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Peer-reviewed / Randomised trial / People

***The Lancet*: First randomised trial finds hearing aids might reduce cognitive decline in older adults—but only in those at higher risk of dementia**

- *Two distinct US study populations were included in the trial—a cohort at higher risk of cognitive decline and one of healthy volunteers, all aged 70-84—and two distinct analyses were performed.*
- *When combining both the cohorts as one population, no difference in cognitive decline was detected over 3 years between the group using hearing aids and the one that wasn't.*
- *In the second analysis, looking specifically at the cohort at greater risk of cognitive decline, there was 48% less cognitive change over 3 years in the group who received hearing aids compared to the one that didn't.*
- *Findings underscore importance of treating hearing loss in older populations as potential way to reduce global burden of dementia.*

While hearing aids and audiological support services did not have any impact on cognitive decline over 3 years in a general population of older adults, treating hearing loss protected against cognitive decline in older adults at greater risk of dementia.

The findings of the first randomised controlled trial (RCT) of its kind involving nearly 1,000 older adults from multiple locations across the USA, published in *The Lancet*, add to the growing evidence that addressing hearing impairment may be a critically important global public health target for dementia prevention efforts. The study is presented at the Alzheimer's Association International Conference (AAIC).

"These results provide compelling evidence that treating hearing loss is a powerful tool to protect cognitive function in later life, and possibly, over the long term, delay a dementia diagnosis," says Professor Frank Lin of Johns Hopkins University School of Medicine and Bloomberg School of Public Health. "But any cognitive benefits of treating age-related hearing loss are likely to vary depending on an individuals' risk of cognitive decline." [1]

Age-related hearing loss is extremely common, affecting two-thirds of adults aged over 60 globally, but less than 1 in 10 individuals with hearing loss in low- and middle-income countries, and fewer than 3 in 10 in high-income countries, currently use hearing aids [2].

Untreated hearing loss is associated with greater cognitive decline and was estimated by the 2020 *Lancet* Commission on Dementia to contribute to around 8% of dementia cases worldwide—equivalent to 800,000 of the nearly 10 million new cases of dementia diagnosed every year [3].

Current thinking suggests several ways that untreated hearing loss may contribute to cognitive decline and dementia. Hearing loss can make the brain work harder to the detriment of other mental functions like thinking and memory. Another possibility is that hearing loss causes the ageing brain to shrink more quickly. A third possibility is that hearing loss leads people to be less socially engaged and the reduced stimulation may result in brain atrophy.

While previous observational research suggests that treating hearing loss may protect against cognitive

decline and dementia, these studies may be biased because individuals who have the means and choose to get their hearing loss treated may be healthier and at lower risk of cognitive decline than those who don't. As a result, the effectiveness of hearing aid use on reducing cognitive decline in cognitively-healthy older adults with hearing loss remained unclear.

To provide more robust evidence, the ACHIEVE randomised trial included 977 adults aged 70–84 years with untreated hearing loss who were free from substantial cognitive impairment in four communities across the USA.

Participants were recruited from two populations at each site: older adults participating in a longstanding observational study of cardiovascular health (Atherosclerosis Risk in Communities [ARIC] study [4]), and new volunteers from the same communities who were generally healthier than participants from ARIC.

Participants were randomised to either a hearing intervention (audiological counselling and hearing aids) or the control intervention involving more generalised counselling on healthy ageing (individual sessions with a health educator covering topics on chronic disease and disability prevention), and were followed-up twice a year over 3 years.

The primary endpoint was 3-year change in a global cognition score from a comprehensive series of tests of executive function, language, and memory completed at the start of the study and then annually. Tests included delayed word recall, incidental learning, logical memory, and digit span backwards among others.

Between January 2018 and October 2019, 977 participants (238 from ARIC and 739 healthy volunteers) were randomly assigned to hearing intervention (490 participants; 120 from ARIC and 370 volunteers) or health education control (487; 118 from ARIC and 369 volunteers).

On average, participants from ARIC were more likely to be older, female, have more risk factors for cognitive decline (e.g., lower education and income, higher rates of diabetes and high blood pressure, be living alone) and have lower cognition scores at the start of the study than the volunteer cohort. Both cohorts had similar hearing levels at the start of the study.

The primary analysis of the results, combining both the ARIC and volunteer cohorts, found that the hearing intervention did not reduce cognitive decline over time—with no significant difference in cognitive change between those receiving the hearing intervention and the health education control over 3 years (-0.200 vs -0.202 standard deviation units).

The researchers also did a sensitivity analysis (pre-specified in the trial design) to examine the effect of the hearing intervention within the ARIC cohort (who are at greater risk of cognitive decline) and the healthy volunteers.

In the ARIC cohort, 3-year cognitive change was 48% lower in the hearing intervention group than the control group (-0.211 vs -0.402 standard deviation units).

In contrast, in the healthy volunteer cohort (who had fewer risk factors for cognitive decline and a much slower rate of cognitive decline), 3-year cognitive change did not differ significantly between the hearing intervention and control groups (-0.213 vs -0.151 standard deviation units).

No significant adverse events were reported in either group.

“Although our primary analysis of the combined ARIC and health volunteer cohorts did not find a difference in cognitive decline for those using hearing aids, when we did sensitivity analyses to test its robustness there was clear evidence indicating a significant benefit for older adults in the ARIC cohort who had more risk factors for cognitive decline,” says Professor Lin.

He continues, “Despite similar levels of hearing at the start of the study, it's likely that volunteers in the

healthier cohort experienced slower rates of cognitive change than ARIC participants because they tended to be younger, had fewer risk factors for cognitive decline, and had better initial cognitive scores. This much slower rate of cognitive decline may have limited any effect of hearing aids in further reducing this decline over the relatively short 3-year follow-up.” [1]

Co-author Professor Marilyn Albert from Johns Hopkins University School of Medicine, USA, adds, “We eagerly await the follow-up of ACHIEVE that is currently underway to examine the longer-term effects of hearing aids on cognition in populations at lower risk of dementia. Further analyses of MRI and social engagement data will also improve our understanding of the ways in which hearing aids may help delay cognitive decline.” [1]

The study provides the first RCT-level evidence to support treating hearing loss to reduce cognitive decline in older at-risk adults, confirming conclusions by the 2020 Lancet Commission on Dementia and the 2022 United States National Plan to Address Alzheimer’s Disease that called for treating age-related hearing loss to supplement existing national dementia risk reduction strategies.

Despite the important findings, the authors note some limitations including that participants and researchers could not be masked to the intervention, which could potentially bias the results, and that two of the 10 neurocognitive tests contained only auditory stimuli, so individuals receiving the health education control with untreated hearing loss could potentially perform more poorly on these tests.

Writing in a linked Comment, Professor Gill Livingston from University College London, UK (who was not involved in the study) says, “We also need long-term follow-up of this unique study to see if the hearing intervention results in cognitive differences over time, particularly in healthy volunteers. Finally, we urgently need more trials in other settings, using the lessons learnt about the need to focus on purposively sampled populations at high risk of cognitive decline and dementia. Overall, the findings from this study are hopeful. Hearing aids could really make a difference for populations at risk of dementia.”

NOTES TO EDITORS

This study was funded by the US National Institutes of Health. It was conducted by researchers from Johns Hopkins University, USA; University of South Florida, USA; University of North Carolina, USA; Edinburgh Napier University, UK; Wake Forest University School of Medicine, USA; Mayo Clinic, USA; University of Mississippi Medical Center, USA; and University of Minnesota School of Public Health, USA.

The labels have been added to this press release as part of a project run by the Academy of Medical Sciences seeking to improve the communication of evidence. For more information, please see: <http://www.sciencemediacentre.org/wp-content/uploads/2018/01/AMS-press-release-labelling-system-GUIDANCE.pdf> if you have any questions or feedback, please contact The Lancet press office pressoffice@lancet.com

[1] Quotes direct from authors and cannot be found in text of paper.

[2] [World report on hearing \(who.int\)](#)

[3] [Risk factors for dementia \(thelancet.com\)](#) / [Dementia \(who.int\)](#)

[4] The Atherosclerosis Risk in Communities (ARIC) observational study is an ongoing longitudinal study of over 15,000 US adults aged 45-64 years when initially recruited (1987-1989) from a random sample of the communities of Forsyth County, North Carolina; Jackson, Mississippi; Minneapolis suburbs, Minnesota; Washington County, Maryland. The aim is to understand risk factors for heart disease and stroke and the connections between cardiovascular and cognitive health. ARIC participants have been followed since 1989 and undergone four sets of neurocognitive testing.

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For embargoed access to the Article and Comment, please see: www.thelancet-press.com/embargo/dementiahearingaids.pdf

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