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ADMINISTRATIVE INFORMATION**Support** - Research Establishment Funds.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202640026**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 April 2026 and was last updated on 8 April 2026.**INTRODUCTION**

Review question / Objective The current literature suggests a possible association between tinnitus and cognitive impairment, and emerging cohort evidence indicates that tinnitus may be linked to an increased risk of later dementia. This review aims to systematically synthesize and summarize the evidence on whether tinnitus contributes to an increased risk of mild cognitive impairment (MCI) or dementia, identify gaps in the literature, and highlight directions for future research. Additionally, where appropriate, meta-analyses will be conducted to calculate a pooled odds ratio comparing the prevalence of tinnitus in patients with MCI or dementia with that in cognitively healthy controls.

Rationale Tinnitus is a common condition among middle-aged and older adults, and growing evidence suggests it may be linked to cognitive decline. Although several recent studies have examined the relationship between tinnitus, MCI, and dementia, no comprehensive synthesis has yet clarified the strength or nature of this association.

Understanding whether tinnitus contributes to increased dementia risk is important for early identification, prevention strategies, and clinical management. A systematic review and meta-analysis are therefore needed to consolidate current evidence and guide future research.

Condition being studied Tinnitus is a perceptual phenomenon defined by the experience of sound in the absence of an external auditory stimulus. The prevalence of tinnitus increases with age, ranging from 10% to 15% in adults and up to 40% among older adults worldwide. Chronic tinnitus is frequently associated with a wide spectrum of psychological and comorbid symptoms, including emotional distress, frustration, difficulty relaxing, challenges in concentration, and mental health conditions such as anxiety, depression, stress, and insomnia.

METHODS

Search strategy We will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines. Several

electronic databases will be searched, including PubMed, Embase, Scopus, Ovid Medline, ProQuest, and ScienceDirect. The search will have no restrictions on language, publication status, or date. The combined search terms will include: "tinnitus" AND ("dementia" OR "Alzheimer*" OR "mild cognitive impairment"). Additionally, the reference lists of all included studies will be manually screened to identify any potentially relevant articles missed in the database search.

Participant or population Peer-reviewed articles on middle-aged or older adults with dementia or MCI, as well as tinnitus.

Intervention Not applicable.

Comparator With or without a control group (cognitively healthy middle-aged or older adults).

Study designs to be included Original research article.

Eligibility criteria Articles other than original research papers (e.g., various types of reviews, books, book chapters, case reports, short reports, commentaries, and editorials) will be excluded.

Information sources Only original research published in peer-reviewed journals will be considered. For studies with missing or unclear data required for meta-analysis, the corresponding authors will be contacted to obtain the necessary information.

Main outcome(s) Main Outcome(s):

The primary outcomes of this review are:

- Risk of dementia in individuals with tinnitus compared to those without tinnitus.
- Risk of MCI in individuals with tinnitus compared to cognitively healthy controls.

Secondary outcomes may include: Associations between tinnitus severity or duration and the risk of MCI or dementia.

Data management All records identified through database searches will be imported into reference management software (e.g., EndNote or COVADANCE) to remove duplicates. Screening of titles, abstracts, and full texts will be conducted independently by two reviewers, with disagreements resolved by discussion or a third reviewer. Data from included studies will be extracted into a pre-designed Microsoft Excel spreadsheet, including study characteristics, participant details, exposure (tinnitus) measures, cognitive outcomes, and key findings. The extracted data will be checked for accuracy and

completeness by a second reviewer. All files and datasets will be securely stored on a password-protected computer, with regular backups to ensure data integrity.

Quality assessment / Risk of bias analysis The Crowe Critical Appraisal Tool (CCAT) will be used to assess the quality of the included studies. Each study will be evaluated across eight domains: preliminaries, introduction, study design, data collection, sampling, ethical considerations, results/outcomes, and discussion. Each domain is scored on a six-point scale (0–5), giving a total possible score of 40, with higher scores indicating higher methodological quality. Studies scoring ≥ 30 ($\geq 75\%$) will be considered "high-quality," scores between 21 ($\geq 50\%$) and 29 ($< 75\%$) will be considered "moderate-quality," and scores ≤ 20 ($< 50\%$) will be classified as "poor-quality." Two reviewers will independently conduct the quality assessment, and any disagreements will be resolved by discussion or consensus. The quality of evidence will also be evaluated and verified by a second reviewer to ensure accuracy and consistency.

Strategy of data synthesis A narrative synthesis will be conducted to summarize the characteristics and findings of all included studies, including study design, population, tinnitus assessment, cognitive outcomes, and key results. Where sufficient quantitative data are available, meta-analyses will be performed using a fixed-effect or random-effects model, depending on the level of heterogeneity. Pooled odds ratios (ORs) with 95% confidence intervals (CIs) will be calculated to compare the prevalence of MCI or dementia between individuals with and without tinnitus. Heterogeneity will be assessed using the I^2 statistic and Cochran's Q test. Publication bias will be assessed using funnel plots and Egger's test.

Subgroup analysis Subgroup analyses will be conducted based on age, sex, and tinnitus severity, where data permit.

Sensitivity analysis Sensitivity analyses will be performed to evaluate the robustness of the findings if enough studies are included in a meta-analysis.

Language restriction The literature search will have no restrictions on language, publication status, or date.

Country(ies) involved Canada.

Keywords Tinnitus; Mild Cognitive Impairment; Dementia; Alzheimer's disease.

Dissemination plans The findings of this systematic review and meta-analysis will be disseminated through publication in a peer-reviewed scientific journal and presentation at relevant national and international conferences. Additionally, summaries of the results may be shared with healthcare professionals, researchers, and patient advocacy groups to inform clinical practice and guide future research on the relationship between tinnitus and cognitive decline.

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