and everyday technologies than their peers without dementia (Malinowsky et al., 2010; Nygard & Starkhammar, 2007; Rosenberg et al., 2009). This evidence highlights an urgent health inequity: if people with dementia cannot successfully use OTC hearing aids, they may be left without an affordable and accessible option for hearing aids.
One potential solution to this problem is to create and disseminate a behavioral intervention that promotes and supports effective OTC hearing aid use in people living with dementia and their family caregivers. The proposed intervention would serve as a set of wraparound services, supports, and training specifically designed to address the complexities of OTC hearing aid use in the dementia care context. Following the NIH Stage Model for behavioral intervention development (Onken et al., 2014), this dissertation includes three studies designed to establish necessary scientific groundwork (NIH Stage Model Stage 0) for subsequent development and testing of a behavioral intervention program to support successful OTC hearing aid use in people with dementia. The first study is a proof-of-concept study examining the effectiveness of OTC hearing aids for older adults with normal cognition. This study answers the question of whether OTC hearing aids are effective under ideal circumstances for well-selected OTC hearing aid candidates with normal cognition. In a single-blind crossover field study of 37 older adults without cognitive impairment, OTC hearing aids produced comparable outcomes to clinically fit hearing aids matched to prescription targets. The results demonstrate that OTC hearing aids are feasible and effective when self-fit and used correctly.

The subsequent studies build on these findings by beginning to consider and explore the potential for OTC hearing aid use in people with dementia. The second study uses a large national dataset of older long-term care recipients to explore whether older adults with dementia report unmet need for hearing aids
and if so, whether reported unmet need varies by residence type. This study answers the question of whether there is a need for OTC hearing aids in people with dementia—as well as where an OTC hearing aid intervention should be targeted and delivered to address currently unmet hearing aid need in this population. The results confirm that people with dementia report meaningful unmet need for hearing aids, and further reveal that their unmet need is disproportionately concentrated among people with dementia living in the community in their own or family home versus other institutional or congregate settings. Based on these results, the proposed intervention will be specifically designed and delivered to reach community-dwelling people with dementia for whom reported unmet hearing aid need is greatest.

The third study builds on Study 2 with a qualitative study examining dementia care stakeholder perspectives on the feasibility and acceptability of currently available OTC hearing aids for community-dwelling people with dementia. Interviews were conducted with community-dwelling older adults with dementia and hearing loss, family caregivers of these individuals, and geriatric care providers. Qualitative thematic analysis revealed perceived advantages for OTC hearing aids in the areas of affordability, accessibility, and control. However, results uncovered a host of perceived barriers to OTC hearing aid use which 1) are unique to the dementia care context and 2) must be addressed to ensure successful device use in these individuals. Subsequent intervention development will target and address these stakeholder-perceived barriers.
Together, the three dissertation studies lay the foundation for advancing toward intervention development, refinement, and initial pilot testing—with the eventual goal of progressing to efficacy testing, effectiveness research, and dissemination/implementation.
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Chapter 1: Introduction

Over-the-counter (OTC) hearing aids have been formally introduced to the United States hearing aid market in an effort to improve the affordability and accessibility of amplification; however, questions remain regarding the person-, device-, and service-related factors that will shape OTC hearing aid outcomes in older Americans with age-related hearing loss. Notably, there is a dearth of evidence for the usability and effectiveness of OTC hearing aids in older adults with dementia who constitute one-fifth of adults aged 80 and above and approximately 40% of adults over age 90 (Plassman et al., 2007). These individuals are likely—in some numbers—to purchase OTC hearing aids or to receive them from well-meaning family members. Their outcomes, however, are yet uncertain.

Older adults with co-occurring hearing loss and dementia are an important subpopulation of potential hearing aid users who, like their cognitively healthy peers, may rely on OTC hearing aids to afford and access amplification. However, evidence from the broader gerontechnology suggests that older people with dementia may face significant challenges when using OTC hearing aids—challenges that could reduce device benefit in these individuals, but which are currently unaddressed by OTC hearing aids and their associated delivery models. Research is needed to better understand the challenges people with dementia and their caregivers are likely to face when using OTC hearing aids toward future development of tailored services and supports that promote
successful OTC hearing aid use in this population. This dissertation begins to address this gap in the current knowledge for OTC hearing aids through several studies that establish the groundwork for subsequent development and evaluation of a behavioral intervention to support effective OTC hearing aid use in people living with dementia and their family caregivers.

**The Problem of Untreated Hearing Loss in Older Adults With Dementia**

Among American older adults, age-related hearing loss affects an estimated one-third of people aged 65 and over, increasing to about 80% of those over age 80 (Dalton et al., 2003; Sharma et al., 2020). For most of these individuals, hearing aids are considered the most effective first-line therapy for age-related hearing loss (Thai et al., 2022). However, hearing aid adoption is stagnantly and concerningly low among American older adults with hearing loss—persistently falling in the range of 30-40% over the past two decades of market research (Jorgensen & Novak, 2020; Kochkin, 2009; Picou, 2022).

Older persons with cognitive impairment, including dementia, adopt hearing aids at about the same rate as the general older adult population (Nirmalasari et al., 2017). The high prevalence of untreated hearing loss in this population is an important public health concern, as people with cognitive impairment may be particularly vulnerable to the negative effects of untreated hearing loss. In these individuals, thinking and memory difficulties can adversely affect social, emotional, and cognitive domains that are also negatively impacted by untreated hearing loss (Dawes et al., 2022; Kricos, 2009). As a result,
untreated hearing loss may exacerbate cognitive impairment and its related symptoms, resulting in overlapping and compounding effects on communication and overall well-being (Dawes et al., 2019; Mamo et al., 2017; Slaughter et al., 2014). Importantly, evidence shows hearing aid use may help relieve the shared symptom burden of both conditions while providing meaningful clinical health benefits to older people living with co-occurring cognitive impairment, including dementia, and hearing (Dawes et al., 2019).

**The Potential Health Benefits of Hearing Aids in Older Adults With Dementia**

Evidence shows hearing aids may provide a variety of cognitive, behavioral, emotional, and social health benefits for older adults with cognitive impairment including dementia, raising concern about the currently low rate of hearing aid adoption in this population (Dawes et al., 2019). This literature is briefly summarized below. Collectively, this evidence underscores the public health significance of untreated hearing loss in dementia and the urgency of increasing hearing aid use in older people living with co-occurring dementia and hearing loss.

The importance of hearing aid use in older people with cognitive impairment, including dementia, is not simply about prevalence—in which both hearing loss and dementia are common conditions in older adulthood and therefore likely to co-occur within individuals. Although both conditions can and often do co-occur (Gold et al., 1996), evidence suggests they may be linked
beyond basic prevalence estimates. A growing literature reveals an independent association between untreated hearing loss and accelerated cognitive decline and incident dementia (Lin et al., 2013; Loughrey et al., 2018). The reason for this association is not yet known but could plausibly reflect a causal link between hearing loss and cognitive decline. Several well-supported hypotheses posit that hearing loss leads to cognitive impairment through one or a combination of the following mechanisms: 1) chronic auditory sensory deprivation; 2) reduced social engagement driven by hearing loss-induced communication difficulties; and/or 3) re-allocation of finite neural resources away from higher-level thinking to support persistently effortful speech processing (Bucholc et al., 2021; Slade et al., 2020; Uchida et al., 2019).

The link between hearing loss and cognitive impairment gives rise to questions about potential cognitive benefits of hearing aid use: namely, do hearing aids mediate the observed association between hearing loss and accelerated cognitive decline? In 2020, the Lancet Commission on dementia prevention, intervention, and care reviewed the available evidence and named hearing loss a modifiable risk factor for dementia via the use of hearing aids (Livingston et al., 2020). The recent ACHIEVE study adds to this body of evidence (Lin et al., 2023). This large-scale multicenter randomized controlled trial examined whether hearing aids and associated audiologic counseling can reduce three-year cognitive decline in cognitively healthy older adults with hearing loss. Interestingly, the authors found differential effects of hearing aid use by
participant recruitment source. De novo participants from the community showed no cognitive effects of hearing aid use; however, a subgroup of participants recruited from a large longitudinal cardiovascular health study (Atherosclerosis Risk in Communities; ARIC) showed a statistically significant 48% reduction in three-year cognitive decline for the hearing aid intervention. Notably, when compared to de novo participants, ARIC participants had more risk factors for cognitive decline, lower baseline cognitive scores, and a greater rate of three-year cognitive change in the control group. Based on these results, the authors posit that hearing aid use may have cognitive benefits for people at increased risk of cognitive decline, but not in populations at lesser (Lin et al., 2023).

The ACHIEVE findings point to the possibility that hearing aids may provide cognitive benefits for those whose cognitive health is most vulnerable, leading to questions about cognitive benefits of hearing aid use in older adults already diagnosed with clinically significant cognitive impairment. Here, more research is needed; however, a recent study by Bucholc and colleagues (2021) shows promising results. Using data from the National Alzheimer’s Coordinating Center, the authors examined the association of hearing aid use with conversion from mild cognitive impairment to dementia. The authors found that patients with mild cognitive impairment and self-reported hearing difficulty who used hearing aids had significantly lower risk of conversion to all-cause dementia than individuals with mild cognitive impairment and self-reported hearing difficulty who did not use hearing aids. Moreover, hearing aid users showed an overall slowed
rate of cognitive decline compared to the non-hearing aid users on annual administrations of a validated clinical assessment of dementia severity (Clinical Dementia Rating scale Sum of Boxes; CDR-SB). The findings suggest that hearing aids may support cognitive health in older adults who have already progressed to clinically significant mild cognitive impairment.

Available evidence is mixed on whether hearing aids provide cognitive benefits to people living with dementia. In a multicenter randomized controlled trial, Nguyen and colleagues (2017) examined the cognitive effects of hearing aid use in older adults with co-occurring moderate Alzheimer’s disease and moderate hearing loss. After six months of hearing aid use, the authors found no evidence of cognitive effects. This finding remained after a secondary activation phase in which the control group received hearing aids for an additional six-month period. Atef and colleagues (2023) reported similar findings. The authors analyzed two-years of follow-up data from 258 people with dementia, of which 54 self-reported using hearing aids. In this sample, hearing aid use was not associated with changes in cognition over time. Other studies, however, report positive findings of cognitive benefit for hearing aid use in people with dementia. A study by Allen and colleagues (2003) revealed slowed cognitive decline in a group of 31 older adults with co-occurring dementia and hearing loss after six months of hearing aid use. In a similar study, Kawade and colleagues (2023) found no evidence of global cognitive benefits for hearing aid use in people with
dementia but found evidence of cognitive benefit via improved attention with hearing aids.

Mixed findings of cognitive effects of hearing aids in people with dementia could reflect several underlying variables, including variability in hearing aid wear time/compliance, duration of auditory deprivation, and/or the possibility that cognitive change is more difficult to achieve in people with more advanced cognitive disease (Nguyen et al., 2017). More research is needed to understand the cognitive effects of hearing aid use in people with cognitive impairment including dementia. Importantly, however, cognition is not the only domain in which hearing aids may provide meaningful health benefits to people living with dementia. A growing literature shows that in people with dementia, hearing aids are associated with clinically meaningful behavioral, emotional, and social health benefits.

Dementia is commonly associated with an array of problematic refractory behavioral and psychological symptoms, including depression (Lyketsos et al., 2002). Notably, several studies demonstrate that hearing aids are associated with clinically significant behavioral and psychological benefits in people with dementia. A study by Palmer and colleagues (1999) found that hearing aid use was associated with significantly reduced caregiver-reported behavioral symptoms in people with Alzheimer’s disease and mild-to-moderately severe hearing loss. Similarly, a study by Mamo and colleagues (2017) found that provision of a direct-to-consumer amplification device decreased problematic
behavioral and neuropsychiatric symptoms in people with dementia who had a high symptom burden at baseline. Importantly, hearing aids have also been associated with improvements in depressive symptoms in people with dementia—mirroring similar findings in cognitively healthy cohorts. Although Atef and colleagues (2023) found no evidence of cognitive effects of hearing aids in their prospective sample of people with dementia, they did find significantly lower increases in depressive symptoms over time with hearing aid use. Mamo and colleagues (2017) also reported a meaningful reduction in depressive symptoms for their amplifier intervention in participants with dementia who had clinically significant depression at baseline. Together, these data suggest a potentially important role of hearing aids in supporting and managing the behavioral and emotional health of people living with dementia.

Fundamentally, hearing aids are dispensed to compensate for impaired hearing. On this point, it is well established that hearing aids reduce hearing-related disability in people with cognitive impairment including dementia—just as they do in cognitively healthy individuals (Dawes et al., 2019). By extension, hearing aids also have a role in supporting communication and social engagement in people with dementia. To date, few studies have examined the effect of hearing aids on communicative and social outcomes in people with cognitive impairment including dementia; however, those that do report positive results. In their pilot hearing intervention program for people with dementia, Mamo and colleagues (2017) gathered qualitative hearing aid outcomes from
people with dementia and their caregivers. The authors reported several caregiver responses pointing to better communication and improved social activity/engagement in people with dementia, as well as several responses from people with dementia who themselves reported functional communication benefits from the study hearing device. Palmer and colleagues (1999) reported similar findings, with six of eight caregivers in their study reporting that hearing aids improved communication of the person with dementia. Importantly, if hearing aids can bolster communication and social activity in people with dementia, it stands to reason that they may also support longer-term social engagement and connectedness. In older adulthood, social engagement is a core component of overall health with well-documented links to both cognitive and emotional well-being (Bath & Deeg, 2005; Herzog et al., 2022). Social engagement has also been shown to improve quality of life in people with dementia by reducing signs of boredom and loneliness (Jones et al., 2015; Moyle et al., 2010). For people with co-occurring dementia and hearing loss, provision of evidence-based amplification should be considered essential for providing these individuals with the best opportunity for successful communication and meaningful social interaction/engagement.

Collectively, the evidence summarized above suggests that hearing aids likely support the cognitive health of people with co-occurring dementia and hearing loss in some way—either directly through a yet unidentified causal pathway from sensory hearing loss to cognitive ability and/or indirectly by
promoting their behavioral, emotional, and social well-being. Hearing aids, therefore, could be considered a key non-pharmacologic intervention in the overall medical management of dementia and its related symptoms. In this case, it should be considered essential that older adults with co-occurring dementia and hearing loss receive and use evidence-based amplification. Available data, however, point to very low hearing aid use in these individuals. A recent study by Nirmalasari and colleagues (2017) reported hearing aid utilization of only 30% in a memory clinic sample of older adults with co-occurring hearing loss and cognitive impairment. This finding implies that about 70% of older adults with co-occurring hearing loss and cognitive impairment are living without the potential cognitive, social, and/or emotional benefits of hearing aids. These benefits, when achieved, are vital to the health and well-being of older people with cognitive impairment. Increasing hearing aid use in older adults with co-occurring dementia and hearing loss is thus imperative.

**OTC Hearing Aid Use in Older Adults With Dementia: Reducing Cost and Improving Accessibility**

Low hearing aid adoption among American older adults, including those with dementia, is attributed to two primary barriers: 1) the high cost of modern digital hearing aids, which cost on average $3600 per pair (Nassiri & Ricketts, 2021); and 2) limited geographic access to specialized hearing care (Planey, 2019; Coco et al., 2018). To address both cost and access barriers to hearing aid adoption, the United States Food and Drug Administration introduced OTC
hearing aids in October 2022 (Establishing Over-the-Counter Hearing Aids, 2022). This new regulatory category for hearing aids now permits adults with perceived mild-to-moderate hearing loss to purchase hearing aids directly, without a prescription and/or the involvement of a licensed hearing care professional. At the time of this writing, the emerging OTC hearing aid market is still growing; however, early indications suggest these devices are available at markedly lower price points than prescription hearing aids and with improved accessibility.

In the absence of government/societal assistance for hearing aid purchase and services, it is essential that older adults have an option for obtaining affordable, accessible hearing aids—especially for those with low socioeconomic status and from remote or rural areas that make travel to a licensed hearing care provider difficult or infeasible. OTC hearing aids serve an important purpose for these individuals—many of whom may rely on OTC hearing aids as their only option for obtaining and using amplification. However, affordability and accessibility are not the only considerations. In addition to being affordable and accessible, OTC hearing aids must also result in quality hearing healthcare for those who purchase and use them. Indeed, the goal of OTC hearing aids is not simply to increase the number of Americans who own hearing aids, but rather to increase the number who experience the health benefits of well-fit, audiometrically appropriate hearing aid amplification.
Attainment of hearing aid benefit depends on *effective device use*. To date, studies show that older adults with normal cognition can successfully self-program, use, and manage OTC hearing aids (e.g., Humes et al., 2017; Nelson et al., 2018; Urbanski et al., 2021; Venkitakrishnan et al., 2023); however, to our knowledge, no research has examined provision and use of OTC hearing aids in older people with dementia. Given the high prevalence of dementia in older adulthood, it is reasonable to anticipate that older adults with dementia will acquire OTC hearing aids—whether through an independent purchase or via well-meaning family members. When they do receive OTC hearing aids, will they be able to use them effectively? How and under what circumstances? This gap in the evidence for OTC hearing aids warrants further examination. Like their peers with normal cognition, older people with dementia face formidable cost and access barriers to hearing healthcare and could thus benefit substantially from lower cost, more accessible OTC hearing aids—*but only if they can use them effectively.*

**OTC Hearing Aid Use in Older Adults With Dementia: Challenges Beyond Cost and Accessibility**

The introduction of OTC amplification has implications beyond cost and access. Indeed, it creates a new service delivery model in which older adults (and in some cases their family caregivers) assume full responsibility for selecting, using, managing, and troubleshooting hearing aids. To date, it is unclear if older adults with cognitive impairment including dementia and/or their
family caregivers are comfortable taking on additional responsibilities for hearing aid use. Research, however, has begun to examine consumer attitudes in the broader population of potential adult OTC hearing aid users. Overall, these studies have found considerable trepidation and hesitance for OTC hearing aid use. In the MarkeTrak 10 survey, over 3,000 adults with self-reported hearing loss were asked to indicate their comfort level for performing a variety of hearing aid tasks required to use and maintain OTC hearing aids (Edwards, 2020). Across a range of tasks—from hearing aid selection to programming to ongoing maintenance and troubleshooting—anywhere from about one-third to one-half of respondents indicated they were not very comfortable or not comfortable at all performing the tasks without the assistance of a hearing care professional. Singh and Dhar (2023) found similar results in a survey of over 1,000 adult non-hearing aid users. In their survey sample, 66% of respondents indicated they were anywhere from extremely to slightly uncomfortable purchasing OTC hearing aids online without a hearing test. Consumer confidence rose only slightly if a hearing test was required. Taken together, these results broadly demonstrate that consumers take seriously the added responsibilities of OTC hearing aid use and, in general, they lack comfort and/or confidence for completing these additional tasks successfully.

It is reasonable to suspect that older adults with dementia and their family caregivers may feel similar discomfort for OTC hearing aid use. In fact, their discomfort might reasonably be intensified by the challenges associated with
progressive cognitive decline, in particular those surrounding memory loss, reduced self-awareness, and difficulty learning new skills (Bier et al., 2008; Hooper et al., 2022). In the absence of published data on this question, it is reasonable to draw parallels between OTC hearing aids and the broader gerontechnology literature for everyday technology use in older people with cognitive impairment. Although OTC hearing aids are regulated by the FDA as medical devices, their service delivery and purchase/user experience mirror that of everyday technologies such as cell phones, tablets, and computers. Moreover, OTC hearing aids often rely on the latter devices for self-programming and fine-tuning of their frequency response(s). If older adults with cognitive impairment, including dementia, demonstrate or report difficulty using everyday technology, they may face similar challenges for OTC hearing aid use.

Here, research consistently shows that older people with cognitive impairment, including dementia, both demonstrate and self-report greater difficulty understanding and effectively managing a variety of everyday technologies compared to their peers without known cognitive impairment (Malinowsky et al., 2010; Nygard & Starkhammar, 2007; Rosenberg et al., 2009). In quantitative studies, these findings are statistically significant and show large effect sizes (Malinowsky et al., 2010; Rosenberg et al., 2009; Schmidt & Wahl, 2019). In qualitative studies, older adults with cognitive impairment report an array of overlapping, compounding challenges for at-home technology use including memory deficits, difficulty attending to multiple processes, inability to
follow sequential instructions, confusion interpreting technology-generated messages, low self-efficacy for technology use, and sensitivity to technology-related stress among others (Albers et al., 2022; Dequanter et al., 2022; Nygard & Starkhammar, 2007). Some people with cognitive impairment even report forgetting what a technology is intended to do or how it is meant to function (Nygard & Starkhammar, 2007). Importantly, studies have found that manufacturer instruction manuals are typically unhelpful for older adults with cognitive impairment, including dementia, who may express optimism in their ability to follow written instructions but often fail to implement them correctly (Nygard & Starkhammar, 2007).

A small but emerging literature has examined challenges to prescription hearing aid use in older adults with cognitive impairment, including dementia, but has not yet (to our knowledge) addressed OTC hearing aid use. This research has demonstrated that older people with cognitive impairment, including dementia, face a host of barriers to effective hearing aid use including limited capacity for hands-on hearing aid skills, insufficient device knowledge, resistance to change, low self-efficacy for hearing aid use, technology-related stress, hearing aid stigma, and lack of awareness of hearing loss and/or the function of hearing aids for remediating hearing loss (Gregory et al., 2020; Hooper et al., 2022). Many of these challenges mirror those faced by the general population of older adult hearing aid users (Meyer et al., 2014; Meyer & Hickson, 2012); however, older people with cognitive impairment, including dementia, are at a
greater disadvantage for overcoming barriers to hearing aid use because of their inhibited problem-solving and planning skills (Mayo et al., 2013). As a result, family caregivers play an important role in supporting hearing aid use in older adults with cognitive impairment including dementia (Hooper et al., 2022). Research shows that in people with dementia, caregiver proficiency and assistance for hands-on hearing aid tasks, troubleshooting, and maintenance facilitates regular hearing aid use (Hooper et al., 2022). Conversely, limited caregiver knowledge or involvement may impede effective, long-term use of hearing (Hooper et al., 2022). In other words, the barriers to hearing aid use in older people with dementia are not limited to factors involving the person with dementia. Rather, barriers may extend to include characteristics of the supporting family caregivers—who may themselves be older adults facing health or cognitive challenges for adopting, learning, and using new technology.

For older adults with dementia, barriers to prescription hearing aid use are probably at least as important for OTC hearing aids. Plausibly, the barriers may be even more significant in a direct-to-consumer hearing aid service delivery model without professional counseling and support. In a prescription delivery model, licensed hearing care professionals may plan an important role in teaching and coaching hands-on hearing aid skills for older people with dementia and their family caregivers. Without this assistance, it is unclear whether and how older adults with dementia and their caregivers will successfully learn and practice essential hearing aid skills. Moreover, it is uncertain if the removal of
professional services will impact other determinants of hearing aid use in this population—including awareness of hearing loss and the purpose of hearing aids, readiness/intention to remediate hearing loss, willingness to acclimate to amplification, and self-efficacy for hearing aid use among others (Hooper et al., 2022).

Studies show that pre-existing cognitive impairment at the time of prescription hearing aid fitting is associated with higher rates of hearing aid non-use and non-adherence (Gregory et al., 2020; Naylor et al., 2022). The underlying reasons and mechanisms for these findings are not yet clear, but one could hypothesize that non-use may reflect the cumulative burden of the many barriers to hearing aid use in this population. To date, it is unexamined whether, how, and in what ways OTC hearing aids will impact the already elevated risk of hearing aid abandonment in older adults with cognitive impairment including dementia. If OTC hearing aids exacerbate existing barriers and/or introduce new challenges for hearing aid use, they could plausibly increase the risk of hearing aid abandonment in older people with cognitive impairment. In this scenario, OTC hearing aids could promote hearing aid ownership for people with dementia via improved cost and access while simultaneously reducing their likelihood for achieving long-term term hearing aid use and its associated benefits. Research is therefore urgently needed to identify services and supports that promote and support successful OTC hearing aid use in people living with dementia and their caregivers.
Creating a Behavioral Intervention Program to Support Successful OTC Hearing Aid Use in People With Dementia

A small but emerging literature suggests that people with mild dementia can learn to use technologies with support from training programs specifically tailored to meet their learning needs (Kerkhof et al., 2021). To this end, one potential solution for making OTC hearing aids a feasible, usable option for people with dementia is to create, test, and disseminate a behavioral intervention program that specifically addresses the challenges people with dementia and their caregivers are likely to face when using OTC hearing aids. Such an intervention could serve as a set of wraparound services, supports, training, and education specifically designed to address and demystify the complexities of OTC hearing aid use in the dementia care context. This service package might supplement or augment currently available OTC hearing aid service delivery models, providing additional support and assistance tailored to meet the needs of people with dementia and their caregivers.

Developing such an intervention should follow a multi-step process to ensure the resulting intervention is both effective and implementable. To this end, the National Institutes of Health (NIH) provides a framework to guide the development of health-focused behavioral interventions known as the NIH Stage Model (Onken et al., 2014). The NIH Stage Model outlines a set of recursive, iterative, multidirectional steps to be followed when creating, refining, and
evaluating behavioral interventions, especially those focused on health-related behavioral change.

Figure 1: NIH Stage Model for behavioral intervention development (Onken et al., 2014)

The model steps are as follows. Stage 0 consists of basic research that occurs prior to intervention development. During this stage, research is conducted to establish the need for the intervention, define the intervention’s intended recipients and setting, and identify the potential behavioral mechanisms that should be targeted by the intervention to achieve its goals for health behavior.
change. Stage I research builds on Stage 0 findings. In Stage 1, basic learnings from Stage 0 are translated into initial creation and pilot testing of the intervention. Additionally, Stage I can include modifications or adaptations to a previously developed intervention to improve its feasibility and acceptability for its intended recipients and/or stakeholders. Stage II research tests the efficacy of the intervention in tightly controlled studies conducted in research settings with research-based providers (high internal validity), while Stage III studies test the hybrid efficacy-effectiveness of the intervention in community settings with community providers while maintaining sufficient experimental control to establish internal validity. Stage IV research progresses to real-world effectiveness testing conducted in community settings by community-based providers with an emphasis on maximizing external validity of the study design and its results. Finally, Stage V consists of dissemination and implementation research that focuses on the scalability and adoption of effective interventions in real-world care settings.

To date and to our knowledge, the OTC hearing aid literature has not addressed the needs of people living with dementia, nor has it explored the potential for developing and delivering an intervention to support direct-to-consumer OTC hearing aid use in people with dementia and their caregivers. For this reason, intervention development must begin at Stage 0 before proceeding to Stage I intervention generation and creation. This dissertation consists of Stage 0 research toward this goal.
Research Questions and Dissertation Studies

The three studies in this dissertation are designed to establish necessary scientific groundwork for progressing to intervention development, refinement, and pilot testing. The first study serves as a proof-of-concept study for OTC hearing aids by examining their efficacy and effectiveness for well-selected older adult hearing aid candidates with mild-to-moderate hearing loss and normal cognition. This study answers the question of whether OTC hearing aids produce quality, rehabilitative hearing aid outcomes under ideal circumstances for well-selected OTC hearing aid candidates with normal cognition. If OTC hearing aids are ineffective under ideal circumstances, there is little reason to consider their use in people with dementia—with or without a behavioral intervention to support OTC hearing aid use. If, however, OTC hearing aids are effective when used correctly by well-selected candidates, it is worthwhile to examine what additional services/supports would make them effective for more challenging use cases—such as for people living with dementia.

The second study establishes the need for the proposed intervention and defines its target recipients. Using a large national dataset of older long-term care recipients, we examined whether reported unmet need for hearing aids differs by dementia status among older adult non-hearing aid owners. From these results, we answer the question of whether people with dementia report unmet hearing aid need comparable to their peers without dementia. In other words, do people with dementia want hearing aids? Is there need for an intervention that promotes
hearing aid use in this population? Study 2 establishes and quantifies the scope of the problem the intervention is intended to address—namely, people living with dementia who are unserved by traditional prescription hearing aids. Additionally, Study 2 defines the target recipients and care setting of the proposed intervention. Using the same dataset, we examined the association of residence type with reported unmet hearing aid need in older adult non-hearing aid owners, as well as the association of residence type conditional on dementia status. The resulting analyses reveal that unmet hearing aid need varies considerably by residence type in people living with dementia—more so than it does in people without dementia. The results are used to determine where the intervention will be delivered to ensure it reaches the greatest proportion of people with dementia who report unmet need for hearing aids.

The third study builds on Study 2’s quantitative findings with a qualitative study of stakeholder perspectives on the feasibility and acceptability of OTC hearing aids for older adults with dementia. This study consists of semi-structured interviews with three groups of dementia care stakeholders: 1) older people living with co-occurring dementia and hearing loss; 2) family caregivers of older people living with co-occurring dementia and hearing loss; and 3) geriatric direct care professionals outside of audiology and speech-language pathology. Interview questions explored the perceived facilitators/advantages of OTC hearing aids for people with dementia, as well as barriers/disadvantages to their use in this population. Thematic analysis revealed several important perceived
advantages for OTC hearing aids in people with dementia; however, enthusiasm was tempered by a multitude of stakeholder-perceived barriers that need to be addressed to promote successful OTC hearing aid use in this population. The results affirm that stakeholders see value in OTC hearing aids, validating the purpose for developing an intervention to support OTC hearing aid use in this population. Additionally, Study 3 identifies anticipated challenges for OTC hearing aid use in people with dementia. These challenges will inform subsequent intervention content generation, as well as identification of preliminary behavioral mechanisms to be targeted by the intervention program.

Together, the results of these studies establish the foundation for subsequent intervention development that supports OTC hearing aid use in people living with dementia and their caregivers. **In summary, the dissertation studies:** 1) establish the efficacy and effectiveness of OTC hearing aids when used correctly by well-selected OTC hearing aid candidates with mild-to-moderate hearing loss and normal cognition; 2) define the need for the intervention and its target recipients; and 3) identify specific stakeholder-perceived barriers to OTC hearing aid use that will be addressed by the intervention. Moving forward, the results of these studies will be used to identify preliminary content areas for the intervention, as well as the behavioral mechanisms it will target to promote successful OTC hearing aid use in people living with dementia and their family caregivers.
Chapter 2: Validation of a Self-Fitting OTC Hearing Aid for Older Adults With Normal Cognition

Introduction

In October 2022, the United States Food and Drug Administration (FDA) issued final regulations for over-the-counter (OTC) hearing aids, a new category of hearing aids available for purchase directly by consumers without a prescription or professional fitting (Establishing Over-the-Counter Hearing Aids, 2022). This landmark regulation marks a significant change in the American hearing aid market—one designed to make amplification more affordable and accessible for millions of Americans living with untreated mild-to-moderate hearing loss (Mamo et al., 2016). For these individuals, professional hearing care remains the benchmark standard; however, research shows that lower-cost, more readily available OTC hearing aids offer an effective alternative. Across a range of studies, self-directed hearing aid fittings have consistently shown comparable outcomes to clinically fit amplification in generally healthy adults with mild-to-moderate hearing loss (e.g., De Sousa et al., 2023; Humes et al., 2017; Nelson et al., 2018; Sabin et al., 2020; Urbanski et al., 2021; Venkitakrishnan et al., 2023).

In this study, we add to this important and growing body of literature by examining clinical outcomes of a novel self-fitting OTC hearing aid designed for older adults with mild-to-moderate hearing loss, a device we term a hybrid self-
fitting OTC hearing aid (abbreviated HSF; described below in *Hybrid Self-Fitting Hearing Aid*). The present investigation is a single-blind crossover randomized clinical trial conducted to evaluate the laboratory efficacy and field effectiveness of the HSF system compared to a best-practice prescription hearing aid fitting for older adult hearing aid candidates with mild-to-moderate hearing loss and normal cognition. Consistent with the existing literature, we hypothesized that for this well-selected user group, the HSF system would yield comparable outcomes to an audiologist-fitting in the domains of self-reported aided communication benefit, speech recognition in noise, and subjective sound quality rating.

**Hybrid Self-Fitting (HSF) Hearing Aid**

The HSF is Eargo’s self-fitting air-conduction hearing aid system that incorporates wireless technology in its programming and use. The hearing aid system consists of a pair of Eargo 6 earbud-style hearing aids (left and right), a charging case, and a companion mobile smartphone application (app) available for iOS and Android mobile devices. The hearing aids are designed to be of a completely-in-the-canal (CIC) form factor. Each hearing aid contains a single omnidirectional microphone to allow for audio input, which is then amplified by the hearing aid. The mobile application facilitates the hybrid self-fitting process using a combination of Eargo’s proprietary ultrasonic (for fitting) and Bluetooth Low Energy (BLE; for programming fitting settings) wireless communication. Additionally, the mobile application allows the user to control the hearing aids using ultrasonic wireless communication and enables firmware updates to the
hearing aid system via BLE. App-based user controls include program changes for different listening environments (not used in this study) and sliders for fine-tuning adjustments.

To self-fit the HSF devices, users first complete a self-administered in situ hearing assessment within Sound Match (Eargo’s proprietary self-fitting feature) using the mobile application while wearing the hearing aids. The hearing aids act as the transducer, emitting tonal stimuli of varying levels at different audiometric frequencies. The measured hearing thresholds are then used as the basis for fitting the user’s appropriate gain profile(s).

Like conventional pure-tone audiometry, Sound Match thresholds are measured by presenting tones at different frequencies/sound levels in each ear independently; however, frequency-modulated (warble) tones are used rather than pure tones. The warble tones are centered (FC) at 500, 1000, 2000, 3000, and 4000 Hz, have a frequency modulation FM of +/- 5% relative to FC, and a modulation rate of 5 Hz. In addition, the test signal is specified to have a duration of 400 milliseconds followed by 400 milliseconds of silence, which repeats until the user progresses to the next test signal or when the hearing assessment is complete. For each frequency, the warble tones are presented at different sound levels following a statistical up-down tracking procedure adapted from the conventional Hughson-Westlake method (Carhart & Jerger, 1959).

Following the self-administered hearing test, each hearing aid prompts the user to accept a recommended preset gain profile selected from a bank of 37
audiograms pre-stored in each device (Bisgaard et al., 2010). These audiograms are intended to span the range of hearing loss suitable for the OTC fitting range (mild-to-moderate hearing loss). In each ear, the mobile application chooses the audiogram closest to the user’s Sound Match results based on the average and slope of the self-administered thresholds. The mobile application sends the result to the hearing aid, which then finds the gain profile associated with the audiogram for the right and left ear independently. Each available gain profile consists of preconfigured, per-channel gain settings calculated using a NAL-NL1 and NL2-based proprietary fitting formula (Byrne et al., 2001; Keidser et al., 2011).

The HSF uses 8-channel wide dynamic range compression (WDRC) spanning a frequency range of 200 Hz to 7500 Hz. Each channel has regions for expansion, linear amplification, compression, and output limiting for loud sounds. Hence, the gain calculated for each audiogram is further constrained by pre-established minimum and maximum per-channel gains. The lower limit ensures that the hearing aid is not too loud for an individual with normal hearing, and the upper limit is designed to ensure a relatively feedback-free experience for most users. Once fitted, the user may use the mobile application to make additional fine-tuning adjustments (e.g., volume, bass/treble) to the left, right, or both hearing aids to achieve a desired fitting.

In summary, the HSF system is designed to follow the main steps of a prescription hearing aid fitting, adapted for the self-fitting OTC hearing aid
context: 1) measurement of audiometric thresholds; 2) match to prescriptive gain targets; 3) fine-tuning for user comfort and satisfaction as needed.

Methods

This single-blind crossover randomized clinical trial evaluated the effectiveness of the HSF system by comparing user outcomes of two hearing aid fitting conditions: 1) HSF; and 2) audiologist fitting. Adult participants with mild-to-moderate sensorineural hearing loss were randomly assigned to a starting condition but completed both conditions following a crossover design. Both study conditions used the same hearing aids to isolate the effects of the fitting method— and its resulting gain-frequency response—on user outcomes. Participants were blinded to their device condition throughout the trial; however, research audiologists and staff were unblinded. Per our within-subject design, all participants are included in the data for each fitting condition. The study procedures are illustrated in Figure 2 and described in detail below in Study

Procedures

All trial activities were conducted at the University of Minnesota in Minneapolis, Minnesota from March through November 2022. The study protocol was approved by the University of Minnesota Institutional Review Board (#33544) and registered on clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT05246904). All participants signed written consent before enrollment and were compensated for their time.
Outcome Measures and Statistical Analysis

The present trial included multiple measures with prespecified descriptive, primary, secondary, and tertiary outcomes. We first present descriptive outcomes of the HSF system, including: 1) average accuracy of the HSF self-administered
in situ thresholds relative to clinically measured audiometric thresholds; and 2) average deviation of HSF gain from NAL-NL2 real-ear aided response (REAR) prescriptive gain targets. These data verify the function of the HSF’s self-fitting system, particularly its self-administered hearing test which forms the basis for its user-directed self-fittings.

The trial’s primary outcome was the Abbreviated Profile of Hearing Aid Benefit (APHAB) global score. The APHAB is a 24-item questionnaire that assesses self-perceived communication ability in different listening situations (Cox & Alexander, 1995). Each question presents a listening situation, for which users rate the percentage of time they have trouble understanding speech in that situation. Response options range from 1 to 99%, and higher scores indicate worse performance. The questionnaire yields an overall global score, as well as four subscale scores for: 1) favorable listening situations (Ease of Communication; EC); 2) reverberant environments (Reverberation; RV); 3) noisy environments (Background Noise; BN), and 4) aversiveness of sound (Aversiveness, AV). In the present trial, the APHAB questionnaire was used to quantify HSF user satisfaction and field effectiveness via self-assessment of overall daily communication difficulties with and without amplification.

Trial participants completed the APHAB for each of three conditions: 1) unaided; 2) aided HSF; and 3) aided audiologist-fit. HSF and audiologist-fit global scores were compared using a one-tailed non-inferiority t-test conducted in MATLAB version 2021A (MathWorks). Non-inferiority testing was used because
OTC hearing aid self-fittings aim to achieve a result no worse than that of a clinical audiologist-fitting; self-fittings are not intended to achieve superior results. APHAB subscale scores are presented as descriptive outcomes.

The secondary outcome was speech recognition in noise, evaluated using AzBio sentences (Spahr et al., 2012) presented at +5 SNR (65/60 dB SPL) in a 10’ x 13’ x 8.5’ double-walled sound booth. AzBio sentences and speech-shaped noise were co-located at 0 degrees azimuth while the participant was seated in the center of the booth facing the speaker. AzBio scores were obtained for each fitting condition (HSF and audiologist-fit) after the two-week field trial and compared using a one-tailed non-inferiority t-test.

Tertiary, exploratory analyses were included to examine areas for future research. The first set of exploratory analyses focused on subjective sound quality ratings. For each fitting condition, participants used a tablet-based slider to rate the sound quality of four recorded sound samples. Ratings were given from 0 to 10, with higher values indicating better sound quality. Stimuli were presented at 60 dB SPL in a double-walled sound booth and included a female lecturer, male lecturer, instrumental music, and a movie trailer—as well as an overall sound quality rating. For each fitting condition, ratings were completed after the two-week field trial. Exploratory analysis consisted of a one-tailed non-inferiority t-test comparing overall sound quality ratings of the two fit conditions.

Additional exploratory analyses were conducted to examine whether HSF deviations from prescriptive NAL-NL2 gain targets were associated with key trial
outcomes, including APHAB global score, speech recognition in noise, and overall subjective sound quality. These analyses were conducted using linear regression of the HSF root-mean-square deviations from 1-4 kHz versus the scores for each key outcome domain. The goal was to determine, for our participant sample, whether self-fittings that produce more significant deviations from prescriptive targets are significantly associated with more positive or negative real-world outcomes.

**Participants and Sample Size**

Participants were aged 18 and over with symmetric mild-to-moderate sensorineural hearing loss defined as: 1) average of thresholds at 1, 2, and 4 kHz > 20 dB HL; 2) threshold at 500 Hz ≤ 50 dB HL; 3) all thresholds 1-4 kHz ≤ 70 dB HL; 4) negative for interaural difference of ≥ 10 dB in two neighboring frequencies or ≥ 15 dB in any single frequency consistent with asymmetric hearing loss (Sommerfeldt et al., 2021).

The trial recruited 41 participants and enrolled a final sample of 33 participants who completed the full clinical trial and comprise the final dataset. This sample size exceeds the sample size (n = 19) needed to achieve 80% power for detecting an effect size of 0.5 using a one-tailed non-inferiority t-test, alpha= 0.05. Participant characteristics and details are described in the **Results** section.
Study Procedures

The trial consisted of three laboratory visits—one at baseline with a follow-up visit after each two-week field trial (HSF and audiologist-fit; see Figure 2 for an overview of trial activities). After signing consent, participants were assigned to Group 1 or 2 using a random number generator. Group assignment determined the starting condition to account for order effect, though all participants completed both conditions consistent with our within-subject, crossover design. As illustrated in Figure 2, participants in Group 1 started with the audiologist-fitting, and participants in Group 2 started with the HSF condition before crossing over to complete the other fitting condition. After each two-week field trial, participants returned to the lab to complete trial outcome measures.

At the baseline laboratory session, participants completed the unaided APHAB followed by a standard clinical hearing test. Next, they conducted the HSF self-administered in situ hearing test using the HSF hearing aids and the accompanying mobile application (see Hybrid Self-Fitting Hearing Aid section above for details). Participants independently completed this procedure following the directions in the mobile application. Once both sets of hearing thresholds (clinical and self-administered) were obtained, participants completed procedures for both fitting conditions (HSF) and audiologist-fit (described below).

In the audiologist-fit condition, a research audiologist fit HSF hearing aids following established best-practice procedures using hearing thresholds from the clinical audiogram. Clinical thresholds were entered into an Audioscan
(Dorchester, Ontario) Verifit 1 real-ear analyzer, and probe microphone measures were conducted to match NAL-NL2 REAR targets to within +/-3 dB at each frequency from .25-4 kHz using the International Speech Test Signal (ISTS; Holube et al., 2010) presented at 65 dB SPL. After target matching, the research audiologist used standard clinical procedures to solicit additional fine-tuning adjustments to ensure participant comfort and satisfaction.

The HSF condition was programmed using the participant’s self-administered in situ thresholds following the procedures described in the Hybrid Self-Fitting Hearing Aid section above. After initial programming of the baseline gain-frequency response, participants could self-adjust the mobile application fine-tuning slider controls for bass (low-frequency cut), treble (high-frequency cut), and overall level of the hearing aids using the HSF mobile application. To facilitate self-adjustment, recorded speech was presented in the laboratory. Across the three sliders, mobile application adjustments are constrained such that the magnitude of all adjustments combined does not exceed 8 dB. Following self-adjustment using the mobile application, no further adjustments were offered, regardless of participant feedback.

After each fitting, the corresponding programming file was saved to a research computer, and the research audiologist measured the final REAR using the Verifit 1 probe microphone system and the ISTS stimuli presented at 65 dB SPL. Then, in a different room, the research audiologist programmed the participant’s take-home field trial devices for the HSF or audiologist-fit condition
according to their randomized group assignment (see Figure 2). Participants were not informed of their fit condition to ensure proper blinding. Before the first field trial, all participants were counseled on proper hearing aid use and care and were given a laboratory telephone number and email address to contact with any questions. Participant support in the lab and during the field trial was designed to emulate a direct-to-consumer hearing aid service delivery model as closely as possible while maintaining appropriate participant protections.

The second laboratory session was scheduled within three days of completing the first two-week field trial (see Figure 2). At this visit, participants completed outcome measures for the fit condition they wore in the field. These measures included aided APHAB, speech recognition in noise, and subjective sound quality ratings (see Outcome Measures section above for details). The hearing aids were programmed for the next fit condition, and the participant was released for the second field trial. The third and final laboratory visit was conducted within three days of completing the second two-week field trial and followed a similar procedure as the second visit. After all outcome measures were collected, participants were debriefed on the study and unblinded to their group assignment and fit conditions.

Results

Participants

In total, 41 eligible participants were consented for participation. Eight participants subsequently withdrew or were excluded from the study and are not
included in the data and analyses. Reasons for exclusion included: hearing loss that did not meet inclusion criteria; noncompliance with wear time; and noncompliance with study activities (e.g., scheduling follow-up visits).

The final dataset consists of 33 participants (mean age (SD) = 71.2 years (10.3); range = 24-84) who completed study outcomes for both fitting conditions. Participants included both new and experienced hearing aid users; however, to reflect the anticipated OTC hearing aid market, our sample was slightly skewed toward new hearing aid users (57.6%), defined as individuals who had not used hearing aids during the previous six months. Of the 33 participants, 17 were randomized to Group 1 and 16 were randomized to Group 2. Participant summary characteristics are listed in Table 1 below.

Table 1: Participant characteristics (n = 33).

<table>
<thead>
<tr>
<th>Characteristic</th>
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<tbody>
<tr>
<td><strong>Age (years)</strong></td>
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<tr>
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<td>Median</td>
<td>73</td>
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<td>Range</td>
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<td><strong>Gender, n (%)</strong></td>
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<td>Female</td>
<td>15 (45.5%)</td>
</tr>
<tr>
<td>Male</td>
<td>18 (54.5%)</td>
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<tr>
<td><strong>Hearing Aid Experience, n (%)</strong></td>
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<tr>
<td>New user</td>
<td>19 (57.6%)</td>
</tr>
<tr>
<td>Experienced user</td>
<td>14 (42.4%)</td>
</tr>
<tr>
<td><strong>Pure Tone Average (0.5, 1, 2 kHz; dB HL)</strong></td>
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<tr>
<td>Mean (SD)</td>
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<tr>
<td>Median</td>
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<td>Range</td>
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<td><strong>High Frequency Pure Tone Average (1, 2, 3, 4 kHz; dB HL)</strong></td>
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Hybrid Self-Fitting Self-Administered Audiometry and Gain-Frequency Response

First, we characterize the accuracy of self-administered in situ audiometry relative to clinically measured audiometric thresholds. Figure 3 compares average right and left ear self-administered and clinical audiometric thresholds. Self-administered in situ thresholds were slightly higher (i.e., poorer) than clinical thresholds at 0.5 and 1 kHz, with close alignment of self-administered and clinical thresholds from 2 to 4 kHz. Figure 4 displays a scatter plot of self-administered versus clinical thresholds. Linear regression showed a close-to-unity slope between self-administered and clinically measured hearing thresholds, adj $r^2 = 0.89$, $p < 0.01$. Finally, Figure 5 shows the percentage of corresponding self-administered and clinical thresholds that agreed within a 10 dB criterion, or test-retest reliability for behavioral audiometry (D'haenens et al., 2008). For all measured thresholds except 500 Hz, over 80% of self-administered measurements fell within 10 dB of their corresponding clinical measurement. Agreement at 500 Hz was just under 80%.
Figure 3: Average left and right thresholds for self-administered in situ and clinically measured hearing thresholds. Error bars indicate 1 SD.
Figure 4: Clinical versus self-administered in situ thresholds and best-fit line determined by linear regression. Adjusted $r^2 = 0.89$, $p < 0.01$. 
Figure 5: Percentage of self-administered in situ and clinically measured thresholds that agree within 10 dB, by audiometric frequency.

We also examined the deviation of HSF gain-frequency responses from prescriptive NAL-NL2 REAR targets. Figure 6 shows the mean REAR for the HSF and audiologist-fit conditions relative to mean NAL-NL2 REAR targets at each frequency using the ISTS presented at 65 dB SPL. To quantify the goodness of fit, we calculated the root mean square error (RMSE) deviation for both fit conditions relative to NAL-NL2 REAR targets. RMSE was calculated from 0.25 to 4 kHz using REAR data from the following nominal frequencies: 0.25, 0.5, 0.75, 1, 2, 3, and 4 kHz. As expected, the audiologist-fit condition was closest to NAL-NL2 targets with an RMSE of 2.44 dB. The HSF group had an RMSE of
4.94 dB. Both values fall under 5 dB RMSE, a commonly used criterion for clinical best-practice match to target in both adult and pediatric hearing aid patients (McCreery et al., 2013; Moodie et al., 2017; Mueller, 2005)

Figure 6: Mean real-ear aided response (REAR) as a function of frequency for the hybrid self-fit and audiologist-fit conditions with mean National Acoustic Laboratory- Non-Linear 2 (NAL-NL2) REAR targets using the International Speech Test Signal (ISTS) at 65 dB SPL. Error bars indicate 1 SD.

**Primary Outcome**

APHAB global scores were analyzed using a one-tailed non-inferiority t-test comparing HSF and audiologist-fit scores. Results yielded t = -0.08, p = 0.47,
indicating non-inferiority of the HSF APHAB global scores to those of the audiologist-fit condition at $p \leq 0.05$. Figure 7 shows global APHAB scores and those for each of the subscales (EC, BN, RV, and AV). Higher scores indicate greater self-perceived communication difficulty, or poorer performance. APHAB subscale scores were not analyzed for statistical non-inferiority and are presented as descriptive data.

For each APHAB domain, we calculated a benefit score by subtracting the aided result from the unaided baseline score. Figure 8 displays the APHAB benefit scores for the audiologist and HSF conditions. Higher scores indicate greater benefit of amplification, or better performance.

Figure 7: Abbreviated Profile of Hearing Aid Benefit (APHAB) scores for the unaided, audiologist-fit, and hybrid self-fit conditions. EC = ease of
communication; BN = background noise; RV = reverberation; AV= aversiveness. Higher scores indicate greater self-perceived communication difficulty (i.e., worse performance).

**Figure 8**: Abbreviated Profile of Hearing Aid Benefit (APHAB) benefit scores for the unaided, audiologist-fit, and hybrid self-fit conditions. Benefit scores are calculated by subtracting the unaided from the aided score. EC = ease of communication; BN = background noise; RV= reverberation; AV= aversiveness. Higher scores indicate greater benefit of amplification.

**Secondary Outcome**

AzBio scores in noise (+5 SNR; 65/60 dB SPL; speech and noise co-located at 0 degrees azimuth) were analyzed using a one-tailed non-inferiority t-test comparing HSF and audiologist-fit percent correct scores. Results yielded t = 0.83, p = 0.21, indicating non-inferiority of the HSF speech recognition scores.
relative to the audiologist-fit scores at \( p \leq 0.05 \). Figure 9 shows AzBio scores for the audiologist-fit and HSF conditions.

Figure 9: Speech recognition for the audiologist-fit and hybrid self-fit conditions for AzBio sentences presented at +5 SNR (65/60 dB SPL) co-located at 0 degrees azimuth in the sound booth.

**Tertiary Exploratory Outcomes**

Several tertiary exploratory analyses were conducted to investigate areas for future research. Although not considered part of the trial’s main outcomes, these data provide additional context and information about trial outcomes and user experiences.
Subjective sound quality ratings were explored as a tertiary outcome. Recall that participants rated subjective sound quality using a scale from 0 to 10 for overall sound quality and four different recorded sound samples (female speaker, male speaker, instrumental music, and movie trailer). To explore potential differences in subjective sound quality, we analyzed overall sound quality ratings using a one-tailed non-inferiority t-test. Results yielded $t = 0.52$, $p = 0.3$, indicating non-inferiority of HSF sound quality ratings relative to the audiologist-fit condition. Figure 10 shows sound quality ratings for each fit condition. Ratings for individual sound samples were not analyzed for statistical significance and are presented as descriptive data.
Additionally, we explored whether self-fit deviations from NAL-NL2 prescriptive gain targets are associated with meaningful differences in key HSF clinical outcomes, including APHAB global score, speech recognition in noise, and overall sound quality. In general, participant self-fittings closely approximated their prescriptive targets; however, we aimed to explore whether—in cases of larger deviations—trends in HSF outcomes might emerge. For each participant, we calculated the mean absolute value deviation of their HSF programming from NAL-NL2 targets from 1-4 kHz (including 1, 2, 3, and 4 kHz nominal frequencies). We present these results as scatter plots of individual participant REAR deviations versus their APHAB global scores, speech recognition in noise percent correct scores, and overall sound quality ratings (Figure 11). Simple linear regression determined there was no significant relationship between the magnitude of HSF deviations from NAL-NL2 targets and any of the selected outcomes in our participant sample. Linear regression yielded the following non-significant results: 1) global APHAB scores: adjusted $r^2 = -0.03$, $p = 0.79$; 2) speech recognition in noise: adjusted $r^2 = 0.01$, $p = 0.93$; 3) overall subjective sound quality rating: adjusted $r^2 = -0.12$, $p = 0.33$. 

Figure 10: Subjective sound quality ratings for each sound sample (instrumental music, female speaker, male speaker, movie trailer, and overall) for the audiologist-fit and hybrid self-fit conditions. Ratings were scored from 0 to 10 using a tablet-based slider control. Higher scores indicate better subjective sound quality.
Figure 11: Scatter plots of absolute value mean hybrid self-fitting deviation from National Acoustic Laboratories- Non-Linear 2 (NAL-NL2) real-ear aided response (REAR) targets from 1-4 kHz versus global Abbreviated Profile of Hearing Aid Benefit (APHAB) score; speech-in-noise percent correct for AzBio sentences (+5 SNR; 65/60 dB; co-located at 0 degrees azimuth); and overall subjective sound quality rating scored from 0 to 10. Adjusted $r^2$ values and p-values determined by linear regression.

Discussion

**Hybrid Self-Fitting Self-Administered Audiometry and Gain-Frequency Response**

Self-administered in situ audiometry closely approximated clinically measured audiometric thresholds in our participant sample using the HSF
system. This result is consistent with well-documented evidence that cognitively healthy adults with mild-to-moderate hearing loss can feasibly and accurately measure their hearing thresholds in situ, provided the technology can adjust for individual differences in ear canal acoustics (Convery et al., 2015; Convery et al., 2019; O’Brien et al., 2010) —as the HSF system is designed to do. The close match between self-administered and audiometric thresholds in our sample validates both the operation of the HSF system and the user experience that facilitates it. As shown in Figure 4, agreement of self-administered and clinical thresholds fell within 10 dB—or the test-retest reliability criterion for behavioral audiometry—over 80% of the time at 1, 2, 3, and 4 kHz. Overall, these results support using self-measured in situ thresholds as a basis for OTC hearing aid self-fitting in well-selected older adults with mild-to-moderate hearing loss and normal cognition.

Deviations were slightly more common at 500 Hz, which may have resulted from slit leaks around the device. Nevertheless, when threshold deviations occurred, they did not change the correct classification of hearing loss severity (i.e., a clinically measured mild loss was identified as a mild loss using self-administered in situ audiometry). These types of threshold discrepancies are unlikely to result in large differences in prescribed NAL-NL2 gain, as the NAL-NL2 formula maps a range of audiometric thresholds to the same—or very similar—gain targets. Especially for lower frequencies, larger differences in audiometric threshold may result in only small differences in the prescribed NAL-
NL2 gain target. In other words, discrepancies between self-administered and clinical thresholds do not always drive meaningful differences in prescribed hearing aid gain.

This principle is evident in Figure 6, which shows the mean REAR for the audiologist-fit and HSF conditions relative to mean NAL-NL2 REAR targets. The HSF REAR reflects the programming that results from mapping a user’s self-administered in situ thresholds to their closest available gain-frequency preset in the HSF system. In our sample, self-administered thresholds drove the selection of gain-frequency responses that closely matched audiologist-fit gain. When expressed as the deviation from target, both the audiologist and HSF conditions fell within 5 dB RMSE of NAL-NL2 targets. An error of 5 dB RMS is a commonly used criterion for determining the goodness of fit in both adult and pediatric hearing aid studies—fittings with lower than 5 dB RMS are often considered, for all intents and purposes, a match to target (McCreery et al., 2013; Moodie et al., 2017; Mueller, 2005). In short, both the HSF and audiologist-fit conditions produced a clinical match to target in our sample.

**Primary and Secondary Outcomes**

Two key user-centered domains comprised the trial’s primary and secondary measures, respectively: 1) self-perceived communication ability (APHAB global score); and 2) speech recognition in noise (AzBio sentences).

After a two-week field trial, participants completed the APHAB for each fit condition (HSF and audiologist; see Figure 2). Results, therefore, reflect
participants’ real-world, everyday experiences wearing both fittings. Comparison of APHAB global scores revealed that HSF outcomes were non-inferior to audiologist-fit scores. This result suggests that users perceived both fitting conditions to be comparable without significant decrement in self-perceived communication ability for using HSF gain instead of audiologist-fit settings. In real-world terms, this result suggests that users were equally satisfied with both fittings and would be no less likely to use their HSF gain than an audiologist-fitting with the same devices. This finding is especially meaningful given our within-subject crossover design, which ensured that both fit conditions comprised the same group of 33 participants. Results, therefore, were not influenced by any unintended or unforeseen baseline group-level differences.

The trial’s secondary outcome was speech recognition in noise for AzBio sentences. Difficulty understanding speech in noisy environments is a chief complaint of adults with mild-to-moderate hearing loss, and hearing aid performance in these environments may influence hearing aid adoption and use (Kochkin, 2007). It is important, therefore, to ensure that self-fit gain yields comparable performance in noise relative to an audiologist-fitting. Using a non-inferiority statistical analysis, we found that participants’ speech recognition in noise was comparable for both HSF and audiologist fittings. This result is unsurprising given the close match between HSF and audiologist-fit REAR (see Figure 6). Indeed, small gain differences of this nature would not be anticipated to drive clinically meaningful differences in speech recognition—and, as
expected, they did not. Our result, however, adds to a growing literature that shows self-fit gain is efficacious for speech-in-noise performance in adults with mild-to-moderate hearing loss and normal cognition.

**Tertiary Exploratory Outcomes**

We examined several tertiary exploratory domains in addition to our primary and secondary outcome measures. These outcomes included subjective sound quality ratings and exploratory analyses of the relationship between HSF deviations from NAL-NL2 prescriptive REAR targets and our key trial outcomes (APHAB global score, speech recognition in noise, and subjective sound quality rating).

Although self-reported communication difficulty and speech understanding are arguably the most important measures of hearing aid benefit, perceived sound quality is a critical driver of hearing aid satisfaction (Abrams & Kihm, 2015). For OTC hearing aids to be successful, they must produce sound quality at least as good as audiologist-fit hearing aids. In this domain, we found that overall sound quality ratings for the HSF system were comparable to those of the audiologist-fit condition (Figure 10). When considered with our primary and secondary findings, this result further supports the real-world feasibility and effectiveness of the HSF system for adults with mild-to-moderate hearing loss and normal cognition.

We also explored whether HSF deviations from NAL-NL2 prescriptive gain targets were associated with differences in key trial outcomes (APHAB global
scores, speech recognition in noise, and subjective sound quality rating). Using linear regression, we found no significant relationship between HSF deviations from target and these outcomes (Figure 10). Importantly, however, our participants’ HSF deviations were generally quite small (Figure 6). Nevertheless, our goal was to explore whether a trend might emerge, even if it was driven by a small number of participants with larger deviations from target. In our participant sample, we found no evidence that self-fit deviations from target drive meaningful differences in key clinical outcomes. This result is consistent with Nelson et al. (2018), which demonstrated significant intrasubject variability in self-fit gain— with deviations from target as large as 20 dB in some cases—without corresponding decrements in speech understanding. Taken together, these results support the feasibility of self-directed hearing aid fittings by showing that OTC hearing users need not precisely match their prescriptive targets to achieve effective amplification.

Broader Implications for Self-Fitting OTC Hearing Aids

This single-blind crossover randomized clinical trial demonstrated the laboratory efficacy and field effectiveness of the HSF system for adults with mild-to-moderate sensorineural hearing loss and normal cognition. Across the trial’s primary, secondary, and tertiary outcomes, the HSF system was comparable to an audiologist best-practice fitting using the same hearing aids for adults with mild-to-moderate hearing loss and normal cognition. In other words, for well-selected adult hearing aid candidates, using the HSF system rather than an
audiologist-fitting is not anticipated to result in any loss of clinical benefit in the domains of self-assessed communication difficulty, speech recognition in noise, or subjective sound quality perception. The results add to a growing literature that demonstrates that when self-fit and used effectively, OTC hearing aids can provide quality, rehabilitative hearing aid outcomes on par with those of traditional prescription hearing aids. As a result, these devices hold significant promise for improving the affordability and accessibility of amplification for those currently un- or underserved by the traditional prescription hearing aid service delivery model.

Limitations and Future Directions

Our participants were well-selected OTC hearing aid candidates, both audiometrically and otherwise. Each participant had a clinical hearing test to confirm the presence of mild-to-moderate symmetric sensorineural hearing loss within the fitting range of the HSF devices. Additionally, participants had normal cognition, were in generally good physical health, and were receptive to trying new technology. As a group, our sample of primarily older adults were likely well-positioned to understand and successfully use self-fitting OTC hearing aids. Future research should examine OTC hearing aid use in older adults with complicating cognitive and physical conditions, who may require additional support, training, education, and/or services to achieve effective OTC hearing aid outcomes.
Conclusion

This single-blind crossover randomized clinical trial demonstrated the laboratory efficacy and field effectiveness of the HSF system for adults with mild-to-moderate sensorineural hearing loss and normal cognition. The results indicate that when self-fit and used correctly by well-selected OTC hearing aid candidates, the HSF OTC hearing aids provide comparable benefit to a prescription hearing aid fitting. Combined with a growing literature demonstrating similar results for other OTC hearing aids, this study supports the use of OTC hearing aids for improving the cost and affordability of hearing aids for older adults with mild-to-moderate hearing loss and normal cognition.
Chapter 3: Unmet Hearing Aid Need in People With Dementia: Insights From the National Core Indicators Survey

Note: This chapter is under peer review for publication.

Introduction

Given the health consequences of untreated hearing loss (Arlinger, 2003; Ciorba et al., 2012) there is a critical need for intervention programs and policy measures to increase hearing aid adoption among older Americans—currently estimated at only 20-40% of those who could benefit from hearing aids (Jorgensen & Novak, 2020; Valente & Amlani, 2017). Recent efforts to increase hearing aid uptake are generally geared to cognitively healthy adults; (Nieman & Lin, 2017) however, promoting hearing aid use is vital for older adults with Alzheimer’s disease and related dementias (ADRD).

Among Americans aged 65 and over, about 33% have hearing loss and 10% have ADRD (Matthews et al., 2019; McKee et al., 2019; Langa et al., 2017). These figures increase considerably with age; after age 80, hearing loss affects over 80% of people and ADRD prevalence rises to one-fifth (Langa et al., 2017; Lin, Thorpe, et al., 2011; Matthews et al., 2019; Plassman et al., 2007). Given their high prevalence, both conditions often co-occur within individuals (Gold et al., 1996). When they do co-occur, hearing difficulty can exacerbate ADRD-related behavioral symptoms including depression, agitation, apathy, and social withdrawal (Atef et al., 2023; Dawes et al., 2022; Mamo et al., 2017). Importantly, hearing aids may relieve the compounding effect of hearing loss on ADRD. In
people with ADRD, hearing aid use is associated with reduced depressive, neuropsychiatric, and behavioral symptoms (Atef et al., 2023; Dawes et al., 2019; Mamo et al., 2017; Palmer et al., 1999). Moreover, growing evidence linking hearing to cognition (Lin et al., 2013; Livingston et al., 2020) has prompted questions about cognitive benefits of hearing aids for ADRD. Here, evidence is uncertain—though it is reasonable to believe that hearing aids at least indirectly support cognition in people with ADRD via sensory stimulation and social engagement. Nevertheless, hearing aid adoption in this group is low, consistent with the general population. (Nirmalasari et al., 2017)

There is a pressing need for intervention programs to increase hearing aid adoption among older adults with co-occurring ADRD and hearing loss, especially among those who rely on long-term services and supports and may therefore be vulnerable to experiencing unmet healthcare needs. (Weaver & Roberto, 2019). Such initiatives, however, will need to consider recipients’ perceived hearing needs, as interventions that directly target hearing aid adoption may be most successful when delivered to people with ADRD who feel they need hearing aids. (Prochaska et al., 2008; Saunders et al., 2016). However, it is unclear where to deploy interventions to find and address perceived unmet hearing aid need in older long-term care recipients with ADRD. With the growing emphasis on home-and community-based services, people with ADRD live in a variety of settings—from nursing homes to assisted living to their own/family home—which may differentially influence their care context,
communication demands, and perceived hearing aid need. (Waymouth et al., 2023; Wysocki et al., 2015). In this study, we aimed to improve our understanding of where to target interventions to address perceived unmet hearing aid need in older long-term care recipients with ADRD. Using data from the National Core Indicators-Aging and Disabilities (NCI-AD) survey, (ADvancing States and Human Services Research Institute) we examined whether respondent-reported unmet hearing aid need in older adults with ADRD: 1) differs compared to those without ADRD; 2) varies in different places of residence; and 3) corresponds with patterns of hearing aid ownership across places of residence.

Methods

Data Source

This cross-sectional study used data from the NCI-AD, a survey developed to assess performance and quality of publicly funded long-term services and supports. In participating states, the NCI-AD is administered annually to a cross-sectional sample of people living in nursing homes or receiving home-and community-based services through Medicaid, state-specific programs, or the Older Americans Act. The survey consists of 1) background demographic, health, and service-use data typically populated from state administrative records; and 2) an in-person interview that gathers the service recipient’s experiences of care and met/unmet needs. Whenever possible, the
service recipient completes the interview; however, for those unable to participate, a close proxy is interviewed instead.

This study used three waves of survey data from the NCI-AD (2015-2019), which include approximately 54,000 respondents from 23 states. For this study, we limited the sample to people aged ≥65 years with non-missing ADRD and hearing aid ownership status, and a residence type reported as anything other than missing, unknown, refused, other, or homeless/temporary shelter. The resulting analytic sample included 25,492 people, who were subsampled into hearing aid owners (n = 3,659) and non-hearing aid owners (n = 21,833). Our main analysis focused on non-hearing aid owners, whose data are most informative for interventions to promote hearing aid adoption. Figure 12 shows the CONSORT flow diagram of the analytic sample selection. This study was deemed exempt by the University of Minnesota Institutional Review Board.
Figure 12: CONSORT flow diagram of the analytic sample selection.

**Variables and Measures**

The primary dependent variable—unmet hearing aid need—was determined by an interview question asking respondents about their perceived hearing aid needs. First, respondents indicated whether they do or do not own hearing aids. Hearing aid owners then reported whether their hearing aids a)
need an upgrade; or b) do not need an upgrade. Non-hearing aid owners answered whether they a) need hearing aids; or b) do not need hearing aids. Unmet hearing aid need was defined as reporting that one does not own hearing aids but needs them. Although perceived need for a hearing aid upgrade could be viewed as an additional category of unmet need, these individuals are not the primary focus of interventions to increase hearing aid adoption.

Predictor variables included ADRD diagnosis and residence type. Both variables are populated from state administrative data whenever possible; otherwise, they are ascertained during the in-person interview. ADRD diagnosis is recorded as a binary yes/no indicator. We classified all “yes” responses as having ADRD and all “no” responses as not having ADRD. Included respondents had a residence type listed as one of the following a) nursing facility or home; b) assisted living or residential care facility; c) group or adult family home; d) senior living apartment or complex; e) own or family house or apartment (owned or rented). Nursing facility or home was treated as its own category, as was own or family house or apartment. All other responses were grouped into a category we term “residential care,” which refers to any non-nursing home congregate care setting.

Based on the literature, we included the following covariates: state fixed effects, age, race/ethnicity, gender, ZIP code rural-urban commuting area code (RUCA), and response type (self vs. proxy). (Bainbridge & Ramachandran, 2014; Knoetze et al., 2023). Age was treated as a categorical variable divided into the
following ranges in years: 65-69, 70-79, 80-89, ≥90. Race/ethnicity was categorized as Black or African American, Hispanic or Latino, White, and other/multiracial. Gender, ZIP code RUCA, and response type were coded with binary indicators: male vs. not male, metropolitan vs. not metropolitan, and self vs. proxy response.

**Statistical Analyses**

All analyses were completed using R version 4.1.3 (R Core Team; R Project for Statistical Computing) and two-tailed $P < 0.05$ was considered statistically significant. Data were analyzed from June 26, 2023, to August 26, 2023. To characterize the analytic sample, we reported the counts and frequencies for all categorical variables conditional on ADRD and hearing aid ownership.

Covariate missingness ranged from 0% to 2.67% among non-hearing aid owners. We performed multiple imputations via chained equations to account for this missingness (Azur et al., 2011). Conditional covariate distributions were fit through logistic and multinomial regression models as functions of all other covariates, ADRD status, residence type, and all pairwise interactions thereof in addition to hearing aid need and state ID. Estimates were generated across 20 imputed datasets.

We used multivariable logistic regression to examine the association of ADRD status and residence type with respondent-reported unmet hearing aid need. Using the data from non-hearing aid owners, logistic regression models
were fit for the probability of reporting unmet need for hearing aids conditional on ADRD status, ADRD status and residence type, and residence type conditional on ADRD status (i.e., an interaction between residence type and ADRD). All models were adjusted for the following covariates: state ID, age, race/ethnicity, gender, ZIP code RUCA, and response type (self vs. proxy response). To summarize the model results, we present estimated adjusted odds ratios (AORs) with two-sided $P$-values and 95% confidence intervals (CIs) for reporting unmet hearing aid need vs. reporting no need. Point estimates, $P$-values, and confidence intervals were obtained by pooling results across imputed datasets according to Rubin’s rules. (Rubin, 1987). Additionally, we conducted sequential tests to compare the regression models using the D1 Wald test to account for extra variability due to the imputation procedure. (Li et al., 1991).

Lastly, we contextualize the model results by examining the unadjusted proportion of people with ADRD who own hearing aids in each residence type. Our aim was to determine whether, for people with ADRD, respondent-reported unmet hearing aid need simply mirrors trends in existing hearing aid ownership across residence types. To evaluate this question, we calculated the percentage of people with ADRD who own hearing aids in each residence type and compared the proportions using a chi-squared test. Hearing aid owners included any respondent who indicated they own hearing aid aids, regardless of whether they indicated their devices needed an upgrade. We report these results to help situate and interpret our main findings of unmet need.
Results

Participant Characteristics

The total analytic sample included 25,492 adults aged ≥65 years old, of which 21,833 (86%) were non-hearing aid owners and 3,659 (14%) were hearing aid owners. Of the 21,833 non-hearing aid owners, 17,174 (79%) had no ADRD diagnosis and 4,659 (21%) had ADRD. The 3,859 hearing aid owners included 2,876 (79%) without ADRD and 783 (21%) with ADRD. Overall, people with ADRD were less likely to live in their own or family home and tended to be older than people without ADRD. Table 2 displays respondent characteristics for the total sample, as well as within hearing aid ownership categories stratified by ADRD status.

Table 2: Sample characteristics and predictor frequencies in the analytic sample from NCI-AD 2015-2019 conditional on hearing aid ownership and ADRD status. Respondents are age 65+ years old with reported residence type, ADRD status, hearing aid ownership, and not homeless or living in temporary shelter.
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<td>6,854 (31%)</td>
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<td>639 (14%)</td>
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<td>ZIP Code RUCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metropolitan</td>
<td>17,134 (67%)</td>
<td>11,638 (68%)</td>
<td>3,148 (68%)</td>
</tr>
<tr>
<td></td>
<td>14,786 (68%)</td>
<td>11,638 (68%)</td>
<td>3,148 (68%)</td>
</tr>
<tr>
<td></td>
<td>14,786 (68%)</td>
<td>11,638 (68%)</td>
<td>3,148 (68%)</td>
</tr>
<tr>
<td>Other non-metropolitan</td>
<td>7,854 (31%)</td>
<td>5,163 (30%)</td>
<td>1,442 (31%)</td>
</tr>
<tr>
<td></td>
<td>6,605 (30%)</td>
<td>5,163 (30%)</td>
<td>1,442 (31%)</td>
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<tr>
<td></td>
<td>6,605 (30%)</td>
<td>5,163 (30%)</td>
<td>1,442 (31%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>504 (20%)</td>
<td>373 (21%)</td>
<td>69 (13%)</td>
</tr>
<tr>
<td></td>
<td>442 (20%)</td>
<td>373 (21%)</td>
<td>69 (13%)</td>
</tr>
<tr>
<td></td>
<td>442 (20%)</td>
<td>373 (21%)</td>
<td>69 (13%)</td>
</tr>
<tr>
<td>Residence Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing facility or nursing home</td>
<td>3,522 (14%)</td>
<td>1,732 (10%)</td>
<td>1,257 (27%)</td>
</tr>
<tr>
<td></td>
<td>2,989 (14%)</td>
<td>1,732 (10%)</td>
<td>1,257 (27%)</td>
</tr>
<tr>
<td></td>
<td>2,989 (14%)</td>
<td>1,732 (10%)</td>
<td>1,257 (27%)</td>
</tr>
<tr>
<td>Residential Care</td>
<td>4,966 (19%)</td>
<td>2,960 (17%)</td>
<td>1,146 (25%)</td>
</tr>
<tr>
<td></td>
<td>4,106 (19%)</td>
<td>2,960 (17%)</td>
<td>1,146 (25%)</td>
</tr>
<tr>
<td></td>
<td>4,106 (19%)</td>
<td>2,960 (17%)</td>
<td>1,146 (25%)</td>
</tr>
</tbody>
</table>

64
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total</th>
<th>Non-Hearing Aid Owners</th>
<th>Hearing Aid Owners</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All N = 25,492</td>
<td>All N = 21,833</td>
<td>No ADRD N = 17,174</td>
</tr>
<tr>
<td>Own or family house or apartment</td>
<td>17,004 (67%)</td>
<td>14,738 (68%)</td>
<td>12,482 (73%)</td>
</tr>
</tbody>
</table>

**Hearing Aid Need**

<table>
<thead>
<tr>
<th></th>
<th>All N = 21,833</th>
<th>ADRD N = 4,659</th>
<th>All N = 3,659</th>
<th>No ADRD N = 2,876</th>
<th>ADRD N = 783</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not need</td>
<td>18,506 (73%)</td>
<td>14,495 (84%)</td>
<td>4,011 (86%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Needs</td>
<td>3,327 (13%)</td>
<td>2,679 (16%)</td>
<td>648 (14%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Needs change/update</td>
<td>1,197 (4.7%)</td>
<td>0</td>
<td>0</td>
<td>1,197 (33%)</td>
<td>976 (34%)</td>
</tr>
</tbody>
</table>

Figure 13 shows the proportion of respondents who reported unmet hearing aid need by ADRD status and residence type (unadjusted). Table 3 displays the numbers and percentages corresponding to the same data.
Figure 13: Unmet hearing aid need by dementia status and residence type among respondents without hearing aids.

Table 3: Unmet hearing aid need according to residence type and ADRD status. Values are the number of subjects who reported unmet hearing aid need divided by the total number of respondents without hearing aids (%).

<table>
<thead>
<tr>
<th>Residence Type</th>
<th>No ADRD</th>
<th>ADRD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing facility or nursing home</td>
<td>201/1732 (11.6%)</td>
<td>113/1257 (9.0%)</td>
</tr>
<tr>
<td>Residential Care</td>
<td>408/2960 (13.8%)</td>
<td>136/1146 (11.9%)</td>
</tr>
<tr>
<td>Own or family house or apartment</td>
<td>2070/12482 (16.6%)</td>
<td>399/2256 (17.7%)</td>
</tr>
</tbody>
</table>

Association of Dementia Diagnosis With Unmet Hearing Aid Need

Table 4 presents nested logistic models for unmet hearing aid need in older adult non-hearing aid owners. Model 1 includes ADRD status and all covariates. The results showed a small but significant association of ADRD and
unmet hearing aid need ($P = 0.04$; Table 4). Adjusting for all covariates, non-hearing aid owners with ADRD were less likely to report unmet hearing aid need than non-owners without ADRD (AOR, 0.90 [95% CI, 0.80-1.00]; Table 4).

Table 4: Logistic regression models for unmet hearing aid need in older adult non-hearing aid owners. Values are adjusted odds ratios (AOR) and 95% confidence intervals (CI) for unmet hearing aid need versus the reference level of no need. All models are adjusted for covariates and State ID. Confidence interval widths have not been adjusted for multiplicity. Sequential test results of the nested models are presented. Tests were performed using the D1 Wald test accounting for extra variability due to the imputation procedure. Model 1 includes ADRD + Covariates, Model 2 includes ADRD + Residence Type + Covariates, and Model 3 includes ADRD * Residence Type + Covariates.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Model 1</th>
<th>Model 2</th>
<th>Model 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AOR 95% CI</td>
<td>AOR 95% CI</td>
<td>AOR 95% CI</td>
</tr>
<tr>
<td>ADRD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No ADRD</td>
<td>— —</td>
<td>— —</td>
<td>— —</td>
</tr>
<tr>
<td>ADRD</td>
<td>0.90 0.80, 1.00</td>
<td>0.96 0.86, 1.07</td>
<td>0.78 0.61, 1.01</td>
</tr>
<tr>
<td>Residence Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nursing facility or nursing home</td>
<td>— —</td>
<td>— —</td>
<td>— —</td>
</tr>
<tr>
<td>Residential Care</td>
<td>— —</td>
<td>1.30 1.10, 1.53</td>
<td>— —</td>
</tr>
<tr>
<td>Own or family house or apartment</td>
<td>— —</td>
<td>1.85 1.61, 2.13</td>
<td>— —</td>
</tr>
<tr>
<td>Residence Type (vs Nursing Home)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential Care * No ADRD</td>
<td>— —</td>
<td>— —</td>
<td>1.26 1.04, 1.53</td>
</tr>
<tr>
<td>Own or family house or apartment * No ADRD</td>
<td>— —</td>
<td>— —</td>
<td>1.69 1.43, 1.99</td>
</tr>
<tr>
<td>Residential Care * ADRD</td>
<td>— —</td>
<td>— —</td>
<td>1.29 0.98, 1.70</td>
</tr>
<tr>
<td>Own or family house or apartment * ADRD</td>
<td>— —</td>
<td>— —</td>
<td>2.29 1.81, 2.90</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65-69</td>
<td>— —</td>
<td>— —</td>
<td>— —</td>
</tr>
</tbody>
</table>
### Association of Residence Type With Unmet Hearing Aid Need in People With Dementia

In Model 2, we added three levels of residence type (nursing home, residential care, and own/family house or apartment). The inclusion of residence type significantly improved model fit over the previous model with ADRD and covariates ($P < 0.001$; Table 4), indicating a significant association of residence type with unmet hearing aid need.
type and unmet hearing aid need. Adjusting for all covariates and ADRD status, older adult non-hearing aid owners living in their own or family house/apartment were significantly more likely to report unmet hearing aid need than those in nursing homes (AOR, 1.85 [95% CI, 1.61-2.13]; Table 4). Respondents in residential care were slightly more likely to report unmet hearing aid need compared to those in nursing homes (AOR, 1.30 [95% CI, 1.10-1.53]; Table 4).

Model 3 tested for an interaction between residence type and ADRD status on unmet hearing aid need. Adjusting for all covariates, we found a significant interaction between the two predictors ($P = 0.02$; Table 4). To examine this interaction, in Table 5, we calculated odds ratios for unmet hearing aid need from the fully adjusted model conditional on ADRD and residence type using nursing home as the reference group.

Table 5: Odds ratios for hearing aid need from the fully adjusted model. The top half represents models with nursing home as the reference category and the lower half has residential care as the reference category. Each section presents adjusted odds ratios (AORs) and confidence intervals (CIs) for a respondent in the listed residence type and with the listed ADRD status vs. the reference category with the same ADRD status, as well as the standard interaction adjusted odds ratios which quantify how the odds of unmet need for one residence type vs. the reference category change with ADRD status. CIs and $P$-values have not been adjusted for multiplicity.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>AOR</th>
<th>95% CI</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>**Residence Type (vs Nursing Home)</td>
<td>ADRD Status**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential Care * No ADRD</td>
<td>1.26</td>
<td>1.04, 1.53</td>
<td>0.02</td>
</tr>
<tr>
<td>Residential Care * ADRD</td>
<td>1.29</td>
<td>0.98, 1.70</td>
<td>0.07</td>
</tr>
<tr>
<td>Own or family house or apartment * No ADRD</td>
<td>1.69</td>
<td>1.43, 1.99</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Characteristic</td>
<td>AOR</td>
<td>95% CI</td>
<td>P-value</td>
</tr>
<tr>
<td>----------------</td>
<td>-------</td>
<td>----------</td>
<td>---------</td>
</tr>
<tr>
<td>Own or family house or apartment * ADRD</td>
<td>2.29</td>
<td>1.81, 2.90</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Interaction Effects (vs Nursing Home)**

<table>
<thead>
<tr>
<th></th>
<th>AOR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residential Care * ADRD</td>
<td>1.02</td>
<td>0.74, 1.42</td>
<td>0.9</td>
</tr>
<tr>
<td>Own or family house or apartment * ADRD</td>
<td>1.36</td>
<td>1.03, 1.79</td>
<td>0.03</td>
</tr>
</tbody>
</table>

**Residence Type (vs Residential Care) | ADRD Status**

<table>
<thead>
<tr>
<th></th>
<th>AOR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing facility or nursing home * No ADRD</td>
<td>0.79</td>
<td>0.65, 0.96</td>
<td>0.02</td>
</tr>
<tr>
<td>Nursing facility or nursing home * ADRD</td>
<td>0.78</td>
<td>0.59, 1.02</td>
<td>0.07</td>
</tr>
<tr>
<td>Own or family house or apartment * No ADRD</td>
<td>1.34</td>
<td>1.19, 1.52</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Own or family house or apartment * ADRD</td>
<td>1.78</td>
<td>1.43, 2.21</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Interaction Effects (vs Residential Care)**

<table>
<thead>
<tr>
<th></th>
<th>AOR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing facility or nursing home * ADRD</td>
<td>0.98</td>
<td>0.71, 1.36</td>
<td>0.9</td>
</tr>
<tr>
<td>Own or family house or apartment * ADRD</td>
<td>1.33</td>
<td>1.04, 1.69</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Pairwise analyses showed that older people with ADRD residing in their own or family house/apartment were significantly more likely to report unmet hearing aid need than people with ADRD in nursing homes (AOR, 2.29 [95% CI, 1.81-2.90]; Table 5). This association was more pronounced in older adults with ADRD than in those without ADRD, who had an AOR of 1.69 (95% CI, 1.43-1.99; Table 5).

We found an interaction between own or family house/apartment and ADRD, indicating that these AORs differ in magnitude (P = 0.03; Table 5). By contrast, there was no interaction between residential care and ADRD (P = 0.90; Table 5). Within both ADRD groups, people in residential care were slightly more likely to
report unmet hearing aid need than their same-ADRD peers in nursing homes (ADRD: AOR, 1.29 [95% CI, 0.98-1.70]; No ADRD: AOR, 1.26 [95% CI, 1.04-1.53]; Table 5).

Next, we calculated odds ratios for unmet hearing aid need from the fully adjusted model using residential care as the reference group. Table 5 displays all comparisons with associated AORs, 95% CIs, and P-values. Notably, our finding of an elevated likelihood of unmet need for people with ADRD living in their own or family house/apartment remained when comparing these individuals to people with ADRD in residential care (AOR, 1.78 [95% CI 1.43, 2.21]; Table 5).

**Patterns of Hearing Aid Ownership in People With Dementia**

Unmet hearing aid need could plausibly correspond with rates of hearing aid ownership. To evaluate this possibility and contextualize our findings, we examined the unadjusted percentage of people with ADRD who already own hearing aids in each residence type. Proportions were computed as hearing aid owners with ADRD over the total number of people with ADRD in each setting. Hearing aid ownership was 14.3% in nursing homes, 14.5% in residential care, and 14.4% in own or family houses/apartments. These results indicate uniform hearing aid ownership across residence types (P = 0.98), suggesting that the observed differences in respondent-reported unmet hearing aid need in people with ADRD were not driven by substantial differences in existing hearing aid attainment.
Discussion

This study examined the association of ADRD diagnosis and residence type with respondent-reported unmet hearing aid need in older long-term care recipients. Our aim was to gain a greater understanding of where to target interventions to reach older people with ADRD who may be opportune targets for hearing aid intervention (i.e., those who report unmet hearing aid need). To our knowledge, this is the first study to examine patterns of unmet hearing aid need in people with ADRD using residence type as a predictor.

Our study revealed that older long-term care recipients with ADRD in their own/family home had 129% higher odds of reporting unmet hearing aid need compared to people with ADRD in nursing homes, and nearly 80% higher odds compared to people with ADRD in residential care. Notably, unadjusted hearing aid ownership rates in people with ADRD were uniform across residence types. Together, the results indicate a relative concentration of unmet hearing aid need in people with ADRD in their own/family home compared to those in institutional and congregate settings—a pattern we observed in people without ADRD, but to a much lesser degree. The findings reflect a significant interaction between ADRD and residence type, suggesting an association of living setting with reported hearing needs which operates differently in people with ADRD than in those without. Here, our interpretation is limited by a lack of audiometric data. Without this information, we cannot rule out the possibility that audiometric need differs by residence type in older people with ADRD. However, given the high
prevalence of age-related hearing loss in this population, we believe that our results more likely reflect differences in *perceived*—rather than audiometric—hearing aid need. Indeed, considerable evidence supports the role of home environments in the experience of disability, including sensory and communication disability in older adulthood (McCreedy et al., 2018; Van Hoof et al., 2010; Wahl et al., 2009; Yorkston et al., 2010). More research is needed to understand how living settings may influence the disablement process for untreated hearing loss—especially in older people with ADRD for whom communication is more challenging (Banovic et al., 2018; Bourgeois, 2002; Kovach et al., 2005).

Importantly, the present findings would be masked in an aggregate analysis of older people with ADRD. Without considering residence type, an ADRD diagnosis was associated with a significantly lower likelihood of respondent-reported unmet hearing aid need compared to people without ADRD. This finding would suggest that people with ADRD are overall disinclined toward hearing aid adoption; however, our results show that perceived unmet hearing aid need in people with ADRD varies considerably by residence type. Older adults with ADRD living in their own/family home—and to a lesser extent, in residential care—are more likely to say they need hearing aids and may therefore be more amenable to interventions that promote new hearing aid use. On the other hand, people with ADRD living in nursing homes and their caregivers may be best served by hearing interventions that consider their overall
lower perceived need for hearing aids—perhaps through initial provision of more
general hearing and communication-related education and/or other assistive
listening technologies. Future research should examine strategies for 1) tailoring
hearing interventions for people with ADRD to suit the characteristics and
constraints of different home and care settings; and 2) training nursing home staff
and home-and community-based providers to better identify and support hearing
needs in the populations they serve.

**Strengths and Limitations**

A main strength of this study is the use of the NCI-AD survey, a rich
national dataset which has been used to explore unmet healthcare needs of
older adults who live in nursing homes or receive publicly funded home-and
community-based services— but which has not previously been analyzed for
unmet hearing aid need. This dataset uniquely captures the healthcare needs of
vulnerable older adults who require long-term care support; however,
generalizability is limited by the NCI-AD inclusion criteria. Another key strength is
our use of respondent-reported unmet hearing aid need, which may better reflect
an individual’s openness to receiving hearing aid intervention than audiometric
data alone. However, the lack of audiometric data in the NCI-AD is also an
important limitation, as respondent-reported unmet hearing aid need could not be
cross-referenced with audiometric candidacy for hearing aids. This limitation may
explain the relatively low rate of reported unmet hearing aid need observed in
this sample of older adults (see Table 3). Research indicates self-perceived
hearing loss and hearing aid need may reflect factors beyond audibility such as stigma, lifestyle, self-awareness, social support, and/or expectations of hearing aid benefit or lack thereof (Edwards, 2020). In this study, we cannot be sure what factors drove our participants’ perceived hearing aid need, thus limiting interpretation of our findings.

Similarly, this study is limited by a lack of clinical cognitive assessment data, which restricted our analysis to binary indicators of ADRD diagnosis. It is possible that factors related to dementia severity could have affected respondents’ perceived unmet need for hearing aids; however, our ability to explore these effects was constrained by the absence of severity information in the dataset. Future research should explore this question.

**Conclusions and Implications**

Using serial cross-sectional survey data from the NCI-AD, we found that older long-term care recipients with ADRD living in their own/family home had 129% and 78% higher odds of reporting unmet hearing aid compared to those with ADRD in nursing homes and residential care, respectively. We observed a similar but significantly less pronounced pattern in people without ADRD, suggesting a unique association of residence type with perceived unmet hearing aid need in people with ADRD. Future hearing care interventions for people with ADRD should consider differences in perceived hearing aid need by residence type. Interventions targeting new hearing aid use among people with ADRD may be most successful when delivered to people with dementia living in their own or
family home in the community, who have higher odds of reporting unmet hearing aid need than people with dementia living in institutional and congregate settings.
Chapter 4: “Who’s on the Other Side of the Counter?”: Facilitators of and Barriers to Over-The-Counter Hearing Aid Use in Community-Dwelling People With Dementia

Introduction

Over-The-Counter Hearing Aids: Reducing Cost and Improving Accessibility

Among American older adults, age-related hearing loss affects an estimated one-third of people aged 65 and over, increasing to about 80% of those over the age of 80 (Dalton et al., 2003; Sharma et al., 2020). For the majority of these individuals, hearing aids are the most effective first-line therapy for age-related hearing loss (Thai et al., 2022), offering well-documented social and emotional health benefits (e.g., Bridges & Bentler, 1998; Dillard et al., 2023; Lin et al., 2023; Mulrow et al., 1992). However, hearing aid adoption is notably low among older Americans with hearing loss—persistently falling in the range of 30-40% over the past two decades of market research (Jorgensen & Novak, 2020; Kochkin, 2009; Picou, 2022). To address this problem, the Food and Drug Administration (FDA) recently released final regulations for over-the-counter (OTC) hearing aids. This action established a new category of OTC hearing aids available directly to consumers without a prescription. Previously, all hearing aids required a professional evaluation and fitting by a licensed hearing care professional. Today, OTC hearing aids—now widely available in stores and online retailers—allow adults with perceived mild-to-moderate hearing loss to
self-direct their hearing healthcare by purchasing and fitting hearing aids of their choosing. This shift is intended to lower the cost and improve the accessibility of hearing aids, namely by removing the expense and travel associated with the recurrent office visits typically required for prescription hearing aid fitting and adjustments. Proponents of the regulation expect that more affordable, widely available OTC hearing aids will substantially lower cost and access barriers to amplification—thus facilitating and increasing hearing aid uptake among the estimated 20 million Americans living with untreated hearing loss (Mamo et al., 2016).

The reasons for low hearing aid adoption are multifactorial, including barriers other than cost and access such as stigma, low readiness to address hearing loss, and poor hearing aid self-efficacy among other factors (Ferguson et al., 2016; Jorbonyan et al., 2021; Kochkin, 2007; Ng et al., 2015). Nevertheless, for many older Americans, cost and access are formidable barriers to prescription hearing aids (Coco et al., 2018; Jilla et al., 2023; Yong et al., 2019). Firstly, conventional prescription hearing aids are expensive, and not covered by Medicare. On average, a pair of prescription costs $3600 (Nassiri & Ricketts, 2021). This price may be cost-prohibitive for many older Americans living on low and/or fixed incomes. Indeed, a recent analysis found that an out-of-pocket cost of $2500 for hearing aids would be a catastrophic, unaffordable expense for upwards of three-quarters of American adults with hearing loss (Jilla et al., 2023). Moreover, prescription hearing aids are geographically inaccessible to many
Americans. A recent study showed that audiologists are unevenly and inequitably distributed across the United States, clustering in metropolitan areas with low rates of self-reported hearing difficulty to the disservice of rural areas with higher rates of self-reported hearing difficulty (Planey, 2019). In short, those living in rural and/or underserved communities may lack access to prescription hearing aids irrespective of cost or insurance coverage. Taken together, the poor affordability and inequitable availability of prescription hearing healthcare necessitate an alternative approach. For many older Americans, OTC hearing aids may offer this much-needed alternative.

**Over-The-Counter Hearing Aids: Considering the Needs of People With Dementia**

While OTC hearing aids address cost and access, they also carry broader implications for older adults with hearing loss. OTC hearing aids introduce a new “do-it-yourself” service delivery model for hearing aids in which older adults assume full responsibility for selecting, using, managing, and troubleshooting hearing aids. To date, a small but growing body of research shows that well-selected, generally healthy older adults with intact cognition can successfully self-program, use, and manage OTC hearing aids (e.g., Humes et al., 2017; Nelson et al., 2018; Urbanski et al., 2021; Venkitakrishnan et al., 2023). However, it remains unclear how varying levels of overall health, disability, and functional capacity may affect an older person’s ability to effectively use OTC hearing aids. In particular, older persons with co-occurring hearing loss and
dementia may pose a significant challenge for OTC hearing aid use. OTC hearing aids are fundamentally designed for self-directed hearing aid selection, fitting, and management (Sheffield et al., 2022); however, people with dementia may lack the cognitive ability to understand and independently use OTC hearing aids. Notably, no study has yet examined OTC hearing aid use for people with dementia (to our knowledge). We contend that this gap in the evidence for OTC hearing aids warrants further consideration. Older people with co-occurring dementia and hearing loss are an important subpopulation of people with untreated hearing loss who—like the general older adult population—may rely on OTC hearing aids to overcome existing cost and access barriers to prescription hearing aids. If people with dementia are to benefit from OTC hearing aids, it is essential that we explore and consider their needs, perspectives, and capabilities for using these devices.

Over-The-Counter Hearing Aids for People With Dementia: Potential Benefits and Challenges

Like age-related hearing loss, dementia prevalence increases with age. Among American adults, dementia affects approximately 10% of people aged 65 and over, 20% of people aged 80 and above, and 40% of those over age 90 (Langa et al., 2017; Matthews et al., 2019; Plassman et al., 2007). Given the high prevalence of age-related hearing loss and dementia in older adulthood, both conditions often co-occur within individuals (Gold et al., 1996). When they do co-occur, untreated hearing loss can compound the effects of dementia on
communication, exacerbating dementia-related behavioral and emotional changes such as depression, agitation, apathy, and social withdrawal (Atef et al., 2023; Dawes et al., 2022; Mamo et al., 2017). Importantly, hearing aids may relieve the negative and compounding effects of hearing loss on dementia. In people with dementia, hearing aid use is associated with reduced depressive, neuropsychiatric, and other problematic behavioral symptoms (Atef et al., 2023; Dawes et al., 2019; Mamo et al., 2017; Palmer et al., 1999). Broadly, these health benefits mirror the social and emotional health benefits observed for hearing aid use in the general older adult population. Notably, the hearing aid adoption rate in people with dementia also mirrors that of the general adult population. In a recent retrospective study, Nirmalasari and colleagues (2017) found overall hearing aid utilization of 30% in a memory clinic sample of patients with co-occurring cognitive impairment and hearing loss—a finding consistent with hearing aid utilization in the general adult population. Put simply, when compared to the general adult population, people with dementia show similarly low hearing aid utilization and similarly meaningful potential for hearing aid benefit, all while facing the same cost and access barriers to prescription hearing aids. As a result, people with dementia, too, may need OTC hearing aids to access and afford amplification.

However, it remains unexplored whether OTC hearing aids are feasible and acceptable for people with dementia and their family caregivers. In the absence of research on this topic, it is reasonable to draw parallels between OTC
hearing aids and the broader literature on everyday and assistive technology use in older people with dementia. Here, studies consistently find that older adults with cognitive impairment, including dementia, both demonstrate and self-report greater difficulty understanding and managing a variety of everyday technologies compared to their peers without known cognitive impairment (e.g., Malinowsky et al., 2010; Nygard & Starkhammar, 2007; Rosenberg et al., 2009). In quantitative studies, these findings are statistically significant and show large effect sizes (Malinowsky et al., 2010; Rosenberg et al., 2009; Schmidt & Wahl, 2019). In qualitative studies, older adults with cognitive impairment report an array of overlapping, compounding challenges for at-home technology use including memory deficits, difficulty attending to multiple processes, inability to follow sequential instructions, confusion interpreting technology-generated messages, low self-efficacy for technology use, and sensitivity to technology-related stress among others (Albers et al., 2022; Dequanter et al., 2022; Nygard & Starkhammar, 2007). Some people with cognitive impairment even report forgetting what a technology is intended to do or how it is meant to function (Nygard & Starkhammar, 2007). Importantly, studies have found that manufacturer instruction manuals are typically unhelpful for older adults with cognitive impairment, including dementia, who may express optimism in their ability to follow written instructions but often fail to implement them correctly (Nygard & Starkhammar, 2007).
Considering these and other challenges, people with dementia will likely need family or other caregiver support for using OTC hearing aids. This is not unexpected, as people with dementia typically need help performing some or all instrumental activities of daily living, or complex tasks required for independent living such as housekeeping, preparing food, taking medication, using transportation, shopping, managing finances, and using the telephone (Altieri et al., 2021). Similarly, people with dementia typically require some level of caregiver assistance for using traditional prescription hearing aids (Hooper et al., 2022). However, in the absence of ongoing professional hearing services and counseling, it is unclear if OTC hearing aids are designed and delivered in ways that facilitate effective family caregiver involvement. It is further unknown if family caregivers are open to and comfortable assuming responsibilities for OTC hearing aid programming, use, care, and maintenance. Research is needed that explores the needs, perspectives, and capabilities of people with dementia and their family caregivers for using OTC hearing aids. This knowledge can inform the development of tailored devices, services and supports that promote successful OTC hearing aid use in people with dementia and their family caregivers—thus ensuring that people with dementia can benefit from lower-cost, more accessible OTC hearing aids.

**Study Objectives**

The present study was conducted to explore perspectives on the feasibility and acceptability of OTC hearing aids as a path for hearing healthcare in
community-dwelling older people with dementia. To achieve this objective, we conducted individual semi-structured interviews with participants from three dementia-care stakeholder groups. Our participants included community-dwelling people with dementia and hearing difficulty, family caregivers of these individuals, and geriatric direct care professionals with expertise in the broader care needs of older people with dementia and hearing loss. Using thematic analysis on the interview data, we sought to identify: 1) facilitators or advantages of OTC hearing aid use for community-dwelling older adults with dementia; and 2) barriers or disadvantages of OTC hearing aid use in these individuals. In this manuscript, we detail our findings and briefly outline areas for future research aimed at tailoring the design and delivery of OTC hearing aids to better address the needs and concerns of community-dwelling older people living with dementia and their family caregivers.

**Materials and Methods**

**Participant Groups and Eligibility Criteria**

Participants were recruited to represent key dementia-care stakeholders directly affected by, or with knowledge pertaining to, OTC hearing aid use in community-dwelling people with dementia. Stakeholders represented three groups (n = 15 each): a) community-dwelling older adults with reported early to mid-stage dementia and mild-to-moderate hearing difficulty; b) family caregivers of community-dwelling older people with reported early to mid-stage dementia and mild-to-moderate hearing difficulty; and c) geriatric direct care professionals
who provide direct healthcare services to community-dwelling older adults with co-occurring dementia and hearing loss. Participants were recruited through a research registry of geriatric care professionals and family caregivers of people living with dementia, as well as via online advertising and word-of-mouth referrals.

To be eligible for inclusion, community-dwelling older adults with dementia met the following criteria: a) aged 65 or older; b) non-nursing home resident; c) self or family caregiver-reported diagnosis of early to mid-stage Alzheimer’s disease or related dementia; d) education-adjusted Telephone Interview for Cognitive Status-modified (TICS-m) score ≤ 27 out of 50 points consistent with the presence of dementia (Knopman et al., 2010; Welsh et al., 1993); e) self-reported perceived mild-to-moderate hearing loss; and f) ability to communicate in English and follow study procedures. We relied on self-reported perceived mild-to-moderate hearing loss, rather than clinical audiometric test results, to align with the FDA’s printed candidacy guidelines for OTC hearing aids. Participants were not required to provide audiometric test results and could have any or no prior or current hearing aid experience.

Family caregivers were recruited separately from older persons with dementia (i.e., caregivers and individuals with dementia were not enrolled as care dyads) and met the following inclusion criteria: a) aged 18 or older; b) self-identified provider of informal or unpaid healthcare assistance to a family member who is a community-dwelling older person aged 65 or older with co-
occurring early to mid-stage Alzheimer’s disease or related dementia; c) self-reported negative history of cognitive impairment or dementia; and d) able to communicate in English and follow study procedures. To ensure study feasibility and accessibility, family caregivers were not required to supply medical records confirming the dementia and/or hearing loss status of their care recipient with dementia. Family caregivers could have any or no experience using hearing aids and/or assisting others in using hearing aids.

Geriatric direct care professionals were required to be at least 18 years old, able to communicate in English, and providers of direct healthcare services for community-dwelling older adults, including those with co-occurring dementia and hearing loss. They could be from any profession or geriatric care specialty outside of audiology, otolaryngology, and speech-language pathology. No specific hands-on hearing aid experience or knowledge was required.

Prior to enrollment, all participants gave informed consent or assent in accordance with the university’s Institutional Review Board requirements. Individuals with dementia gave their verbal assent for participation, while written informed consent was obtained from a legally authorized representative. Family caregivers and geriatric direct care professionals provided written informed consent. All participants were compensated for their time and contributions.

**Descriptive Measures**

We collected sociodemographic information from all participants. Additionally, several screening and descriptive measures were administered to
characterize our participant sample of older persons with dementia; a) Telephone Interview for Cognitive Status-modified (TICS-m; Welsh et al., 1993); b) Hearing Handicap Inventory for the Elderly (HHIE; Ventry & Weinstein, 1982); and c) Lawton-Brody Instrumental Activities of Daily Life Scale (Lawton & Brody, 1969).

We used the Telephone Interview for Cognitive Status-modified (TICS-m) as a quantitative measure of cognitive function. The Telephone Interview for Cognitive Status-modified (TICS-m; Welsh et al., 1993) is a widely used telephone-administered screening test of cognitive functioning designed for use when in-person assessment is impractical or infeasible. The test consists of 11 items (50 points total) covering several cognitive domains, including orientation to time and place, receptive and expressive language ability, verbal memory, calculation, and verbal abstraction. Scores have shown good sensitivity for detecting dementia in older adults when using a cutoff of ≤ 27 points for education-adjusted TICS-m scores (Knopman et al., 2010). In this study, TICS-m scores were adjusted for years of education using the corrections in Knopman et al., 2010 and required to meet the ≤ 27 cutoff, providing additional evidence for participants’ cognitive status over and above their self- and/or caregiver-reported dementia status.

As previously mentioned, participants with dementia were not required to provide audiometric test results confirming their self-perceived hearing loss—consistent with FDA candidacy guidelines for OTC hearing aids. To provide additional information regarding participants’ hearing ability, we administered the
Hearing Handicap Inventory for the Elderly (HHIE; Ventry & Weinstein, 1982) to participants with dementia. The HHIE is a validated self-assessment of hearing impairment consisting of 25 questions that measure situational and emotional effects of hearing loss in older adults. Each item presents a potential everyday impact of hearing loss, which the respondent rates as “yes,” “sometimes,” or “no.” Each “yes” response is worth four points, “sometimes” is two points, and “no” is zero points, giving a maximum possible score of 100 points for the highest level of perceived hearing difficulty. The results give a useful measure of subjective hearing difficulty; however, it should be noted that the HHIE is not specifically validated for use in people with dementia, who face unique challenges when completing questionnaires. To improve feasibility for our participants, we introduced necessary flexibility into our administration of the HHIE. Whenever possible, we encouraged the older person with dementia to be actively involved in completion of the HHIE—whether independently or together with a family caregiver. We felt this was important for reflecting the perspectives of our participants with dementia to the greatest extent possible. However, when necessary, family caregivers completed the HHIE for the individual with dementia based on their own perception of the person with dementia’s hearing difficulty.

When presenting HHIE scores, we specify the mode of administration used to complete the questionnaire.

We used the Lawton-Brody Instrumental Activities of Daily Living Scale (Lawton & Brody, 1969) to quantify independent living skills and the level of
assistance participants with dementia require for completing complex, or instrumental, activities of daily living—such as OTC hearing aid use. The Lawton-Brody scale includes eight questions covering the following functional domains: using the telephone, shopping, food preparation, housekeeping, laundry, transportation, medication management, and finances. Each item is rated dichotomously as able (one point) or less able (zero points). Points are summed to give a total score, and dependence is defined as a score <8 points for women and <5 points for men due to differences in traditional gender roles (Chen et al., 2023). The questionnaire may be administered to either persons with dementia or family caregivers. In this study, we requested that a family caregiver complete the Lawton-Brody whenever possible, as people with dementia may be hesitant to report functional deficiencies in the home. If a family caregiver was unavailable, the person with dementia completed the questionnaire independently. For each participant with dementia, we present the Lawton-Brody scale score and specify who completed the questionnaire.

Interviews

Participants completed an individual interview conducted via secure Zoom videoconferencing. Interviews followed a semi-structured interview guide consisting of open-ended questions designed to gather stakeholder-perceived facilitators of and barriers to OTC hearing aids for community-dwelling older people with co-occurring early to mid-stage dementia and hearing loss. Consistent with semi-structured qualitative interviewing techniques, each
interview followed a set of predefined questions; however, the interviewer followed the participant’s lead in conversation and asked tailored follow-up questions as appropriate. Participants were allowed and encouraged to explore any issue of interest to them at the intersection of hearing loss, communication, hearing aid use, dementia, and dementia caregiving.

Each interview began with a brief introduction to OTC hearing aids and their main differences from prescription hearing aids, focusing on factual distinctions between regulatory categories to avoid biasing participant responses. Subsequent interview questions followed the main steps of the OTC hearing aid consumer pathway, eliciting participant views on determining OTC hearing aid candidacy, purchasing OTC hearing aids, configuring OTC hearing aids, assessing OTC hearing aid benefit, and using, maintaining, and troubleshooting OTC hearing aids. The interview guide was adapted slightly for each participant group but maintained the same overall structure and sequencing of topics to ensure similarity of interview content across participants. Interview guides for each participant group are included in the Appendix.

Several accommodations were needed for individuals with dementia. For most participants with dementia, a family member assisted with Zoom and other study logistics. In these cases, family caregivers were instructed to allow the person with dementia to answer interview questions independently and to assist only as necessary to help the participant understand study directions and remain on task. Additionally, interview questions were modified as needed to ensure
understandability for participants with dementia, who present with individual
differences in cognitive and language ability not well predicted by their self-
and/or caregiver-reported dementia status and/or quantitative measures of
cognitive functioning. However, even with question modifications, participants
with dementia often could not answer all interview questions. In these cases,
participants with dementia were included in the study if they demonstrated
understanding of the definition of OTC hearing aids and engaged in the interview
by providing clear, independent, and relevant responses to a subset of questions.

The first author conducted all interviews, which were audio-recorded,
transcribed verbatim, and anonymized. Interviews typically lasted between 30
and 60 minutes each. The interview guide and all study procedures were
approved by the university’s Institutional Review Board.

Data Analysis

Interview transcripts were reviewed and analyzed in NVivo 12 (QSR
International Pty Ltd., 2022) using Braun and Clarke’s (2006) six steps for
thematic analysis: 1) familiarization; 2) generation of initial codes; 3) search for
themes; 4) review; 5) name and define themes; and 6) write-up. First, two
qualitative coders with expertise in hearing loss and hearing aids independently
read the transcripts to familiarize themselves with participant responses (Step 1).
Then, the coders convened to discuss emerging patterns and generate an initial
coding framework (Step 2). The coding framework considered all participants
together—rather than partitioning them into their stakeholder groups—to facilitate
eventual comparison and contrast of participant perspectives. Next, the two coders individually coded one randomly selected transcript from each participant group and convened to compare interpretations and refine/clarify the coding framework. The first author coded all remaining transcripts, with the second coder double coding 20% of transcripts to ensure consistency of code application. During this process, regular meetings were held to review codes and disagreements were resolved through discussion. After coding was complete, the coders collated codes into themes and subthemes (Step 3), which were subsequently reviewed, named, and defined by the research team (Steps 4 and 5). The resulting themes were grouped under two main headings, which frame the results narrative (Step 6): a) facilitators or advantages of OTC hearing aid use for community-dwelling older adults with dementia; and b) barriers to or disadvantages of OTC hearing aid use in these individuals.

Results

Participant Characteristics

The study included a total of 45 participants split equally between the three stakeholder groups (n = 15 each). Most family caregivers and direct care professionals were female, consistent with published demographics of both groups (Alzheimer’s Association, 2022; Boxer et al., 2019; Dunkin & Anderson-Hanley, 1998). Family caregivers had a mean age of 62.7 years (range: 32-79; SD = 13.1) and just over half had experience assisting their care recipient with hearing aids (n = 8). Direct care professionals had a mean age of 46.7 years.
(range: 26-74; SD = 14) and all but one (n = 14) reported assisting their patients with routine hearing aid use, such as insertion and removal, changing batteries/charging hearing aids, and routine clean/care. In contrast with family caregivers and direct care professionals, people with dementia were majority male. This outcome could be considered somewhat unexpected, as Alzheimer’s or related dementia disproportionately affects women; however, it is well documented that men are more likely than women to have hearing loss (Lin, Niparko, et al., 2011). Participants with dementia had a mean age of 81.8 years (range: 68-90; SD = 7.2) and most were current hearing aid users (n = 11). Note that one participant with dementia was aged 90 or above; however, to ensure proper data deidentification, their exact age is not given and is considered as 90 years in calculations. Detailed participant characteristics are provided in Table 6 below.
Table 6: Participant characteristics

### Persons with Dementia (n = 15)

<table>
<thead>
<tr>
<th>ID</th>
<th>Gender</th>
<th>Age</th>
<th>Education</th>
<th>Marital Status</th>
<th>Living Situation</th>
<th>TICS-m*</th>
<th>HHIE</th>
<th>Lawton Brody</th>
<th>Hearing aid user</th>
</tr>
</thead>
<tbody>
<tr>
<td>PWD001</td>
<td>F</td>
<td>89</td>
<td>High school</td>
<td>Widowed</td>
<td>Not alone</td>
<td>27</td>
<td>46</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>PWD002</td>
<td>M</td>
<td>83</td>
<td>High school</td>
<td>Married</td>
<td>Not alone</td>
<td>19</td>
<td>26</td>
<td>2</td>
<td>Yes</td>
</tr>
<tr>
<td>PWD003</td>
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<td>80</td>
<td>Graduate</td>
<td>Divorced</td>
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<td>10</td>
<td>8</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>PWD004</td>
<td>M</td>
<td>76</td>
<td>Undergraduate</td>
<td>Married</td>
<td>Not alone</td>
<td>10</td>
<td>44</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>PWD005</td>
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<td>87</td>
<td>Graduate</td>
<td>Married</td>
<td>Not alone</td>
<td>14</td>
<td>70</td>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td>PWD006</td>
<td>M</td>
<td>68</td>
<td>Some college</td>
<td>Married</td>
<td>Not alone</td>
<td>23</td>
<td>34</td>
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</tr>
<tr>
<td>PWD007</td>
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<td>Not alone</td>
<td>21</td>
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<td>4</td>
<td>Yes</td>
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<tr>
<td>PWD008</td>
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<td>79</td>
<td>Technical</td>
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<td>Not alone</td>
<td>9</td>
<td>20</td>
<td>1</td>
<td>Yes</td>
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<tr>
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<td>High school</td>
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<td>Alone</td>
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<tr>
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<td>74</td>
<td>Graduate</td>
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<td>Not alone</td>
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<td>10</td>
<td>2</td>
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<td>90+</td>
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<td>13</td>
<td>16</td>
<td>2</td>
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<td>Undergraduate</td>
<td>Widowed</td>
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<td>22</td>
<td>60</td>
<td>8</td>
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<tr>
<td>PWD013</td>
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<td>75</td>
<td>Graduate</td>
<td>Married</td>
<td>Not alone</td>
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<td>42</td>
<td>5</td>
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<tr>
<td>PWD014</td>
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<td>89</td>
<td>Some college</td>
<td>Widowed</td>
<td>Alone</td>
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<td>22</td>
<td>4</td>
<td>Yes</td>
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<tr>
<td>PWD015</td>
<td>M</td>
<td>84</td>
<td>Undergraduate</td>
<td>Married</td>
<td>Not alone</td>
<td>9</td>
<td>66</td>
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</table>

### Family Caregivers (n = 15)

<table>
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<tr>
<th>ID</th>
<th>Gender</th>
<th>Age</th>
<th>Education</th>
<th>Relation to Care Recipient</th>
<th>Lives w/ Care Recipient</th>
<th>Care Recipient Uses Hearing Aids</th>
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</thead>
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<tr>
<td>FCG001</td>
<td>F</td>
<td>79</td>
<td>Some college</td>
<td>Spouse</td>
<td>Yes</td>
<td>Yes</td>
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<td>FCG002</td>
<td>F</td>
<td>65</td>
<td>Undergraduate</td>
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<td>Yes</td>
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<tr>
<td>FCG003</td>
<td>Non-binary</td>
<td>72</td>
<td>Graduate</td>
<td>Child</td>
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<td>Yes</td>
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<tr>
<td>FCG004</td>
<td>F</td>
<td>74</td>
<td>Graduate</td>
<td>Spouse</td>
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<td>No</td>
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<tr>
<td>FCG005</td>
<td>F</td>
<td>40</td>
<td>Graduate</td>
<td>Child</td>
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<td>No</td>
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<tr>
<td>FCG006</td>
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<td>65</td>
<td>Graduate</td>
<td>Spouse</td>
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<td>Yes</td>
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<tr>
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<td>61</td>
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<tr>
<td>FCG008</td>
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<td>50</td>
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<td>Child</td>
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**Direct Care Professionals (n = 15)**

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<th>Code</th>
<th>Gender</th>
<th>Age</th>
<th>Education</th>
<th>Occupation</th>
<th>Years of Experience</th>
<th>Assists Patients w/ Hearing Aid Use</th>
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<tr>
<td>FCG009</td>
<td>F</td>
<td>66</td>
<td>Graduate</td>
<td>Spouse</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>FCG010</td>
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<td>57</td>
<td>Graduate</td>
<td>Child</td>
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<td>Yes</td>
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<td>FCG011</td>
<td>F</td>
<td>32</td>
<td>Graduate</td>
<td>Grandchild</td>
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<td>Yes</td>
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<tr>
<td>FCG012</td>
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<td>74</td>
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<td>Spouse</td>
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<td>FCG013</td>
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<td>73</td>
<td>Graduate</td>
<td>Spouse</td>
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<td>Spouse</td>
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<td>FCG015</td>
<td>F</td>
<td>66</td>
<td>Undergraduate</td>
<td>Spouse</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

* - education-adjusted TICS-m calculated using corrections from Knopman et al., 2010.
†- completed by family caregiver; ¶- completed by person with dementia; §- completed by person with dementia and family caregiver together; HHIE, Hearing Handicap Inventory for the Elderly.
**Interview Themes**

In the following sections, we present key themes and subthemes generated from the thematic analysis process described above. Table 7 summarizes these themes and provides exemplar quotes for each.

**Facilitators of OTC Hearing Aid Use in People With Dementia**

Across the three stakeholder groups, participants identified important facilitators/advantages of OTC hearing aid use for community-dwelling older people living with co-occurring dementia and hearing loss. Under this heading, we identified three main themes described below.

**Facilitator Theme #1: Accessibility**

Consistent with the FDA's rationale for OTC hearing aids, participants in all three groups expressed optimism that OTC hearing aids can increase access to hearing aids for older people with dementia. Improved accessibility, participants noted, benefits many older adults with hearing loss and not solely those with dementia. However, participants also explained that better access to amplification carries especially high salience and importance in the dementia caregiving context. In particular, family caregivers and direct care professionals highlighted the advantage of eliminating the need for recurrent office visits to fit and adjust prescription hearing aids. Both family caregivers and care professionals emphasized that dementia caregiving is “consuming” (FCG015), involving round-the-clock care as well as providing transportation to and from frequent healthcare appointments for dementia and its associated complications.
From this perspective, a subtheme emerged that family caregivers may view recurring hearing aid office appointments as “burdensome” [DCP011], a “struggle” [DCP006], and “too hard.” [FCG007] As a result, many family caregivers are “apt to not show up for the appointments or not do it at all.” [DCP011] Conversely, participants across groups viewed accessing OTC hearing aids as a fast, easy, and convenient alternative. As one person with dementia remarked, OTC hearing aids are “probably the easiest way to start.” [PWD011]

Participants explained that the time and travel involved in prescription hearing aid fittings are not only inconvenient but can also have financial, social, and emotional ramifications. Family caregivers and care professionals explained that people with dementia spend large amounts of time seeing healthcare providers. This “time investment” [DCP006] carries high costs for individuals with dementia and their family caregivers. For caregivers, the cost is often measured in terms of financial and employment consequences of taking time off work to transport and accompany care recipients with dementia to healthcare appointments.

As one family caregiver remarked:

“If I have to schedule with the audiologist … it requires me to take time off work and then travel there, so it’s costly in a number of ways, you know?” [FCG007]

For people with dementia, the cost is measured indirectly in lost time for social engagement and other activities. Among both family caregivers and care
professionals, a subtheme emerged around the importance of striking the right balance between the medical and social/emotional needs of people with dementia. Several participants noted that frequent, time-consuming healthcare appointments—including those to a hearing care professional—may take the place of social and other activities for people with dementia. As one family caregiver commented:

“Going to the audiologist is not the most exciting thing for her [person with dementia]. I mean, she’s kind of missing out on other activities and social opportunities and things if she’s having to go to a lot of appointments.”

[FCG11]

Many family caregivers and care professionals also raised concerns about the emotional impact of healthcare appointments on people with dementia. They shared that healthcare appointments can be a difficult experience for people with dementia, who may struggle to recognize, navigate, and understand large medical buildings and unfamiliar healthcare providers. One care professional commented on this challenge for prescription hearing care and shared how OTC hearing aids might help:

“As they get further into the dementia, going to a new doctor or a place that’s different—like having their hearing checked—being in that office situation can be scary for them. So if it’s [hearing aid fitting] something they could do at home with a loved one, that would definitely be helpful for them.” [DCP006]
Similarly, one care professional observed:

“Sometimes the medical buildings are hard to navigate… and that can be overwhelming for people with dementia. So, I think it’d be easier being able to go to the pharmacy up the street or something they’re familiar with to buy hearing aids.” [DCP008]

Put simply, one person with dementia anticipated that if they decided to purchase OTC hearing aids, “it would be easy to get there.” [PWD003]

**Facilitator Theme #2: Affordability**

Unsurprisingly, participants in all three groups identified affordability as a key advantage or facilitator of OTC hearing aid use in people with dementia. Like the previously mentioned theme of accessibility, participants felt that more affordable hearing aids are beneficial to older adults in general, including those with dementia. One care professional remarked:

“The cost saving is one of the biggest advantages [of OTC hearing aids]. I find a lot of older adults, even if they have savings and they have a decent retirement, are worried about how long that’s gonna last ‘em and if it’s gonna be enough. So, I think that’s a big issue for all older adults”

[DCP006]

A participant with dementia echoed this sentiment, saying:

“Well, I think the cost of course is always important. I’m a senior now, and I don’t have extra money that I can always just buy everything I want. So
certainly, the economy is something that I have to watch. I have a wife and responsibility there, too.” [PWD011]

Participants were optimistic that OTC hearing aids will ensure cost is no longer “the main barrier to getting hearing aids” [DCP002] for the general population of older adults with hearing loss. However, the perception of cost took on greater nuance when discussed in the context of dementia caregiving. Rather than emphasizing cost alone, many family caregivers spoke in terms of value (i.e., expected benefit/worth relative to price). The value subtheme was exemplified by a subset of family caregivers who shared that although they could afford prescription hearing aids, they questioned their benefit for people with dementia. In particular, several family caregivers shared that advancing dementia seemed to make their care recipient content to avoid conversation. They wondered if their loved one was interested in hearing better and participating in conversations—and in turn, whether expensive hearing aids were worth the cost. For example, one family caregiver reflected:

“The interesting thing about Alzheimer’s is like … he’s happy in his own little world and so he likes being with people—but no, he doesn’t necessarily want to talk … or be part of the conversation. That’s not necessarily important to him right now. So, it makes it like … what’s it gonna cost me? What’s gonna be the benefit?” [FCG015]

Family caregivers also raised concerns about whether people with dementia can take full advantage of the advanced features and professional fitting services that
come with prescription hearing aids. Many noted that Bluetooth technologies, cell
phone apps, and other hearing aid accessories are “technically more challenging
than people with dementia can work with” [FCG003] and would therefore go
unused. Several family caregivers also questioned whether people with dementia
can provide sufficiently meaningful, reliable input to justify the added cost of
professional hearing aid adjustments. As one family caregiver said,

“It might be better that they go to an audiologist and really get the exact fit
for what they need, but my husband is at the point right now where he
can’t tell you what the exact right fit is, so that’s not applicable to him.”

[FCG006]

Finally, family caregivers expressed concern about the expense of prescription
hearing aids relative to their high risk of being lost and/or damaged by people
with dementia. One family caregiver explained:

“I think it’s [OTC hearing aids] a lower risk because financially it’s a lower
risk. So, if I go lower risk versus these very, very expensive hearing aids,
I’m not gonna be so frustrated if I see them one here and one there all
around the house.” [FCG008]

Similarly, another family caregiver commented:

“Well, and I know a lot of dementia patients lose things. So honestly, if I
think he’s [person with dementia] gonna lose his hearing aids again, I’m
gonna go with the cheapest ones around because they’re only gonna last
until the next time he loses ‘em.” [FCG006]
Importantly, many family caregivers felt lower-cost OTC hearing aids could help mitigate their concerns about the value of hearing aids for people with dementia. For example, one family caregiver remarked:

“I would hate to get those professional hearing aids and either they’re lost or damaged, or she can’t utilize them in the way they need to be. Yeah, I could swallow it a little bit easier if it’s a thousand-dollar OTC hearing aids.” [FCG008]

This and other family caregiver responses suggest OTC hearing aids may help tip caregivers’ value calculations in favor of purchasing and/or trying amplification. However, as will be described later, several stakeholder-identified barriers/disadvantages for OTC hearing aid use in people with dementia point to a more complicated value proposition.

**Facilitator Theme #3: Control**

Another facilitator theme emerged around control—or the freedom, flexibility, and autonomy to efficiently try OTC hearing aids and make decisions about them. Across all three groups, several participants saw OTC hearing aids as an opportunity for people with dementia and their family caregivers to “scope out hearing aids for themselves” [DCP011] and more rapidly evaluate their benefit. As one family caregiver put it:

“I think that, in general, to have a fast way … to just get a hearing aid to your person and see if it works is a wonderful, wonderful thing.” [FCG015]
In particular, many family caregivers and care professionals highlighted the advantage of being able to quickly gauge the likelihood of hearing aid tolerance and acceptance in people with dementia. One care professional explained:

“With OTC hearing aids, they [family caregivers] could probably get a general idea of if they’re [person with dementia] gonna be compliant with hearing aids right away.” [DCP001]

Additionally, a prominent subtheme emerged around stigma. Direct care professionals in particular stressed the deep-seeded stigma and “embarrassment” [DCP005] that accompany a diagnosis of age-related hearing loss. Receiving this diagnosis, participants explained, means a person is “labeled as old now.” [DCP012] As a result, older adults—including those with dementia—avoid seeing a hearing care professional altogether. Several care professionals felt OTC hearing aids could help solve this problem by giving older adults the control and autonomy to try hearing aids “on the sly without actually having it in their medical records.” [DCP011]

Care professionals further underscored the especially profound impact of hearing loss stigma on older people with dementia. They noted that community-dwelling older people with dementia fear losing independence and being moved from their home into a long-term care facility. As a result, many people with dementia try to avoid and conceal their functional deficits—including hearing loss—for as long as they can. One care professional explained:
“They [people with dementia] don’t want hearing loss to be another thing that makes them feel incapable of taking care of themselves … They’re at home. They don’t want to move, so then they don’t want to bring attention to their hearing.” [DCP008]

Many care professionals and family caregivers felt that some people with dementia might be more open to OTC hearing aids, which allow them to try amplification without “admitting to a loss.” [DCP011] or “involving other people.” [PWD011] As one family caregiver reflected:

“It might be easier for him [person with dementia] to accept not going in to see a doctor … There might be an advantage that I could at least introduce him to hearing aids this way.” [FCG009]

Finally, some family caregivers expressed interest in having greater control over hearing aid programming and adjustments for their care recipient, such as that afforded by OTC hearing aids. This subtheme was characterized by a perception of prescription hearing aids as a “black box” [FCG010] where “you get what you get.” [FCG015] Conversely, OTC hearing aids were viewed as an opportunity for better “visibility” [FCG010] and “understanding of what hearing aids would do.” [FCG006]. As one family caregiver said, “I would like to be able to flip that switch myself.” [FCG010] This topic, however, was a point of divergence among family caregivers. As will be described later, many family caregivers considered caregiver-facilitated programming and adjustment a significant challenge and barrier to OTC hearing aid use in people with dementia.
Barriers to OTC Hearing Aid Use in People With Dementia

Although participants described meaningful potential facilitators/advantages of OTC hearing aids for people with dementia, they also identified several unaddressed barriers or disadvantages. Below, we describe five main barrier themes.

Barrier Theme #1: Mistrust of OTC Hearing Aids

Across all three groups, many participants expressed a general mistrust of OTC hearing aids. This theme emerged from a variety of statements revealing apprehension, hesitance, and skepticism about the quality and effectiveness of OTC hearing aids and their associated support services. Specifically, some participants raised concerns that OTC hearing aids may lack sufficient customization of their frequency response(s) to match individual hearing losses. These participants viewed OTC hearing aids as simple “amplifiers” [FCG001; DCP002; PWD012], which they believed to be too “generic” [FCG007; FCG009] for people with hearing loss—especially those with dementia whose hearing loss is further complicated by the effects of cognitive decline. A participant with dementia commented:

“I am suspicious of [OTC hearing aids] … because it’s not talking about my hearing in each ear. It is trying to be an amplifier. I got a friend who doesn’t wanna pay for [prescription hearing aids]. He says, ‘I’ll a buy a set of those [OTC hearing aids].’ And I said, ‘Good luck. You’re gonna waste your money.’” [PWD012]
A subtheme emerged in which participants questioned the competence, training, and expertise of OTC hearing aid vendors and customer support staff. Across groups, participants overwhelmingly endorsed the need for readily available, knowledgeable, and trustworthy technical support to facilitate OTC hearing aid use in people with dementia. At the same time, participants expressed uncertainty that OTC hearing aids would include “any technical assistance that you can count on.” [FCG003] In particular, participants raised concerns that the people who sell and service OTC hearing aids may have insufficient training and experience in hearing loss and hearing aids—and therefore might not provide helpful, actionable recommendations. This sentiment was especially prominent among people with dementia. As one participant with dementia remarked:

“Well, not being familiar with buying over the counter—the clerk would not know how to explain properly how to do it versus a doctor at the clinic.”

[PWD014]

Along the same lines, another participant with dementia said:

“I don’t know if it [OTC hearing aids] would be easier. ‘Cause sometimes they don’t know exactly what you need or to tell you how to use it.”

[PWD008]

Participants with dementia in particular expressed doubt about the ethics and morality of the people who sell and service OTC hearing aids. They described feeling skeptical—“iffy” [PWD013]—about the veracity of the “smiley ads” [PWD012] for OTC hearing aids and questioned their underlying motives. Many
participants with dementia felt that OTC hearing aids only emphasized sales and profits at the expense of older adults on fixed incomes. As one participant with dementia explained, “you could be fooled by somebody that’s just trying to make some money.” [PWD007] Another participant with dementia asked:

“Who’s on the other side of the counter? … I wouldn’t even consider that. Not at all. To me that would be like a crapshoot.” [PWD002]

Barrier Theme #2: Assessing OTC Hearing Aid Candidacy in People With Dementia

An important barrier theme emerged around assessing OTC hearing aid candidacy in people with dementia. According to FDA regulations, OTC hearing aids are intended for adults with perceived mild-to-moderate hearing loss. However, many care professionals and family caregivers questioned the accuracy and reliability of perceived hearing loss in people with dementia. Both participant groups overwhelmingly agreed that people with dementia cannot be expected to accurately self-classify their own degree of hearing loss. Specifically, a subtheme emerged surrounding the memory demands of self-assessing one’s own hearing loss. As several family caregivers and care professionals noted, age-related hearing loss gradually “creeps up” [DCP007] on older adults, thus requiring that they recall and reflect on their hearing experiences over both long and short periods of time. Many people with dementia, participants explained, simply do not have the memory and cognitive capacity to remember and compare their listening experiences. As a result, family caregivers and care
professionals were doubtful that people with dementia could accurately describe their own hearing loss progression and categorize its severity relative to others’ hearing ability. One care professional explained:

“I think people with dementia could identify profound hearing loss—that they can’t hear. But anything less, you add the complication of dementia. What are they not remembering? To say mild or moderate versus getting moderate to severe, they wouldn’t know.” [DCP015]

During semi-structured interviews, many participants with dementia struggled to answer questions about determining their own candidacy for OTC hearing aids. However, those who could respond shared a similar opinion. For example, when asked if he was confident self-classifying their degree of hearing loss, one participant with dementia responded:

“Probably not because it comes on so gradually. And after you’ve been living with the condition, you sort of just accept that’s the way your hearing is … It gets integrated into your life.” [PWD014]

Family caregivers and care professionals agreed that in many cases, family members would be responsible for determining OTC hearing aid candidacy for people with dementia. Generally speaking, however, family caregivers lacked confidence that they could accurately classify their care recipient’s degree of hearing loss without a professional hearing examination. Here, a notable subtheme emerged regarding the challenge of separating the effects of cognitive decline/dementia and hearing loss on communication in people with dementia.
Many family caregivers shared that they were unsure whether they had attributed symptoms of cognitive decline to hearing loss and vice versa. As one family caregiver reflected:

“I don’t know if she’s [person with dementia] not holding that conversation because she doesn’t have the capacity and the wherewithal to hold that conversation, or if she’s really not hearing the other person speak.”

[FCG004]

Given the challenges described above, participants in all three groups felt it was important that people with dementia have a professional hearing examination—regardless of their and/or their family’s interest in OTC hearing aids. As one care professional explained:

“Even though it’s over the counter, I still feel like there would be a need for … some type of evaluation and referral from a specialist. Not just that the caregiver says, ‘Well, I’ve been talking recently, and they’ve not been responding back.’” [DCP005]

Similarly, one participant with dementia observed:

“People try to guess their hearing loss. But you have to use technology to figure it out. You have to sit in that box. And they do the little noises back and forth, and then when you’re done each ear is tested for its own hearing.” [PWD012]
Barrier Theme #3: Caregiver-Facilitated Programming and Adjustment

Participants in all three groups overwhelmingly expressed uncertainty and trepidation about the process of programming and adjusting OTC hearing aids for people with dementia. First and foremost, there was strong agreement that by and large people with dementia cannot independently self-program and customize OTC hearing aids—regardless of the specific self-programming or fitting process employed. Indeed, many family caregivers and care professionals pointed out that people with dementia—even in the early stages of the disease—often need help using everyday technologies such as smartphones, televisions, computers, and tablets. Similarly, participants anticipated that family caregivers would play a significant role in programming and adjusting OTC hearing aids for people with dementia.

However, most caregivers questioned whether they themselves possess sufficient knowledge, skills, and experiences to program OTC hearing aids for care recipients with dementia. Here, a subtheme emerged regarding the perceived importance of a family caregiver’s own personal experiences with technology and hearing aids. Across groups, participants felt that family caregivers with a high level of technology proficiency and/or personal experience using hearing aids might be better at programming and adjusting OTC hearing aids for care recipients with dementia. As one family caregiver commented:

“I’m not familiar with using hearing aids myself, so I’m not sure what the original or traditional steps are to getting them tuned. So, I don’t know if I
could offer the best help or advice about [programming OTC hearing aids].” [FCG005]

Similarly, when asked if he would allow family or friends to program OTC hearing aids for him, one participant with dementia replied:

“It depends on their knowledge—if they’re familiar with this type of thing.”

[PWD014]

However, both family caregivers and direct care professionals raised concerns about family caregivers’ preparedness for programming and adjusting OTC hearing aids. Some participants highlighted that family caregivers are not “educated in hearing” [PWD007], while others stressed that many dementia caregivers are themselves older adults who may face barriers to learning and using new technologies. As one family caregiver reflected:

“When you think about it, a lot of the people that need hearing aids are old, right? And most people my age do not understand technology very well and they wouldn’t be able to program hearing aids for their spouse.”

[FCG013]

Caregiver background notwithstanding, most participants expressed a preference for and confidence in professional hearing aid programming and adjustments. Across groups, participants emphasized the complexity of human hearing and hearing aids, along with the education and training of licensed hearing care professionals—“there’s a lot to hearing,” [FCG007] one family caregiver commented. Participants especially valued professional expertise in fine-tuning
hearing aids based on an individual’s audiometric thresholds, behavioral responses, and preferences. Specifically, several family caregivers and participants with dementia viewed hearing care professionals as uniquely attuned to “the correct questions to ask” [PWD001] a person with hearing loss—including those with dementia—when tailoring and optimizing an individual’s hearing aid settings. As one family caregiver explained:

“I’d prefer [care recipient’s hearing aids] be programmed by a professional who asks the questions and compares, ‘How is it now? How is it not now?’ Whether that same quality of observation could happen with me doing it—I don’t know.” [FCG012]

Similarly, one participant with dementia shared:

“I’d rather go to someone that [programmed hearing aids] all the time…. Because they had probably done a lot of work with people with hearing aids, so they would know a lot of questions to ask about how I was hearing.” [PWD003]

Family caregivers were unsure if they would ask the right questions of their care recipient when programming OTC hearing aids. This concern was magnified by a subtheme regarding the challenge of obtaining reliable self-report of sensory symptoms from people with dementia. Both family caregivers and direct care professionals emphasized that people with dementia lose the “self-reflective ability” [FCG013] and “correct words” [DCP006] to clearly identify and describe bodily and sensory sensations. Consequently, participants expressed concern
that family caregivers would not be able to elicit and properly interpret feedback from their care recipient to facilitate effective OTC hearing aid programming. As a result, caregivers anticipated that they “[would] not trust” [FCG014] and “would not feel confident” [FCG002] in their “amateur” [FCG012] programming results. Several participants with dementia echoed this sentiment, one of whom explained:

“She’s [family caregiver] good with a lot of things, but I don’t know that she’s an expert in that [OTC hearing aid programming]. She is not educated in hearing, and I believe that you have to be educated with the body in order to work with improving hearing.” [PWD007]

One family caregiver summarized the concerns by saying:

“I think [programming is] the major disadvantage, not knowing if you’ve programmed it for the best quality of hearing, especially for somebody else” [FCG002]

**Barrier Theme #4: Assessing the Effectiveness of OTC Hearing Aids**

Following OTC hearing aid programming, participants raised concerns about their ability to assess the effectiveness of OTC hearing aids in people with dementia. Across groups, most participants felt they could determine if OTC hearing aids were helpful to *some degree*— but they questioned their ability to judge whether the aids had “optimized” [FCG014] or achieved a person with dementia’s full hearing potential. Here, participants sought some form of assurance that OTC hearing aids had delivered “the very best benefit” [FCG001]
for speech understanding and communication. However, many participants felt such assurance could only be obtained by seeing a hearing care professional for a prescription hearing aid fitting. Participants in all three groups expressed trust and confidence in a hearing care professional’s ability to ensure hearing aids are “correct… and fit beautifully enough for [people with dementia] to hear.”

[DCP010] As one participant with dementia explained:

“Since I’m a perfectionist, I wanna talk to somebody who is in the [hearing aid] business.” [PWD007]

Without the assistance of a professional, participants in all three groups were unsure how they would assess and quantify the effectiveness of OTC hearing aids. Specifically, family caregivers and direct care professionals noted two prominent subthemes described earlier: 1) the challenge of separating the effects of cognitive decline/dementia and hearing loss on communication in people with dementia; and 2) the challenge of obtaining reliable self-report of sensory symptoms from people with dementia. Together, these two challenges made family caregivers and direct care professionals apprehensive about evaluating the amount and extent of OTC hearing aid benefit in people with dementia— “it’s “tricky because you’re also observing cognition,” [FCG004] one family caregiver noted. Another family caregiver reflected:

“When you have cognitive decline, all parts of the brain are dying literally and not functioning as well. It takes [person with dementia] longer to
Most participants emphasized the importance of programming OTC hearing aids for optimal speech understanding and communication; however, several family caregivers and direct care professionals raised concerns about the possibility of sensory agitation from poorly fit OTC hearing aids. Responses in this subtheme emphasized the sensitivity of people with dementia to changes in their environment and sensory inputs. Namely, participants wondered if suboptimal OTC hearing aids could produce uncomfortable sound quality and/or low-level acoustic feedback that might make a person with dementia startled, agitated, frustrated, or withdrawn. In particular, participants raised concerns about “loud sounds,” [FCG005] “echoing,” [DCP014] “ringing,” [DCP008] and “buzzing” [DCP009] as likely sources of sensory agitation from hearing aids that might be overlooked or poorly managed in OTC hearing aids. Notably, participants lacked confidence in both people with dementia and their family caregivers to accurately identify, assess, and resolve these issues. One care professional explained:

“If they [people with dementia] can’t tell you that the [hearing aid] volume’s too loud, it could be echoing and stuff. You never would know that because they have dementia, and they just won’t talk at all because the sound in their ear is not correct… like a buzz or a ringing.” [DCP014]

Adding further challenge, caregivers and care professionals felt they might have limited time to identify and resolve OTC hearing aid issues before their care
recipient could become frustrated or uncooperative. Here, a subtheme emerged for the tendency of people with dementia to “give up early” [DCP015] on new technologies. In this context, several participants stressed that if the effectiveness and benefit of OTC hearing aids were not quickly apparent, a person with dementia might abandon the hearing aids altogether. One family caregiver explained:

“My husband [person with dementia] would expect me to be the expert on it [OTC hearing aids], and then if it didn’t work, he’d get cranky at me, and he might give up.” [FCG014]

A participant with dementia shared his expectations for immediate OTC hearing aid benefit:

“If it's [OTC hearing aids] wrong, I wouldn’t have any idea what to do. It's so simple…. You put it [hearing aid] in your ear and press the button. If it doesn’t work… that isn’t right.” [PWD002]

Barrier Theme #5: Ongoing OTC Hearing Aid Use and Caregiver Burden/Burnout

Family caregivers and direct care professionals agreed that the challenges of OTC hearing aid use in people with dementia extend beyond the initial purchase and programming. Indeed, both groups stressed that OTC hearing aid use is an ongoing commitment involving daily responsibilities for hearing aid use, care, maintenance, and troubleshooting. Across groups, participants had differing views on the amount and type of hearing aid tasks a person with dementia could
complete independently, reflecting individual differences between care recipients. Nevertheless, participants concurred that family caregiver(s) would have to assume ultimate responsibility for overseeing and managing continued OTC hearing aid use for a person with dementia—especially as their cognitive and functional abilities further declined. This responsibility raised significant concerns. Nearly all family caregivers pointed out their multiple competing caregiving responsibilities, with many describing themselves as overwhelmed, overloaded, and burned out. For this reason, many family caregivers questioned their patience and capacity for self-learning and implementing OTC hearing aid tasks without the assistance of a hearing care professional. “The caregiver needs to be supported and educated to be successful… that’s pretty important in dementia care,” [FCG007] one family caregiver explained. Another family caregiver shared her initial reaction to learning about OTC hearing aids on television:

“What I thought about [OTC hearing aids] is, I would find it challenging to figure out. I have to say as a caregiver and being kind of burned out that I’m not as confident doing things as I used to be. I mean, I’m aging, too, but I think it has more to do with being overwhelmed and burned out. It’s harder for me to learn things right now that I would normally be able to manage.” [FCG002]

Another family caregiver echoed this perspective:

“I can figure out technology without any problem…but I get very frustrated very easily when I have to do anything on my own. It’s not that I can't do it,
it’s just that you have so much on your plate that if somebody puts one more thing on your plate, it puts you on overload.” [FCG013]

A direct care professional made a similar observation:

“Most caregivers are stressed out and overwhelmed, so then you put a project in front of them and it’s just too much. Even if maybe without that stress, they could comprehend it [OTC hearing aids].” [DCP006]

Family caregivers were unsure if the challenges of long-term OTC hearing aid use would be worth their effort. Here, family caregivers returned to the subtheme of value discussed earlier—however, they replaced their previous calculation of price versus expected hearing aid benefit with a new calculation of their caregiving work (cost) versus observed hearing aid benefit. In this context, family caregivers anticipated that their work would be substantial while OTC hearing aid effectiveness would be uncertain or unclear (returning to the previous barrier theme). Furthermore, family caregivers questioned whether their care recipient would be cooperative, compliant, or equally invested in using OTC hearing aids.

As one family caregiver described:

“It’s [OTC hearing aid use] one more thing to do. It’s questionable benefit…. And unclear how much cooperation you’re gonna get from your partner. And you learn where to fight your battles.” [FCG012]

Another family caregiver elaborated:

“It’s always gonna be how much work is it versus the benefit. That’s always gonna be, as a caregiver, the scale you’re in.” [FCG015]
Finally, when considering whether she would use OTC hearing aids with her spouse who has dementia, one family caregiver shared her competing priorities as a dementia caregiver, “I need to make my husband's [person with dementia] life easier, but I also need to make our lives easier.” [FCG009]
Table 7: Interview themes and example quotes.

<table>
<thead>
<tr>
<th>Facilitators</th>
<th>Description</th>
<th>Example Quote</th>
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<tbody>
<tr>
<td><strong>Theme 1: Accessibility</strong></td>
<td>Across groups, participants highlighted the ease of purchasing OTC hearing aids and the benefit of eliminating the need for office visits for hearing aid fitting and adjustments.</td>
<td>“The fact that that [OTC hearing aids] do not require a prescription makes them more accessible to people who need them.” [FCG010]</td>
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<tr>
<td>Subtheme 1.1: Prescription hearing aid appointments are burdensome.</td>
<td>Family caregivers and care professionals stressed the time and travel involved in prescription hearing aid appointments. They emphasized the value of reducing/eliminating the appointments required for obtaining hearing aids.</td>
<td>“[OTC hearing aids are] gonna be positive for caregivers because it's going to be less time that they're spending bringing this person with dementia out into the public, getting 'em in and out of the car, explaining to them over and over again, where they're going or what they're doing or why we're doing this… it's gonna make the process of getting that hearing aid a lot easier.” [DCP006]</td>
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<tr>
<td>Subtheme 1.2: Importance of striking a balance between the medical and social/emotional needs of people with dementia</td>
<td>Family caregivers and care professionals emphasized the importance of limiting frequent healthcare appointments to ensure time for social activities and well-being.</td>
<td>“Going to the audiologist is not the most exciting thing for her [person with dementia] … she’s missing out on other activities and social opportunities.” [FCG011]</td>
</tr>
<tr>
<td><strong>Theme 2: Affordability</strong></td>
<td>Across groups, participants appreciated the lower cost of OTC hearing aids.</td>
<td>“That would probably be the biggest thing is … being able to hear and being able to afford it.” [FCG014]</td>
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<tr>
<td>Subtheme 2.1: Value</td>
<td>Rather than cost, family caregivers emphasized value, or expected benefit/worth of hearing aids relative to their price. Participants questioned whether people with dementia can take full advantage of the benefits of prescription hearing aids and professional fitting</td>
<td>“I would hate to get those professional hearing aids and either they're lost or damaged, or she can't utilize them in the way they need to be. Yeah, I could swallow it a little bit easier if it’s a thousand-dollar OTC hearing aids.” [FCG008]</td>
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services. Additionally, they raised concerns about the risk of loss/damage in relation to the price of hearing aids.

**Theme 3: Control**
Across groups, participants saw benefit in the freedom, flexibility, and autonomy to efficiently try OTC hearing aids and make decisions about them.

> “I think that … to have a fast way … to just get a hearing aid to your person and see if it works is a wonderful, wonderful thing.” [FCG015]

**Subtheme 3.1: Stigma**
Care professionals highlighted the stigma of receiving a formal medical diagnosis of hearing loss and the fear of losing independence among people with dementia.

> “[People with dementia are] at home. They don’t want to move, so then they don’t want to bring attention to their hearing.” [DCP008]

### Barriers

**Theme 1: Mistrust of OTC hearing aids**
Across groups, participants expressed a general mistrust of OTC hearing aids and those who sell them.

> “I really don’t trust the ads [for OTC hearing aids] as a great source of … I just don’t know what the quality of the manufactured instrument is. I wouldn’t … expect that there’s any technical assistance that you can count on.” [FCG003]

**Subtheme 1.1: Mistrust of OTC vendors and customer support staff**
Across groups, participants expressed lack of confidence in the competence, training, and expertise of OTC vendors and customer support staff. They further questioned the profit motives of these individuals.

> “Well, not being familiar with buying over the counter—the clerk would not know how to explain properly how to do it versus a doctor at the clinic.” [PWD014]

**Theme 2: Assessing OTC hearing aid candidacy**
Family caregivers and care professionals questioned the accuracy and reliability of self-perceived hearing loss in people with dementia.

> “I don't know if [person with dementia] would give you an answer that would match up with reality. I don’t know how accurate her perceptions are around that [hearing loss].” [FCG010]

**Subtheme 2.1: Memory demands of self-assessing one’s own hearing loss**
Family caregivers and care professionals felt that classifying and describing self-perceived hearing loss relies on memory of

> “What are [people with dementia] not remembering? To say mild or moderate versus getting moderate to severe, they wouldn’t know.” [DCP015]
<table>
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<tr>
<th>Subtheme 2.2: Challenge of separating the effects of cognitive decline/dementia and hearing loss on communication</th>
<th>Family caregivers expressed lack of confidence distinguishing between communication difficulties due to cognitive processing (dementia) versus audibility (hearing loss), leading to uncertainty in assessing the person with dementia’s degree of hearing loss.</th>
<th>“I don’t know if she’s [person with dementia] no holding that conversation because she doesn’t have the capacity and the wherewithal … or if she’s really not hearing the other person speak.” [FCG004]</th>
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</thead>
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<tr>
<td>Theme 3: Caregiver-facilitated programming and adjustment</td>
<td>Across groups, participants were unsure if family caregivers could successfully facilitate the process of programming and adjusting OTC hearing aids for people with dementia.</td>
<td>“She’s [family caregiver] good with a lot of things, but I don’t know that she’s an expert in that [OTC hearing aid programming]. She is not educated in hearing, and I believe that you have to be educated with the body in order to work with improving hearing.” [PWD007]</td>
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<tr>
<td>Subtheme 3.1: Caregiver experience with technology and/or hearing aids</td>
<td>Across groups, participants felt that family caregivers with a high level of technology proficiency and/or experience with hearing aids might be better at programming and adjusting OTC hearing aids.</td>
<td>“I’m not familiar with using hearing aids myself, so I’m not sure what the original or traditional steps are to getting them tuned. So, I don’t know if I could offer the best help or advice about [programming OTC hearing aids].” [FCG005]</td>
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<tr>
<td>Subtheme 3.2: Challenge of obtaining reliable self-report of sensory symptoms from people with dementia</td>
<td>Family caregivers and care professionals emphasized that people with dementia may struggle to identify and describe changes in hearing during OTC hearing aid programming.</td>
<td>“And even to the degree that I understand [OTC hearing aid programming], I can’t experience her subjective experience in order to be able to know when I’m getting it right … And she’s not a competent reporter even of her own experience.” [FG003]</td>
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<td>Theme 4: Assessing the effectiveness of OTC hearing aids</td>
<td>Across groups, participants were unsure if they could accurately evaluate the amount and extent of OTC hearing aid benefit in people with dementia.</td>
<td>“I think we’ll go to a hearing professional, because I wanna make sure that his [person with dementia] level of hearing would be optimized, and I can’t judge that. I don’t know that he could judge it.” [FCG014]</td>
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<tr>
<td>Subtheme 4.1: Challenge of separating the effects of cognitive decline/dementia and hearing loss on communication</td>
<td>Family caregivers expressed lack of confidence distinguishing between communication difficulties due to cognitive processing (dementia) versus audibility (hearing loss), leading to uncertainty in evaluating the performance of OTC hearing aids.</td>
<td>“When you have cognitive decline, all parts of the brain are dying literally and not functioning as well. It takes [person with dementia] longer to process things that are said. And I might have less confidence in [person with dementia’s] ability to describe it [hearing aid performance].” [FCG001]</td>
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<td>Subtheme 4.2: Challenge of obtaining reliable self-report of sensory symptoms from people with dementia</td>
<td>Family caregivers and care professionals emphasized that people with dementia may struggle to identify and describe changes in hearing while using OTC hearing aids.</td>
<td>“He [person with dementia] just doesn't have the self-reflective ability to know what he’s hearing and what he isn’t.” [FCG013]</td>
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<td>Subtheme 4.3: Concern about sensory agitation from poorly fit OTC hearing aids</td>
<td>Family caregivers and care professionals raised concerns that OTC hearing aids could produce uncomfortable sound quality and/or feedback that could lead to agitation in people with dementia.</td>
<td>“If they [people with dementia] can’t tell you that the [hearing aid] volume’s too loud, it could be echoing and stuff. You never would know that because they have dementia, and they just won’t talk at all because the sound in their ear is not correct … like a buzz or a ringing.” [DCP014]</td>
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<td>Subtheme 4.4: Technology frustration and abandonment in people with dementia</td>
<td>Across groups, participants expressed that people with dementia may abandon OTC hearing aids quickly if their benefit is not quickly apparent.</td>
<td>“My husband [person with dementia] would expect me to be the expert on it [OTC hearing aids], and then if it didn’t work, he’d get cranky at me, and he might give up.” [FCG014]</td>
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**Theme 5: Ongoing OTC hearing aid use and caregiver burden**

| Family caregivers and direct care professionals raised concerns about the amount of responsibility family caregivers would need to assume for OTC hearing aids considering caregiver burden/burnout. | “I would find [OTC hearing aids] challenging to figure out. I have to say as a caregiver and being kind of burned out that I’m not as confident doing things as I used to be … I think it has … to do with me being overwhelmed and burned out. It’s harder for me to learn things right now that I would normally be able to manage.” [FCG002] |
| Subtheme 5.1: Value | Family caregivers explained that their decision to support ongoing OTC hearing aid use would depend on a value calculation of the caregiving work required (cost) versus the observed OTC hearing aid benefit in their care recipient. | “It’s always gonna be how much work is it versus the benefit. That’s always gonna be, as a caregiver, the scale you’re in.” [FCG015] |
Discussion

This study is the first of its kind to explore the feasibility and acceptability of now widely available OTC hearing aids for community dwelling older people with dementia and their family caregivers. We approached this question from the perspectives of key dementia stakeholders via semi-structured interviews with individuals from three stakeholder groups: a) community-dwelling older adults with co-occurring dementia and hearing difficulty; b) family caregivers of community-dwelling older adults with co-occurring dementia and hearing difficulty; and c) geriatric direct care professionals. Using thematic analysis, we identified and described specific facilitators of and barriers to OTC hearing aid use in community-dwelling older people with dementia. Below, we discuss our findings and their clinical implications.

Facilitators of OTC Hearing Aid Use in People With Dementia

Summary of Findings

Facilitators or advantages of OTC hearing aid use included accessibility, affordability, and cost. While these benefits extend to older adults in general, our participants highlighted their specific importance within the dementia caregiving context. In terms of accessibility, participants endorsed the benefit of OTC hearing aids in eliminating the recurrent in-person appointments typically required for prescription hearing aid fitting and adjustments. Both family caregivers and care professionals emphasized that in-person healthcare appointments can be time-consuming and burdensome for caregivers, and
confusing and distressing for people with dementia. Participants felt that removing the need for in-person appointments could make hearing healthcare more feasible and palatable for dementia caregivers and their care recipients.

Additionally, participants appreciated the affordability of OTC hearing aids. However, family caregivers tended to emphasize value considerations rather than cost. Here, family caregivers viewed OTC hearing aids as a potentially better value than prescription hearing aids when considering their care recipients’ simple listening environments, low technology proficiency, and high proclivity for losing/damaging hearing aids and other technologies. Although many caregivers mentioned that they could afford prescription hearing aids, they questioned whether the money would be well spent given their care recipients’ cognitive and memory limitations for communication and hearing aid use.

Finally, participants also identified benefits of OTC hearing aids in the realm of control. Across stakeholder groups, participants appreciated the autonomy and flexibility OTC hearing aids offer for deciding when, where, and how to try hearing aids for people with dementia. Participants viewed this enhanced control as particularly important within the context of stigma, noting that the combined stigmas of dementia and hearing loss may prevent individuals with dementia from seeking or agreeing to formal hearing testing and/or prescription hearing aids. Participants in all three groups agreed that OTC hearing aids could offer a more discrete alternative by allowing people with
dementia to circumvent formal hearing testing and documentation of prescription
hearing aid use.

**Discussion-** **Facilitators**

These findings generally align with the larger hearing aid and dementia
caregiving literature. Regarding accessibility, the benefits of OTC hearing aids
are evident. Studies show family dementia caregivers bear heavy responsibility
for driving their care recipient to healthcare appointments, which can contribute
to caregiving-related emotional, psychological, financial, and physical burden
(Liddle et al., 2016; Taylor & Tripodes, 2001). Furthermore, healthcare
appointments may—as our participants discussed—cause emotional and
physical distress for people with dementia, particularly when healthcare providers
are not specifically trained in dementia (Challen et al., 2018). Given these
considerations, our participants’ desire to avoid recurrent in-person hearing aid
appointments is understandable and may constitute a significant advantage for
OTC hearing aids in the dementia caregiving context.

Our participants’ preference for lower-cost, more affordable hearing aids is
unsurprising and consistent with the underlying rationale for OTC hearing aids.
Recall, however, that our family caregiver participants emphasized value rather
than cost alone. To date, most studies on hearing aid adoption focus on cost.
Some research, however, has shown that value perceptions drive hearing aid
purchase decisions (Amlani, 2013; Amlani et al., 2011). For older adults broadly,
perceived hearing aid value may include emotional, social, quality, and price
considerations (Amlani, 2013). Our results suggest that these factors may operate differently in the dementia caregiving context, where family caregivers consider their care recipient’s functional limitations when forming expectations of hearing aid benefit relative to price. By lowering the cost of amplification, OTC hearing aids may play a unique role in improving perceived hearing aid value for people with dementia and their family caregivers.

Our participants’ emphasis on control and patient autonomy is consistent with the priorities of early policy and critique documents that led to the formal introduction of OTC hearing aids, though somewhat less consistent with the OTC hearing aid regulations themselves (Menon et al., 2023). Autonomy is seldom discussed in the context of OTC hearing aids, possibly because it is viewed as an aspect of accessibility. Indeed, accessibility does contribute to the ease of obtaining OTC hearing aids. However, our family caregivers and care professionals viewed control as having significance beyond more easily obtaining hearing aids. Specifically, our participants emphasized the importance of autonomy for overcoming stigma barriers to hearing aid adoption in people with dementia. Among older adults, dementia and hearing loss each carry stigma—but together, their impact may be even more harmful. For older adults living with both dementia and hearing loss, the two stigmas may combine to produce unique fears around loss of independence, aging, and social isolation (da Silva et al., 2023; David & Werner, 2016; Milne, 2010; Rapaport et al., 2020; Swaffer, 2014; Wallhagen, 2010). Although OTC hearing aids still entail some acknowledgement
of hearing loss, they may help overcome stigma by giving older people with dementia the right to circumvent formal medical documentation of hearing loss and hearing aid use.

**Barriers to OTC Hearing Aid Use in People With Dementia**

**Summary of Findings**

Although participants endorsed several facilitators of OTC hearing aid use in community-dwelling older people with dementia, they also described meaningful barriers that tempered their enthusiasm. From our participants’ responses, we identified the following barriers or disadvantages of OTC hearing aid use: mistrust of OTC hearing aids; assessing OTC hearing aid candidacy in people with dementia; caregiver-facilitated programming/adjustment; assessing the effectiveness of OTC hearing aids; and ongoing OTC hearing aid use and caregiver burden/burnout.

In this study, participants expressed significant mistrust of OTC hearing aids. Their mistrust included considerations of device quality and customizability of gain-frequency response(s), along with concerns about the qualifications and motivations of those who sell and service OTC hearing aids. This theme emerged across all three groups, but was particularly prominent among people with dementia, who expressed trepidation that they might be misled or exploited when buying OTC hearing aids.

Additionally, participants in all three groups questioned whether they could accurately assess OTC hearing aid candidacy in people with dementia. OTC
hearing aids are labeled for self-perceived mild-to-moderate hearing loss; however, participants in all three groups questioned whether people with dementia can accurately categorize their own hearing loss. In particular, family caregivers and care professionals raised concerns that people with dementia might lack sufficient memory of their hearing experiences to benchmark their own hearing ability. Moreover, family caregivers were doubtful that they could accurately assess their care recipient’s degree of hearing loss without a professional evaluation—largely due to the challenge of separating the overlapping effects of cognitive decline/dementia and hearing loss on communication.

Our participants also raised concerns about the feasibility of caregiver-facilitated programming and adjustment of OTC hearing aids. Here, participants in all three groups agreed that people with dementia would likely need the assistance of caregivers for programming and adjusting OTC hearing aids, regardless of the fitting or programming strategy. However, family caregivers questioned whether they have the knowledge, expertise, and training in hearing loss and technology proficiency to complete the process successfully. Additionally, both family caregivers and care professionals questioned whether people with dementia could describe and report changes in their hearing with sufficient detail and accuracy to successfully guide a caregiver’s programming decisions.
Following OTC hearing aid programming, participants raised concerns about their ability to accurately assess the effectiveness of OTC hearing aids. For family caregivers and care professionals, this concern was magnified by the previously mentioned challenges of eliciting feedback from people with dementia regarding changes in hearing and of disentangling the effects of cognitive decline/dementia and hearing loss on communication. Family caregivers worried that if their assessments of OTC hearing aid benefit were incorrect, their care recipients might experience sensory agitation and/or abandon the hearing aids altogether.

Finally, family caregivers and care professionals stressed that the tasks for OTC hearing aid use are ongoing and require substantial caregiver assistance. Participants underscored that these responsibilities pose a significant challenge for family caregivers juggling multiple and competing caregiving demands. In particular, family caregivers questioned whether they could achieve ongoing OTC hearing aid use given their existing levels of caregiver burnout and burden. Family caregivers anticipated that their commitment to OTC hearing aid use would depend on their overall perception of OTC hearing aid benefit, as well as their care recipient's level of cooperation for using hearing aids.

Discussion- Barriers

Our findings broadly support and add to the emerging literature on consumer attitudes toward and barriers to OTC hearing aid use. In our study, mistrust emerged as a substantial barrier to OTC hearing aid use for people with
dementia and their family caregivers. A recent study of consumer attitudes toward OTC hearing aids also describes trust barriers to OTC hearing aid use. In a survey of 1,377 adults without prior hearing aid experience, Singh and Dhar (2023) found overall low interest in OTC hearing aids, which they largely attributed to lack of knowledge and/or trust in OTC hearing aids. In our study, some participants’ mistrust stemmed from lack of knowledge or misinformation, such as the belief that OTC hearing aids are simple, one-size-fits-all amplifiers. However, participants also conveyed deeper mistrust regarding the competence, motivations, and ethics of those who sell and service OTC hearing aids. Here, it is plausible that people with dementia and their family caregivers may have heightened mistrust for OTC hearing aids compared to the general population. Research indicates that individuals with dementia are particularly vulnerable to financial fraud and exploitation (Ebner et al., 2023; Fenge & Lee, 2018), potentially leading those with earlier-stage disease and higher self-awareness to approach new products and sales claims with increased caution. Additionally, family dementia caregivers have been shown to harbor mistrust for a variety of dementia care services and interventions, stemming from previous negative experiences and a strong desire to protect their care recipients (MacLeod et al., 2017; Teel & Carson, 2003).

The next barrier involves assessing OTC hearing aid candidacy in individuals with dementia. As discussed previously, both family caregivers and care professionals raised serious concerns about the accuracy and reliability of
self-perceived hearing loss in people with dementia. This concern is supported by numerous studies in the general older adult population demonstrating that even without known cognitive impairment, self-reported hearing ability is generally unreliable compared to measured audiometric thresholds (e.g., Kamil et al., 2015; Kiely et al., 2012; Kim et al., 2017). However, as our participants highlighted, this problem may be even more pronounced in people with dementia. In a recent study, Kim and colleagues (2021) found lower concordance between self-reported and audiometric hearing status in older adults with cognitive impairment than in those without. Notably, the authors also found poor sensitivity of proxy-reported hearing ability in older adults with cognitive impairment, suggesting that family or friends' hearing loss judgements are an unreliable substitute for self-report in this population (Kim et al., 2021). Our qualitative results echo these findings, indicating that family caregivers not only lack confidence in their care recipient's self-reported hearing status—but also in their own ability to assess and categorize their care recipients' hearing and communication abilities. Interestingly, our family caregiver participants attributed this lack of confidence, in large part, to the challenge of distinguishing the effects of hearing loss and dementia on communication (Dawes et al., 2019; Mamo et al., 2017; Slaughter et al., 2014). This insight could help explain Kim et al.'s finding of poor sensitivity for proxy-reported hearing loss in their sample of older people with dementia.
Our participants also raised concerns about the process of programming and adjusting OTC hearing aids. As mentioned earlier, participants in all three groups agreed that people with dementia cannot independently program and adjust OTC hearing aids. This sentiment is well supported by a host of studies documenting the myriad challenges and barriers faced by people with dementia when using both everyday and assistive technologies (e.g., Malinowsky et al., 2010; Nygard & Starkhammar, 2007; Rosenberg et al., 2009). However, our family caregiver participants also lacked confidence in their own ability to assist their care recipients with OTC hearing aid programming.

To date and to our knowledge, no studies have examined hands-on OTC hearing aid use in dementia caregiving dyads. However, a study by Convery and colleagues (2017) found that in a sample of older adults with a range of cognitive abilities, lay partner participation in the OTC hearing aid self-fitting process did not significantly influence or improve outcomes. The authors suggest that fitting outcomes might have improved with knowledgeable support from trained personnel (Convery et al., 2017). Here, it is important to consider—as some of our participants mentioned—that many partners and caregivers of older people with co-occurring dementia and hearing loss are themselves older adults who may encounter challenges in using technology. Studies show that older adults face a variety of barriers to technology use including lack of knowledge, age-related vision loss and fine motor difficulties, and negative attitudes and anxiety toward technology (Chen & Chan, 2014; Chen & Lou, 2020; Gitlow, 2014). Our
primarily older adult family caregiver participants exemplified these barriers, expressing great apprehension about their technology proficiency and hearing aid knowledge. Notably, in this context, our caregivers’ concerns about technology use were compounded by the previously mentioned barrier surrounding self- and proxy-report of hearing ability in people with dementia. In short, our family caregivers lacked confidence in their care recipients’ ability to self-report changes in hearing to guide caregivers' programming decisions, and caregivers were also unsure if they could intuit whether they made the correct programming decisions.

Across stakeholder groups, our participants were unsure if they could accurately assess the effectiveness of OTC hearing aids in people with dementia. Specifically, our participants raised concerns that self- and/or caregiver-programmed settings might be suboptimal in ways that could go undetected—potentially leading to sensory agitation, missed benefits, and hearing aid abandonment in people with dementia. To our knowledge, no research has examined the effectiveness of self- and/or caregiver-fit OTC hearing aids in people with dementia. In the general older adult population, self-programmed OTC hearing aids have consistently shown comparable outcomes to prescription hearing aids (e.g., Humes et al., 2017; Nelson et al., 2018; Urbanski et al., 2021; Venkitakrishnan et al., 2023). However, outcomes of OTC hearing aids in people with dementia are yet unknown. This uncertainty may have contributed to our participants’ strong preference for prescription hearing
aids and professional guidance. However, this finding is broadly consistent with the results of recent consumer surveys, which show that most adults with self-reported hearing difficulty prefer having professional assistance with their healthcare (Edwards et al., 2020; Singh & Dhar, 2023). Research is urgently needed to determine how OTC hearing aid outcomes compare to those of prescription hearing aids in community-dwelling people with dementia.

Lastly, our family caregiver and care professional participants stressed the need for ongoing caregiver involvement to support long-term OTC hearing aid use in people with dementia. Here, our family caregiver participants raised serious concerns about adding OTC hearing aid responsibilities to their already significant caregiving load. Many described feeling overwhelmed and burned out, echoing a large and well-established literature on caregiver burden, burnout, and stress among informal dementia caregivers (Connors et al., 2020; Etters et al., 2008; Chiao et al., 2015; Liu et al., 2020). Furthermore, several of our caregiver participants questioned whether OTC hearing aids would be worth their caregiving effort, especially if OTC hearing benefit was unapparent and/or their care recipient was apathetic—or even uncooperative—about using hearing aids.

Considerations of caregiver burden/burnout augment the value theme described earlier to include caregiver perceptions of their work/effort for OTC hearing aid use versus the expected or observed OTC hearing aid benefit. Caregivers may use this calculation of work/effort versus benefit to decide whether to 1) initiate OTC hearing aid use for their care recipient; and/or 2)
continue using OTC hearing aids with their care recipient. Research shows that although people with dementia prefer to be included in important decisions, caregivers often make important medical and treatment decisions for them (Miller et al., 2016). In this case, caregivers may ultimately decide whether to invest time and energy into using OTC hearing aids with and for their care recipient. To be fair, this situation is not unique to OTC hearing aids; it also applies to prescription hearing aids. Indeed, research shows that caregiver assistance is an important determinant of successful prescription hearing aid use in people with dementia (Hooper et al., 2022). However, the lack of professional support and services for OTC hearing aids could add additional stress on caregivers, potentially increasing the caregiver burden involved in hearing aid use. Research is needed that compares caregiver outcomes for prescription versus OTC hearing aids.

**Clinical Implications and Future Directions**

Unless and until major cost and accessibility barriers to prescription hearing aids are removed, people with dementia may depend on OTC hearing aids to afford and access hearing healthcare. Future research should focus on determining whether and how OTC hearing aids can be a viable option for community-dwelling people with dementia and their family caregivers.

As demonstrated by this study, there are several valuable advantages of OTC hearing aids for people with dementia and their family caregivers. However, there are also meaningful barriers that need to be addressed to make OTC hearing aids a feasible, acceptable solution for this population. Future research
should examine and quantify these barriers in the context of hands-on OTC hearing aid with dementia caregiving dyads in laboratory and real-world settings. Quantifying the magnitude and underlying mechanisms for the barriers described in this manuscript—as well as other barriers that may not have been apparent in this study—could help determine the specific problems that may need to be solved to ensure dementia caregiving dyads can effectively use and take advantage of OTC hearing aids.

Once OTC hearing aid outcomes and barriers in this population are better understood, future work might focus on tailoring OTC hearing aid design and delivery to optimize outcomes for people with dementia and their family caregivers. On the one hand, there may be paths for modifying the physical design, technology, and self-programming procedures to improve functionality for dementia caregiving dyads. Here, researchers and OTC hearing aid manufacturers might consider participatory design strategies that actively involve people with dementia and their caregivers in the design process for OTC hearing aids (e.g., Eisapour et al., 2020; Rai et al., 2020; Span et al., 2018). Doing so might uncover ways of adjusting current OTC hearing aid designs and user experiences to maximize success for end users with dementia. On the other hand, behavioral intervention may also offer a promising route for addressing barriers to OTC hearing aid use in this population. Research in this area might focus on the development, evaluation, and implementation of tailored services,
supports, and training that address and demystify the challenges dementia caregiving dyads may face when using OTC hearing aids.

**Limitations**

A key strength of this study is its inclusion of multiple different stakeholder perspectives, providing a more robust exploration of the question than any one stakeholder group alone. However, several important limitations should be noted.

Firstly, most of our participants with dementia are current hearing aid users. This outcome resulted from our inclusion criterion requiring that participants with dementia self-report mild-to-moderate hearing difficulty. During recruitment, we found that people with dementia who already used hearing aids were more likely to self-identify as having hearing difficulty than those who did not use hearing aids.

Relatedly, we relied on self- and/or caregiver-reported hearing loss and dementia status rather than confirmed medical diagnoses. We made this decision to ensure the feasibility and accessibility of this study for dementia caregivers and people with dementia, for whom additional testing or records requests would have been cumbersome and likely infeasible. In terms of hearing loss, our use of self-reported hearing ability aligns with OTC hearing aid candidacy, which does not require a formal hearing evaluation. Although audiometric results would have been informative for crosschecking self- and caregiver-reported hearing ability, all participants reported mild-to-moderate hearing difficulty consistent with OTC hearing aid candidacy guidelines.
Regarding dementia status, our reliance on self- and/or caregiver report introduces some uncertainty regarding participants’ cognitive abilities and underlying conditions. However, the combination of self- and/or caregiver report with the TICS-m cognitive test increases confidence that our sample includes people with early to mid-stage dementia.

Finally, our study required that participants speak English, limiting the potential racial and ethnic diversity of our sample. Family caregivers and people with dementia who do not speak English may face additional challenges in using OTC hearing aids, which warrant further attention and study.

Conclusions

This study identified and described stakeholder-perceived facilitators of and barriers to OTC hearing aid use in community-dwelling people with dementia and their family caregivers. Key facilitators or advantages of OTC hearing aid use included improved accessibility and affordability, as well as enhanced control/autonomy. However, significant barriers underscore the complexity of implementing OTC hearing aids in this population. Key stakeholder-perceived barriers included mistrust of OTC hearing aids; assessing OTC hearing aid candidacy in people with dementia; caregiver-facilitated programming/adjustment; assessing the effectiveness of OTC hearing aids; and ongoing OTC hearing aid use and caregiver burden/burnout. Future research should further explore and quantify these and other barriers toward development of tailored devices, services, and supports that promote successful OTC hearing
aid use in people with dementia and their family caregivers. We argue that this work is essential for ensuring that people with dementia can benefit from the introduction of lower-cost, more accessible OTC hearing aids.
Chapter 5: Conclusions and Future Directions

The goal of this dissertation was to establish necessary scientific groundwork for subsequent development and pilot testing of a behavioral intervention to facilitate effective OTC hearing aid use in community-dwelling older people with co-occurring dementia and hearing loss and their family caregivers. As discussed previously, OTC hearing aids were introduced to significantly reduce cost and access barriers to amplification for an estimated 20 million Americans living with the social, emotional, and potential cognitive consequences of untreated hearing loss (Mamo et al., 2016). However, for OTC hearing aids to be a viable solution for treating age-related hearing loss, they must consider the needs of older adults with complicating physical and/or cognitive co-morbidities. In particular, older people with dementia are an important subpopulation in need of an affordable, accessible option for their hearing healthcare.

Like their peers with intact cognition, older people with co-occurring dementia and hearing loss may rely on OTC hearing aids to afford and access hearing healthcare. However, OTC hearing aids are not currently designed nor delivered to facilitate effective use by people with dementia and their family caregivers. To date, a small but growing literature shows that OTC hearing aids are effective in generally healthy, well-selected older adults with intact cognition (e.g., Humes et al., 2017; Nelson et al., 2018; Urbanski et al., 2021; Venkitakrishnan et al., 2023); however, to our knowledge, no research has
examined OTC hearing aid use in people with dementia. Evidence from the broader gerontechnology literature, however, implies that people with dementia are likely to struggle with understanding, using, and managing OTC hearing aids (e.g., Malinowsky et al., 2010; Nygard & Starkhammar, 2007; Rosenberg et al., 2009). As a result, community-dwelling people with dementia will likely rely on family caregiver support for using OTC hearing aids. It is unclear, however, whether family caregivers have the necessary knowledge, training, and support to assist care recipients with dementia in using and benefitting from OTC hearing aids.

One potential solution to this problem is to create and disseminate a behavioral intervention that promotes and supports effective OTC hearing aid use in people with dementia and their family caregivers. The intervention might consist of a set of wraparounds, supports, training, and coaching that address and demystify challenges people with dementia and their caregivers may face when using OTC hearing aids. It could be disseminated separately from OTC hearing aids—or could be conceived as an additional service package that supplements or augments existing OTC hearing aids by providing additional support and assistance specifically tailored to meet the unique needs of people with dementia and their caregivers.

Development and evaluation of healthcare interventions should be guided by a clear and well-tested framework for behavioral intervention development. The NIH Stage Model (Onken et al., 2014) for behavioral intervention provides
such a framework, offering a structured approach that guides researchers through the process of moving from the initial conceptualization of an intervention to its widespread implementation. The NIH Stage Model consists of six stages or phases of intervention development. Together, these stages outline a linear progression of intervention development, evaluation, and dissemination, while also allowing flexibility for iterative, recursive, and multidirectional approaches.

This dissertation is aligned with NIH Stage Model Stage 0, which involves basic science that occurs prior to initial intervention generation and pilot testing. Stage 0 research is essential for the present research direction, as no previous studies have explored the need and feasibility of using now widely available OTC hearing aids in people with dementia—nor have they investigated the specific challenges this population might encounter while using OTC hearing aids. An exploration of these aspects is essential for informing the development of tailored services and supports aimed at addressing the unique challenges people with dementia and their family caregivers may face when using OTC hearing aids.

Summary of Results

The dissertation studies are designed to establish a rationale, purpose, and general direction for subsequent intervention development that addresses OTC hearing aid use in people with dementia. The three studies answered the following questions:
Chapter 2 (Study 1): Are OTC hearing aids efficacious and effective under ideal circumstances for well-selected OTC hearing aid candidates with normal cognition?

Chapter 3 (Study 2): Are older people with co-occurring dementia and hearing loss underserved by prescription hearing aids? If so, in which residence type(s) are individuals with dementia and unmet need for hearing aids most likely to be found?

Chapter 4 (Study 3): Do dementia care stakeholders view currently available OTC hearing aids as feasible and acceptable for community-dwelling older adults with dementia? What are the stakeholder-perceived facilitators of and barriers to OTC hearing aid use in people with dementia?

The first study (Chapter 2) comprised a single-blind crossover randomized clinical trial examining the efficacy and effectiveness of a commercially available self-fitting OTC hearing aid for well-selected older adult hearing aid candidates with mild-to-moderate hearing loss and normal cognition. Thirty-three participants completed laboratory and field measures for each of two hearing aid fitting conditions in randomized order: 1) a self-fit condition, where participants independently programmed and adjusted OTC hearing aids; and 2) an audiologist-fit condition, where the same hearing aids were custom-programmed to match prescriptive targets in each ear. Results indicated that self-fit OTC hearing aid outcomes were comparable to audiologist-fit outcomes in
the domains of self-assessed communication difficulty, speech recognition in noise, and subjective sound quality perception. This study served as a proof-of-concept, demonstrating that OTC hearing aids are feasible, efficacious, and effective when correctly programmed and used by well-selected OTC hearing aid candidates with intact cognition.

The second study (Chapter 3) was a secondary data analysis of reported unmet hearing aid need among older adults receiving publicly funded home-and community-based services. Using data from the National Core Indicators-Aging and Disabilities (NCI-AD) survey, we investigated whether respondent-reported unmet hearing aid need in older adults with dementia: 1) differs compared to those without dementia; 2) varies in different places of residence; and 3) corresponds with patterns of hearing aid ownership across places of residence. The results showed that reported unmet hearing aid need is comparable between older adults with and without dementia, indicating that people with dementia have high levels of reported unmet hearing aid need just like their peers without dementia. Importantly, however, reported unmet hearing aid need among people with dementia varies considerably by residence type. Results showed that people with dementia living at home in the community had significantly higher odds of reporting unmet hearing need than people with dementia residing in assisted living or nursing facilities. Notably, in the same sample of people with dementia, the unadjusted hearing aid ownership rate was comparable across residence types—suggesting that differences in reported
unmet hearing aid need were not driven by substantial differences in hearing aid ownership. The results demonstrate meaningful unmet hearing aid need among people with dementia, with this need disproportionately concentrated among those living in the community in their own or family home compared to other institutional or congregate settings.

The third study (Chapter 4) was a qualitative study of dementia-care stakeholders’ views on the feasibility and acceptability of OTC hearing aids for use in community-dwelling people with dementia. The study consisted of semi-structured individual interviews with participants from three groups of dementia care stakeholders (n = 15 each): 1) older people with co-occurring dementia and hearing loss; 2) family caregivers of older people with co-occurring dementia and hearing loss; and 3) geriatric direct care professionals. Interview questions explored the perceived facilitators of and barriers to OTC hearing aid use in community-dwelling people with dementia. Qualitative thematic analysis revealed several important perceived advantages of OTC hearing aids for people with dementia in the areas of affordability, accessibility, and control. However, stakeholders identified several barriers which need to be addressed to promote successful OTC hearing aid use in this population, including: 1) mistrust of OTC hearing aids; 2) assessing OTC hearing aid candidacy; 3) caregiver-facilitated programming and adjustments; 4) assessing the effectiveness of OTC hearing aids; and 5) ongoing OTC hearing aid use and caregiver burden/burnout. Taken together, the results show that dementia care stakeholders see potential value in
using OTC hearing aids for people with dementia, but only if key barriers and challenges are adequately addressed.

To summarize, the first study demonstrates the effectiveness of OTC hearing aids when used correctly. Hence, it is logical to pursue intervention development that facilitates successful OTC hearing aid use in people with dementia and their family caregivers. The second study reveals substantial unmet hearing aid need among older people with dementia living in the community. This finding establishes the need and target population for the proposed intervention (i.e., community-dwelling older adults with co-occurring dementia and hearing loss). Finally, the third study identifies specific stakeholder-perceived challenges that must be addressed by the proposed intervention to ensure effective OTC hearing aid use in community-dwelling older people with dementia and their family caregivers. These findings begin to define potential intervention components and behavioral mechanisms of change.

Future Directions

One limitation of the third study is that it gathers stakeholder perceptions of the barriers to OTC hearing aid use in people with dementia but does not directly measure them. A future study should collect outcomes of OTC hearing aid use in community-dwelling people with dementia and their family caregivers through a hands-on field trial. This mixed-methods field trial would recruit approximately 30-50 dementia caregiving dyads from the community, who would complete both quantitative and qualitative measures in the laboratory and the
field. Possible laboratory outcomes include measures of hands-on usability, deviation of self-fit programming from prescriptive targets, and predicted and/or measured speech recognition. Field measures might include ecological momentary assessment ratings of hearing aid benefit, validated assessments of perceived communication difficulty (informant and self-rating), and semi-structured dyadic interviews exploring areas of success and difficulty in using OTC hearing aids. The results could confirm stakeholder-perceived barriers identified in the third dissertation study, but they could also reveal new barriers and facilitators not previously identified via stakeholder interviews. Such findings would offer a more comprehensive, robust understanding of OTC hearing aid use outcomes in community-dwelling older people with dementia and their family caregivers to inform subsequent intervention design and development.

A subsequent step should also address the need for a conceptual model of the factors and behavioral processes driving OTC hearing aid use outcomes in dementia caregiving dyads. Although conceptual models of adult technology use already exist (e.g., Chen & Chan, 2014; Chen & Lou, 2020; Davis, 1989; Davis et al., 1989; Fong et al., 2022; Jaschinski et al., 2021; Martín-García et al., 2022; Tsai et al., 2019; Venkatesh et al., 2012; Wang et al., 2011), the complex interplay of dementia caregiving with the sensory, health, and device-related demands of effective OTC hearing aid use suggests a new model is needed. The proposed model would serve to operationalize the previously obtained research findings and inform subsequent intervention development. To develop this model,
qualitative and quantitative data from the third dissertation study and the proposed field trial will be distilled into a comprehensive set of barrier and facilitator domains for potential inclusion in the model. Then, qualitative analysis and empirical correlational data will be used to identify associations, linkages, and mediating or moderating relationships between the barrier and facilitator domains. This information, along with existing technology use models, will be used to drive identification of mechanistic pathways and processes. From the resulting model, modifiable behavioral factors will be chosen as potential intervention targets to inform subsequent intervention design and development to promote effective OTC hearing aid use in older adults with dementia and their family caregivers.

With the proposed conceptual model in place, the next step entails intervention design and development in alignment with Stage 1 of the NIH Stage Model (Onken et al., 2014). Using the modifiable intervention targets identified in the conceptual model, I will create and pilot test a behavioral intervention program aimed at supporting OTC hearing aid use in community-dwelling older people with dementia and their family caregivers. The program’s content, format, and delivery will be informed by the conceptual model, existing chronic care models (Davy et al., 2015; Wagner et al., 2001), and published studies of similar interventions developed to treat other chronic conditions in older adults (Kaster et al., 2018). Intervention design will address the key elements of the Intervention Taxonomy (ITAX), including delivery modality, frequency, content, and
adaptability (Schulz et al., 2010). The resulting intervention is expected to target both health and technology-related attitudes, behaviors, and skills of older persons with dementia and their family caregivers. Throughout the intervention development process, community-engaged research approaches will be employed to gather feedback and guidance from stakeholders to ensure feasibility and acceptability of the intervention.

Following intervention design and development, I will conduct a three to six-month mixed methods pilot study to evaluate feasibility and acceptability of the program. In alignment with published guidance for conducting preliminary feasibility studies, the objectives of the proposed study will be to determine: a) access to participants; b) barriers to participation; c) the feasibility and suitability of intervention procedures and outcome measures; d) the training needs and competence of individuals delivering the intervention; e) barriers to intervention delivery; f) appropriateness of the target group for intervention; g) acceptability of the intervention to its recipients; and h) the time and resources needed for intervention delivery (the latter three objectives based on implementation science principles to create a potentially scalable intervention (Abbott, 2014). Results of the preliminary study will guide subsequent modifications, adaptations, and refinements to the intervention program to improve its feasibility and acceptability for future investigations. Ultimately, the long-term goal is to move through this work through the NIH Stage Model, applying the model steps as appropriate to ensure maximum potency, scalability, and success of the proposed intervention.


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Appendix: Chapter 4 Interview Guides

Persons with Dementia

1. Had you heard about over-the-counter hearing aids?
2. Do you think over-the-counter hearing aids would be useful to you?
3. If you decide to buy hearing aids, how will you decide whether to purchase them from a hearing care professional or purchase them over the counter?
4. If you wanted to buy over-the-counter hearing aids, where would you look for them?
5. What characteristics would you look for in over-the-counter hearing aids?
6. Imagine you purchased over-the-counter hearing aids. They come in a box, and you have the box in your home. You need to take the hearing aids out of the box, turn them on, and put them in your ears. Would you set them up on your own?
   a. If no, who would you ask for help?
   b. Are you confident they could help?
   c. What kinds of things would they need to help you set up the hearing aids successfully?
7. Do you think over-the-counter hearing aids would be easy for you to use?
   a. What kinds of things could make them easier to use?
8. Imagine you’ve started wearing over-the-counter hearing aids. Could you tell if they were helping your hearing?
   a. If yes, how would you tell?
b. *If no, why not?*

9. If you purchased over-the-counter hearing aids and weren’t happy with them, what would you do?

10. Imagine you purchased over-the-counter hearing aids and you’ve decided to keep wearing them. What tasks would you need to perform to use the hearing aids successfully?
   a. Which hearing aid tasks could you do on your own?
   b. Which hearing aid tasks do you think you might need help with?
   c. Who would you ask for help?
   d. Are you confident they could help?

11. For you, what are the advantages of over-the-counter hearing aids?

12. For you, what are the disadvantages of over-the-counter hearing aids?

13. Is there anything else about this topic that you’d like to share?

**Family Caregivers**

1. Had you heard about over-the-counter hearing aids?

2. Do you think over-the-counter hearing aids would be useful to [care recipient]?

3. If you and [care recipient] decide to buy hearing aids, how will you decide whether to purchase them from a hearing care professional or purchase them over the counter?
4. Over-the-counter hearing aids are intended for adults with self-perceived mild-to-moderate hearing loss. Do you think [care recipient] can tell their degree of hearing loss?
   a. Can you tell their degree of hearing loss?

5. If you and [care recipient] wanted to purchase over-the-counter hearing aids, who would primarily shop for them?
   a. [If primarily the care recipient], where do you think they would look for over-the-counter hearing aids?
   b. [If primarily the family caregiver], how would you go about looking for over-the-counter hearing aids? Where would you shop for over-the-counter hearing aids?

6. In the shopping process, what characteristics would you look for in over-the-counter hearing aids that you would consider buying for [care recipient]?
   a. What characteristics of over-the-counter hearing aids would be must-haves for [care recipient]?
   b. Are there any characteristics of over-the-counter hearing aids that would stop you from buying them for [care recipient]?
   c. What do you think [care recipient] would look for in over-the-counter hearing aids?
7. Imagine you purchased over-the-counter hearing aids. They come in a box, and you have the box in your home. The hearing aids need to be unboxed, turned on, and placed in [care recipient’s] ears. Who would be primarily responsible for setting up the hearing aids?
   a. *If primarily care recipient*, what kinds of things would they need to be successful in setting up the devices?
   b. *If primarily family caregiver*, what kinds of things would you need to help [care recipient] set up the hearing aids successfully?
   c. *If primarily family caregiver*, are you confident that you could set up the devices successfully?

8. Do you think over-the-counter hearing aids would be easy for [care recipient] to use?
   a. If you are helping [care recipient], do you think they will be easy for you to use?
   b. What might make over-the-counter hearing aids easier to use?

9. Imagine [care recipient] has started wearing over-the-counter hearing aids. Could you tell if they were helping [care recipient’s] hearing?
   a. *If yes*, how would you tell?
   b. *If no*, why not?

10. Imagine [care recipient] has started wearing over-the-counter hearing aids. Do you think [care recipient] could tell if the hearing aids were helping their hearing?
a. *If yes, how would they tell?*

b. *If no, why not?*

11. If you and [care recipient] purchased over-the-counter hearing aids and weren't happy with them, what would you do?
   a. What do you think [care recipient] would do if they weren't happy with the devices?

12. Imagine you purchased over-the-counter hearing aids and you and [care recipient] have decided to keep wearing them. What tasks do you think [care recipient] would be able to complete independently to use the hearing aids successfully?
   a. Which hearing aid tasks do you think they might need help with?
   b. Are you confident providing this help?

13. For you and [care recipient], what are the advantages of over-the-counter hearing aids?

14. For you and [care recipient], what are the disadvantages of over-the-counter hearing aids?

15. Is there anything else about this topic that you'd like to share?

**Direct Care Professionals**

1. Had you heard about over-the-counter hearing aids?

2. Do you think over-the-counter hearing aids would be useful to older adults with dementia?
3. If you were providing services to an older adult with early to mid-stage dementia and they or their family caregiver asked your opinion, would you recommend they purchase a hearing aid over the counter or from a licensed hearing care provider?

4. Over-the-counter hearing aids are intended for adults with mild-to-moderate hearing loss. Imagine an individual with early to mid-stage dementia and/or their family caregiver want to determine if the care recipient’s hearing is appropriate for over-the-counter hearing aids. Do you think the individual with dementia could assess their degree of hearing loss?
   a. Could a family caregiver determine the individual’s degree of hearing loss?
   b. Do you feel confident classifying the hearing status of individuals under your care?
   c. How would you make this determination?

5. Imagine that the care recipient and their family caregiver decide to purchase over-the-counter hearing aids. They ask you where to find over-the-counter hearing aids. How would you recommend they go about looking for over-the-counter hearing aids?

6. For individuals under your care with early to mid-stage dementia, what would you recommend they or their family caregivers look for in over-the-counter hearing aids?
a. What features or characteristics might they need to be successful with the devices?

b. Are there features or characteristics you think could be detrimental for these individuals?

c. Do you think individuals with dementia will be self-aware of these factors?

d. How about their family caregivers?

7. Imagine the care recipient and/or their family caregiver purchased over-the-counter hearing aids. They now have the box in their home. Do you think the person with dementia could independently set up the hearing aids? In other words, take the hearing aids out of the box, turn them on, place them on their ears, and start wearing them.

a. Do you think a family caregiver could assist them in setting up the hearing aids?

b. What kinds of things do you think the person setting up the hearing aids would need to be successful?

8. Do you think over-the-counter hearing aids will be easy to use for individuals with early to mid-stage dementia?

a. What things could make them easier to use for this population?

9. Imagine a person under your care with early to mid-stage dementia has started wearing over-the-counter hearing aids. Could you tell if the hearing aids were helping the person hear better?
a. How would you tell?

b. Do you think a family caregiver could tell that the hearing aids were helping? And how?

10. Thinking of people under your care with early to mid-stage dementia, do you think they could tell if over-the-counter hearing aids were helping their hearing?
   a. *If yes*, how would they tell?
   b. *If no*, why not?

11. Imagine the care recipient and their family caregiver decide they aren’t satisfied with the over-the-counter hearing aids they purchased; what would you recommend they do?

12. Thinking of individuals under your care with early to mid-stage dementia, do you think they could handle and maintain over-the-counter hearing aids independently?
   a. Which hearing aid tasks do you think they might need help with?
   b. Do you think family caregivers could help with these tasks?
   c. Could you help these tasks?

13. From your perspective as a care professional, what are the advantages of over-the-counter hearing aids for individuals with early to mid-stage dementia?
14. From your perspective as a care professional, what are the disadvantages of over-the-counter hearing aids for individuals with early to mid-stage dementia?

15. Is there anything else about this topic that you'd like to share?