# **CADTH Horizon Scan**

# Hearing Restorative Devices and Dementia



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### **Key Messages**

- This Horizon Scan summarizes the available information regarding hearing restorative devices for improving cognition or delaying disease progression for people living with dementia.
- Hearing loss is 1 of the largest modifiable risk factors for dementia.
- Evidence regarding the effectiveness of hearing devices to improve cognition in people living with dementia is still evolving. However, in individuals without dementia, managing hearing loss may prevent cognitive decline in the long term.
- Early evidence suggests that hearing aids may be a cost-effective intervention for preventing dementia in the long term.
- Barriers to access such as high out-of-pocket costs, equitable access to health care, and low
  utilization even in the general population are issues to consider. If managing hearing loss with
  hearing restorative devices indeed prevents cognitive decline, if they are accessible only to those with
  the financial means to pay high out-of-pocket costs, this could exacerbate systemic health inequities.

## **Purpose**

The purpose of this Horizon Scan is to present health care stakeholders in Canada with an overview of information related to hearing restorative devices to prevent or delay the progress of major neurocognitive disorders or dementia. In this report, we outline the current availability of hearing devices and the clinical and economic evidence regarding their potential role for people living with dementia. Furthermore, we briefly discuss equity considerations, facilitators and barriers to uptake, and user and caregiver perspectives.

This report is not a systematic review and does not involve critical appraisal or include a detailed summary of study findings. It is not intended to provide recommendations for or against the use of hearing restorative devices.

#### **Methods**

### Literature Search Strategy

An information specialist conducted a literature search on key resources including MEDLINE, Scopus, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, and a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were dementia and hearing aids. The search was completed on February 23, 2023, and limited to English-language documents published since January 1, 2018.



#### **Study Selection**

One author screened the literature search results and reviewed the full texts of all potentially relevant studies. Studies were considered for inclusion if the intervention was hearing aids, cochlear implants, or other hearing devices. Conference abstracts and grey literature were included when they provided additional information to that available in the published studies.

#### **Peer Review**

A draft version of this bulletin was reviewed by a clinician with expertise in dementia.

## **Background**

Dementia is a chronic, progressive syndrome characterized by loss or deterioration of cognitive functions such as memory, speech, mood and behaviour, intellectual function, and ability to perform day-to-day living tasks. It is an acquired condition that results from disease or injury. The Diagnostic Statistical Manual of Mental Disorder, Fifth Edition (DSM-5) uses the term "major neurocognitive disorder" for dementia to denote the substantial cognitive impairment the disease causes, and to differentiate from mild cognitive impairment in which the cognitive impairment is not affecting the day-to-day life of the individual.<sup>2</sup> Both "dementia" and "major neurocognitive disorder" will be used synonymously in this report. A major neurocognitive disorder is characterized by a significant decline (from preexisting cognitive abilities) in 1 or more of various cognitive domains, including executive function, complex attention, language, learning, memory, and perceptual-motor or social cognition.<sup>1,2</sup> Alzheimer disease is the most common type of dementia, accounting for more than 70% of all people living with dementia. Alzheimer disease is caused by extensive atrophy of the cerebral cortex and deposits of amyloid plagues and tau proteins in the neurons, which result in their degeneration. Other less common types of dementia include vascular dementia, frontotemporal lobar degeneration, Lewy body dementia, and Parkinson disease dementia. Additionally, infections such as HIV and prion diseases, alcohol or substance use, and traumatic brain injuries have all been linked with loss of cognitive functions that progress to dementia.<sup>1,2</sup> In Canada, about 1 in 4 individuals aged 85 or older have been diagnosed with dementia.3 Studies have estimated that there were around 597,300 individuals living with dementia in Canada.<sup>4</sup> Dementia has a poor prognosis with no available cure. Pharmacological and nonpharmacological management options aim to improve existing cognitive functions and delay the progression of cognitive decline.1

Hearing loss, another major health concern of advanced age, has been associated with cognitive decline and dementia. It is 1 of the most common disabilities worldwide. According to the 2020 report of the Lancet commission on dementia, hearing loss in midlife (45 to 65 years of age) is potentially the largest modifiable risk factor for dementia.<sup>5</sup> Evidence from multiple observational studies and systematic reviews have found a consistent association of hearing loss with increased cognitive decline and increased risk of incident (newly diagnosed) dementia.<sup>6-10</sup> A complete picture of the pathophysiological causal pathways linking hearing loss and incident dementia is not yet understood. A bidirectional association is possible, in which cognitive impairment occurs as a consequence of hearing loss, as well as hearing loss resulting from



dementia-related changes.<sup>11,12</sup> It is proposed that hearing loss—related cognitive decline occurs due to both behavioural and neural mechanisms. Social isolation and depression as well as frontotemporal brain atrophy and changes to neural systems are associated with impaired cognition.<sup>13,14</sup> Additionally, age may play a role in the association of hearing loss and cognitive decline.<sup>15</sup> To summarize, hearing loss is associated with an increased risk of incident dementia, but more research is required to further our knowledge on the underlying mechanism of this association.

Based on this growing body of evidence regarding hearing loss being a modifiable risk factor for dementia, use of hearing restorative devices for delaying the progression of dementia or for preventing it has been of interest. 14,16,17 This report aims to provide an overview of information on the emerging use of this existing technology.

# The Technology

Hearing restorative devices include hearing aids, cochlear implants, and other implantable hearing devices. Hearing aids are sound amplifying devices the help the user detect noise. They may be indicated in various conditions that result in sensorineural hearing loss, conductive hearing loss, or single-sided hearing loss. Since the invention of the first electronic hearing aid in 1898, the technology has evolved and improved considerably. Present day hearing aids consist of a microphone, an amplifier, a receiver, and a battery (rechargeable or replaceable). Types of hearing aids include behind-the-ear, receiver-in-the-canal, and in-the-canal depending on the placement of the devices in one's ear. In the case of single-sided hearing loss or asymmetrical hearing loss, contralateral or bilateral contralateral routing of signals are used to transmit signals to the better hearing ear. Newer digital hearing aids may have high efficiency acoustic and motion sensors, automatic environmental detection, Bluetooth connectivity, improved speech clarity, integrated smartphone apps, and even artificial intelligence capabilities for language translation and health monitoring. Today's newer hearing aids are small, barely visible, and easy to wear.

Cochlear implants are implantable devices that improve hearing by stimulating the nerves in the inner ear. Cochlear implants are indicated for severe to profound hearing loss. They have an external component to capture and transmit sound, and an internal component to receive and process the signals to the inner ear. A surgical process is required to implant the internal component. Other implantable hearing restorative devices include implantable middle ear hearing devices (IMEHDs) that are attached to the bones in the middle ear, and bone-anchored hearing devices that are surgically attached to the skull to transmit vibrations directly to the inner ear. Lastly, assistive listening devices are hand-held instruments with amplifiers and microphones that help individuals improve listening in public places and small settings. They can be used with or without hearing aids or a cochlear implant.<sup>22</sup>

In conjunction with improved hearing, the use of hearing aids can benefit the mental well-being, health-related quality of life, and communication of those who use them.<sup>23</sup> Hearing loss is often associated with emotional distress,<sup>24,25</sup> depression,<sup>26</sup> and loneliness,<sup>27</sup> and studies have shown that the use of hearing aids



can lower the risk of depression and improve mental health quality of life. <sup>23,28,29</sup> Furthermore, other health benefits of hearing aids such as lower risk of heart attack or stroke have been explored. <sup>30</sup>

## **Cost and Availability**

Hearing restorative devices and assistive listening devices are not a new technology. They have been approved by Health Canada and available in Canada for decades for individuals with hearing loss.<sup>31</sup> However, it is unclear whether these devices are being offered with the intention of improving of cognitive outcomes for people living with dementia.

For people using hearing aids, costs and availabilities differ depending on the province or territory they live in. Across Canadian provinces and territories, the government coverage and subsidies vary considerably.32 For example, in Ontario, hearing aids are available from registered vendors through the Assistive Devices Program and require consultation and fitting through an audiologist. The program will cover 75% of the cost of 1 hearing aid up to \$500 or \$1,000 for 2 hearing aids.33 The cost of a single hearing aid ranges from \$1,000 to \$6,000, depending on the type of technology, accessories, and services (e.g., warranty).<sup>34</sup> For cochlear implants, the program covers 75% of the cost of a cochlear implant replacement speech processor (up to a maximum of \$5,444). Additionally, the program requires a waiting period of a minimum of 3 years from the implant surgery to qualify for a replacement processor.<sup>33</sup> While the cost of the initial implant, including surgical care, is covered under the Ontario Health Insurance Plan, there are out-of-pocket costs for the individual. In Alberta, the expected out-of-pocket cost for hearing services over a 4-year term was estimated to be up to \$11,000.34 Though private or employer-based insurances may provide coverage for some individuals, only around one-third of older adults in Ontario were found to have retiree health insurance or private insurance, and those rates have been in decline. 35,36 Thus, cost can be an important barrier for individuals for accessing these devices. 37 For First Nations people, hearing aids and supplies are provided free of cost to eligible individuals through the Non-Insured Health Benefits program. 38,39

In countries like the US and UK, access to hearing restorative devices is different than in Canada. Since the fall of 2022, hearing aids have been made available over the counter in the US.<sup>40</sup> This approval by the US FDA was made to expand access to and increase the affordability of hearing aids. Thus, people with mild or moderate hearing loss can purchase hearing aids over the counter from pharmacies and big box stores without consulting a specialist or being fitting by an audiologist. However, with an average cost of \$2,500, over-the-counter hearing aids could be unaffordable for around 75% people in the US with functional hearing loss.<sup>41</sup> Furthermore, for individuals with severe hearing loss, hearing restorative devices continue to be prescription based, and require a hearing exam and fitting by an audiologist.<sup>42</sup> In the UK, hearing aids are available free of charge through the National Health Service.<sup>43</sup>

## Who Might Benefit?

If effective, individuals with dementia or those who are at risk of dementia with hearing loss, as well as their caregivers, could benefit from the use of this technology. In Canada, about 1 in 4 individuals aged 85 or older



have been diagnosed with dementia.<sup>3</sup> The average lifespan of people in Canada is increasing and, due to an aging population,<sup>44</sup> the number of people living with dementia is also increasing every year. In 2022, the Alzheimer Society of Canada published the results of the Landmark Study,<sup>4</sup> which projected the number of people who will develop dementia over the next 30 years in Canada. It is estimated that in 2020, there were 597,300 individuals living with dementia in Canada and the findings of the Landmark Study suggest that this number will be 1 million by the year 2030.<sup>4</sup> Globally, it is estimated that around 152 million people will be living with dementia by 2050.<sup>45</sup>

Known risk factors for dementia include low socioeconomic indices and higher rates of comorbid conditions (e.g., hypertension, diabetes), factors that are more prevalent in populations that have experienced systemic inequities. <sup>46,47</sup> For Indigenous Peoples in Canada, these are associated with the systemic inequities arising from colonization; <sup>46,47</sup> furthermore, this population also includes an aging population, <sup>48</sup> a higher prevalence of dementia, and a disproportionately higher risk of developing dementia. <sup>49</sup> Studies conducted in the US have found that there is a disproportionately higher incidence of dementia among Black people. <sup>50,51</sup> In the coming decades, notable changes in the ethnic profile of people living with dementia are expected in Canada. <sup>52</sup> The Canadian Centre for Economic Analysis projects that by 2050, the percentage of people of Asian descent living with dementia will triple, despite this population having a relatively lower risk for dementia. While those of European descent would still be the most common group at risk for dementia (around 50%), their proportional risk is projected to decrease partially due to migration patterns and aging of immigrants from various ethnic groups. <sup>52</sup>

Socially excluded people, such as those experiencing homelessness or those with precarious housing, have a higher risk of cognitive impairment and dementia.<sup>53,54</sup> This relationship is complex due to multiple factors like traumatic brain injuries, substance use disorders, or psychiatric illnesses that are risk factors for both cognitive decline and experiencing homelessness.<sup>53,54</sup> Stress, malnutrition, social isolation, and environmental exposures could also affect cognitive functions.<sup>55</sup>

Family caregivers of people living with dementia provided 19.2 million unpaid hours of care in 2011; this number is expected to double by 2030.<sup>56</sup> Around 45% of individuals who are caregivers for people living with dementia report distress, which can subsequently result in burnout, affect their physical and mental health, disrupt their social lives, and even increase risk of death.<sup>57</sup> These statistics highlight the importance of providing improved care for people living with dementia so that they can lead more independent lives for a longer period of time. With a current annual cost of more than \$10.4 billion to the Canadian economy and the country's health care systems, the predicted increase in the prevalence of dementia will likely have an impact on public health and economic resources.<sup>58</sup>

#### **Current Practice**

As of this writing, there is no complete cure for dementia,<sup>59</sup> and in Canada, no disease-modifying drugs have been approved for dementia.<sup>60</sup> The current goal of care is to reduce cognitive and behavioural symptoms, improve quality of life and independence, and delay the progression of cognitive decline. Pharmacological



and nonpharmacological management options are used to meet these goals.<sup>1,60</sup> Pharmacological options are mainly used for Alzheimer disease and include acetylcholinesterase inhibitors (e.g., donepezil), N-methyl D-aspartic acid receptor antagonists (e.g., memantine), and combination drugs to improve cognitive functions and daily living by counteracting the disease mechanisms.<sup>1,61</sup> Medications for coexisting behavioural and neuropsychiatric conditions and other age-related comorbidities with an increased risk of stroke (e.g., hypertension, diabetes) are also often prescribed.<sup>1</sup>

Nonpharmacological options include behavioural exercises such as cognitive stimulation therapy, social interactions, physical exercises, adequate sleep and nutrition, and appropriate medical care. <sup>60</sup> People living with dementia often require caregivers to help manage day-to-day living. <sup>1,62</sup> Diagnosis and management of sensory deficits such as vision or hearing impairment are also crucial in delaying the progression of symptoms. Canadian guidelines recommend the diagnosis of audiologic rehabilitation if a hearing impairment is diagnosed. <sup>62</sup> However, recommendations related to the use of hearing devices for the improvement of cognitive outcomes have not been made.

# Summary of the Evidence

Evidence regarding possible benefits and harms of using hearing aids (and other hearing restorative devices) for the cognitive improvement of people living with dementia or mild cognitive impairment is evolving. Overall, the authors of several systematic reviews have reported that the evidence is of low quality, with a high risk of bias and other methodological limitations. Inconsistent and often subjective outcome measures across the evidence also make it challenging to synthesize the findings and arrive at a conclusion. In this section we summarize the evidence regarding the use of hearing restorative devices for improved cognition in patients with dementia.

#### **People Living With Dementia**

For people living with major neurocognitive disorders or dementia and hearing loss, the evidence regarding the potential benefits of hearing aids for improvement in cognition is uncertain. Two systematic reviews, published in 2022<sup>63</sup> and 2018,<sup>64</sup> assessed the clinical effectiveness of hearing aids and cochlear implants for cognitive improvement for people living with dementia. While quality of life and communication were improved with the use of hearing aids, the reviews reported no statistically significant benefit of the intervention on cognitive decline. There was considerable overlap of primary studies across the systematic reviews. A scoping review<sup>17</sup> of interventions to improve vision and hearing impairment in people living with dementia also found that while there may be sensory improvements, evidence regarding cognitive outcomes were uncertain due to limitations of the available evidence. The authors highlighted the key limitations of the evidence: first, most of the evidence was from case reports, case series, and single-arm uncontrolled studies. One double-blind randomized controlled trial was identified by both systematic reviews.<sup>63,64</sup> The trial evaluated cognitive outcomes among 38 people living with Alzheimer disease after either hearing aid or placebo use. After 6 to 12 months of follow-up, there were no between-group difference for any cognitive performance measures. Second, inconsistent use of outcome measures across the studies makes the



synthesis of evidence challenging. The cognitive assessment tests used in studies are often self-reported and/or verbally reported, which might be biased due to the subjective nature of the tests and issues with outcomes assessment (e.g., people with hearing loss may be unable to correctly hear or answer the questions). Third, and perhaps most importantly, the authors noted that the lack of conclusive evidence is due to a lack of understanding of the causal relationship between dementia and hearing loss. Cognitive decline could be not only due to decreased sensory input, but also due to deterioration in one's ability to process the information. In those cases, increased sensory input through hearing aids may not improve cognition.

The research on the potential benefits of hearing aids to improve cognitive outcomes is still evolving. The ACHIEVE trial is an ongoing multicentre randomized controlled trial examining cognitive outcomes among older adults with hearing aid use compared to a "successful aging intervention" (i.e., sessions with a health educator about healthy aging). Following the positive results from a feasibility trial,<sup>65</sup> a randomized controlled trial (SENSE-Cog) will examine the effectiveness of a sensory intervention (hearing and vision) on dementia-related outcomes among older adults living with dementia.<sup>66</sup> Well-designed randomized controlled trials and large observational studies are necessary to conclusively assess the cognitive effects of hearing restorative devices for people living with dementia.

#### People Living With Hearing Loss and Without Dementia

We identified 4 systematic reviews that evaluated the potential cognitive benefits of hearing devices in individuals with hearing loss and without dementia cognition. <sup>63,67-69</sup> The evidence from these reviews suggests that use of hearing aids or cochlear implants may improve cognition or prevent cognitive decline. However, methodological limitations and the high risk of bias of the primary studies included in the systematic reviews lower the certainty of evidence. The authors of a large systematic review and meta-analysis of 19 trials (with more than 120,000 participants)<sup>69</sup> found that the use of hearing restorative devices for people with hearing loss was associated with a significantly lowered risk of long-term and short-term cognitive decline. Another systematic review by Yang et al. (2022)<sup>63</sup> found that in patients without dementia, the use of hearing aids was associated with an improvement in cognitive performances. A third systematic review with meta-analysis<sup>67</sup> examined the association of cochlear implants and cognitive status among individuals with profound hearing loss and the authors concluded that cochlear implants may have improved the cognitive abilities of the participants; however, the authors highlighted the low certainty of the evidence and limitations related to inconsistent and inappropriate outcome measures. Finally, in a comprehensive systematic review by Sanders et al. (2021),68 the authors were unable to draw conclusions on the effectiveness of hearing aids on cognition and the authors highlighted the high risk of bias across the relevant literature.

#### Cost-Effectiveness

A UK-based cost-effectiveness modelling study of several modifiable risk factors for late-onset dementia considered hearing loss along with hypertension, smoking, and diabetes. At a threshold of £20,000 per quality-adjusted life-year, hearing aid use for middle-aged adults was found to result in higher quality-adjusted life-years and lower costs from a societal perspective compared to not using hearing aids. Thus, the



authors concluded that use of hearing aids is worthwhile and a cost-effective intervention for the prevention of dementia in the long term. However, considering the limitations of the clinical evidence outlined in the earlier sections, the applicability of these findings is uncertain. A cost-benefit analysis conducted in the US also found that the total benefits of using hearing aids were significantly large compared to the costs, making them a worthwhile intervention to reduce dementia symptoms; however, we did not identify studies that examined the cost-effectiveness of using hearing devices for cognitive improvement in people living with dementia.

## **Future Developments**

Several treatment options for dementia are currently on the horizon. There are ongoing trials that focus on prevention, delaying disease onset and progression, and improving cognitive outcomes in Alzheimer disease. Pharmacological options that aim to target the beta-amyloid plaques, decrease the Tau protein aggregation, or reduce inflammation are being evaluated in trials. New disease-modifying immunotherapy drugs, such as aducanumab and lecanemab, aim to decrease amyloid levels in the brain. However, evidence for their benefit has not been reviewed in this report. Lecanemab, a humanized monoclonal antibody that aims to reduce the levels of amyloid plaques and prevent plaque deposition, was approved for the treatment of early Alzheimer disease in the US in early 2023. Trials evaluating next-generation biotherapeutics such as stem cell therapy, gene therapy, and nucleotide therapy are also being conducted.

#### **Additional Considerations**

#### **Perspectives and Experiences**

Hearing aids are 1 of the most common assistive devices used in the world. However, uptake is low — it is reported that around 17% of people who require hearing aids use them.<sup>75</sup> A recent systematic review of qualitative studies explored the perspectives of hearing aid users; patient-centred care, information counselling before and after fitting for hearing aids, factors regarding scheduling of follow-up appointments, and social connections emerged as core concepts in improving audiological service delivery.<sup>76</sup> A survey among staff of care homes in the UK identified that lack of maintenance and care of devices, and low adherence are some of the challenges among residents living with dementia in using hearing and vision aids.<sup>77</sup>

#### Facilitators and Barriers for Uptake

A systematic review of factors associated with hearing aid use among people living with dementia found facilitators and barriers to be similar to those found in the general population.<sup>78</sup> A person's level of proficiency in handling the hearing aid emerged as 1 of the strongest factors that influenced the use of hearing aids. Experiencing positive consequences of hearing aids, the fit and comfort of the device itself, social reinforcement, and factors related to person-environment interactions were the other important markers of hearing aid use. Equity considerations while discussing the facilitators and barriers to hearing aid usage



are crucial in ensuring access regardless of race, gender, and socioeconomic or educational differences. Ethnicity (i.e., people who are white are more likely to use hearing aids), poor economic status, and level of procedural knowledge about hearing aids were related factors affecting the uptake and adherence to hearing aids; however, there were moderate to substantial concerns about the evidence making this claim. In a study of hearing aid use in Ontario, income was identified as 1 of the factors determining use — in that individuals living in low income neighbourhoods were less likely to use hearing devices when they needed them compared to those living in high income neighbourhoods. On Considering the 25% out-of-pocket costs to the customer after provincial coverage, the cost of restorative hearing devices can be a barrier to access.

#### **Final Remarks**

Hearing loss is an important modifiable risk factor for dementia. Evidence regarding the effectiveness of hearing restorative devices in improving cognitive outcomes among people living with dementia is still evolving. Future large observational studies and well-designed randomized trials are warranted to fill the knowledge gap. Despite having a disproportionately higher prevalence of dementia,<sup>80</sup> most studies did not have a proportional representation of Indigenous participants. The Canada Research Coordinating Committee strategic plan suggests that Indigenous research should have priorities set by Indigenous Peoples, be guided by principles of decolonization of research, respect Indigenous ethics and protocols, and ensure equitable access for Indigenous researchers.<sup>81</sup> Further research examining the effects and appropriateness of hearing restorative devices in improving cognitive outcomes among Indigenous people living with dementia would benefit from following those or other such principles developed to support reconciliation.

Given that hearing aids are relatively safe, often needed for age-related hearing loss, cost-effective, and easy to use, there may be a role for this intervention in Canada's armamentarium of dementia care. However, the current model of obtaining appropriate hearing devices in Canada may be a major barrier to the uptake of this technology. Those who already face systemic barriers to health care, such as having low income, not having employee or private health insurance, and being part of a racialized population are presently facing challenges in accessing hearing devices. <sup>79</sup> If the technology is expanded to be used among people living with dementia in addition to those with hearing loss, a large increase in demand is to be expected. Adequate availability of professionals and the waiting period to access the technology are concerns that should be addressed in addition to the high out-of-pocket costs of hearing devices in Canada.



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