# Initiation of Hearing Aids Use and Incident Dementia Among Mid-to-late Life Adults: The Health and Retirement Study 2010-2018

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#### **Abstract**

Background and Objectives: Hearing aids may reduce the risk of dementia among individuals with hearing loss. However, no evidence is available from randomized controlled trials (RCTs) on the effectiveness of hearing aids use in reducing incident dementia. Using target trial emulation, we leveraged an existing longitudinal cohort study to estimate the association between hearing aids initiation and risk of dementia. Research Design and Methods: The Health and Retirement Study was used to emulate target trials among non-institutionalized participants aged ≥50 years with self-reported hearing loss, without dementia at baseline, and without use of hearing aids in the previous 2 years. Intention-to-treat analysis was conducted to estimate the risk of dementia associated with hearing aids initiation vs controls who did not initiate hearing aids. Pooled logistic regression models with inverse-probability of treatment and censoring weights were applied to estimate risk ratios, and 95% confidence intervals were calculated using 1000 sets of bootstrapping. Results: Among 23 14 participants (328 in the intervention group and 1986 in the control group; average age: 72.3 ± 9.7 years, 49% women, and 81% White), after 8 years of follow-up, risk of dementia was significantly lower among individuals who initiated hearing aids (risk difference (RD): −0.05, 95% confidence interval (CI): −0.08, −0.01). A lower risk was observed particularly among adults aged 50-74 years, men, and individuals with cardiovascular disease. Discussion and Implications: Hearing aids use was associated with a significant reduction of incident dementia. Future interventional studies are needed to further assess the effectiveness of hearing aids in preventing dementia.

#### Keywords

hearing loss, hearing aids, primary prevention, dementia, cognitive aging

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## Introduction

Hearing loss, which affects 1 of every 5 people in the U.S., has been identified as a potentially modifiable risk factor for dementia.<sup>2</sup> Hearing loss may potentially lead to dementia through greater consumption of cognitive resources for auditory perceptual processing, adverse effects on brain structure and function, reduced social engagement, or other shared pathophysiology between hearing loss and dementia.<sup>3</sup> According to a prior meta-analysis, hearing loss is associated with twice the risk of incident dementia, 4 which is consistent with recent findings from the Mayo Clinic Study of Aging.<sup>5</sup> Given the increased risk of cognitive impairment associated with hearing loss, interventions to address hearing loss are a potentially important strategy for reducing the risk of dementia. A few observational studies have suggested that use of hearing aids is associated with a lower risk of dementia. <sup>6,7</sup> A recent systematic analysis of 8 studies showed that use of hearing aids among individuals with hearing loss was associated with a 19% reduction in hazard of cognitive decline, 8 thus suggesting that hearing aids are a promising tool for reducing risk of severe cognitive outcomes. However, it is notable that only 2 out of 8 studies included in the metaanalysis yielded significant results, and the largest such study was based on claims data, which may be susceptible to unmeasured confounding.

Recently, The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) trial emerged as the first randomized controlled trial (RCT) to estimate the effect of hearing intervention on cognitive outcomes among cognitively healthy older adults with hearing loss. Although there was no significant overall difference in cognitive decline between the hearing intervention and control groups, a sensitivity analysis indicated that hearing intervention reduced 3-year cognitive decline among participants of the ARIC study, who had more risk factors for dementia, but not among healthy volunteers from the same communities. 10 These results were suggestive but inconclusive. Particularly, the length of the ACHIEVE trial was only 3 years, whereas a lengthier intervention period may be required to observe the full effects on incident dementia. In this circumstance where evidence from RCTs is insufficient, rigorous observational studies are needed to further elucidate the effectiveness of hearing aids use on dementia risk. 11,12

Target trial emulation is an observational research approach that integrates design elements from idealized randomized trials, or target trials, to enhance the quality and interpretability of observational studies. <sup>13</sup> Target trial emulation is an approach for deriving results of target trials from information garnered from observational studies. <sup>14-18</sup> Using the principles of RCTs when an actual trial is not available can help improve the quality of observational

evidence. The validity of target trial emulation has been confirmed through replication of estimates from existing RCTs. <sup>14</sup> We aimed to emulate a target trial of initiating hearing aids use on incident dementia among older adults in the U.S.

#### **Methods**

To emulate the target trial, we used data from the Health and Retirement Study (HRS), a nationally representative, longitudinal study initiated in 1992 focusing on adults ≥50 years or older and their spouses. Participants completed questionnaires every 2 years. Participants of the HRS were replenished every 6 years. For this study, Wave 10 (2010) of HRS was set as the baseline, and we incorporated data from Wave 10 (2010) to Wave 14 (2018) for analysis. This timeline was selected as it has a wider range of ages and because information on self-reported dementia was first collected from Wave 10 (2010), which was used to identify participants free of dementia at baseline. All participants provided informed written consent, and individual participants were deidentified in the dataset for analysis.

Data on hearing impairment and hearing aids use was obtained through self-report questionnaires, with questions "Is your hearing excellent, very good, good, fair, or poor (using a hearing aid as usual)" and "Do you ever wear a hearing aid?". Participants who responded "fair" or "poor" to the first question or "yes" to the second question were considered having hearing loss, and participants who answered "yes" to the second question were considered using hearing aids.

Self-reported dementia was obtained from 2010 for participants in each wave. Participants were asked whether they had ever been diagnosed with dementia. This self-reported dementia has been used in prior studies and showed moderate agreement with cognitive assessment for dementia. <sup>20-23</sup> Death and year of death were recorded from report by household members, and were matched with the National Death Index.

## Design and Specification of Target Trial

The design and specification of the target trial and its emulation are described below.

*Eligibility Criteria.* Eligible participants are individuals ≥50 years with hearing impairment without use of hearing aids in the previous 2 years, and who are free of dementia at baseline.

Intervention Strategies and Randomized Assignment. Participants will be randomly assigned to 1 of the strategies: initiating hearing aids, or not initiating hearing aids. All participants are informed of the intervention strategy to which they have been assigned.

Outcomes of Interest. The primary outcome is incident dementia.

Start and End of Follow-Up. Participants will be followed from baseline until the occurrence of incident dementia, death, or the end of follow-up, whichever occurs first.

Causal Contrasts of Interest. The study will estimate intention-to-treat effect, which indicates the effectiveness of assignment to hearing aids intervention on incident dementia.

Analysis Plan. Pooled logistic regression models will be fitted to predict the cumulative 8-year risk of dementia in both the intervention and control groups.

# **Emulation of Target Trial**

Eligibility Criteria. We included individuals aged ≥50 years at baseline (Wave 10, 2010) in the HRS study, who were free of dementia and had hearing impairment but hearing aids use in the previous 2 years. Hearing impairment, prior hearing aids use, and dementia status were obtained from self-report questionnaire in the HRS.

Intervention Strategies and Assignment. The intervention strategies were consistent with the target trial, and hearing aids initiation was obtained from self-report questionnaire in the HRS. Baseline covariates were balanced between the intervention and control groups.

Outcome of Interest, End of Follow-Up, and Outcome. The outcome was incident dementia during 8 years of follow-up from 2010 to 2018, which was based on self-report. Participants were followed from baseline (Wave 10, 2010) until the occurrence of dementia, loss to follow-up, death, or the end of 2018, whichever occurred first.

Causal Contrasts of Interest. We estimated observational analogue of intention-to-treat effect in the emulated target trial, which was the effect of hearing aids initiation vs no hearing aids initiation.

Analysis Plan. We fit the pooled logistic regression model, weighted with stabilized inverse-probability of treatment weights (IPTW) and inverse-probability of censoring weights (IPCW) to calculate the cumulative incidence of dementia in both the intervention and control groups. The IPTW and IPCW were based on the joint distribution of baseline covariates, including baseline age, sex, race, education, body mass index, current smoking, cognitive function, prevalent hypertension, diabetes, heart disease, and stroke to calculate the cumulative incidence of dementia in the intervention group and control group.<sup>24</sup>

## Statistical Analysis

Risk differences (RDs) over 8 years of follow-up were calculated based on the cumulative risk in the 2 groups. We used 1000 sets of bootstrapping to calculate the 95% confidence intervals (CIs) for the RDs. The effects were statistically significant if the CIs for RDs did not include 0. Deaths were censored in the analysis. In addition, we conducted the emulated target trials above after stratifying by age (50–74 years, ≥75 years), sex, and cardiovascular disease (CVD) status at baseline (having heart disease and/or stroke vs not). All statistical analyses were conducted using SAS 9.4 (Cary, NC).

### **Results**

## Characteristics of Participants

A total of 2314 participants met the eligibility criteria, including 328 in the intervention group and 1986 in the control group. The average age was  $72.3 \pm 9.7$  years, with 48.8% women, and 81.1% identifying as White. The prevalence of hypertension, diabetes, heart disease, and stroke was 69.7%, 28.1%, 34.6%, and 10.1%, respectively, and had no statistically significant difference between initiators and non-initiators of hearing aids. Although initiators had a higher proportion of Whites (89.3% vs 79.7%), higher level of education (at least some college: 50.9% vs 33.7%), lower body mass index (27.5 kg/m<sup>2</sup> vs 28.5 kg/m<sup>2</sup>), and lower prevalence of current smoking (7.9% vs 12.2%), all of these covariates were balanced between initiators and noninitiators with no statistical difference after applying IPTW (Table 1).

## Hearing Aids Initiation and Incidence of Dementia

During 8 years of follow-up with a total of 14 728 person-years, a total of 149 incident dementia cases occurred. Participants who initiated hearing aids had lower risk of incident dementia after 2, 4, 6, and 8 years of follow-up (2 years: RD = -0.02, 95% CI: -0.03, -0.01; 4 years: RD = -0.03, 95% CI: -0.05, -0.01; 6-years: RD = -0.04, 95% CI: -0.07, -0.01; 8 years: RD = -0.05, 95% CI: -0.08, -0.01) (Figure 1, Table 2).

# Results by Age

Stratifying by age, among participants aged 50 to 74 years old, those who initiated hearing aids had lower risk of incident dementia after 2, 4, 6, and 8 years of follow-up (2 years: RD = -0.01, 95% CI: -0.02, -0.003; 4 years: RD = -0.03, 95% CI: -0.04, -0.02; 6 years: RD = -0.04, 95% CI: -0.06, -0.03; 8 years: RD = -0.04, 95% CI: -0.07, -0.02). Among participants aged  $\geq 75$  years, those

	Without IPTW		With IPTW	
	Initiators (n = 328)	Non-initiators (n = 1986)	Initiators (n = 312)	Non-initiators (n = 1989)
Age, years	76.5 ± 8.4	71.6 ± 9.8	73.4 ± 8.6	72.3 ± 10.0
Female, n (%)	154 (47.0)	975 (49.1)	146 (46.7)	969 (48.7)
Race				
White/Caucasian	293 (89.3)	1583 (79.7)	257 (82.4)	1614 (81.1)
Black/African American	18 (5.5)	295 (14.9)	39 (12.5)	269 (13.5)
Other	17 (5.2)	108 (5.4)	16 (5.1)	107 (5.4)
Education				
Below high school	43 (13.1)	594 (29.9)	74 (23.8)	547 (27.5)
GED	18 (5.5)	125 (6.3)	24 (7.8)	123 (6.2)
High school graduate	100 (30.5)	597 (30.1)	98 (31.3)	599 (30.1)
Some college	77 (23.5)	362 (18.2)	57 (18.2)	376 (18.9)
College and above	90 (27.4)	308 (15.5)	59 (19.0)	344 (17.3)
Current smoking	26 (7.9)	243 (12.2)	40 (12.7)	231 (11.6)
Body mass index, kg/m <sup>2</sup>	27.5 ± 5.5	28.5 ± 6.3	28.1 ± 5.5	28.4 ± 6.2
Hypertension, n (%)	217 (66.2)	1394 (70.2)	214 (68.7)	1384 (69.6)
Diabetes, n (%)	80 (24.4)	570 (28.7)	88 (28.1)	559 (28.1)
Heart disease, n (%)	118 (36.0)	684 (34.4)	114 (36.7)	691 (34.7)
Stroke, n (%)	26 (7.9)	207 (10.4)	34 (10.9)	200 (10.1)

 $<sup>^{</sup>a}$ IPTW: inverse probability of treatment weight; GED: general educational development. The bolded parts indicate statistically significant difference between groups (P < 0.05).

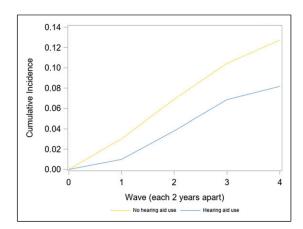


Figure 1. Cumulative incidence of dementia for initiators and non-initiators of hearing aids.

who initiated hearing aids had lower risk of incident dementia after 2 years of follow-up (RD = -0.03, 95% CI: -0.05, -0.004), but not after 4, 6, or 8 years (Figure 2(A) and (B), Table 3).

## Results by Sex

Stratifying by sex, men who initiated hearing aids had lower risk of incident dementia after 2, 4, 6, and 8 years of follow-up (2 years: RD = -0.01, 95% CI: -0.02, -0.0005; 4 years: RD = -0.03, 95% CI:

**Table 2.** Cumulative Incidence of Dementia Among Initiators and Non-initiators of Hearing Aids.

	Cumulative in	ncidence	
	Non-initiators	Initiators	Risk difference (95% CI)
2 years	0.030	0.010	-0.02 (-0.03, -0.01)
4 years	0.069	0.038	$-0.03\ (-0.05, -0.01)$
6 years	0.104	0.069	-0.04 (-0.07, -0.01)
8 years	0.127	0.082	-0.05 (-0.08, -0.01)

$$-0.05$$
,  $-0.001$ ; 6 years: RD =  $-0.04$ , 95% CI:  $-0.08$ ,  $-0.01$ ; 8 years: RD =  $-0.05$ , 95% CI:  $-0.09$ ,  $-0.01$ ).

Among women, those who initiated hearing aids had lower risk of incident dementia after 2 and 4 years, but not after 6 or 8 years (Figure 2(C) and (D), Table 3).

# Results by CVD Status

Among participants with heart disease or stroke, those who initiated hearing aids had lower risk of incident dementia after 2, 4, and 8 years of follow-up (2 years: RD = -0.05, 95% CI: -0.07, -0.03; 4 years: RD = -0.07, 95% CI: -0.11, -0.02; 8 years: RD = -0.07, 95% CI: -0.15, -0.01).

Among participants without heart disease or stroke, no significant difference in risk of dementia was observed

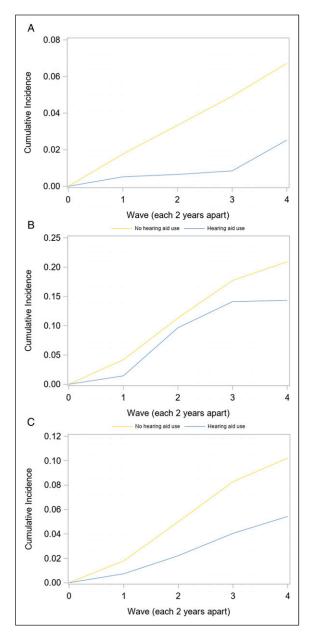


Figure 2. Cumulative incidence of dementia for initiators and non-initiators of hearing aids among participants who were (A) 50-74 years, (B) ≥75 years, (C) men, (D) women, (E) with cardiovascular disease at baseline, (F) without cardiovascular disease at baseline.

over time between initiators and non-initiators of hearing aids (Figure 2 (E) and (F), Table 3).

# **Discussion**

In an emulated target trial of hearing aids initiation and incident dementia, we found that midlife and late-life adults who initiated hearing aids had reduced subsequent risk of dementia after controlling for other dementia risk factors. After 8 years of follow-up, initiation of hearing aids was associated with a reduced risk of dementia particularly among adults aged 50-74 years, men, and individuals with CVD.

Prior observational studies have explored associations between hearing aids use and cognitive outcomes, including cognitive function, cognitive decline, mild cognitive impairment, and incident dementia. The results of these studies were inconsistent—while some studies showed associations between hearing aid use and more favorable cognitive outcomes, others did not. Potential explanations of these discrepancies may include differences in severity and duration of hearing loss, duration of hearing aid use, as well as different availability of hearing aid use, which could potentially cause underlying confounding even after adjustment for covariates.

Despite positive findings in some observational studies, prior evidence regarding the effectiveness of using hearing aids for reducing risk of dementia is lacking. In the ACHIEVE trial, based on participants of ARIC study and healthy de novo community volunteers, the overall results did not indicate significant effectiveness. However, among ARIC participants, who had high risk of dementia, the results suggested slower cognitive decline with hearing aids use. This suggests that hearing aids may be part of a strategy for prevention of dementia particularly in individuals with high levels of dementia risk factors. Nonetheless, the ACHIEVE trial was inconclusive and left key questions unanswered, including (1) the effectiveness of hearing aids use on dementia risk over a longer period of time, and (2) the effectiveness among younger adults in midlife. To further explore the potential benefits of using hearing aids, we estimated the risk of dementia associated with hearing aids initiation across a longer period of follow-up, which is difficult to achieve in a typical RCT.

Several mechanisms may potentially explain our findings. First, by improving hearing, hearing aids enable better social interaction, <sup>27</sup> which may stimulate brain activity and potentially reduce the development or delay the onset of dementia. Similarly, the increased social engagement enabled by hearing aids may help alleviate emotional issues (eg, depressive symptoms, loneliness), <sup>28</sup> which may also reduce the risk of dementia. Although amplification of sound could facilitate processing of auditory information and thus reduce cognitive load, <sup>29</sup> ACHIEVE showed no interaction between hearing intervention and severity of hearing loss, suggesting that social interactions and their associated risk factors may be the major underlying mechanisms.

We found that the relationship between hearing aids initiation and incident dementia differed across

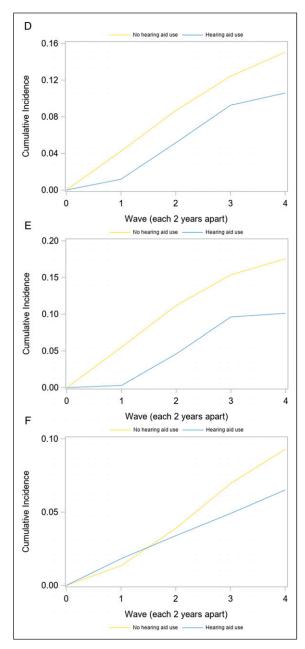


Figure 2. Continued.

subgroups, particularly by age and CVD status. Significantly lower risk of dementia was found after initiation of hearing aids among individuals with existing CVD, who have higher baseline risk of dementia, but not among those without CVD. This is consistent with findings from the ACHIEVE trial, which indicated significantly less cognitive decline with hearing intervention among individuals with high risk of dementia. Also, our results suggested that hearing aid initiation was associated with long-term reduction in dementia risk among participants aged 50-74 but not ≥75 years. This is potentially

explained by the fact that cognitive decline starts from midlife, <sup>30</sup> and thus irreversible changes may have occurred so that the intervention was less effective among older adults. This suggests that early initiation of hearing aids among those with hearing loss may be especially important for the prevention of dementia. It is also possible that accumulation of unfavorable factors associated with hearing loss (eg, loneliness or depressive symptoms) over a longer period may be associated with higher risk of dementia, further calling for timely intervention. While it is possible that people in midlife to early older adulthood may have longer adherence to hearing aids use compared to adults aged ≥75 years, their time with hearing aids in the present study was similar (3.1 vs 2.8 years).

Given the high prevalence of hearing loss and dementia in the U.S., our findings suggest that hearing aids may be an important tool to help reduce the risk of dementia. However, there are barriers that frequently prevent people from using hearing aids.<sup>31</sup> First, hearing loss remains underdiagnosed and undertreated in the U.S., which may reflect a lack of awareness among the general public and health professionals about the important health consequences of hearing loss.<sup>32</sup> Also, hearing aids can be expensive and insurance coverage is limited, which may be prohibitive for many individuals with hearing loss.<sup>33</sup> In addition, accessing hearing care can be a challenge, particularly in rural or underserved areas.<sup>34</sup> Last but not least, hearing aids can be complex devices to operate without appropriate guidance. To alleviate these difficulties, it is essential to raise awareness of the benefits of using hearing aids among people with hearing loss, promote equal access and insurance coverage, and provide guidance to enable appropriate use of hearing aids.

Our study has a few limitations. First, hearing loss, hearing aids use, dementia, and most covariates were based on self-report, which might be subject to misclassification. We could not rule out the possibility of unknown and unmeasured confounding, which may be associated with both hearing aids use and dementia, although we used statistical weighting methods to balance various observed covariates between the intervention and control groups. In addition, the study population only includes participants who are 50 years or older, whereas it may be optimal to include even younger participants. Despite these limitations, we were able to emulate a target trial to estimate the reduced risk of dementia after hearing aids initiation in a longitudinal cohort with a large sample and substantial follow-up period.

In conclusion, in an emulated target trial, initiation of hearing aids use among midlife and late-life adults was associated with a lower risk of dementia after controlling for other dementia risk factors. Future interventional

**Table 3.** Cumulative Incidence of Dementia Among Initiators and Non-initiators of Hearing Aids, Stratified by Age, Sex, and Cardiovascular Disease at Baseline.

		Cumulative incidence		Risk difference (95% CI)
50-74 years (n = 1358)		Non-initiators	Initiators	
,	2 years	0.018	0.005	-0.01 (-0.02, -0.003)
	4 years	0.033	0.006	-0.03(-0.04, -0.02)
	6 years	0.049	0.008	-0.04 (-0.06, -0.03)
	8 years	0.067	0.025	-0.04 (-0.07, -0.02)
≥75 years (n = 956)		Non-initiators	Initiators	Risk difference (95% CI)
, , ,	2 years	0.042	0.014	-0.03 (-0.05, -0.004)
	4 years	0.113	0.097	-0.02 (-0.07, 0.04)
	6 years	0.177	0.141	-0.04 (-0.11, 0.03)
	8 years	0.209	0.143	-0.07 (-0.14, 0.01)
Men (n = 1185)		Non-initiators	Initiators	Risk difference (95% CI)
	2 years	0.018	0.007	-0.01 (-0.02, -0.0005)
	4 years	0.050	0.022	$-0.03 \; (-0.05,  -0.001)$
	6 years	0.083	0.040	$-0.04 \; (-0.08,  -0.01)$
	8 years	0.102	0.054	$-0.05 \; (-0.09,  -0.01)$
Women (n = 1129)		Non-initiators	Initiators	Risk difference (95% CI)
	2 years	0.042	0.012	$-0.03 \; (-0.05,  -0.01)$
	4 years	0.087	0.052	$-0.03 \; (-0.07,  -0.001)$
	6 years	0.124	0.093	-0.03 (-0.08, 0.02)
	8 years	0.150	0.106	$-0.04 \; (-0.10,  0.01)$
With heart disease or stroke (n = 942)		Non-initiators	Initiators	Risk difference (95% CI)
	2 years	0.055	0.003	-0.05 (-0.07, -0.03)
	4 years	0.112	0.046	-0.07 ( $-$ 0.11, $-$ 0.02)
	6 years	0.154	0.096	$-0.06 \; (-0.13,  0.001)$
	8 years	0.176	0.101	$-0.07 \; (-0.15,  -0.01)$
Without heart disease or stroke (n = 1372)		Non-initiators	Initiators	Risk difference (95% CI)
	2 years	0.013	0.018	0.005 (-0.02, 0.02)
	4 years	0.039	0.034	-0.005 (-0.04, 0.02)
	6 years	0.069	0.049	$-0.02 \; (-0.05,  0.01)$
	8 years	0.093	0.065	$-0.03 \ (-0.06, \ 0.01)$

studies are needed to further assess the effectiveness of hearing aids in preventing dementia.

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The data and analytic methods are available to other researchers for replication purposes. The data can be accessed at <a href="https://hrs.isr.umich.edu/data-products">https://hrs.isr.umich.edu/data-products</a>, and the study reported in the manuscript was not pre-registered.

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