

**Effects of Cognitive Behavioural Therapy on insomnia in adults with tinnitus:
systematic review and meta-analysis of randomised controlled trials**

¹Ffion Curtis, ¹Despina Laparidou, ²Chris Bridle, ¹Graham Law, ¹Simon Durrant, ^{1,3}Alina Rodriguez ^{4,5}Robert H. Pierzycki, ¹A. Niroshan Siriwardena

¹Lincoln International Institute for Rural Health, University of Lincoln

²University of Bedfordshire, Luton

³School of Public Health, Imperial College London

⁴NIHR Nottingham Biomedical Research Centre, Ropewalk House, 113 The Ropewalk, Nottingham NG1 5DU, UK.

⁵Hearing Sciences, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, Nottingham NG7 2UH, UK.

Corresponding author: Dr Ffion Curtis, Email: fcurtis@lincoln.ac.uk

Lincoln International Institute for Rural Health,

University of Lincoln,

Brayford Pool.

LN6 7TS

Summary

Insomnia is common in patients with tinnitus and negatively affects tinnitus symptoms and quality of life. This systematic review aimed to synthesise evidence of the effectiveness of cognitive behavioural therapy (CBT) based interventions on insomnia in adults with tinnitus. We conducted a comprehensive database search (MEDLINE, CINAHL, Web of Science, CENTRAL, ClinicalTrials.gov and PROSPERO) for published, unpublished and ongoing randomised controlled trials of CBT in adults with tinnitus. Five trials met the inclusion criteria for the systematic review, with four of these providing data for the meta-analysis. This demonstrated a statistically significant reduction in Insomnia Severity Index (a standard diagnostic questionnaire of insomnia used in clinical settings) following CBT (-3.28, 95% CI -4.51, -2.05, $P < 0.001$). There was no evidence of statistical heterogeneity ($I^2 = 0\%$). Risk of bias was considered low in all categories except blinding of participants, personnel, and/or the assessment of outcomes. Here, for the first time, we demonstrate that CBT based interventions can significantly improve sleep in adults with tinnitus.

Keywords:

Insomnia; Cognitive behaviour therapy; Tinnitus

Glossary of terms

CBT cognitive behavioural therapy

CBTi cognitive behavioural therapy for insomnia

CI confidence intervals

ISI insomnia severity index

MD mean difference

PRISMA preferred reporting items for systematic review and meta-analysis

RevMan review manager

THI Tinnitus Handicap Inventory

TRQ Tinnitus Reaction Questionnaire

Background

Tinnitus is defined as the perception of sound in the absence of a corresponding external acoustic stimulus [1]. Due to variations in the definitions and diagnostic criteria, the prevalence rates of tinnitus range widely with estimates varying from 5.1 to 42.7% [2]. At least 13% of the UK population are living with persistent tinnitus [3], with prevalence rates set to rise as a consequence of increased leisure and occupational noise-induced hearing loss [1]. Tinnitus is often associated with symptoms such as anxiety, depression, and difficulties with sleep which can contribute to the perceived distress from tinnitus and reduced quality of life [4]. Whilst causal pathways have not been confirmed, correlations have been observed between reported sleep disturbances and tinnitus severity [5, 6]. Despite the well documented association between tinnitus and insomnia, and the significant impact of both conditions, insomnia is currently rarely treated directly in this population. As many as 80% of patients with tinnitus report comorbid insomnia [7], and the management of tinnitus-related insomnia has been identified as a priority for further research [8].

Patients with tinnitus related insomnia have sleep architecture abnormalities very similar to those with primary insomnia [9], and different to healthy controls [10]. Once present, it is thought that tinnitus related insomnia is maintained via the same cognitive, behavioural, emotional and attentional mechanistic pathways as primary insomnia [9]. It is well established that cognitive behavioural therapy (CBT) is an effective treatment for the management of primary insomnia [11], and there is emerging evidence to suggest that it may also improve tinnitus related insomnia. Findings from single arm study demonstrated that a

CBT intervention for tinnitus related insomnia (CBTi) significantly reduced both insomnia and tinnitus distress in 24 patients with chronic distressing Tinnitus [12]. CBT is also effective in the management of tinnitus [13, 14], and some randomised controlled trials of CBT interventions for tinnitus have included insomnia as a secondary outcome. CBT for tinnitus significantly improved both tinnitus distress and measures of insomnia [15].

Considering the potential complex interaction between these two conditions there is a need to provide the evidence to underpin treatment options for tinnitus related insomnia.

The aim of this systematic review was to synthesise evidence of the effectiveness of CBT interventions on insomnia in adults with tinnitus.

Methods

This review was reported in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) guidelines [16], see supplementary material: S 1 PRISMA Checklist. The inclusion criteria and methods of analysis were pre-specified and documented in a protocol (ID = CRD42018093355) which is available on the International Prospective Register of Systematic Reviews (<http://www.crd.york.ac.uk/PROSPERO>).

Eligibility Criteria

Studies were considered for inclusion if they were randomised controlled trials (RCTs) or quasi-randomised controlled trials that reported sleep outcomes for adults with tinnitus in a home or a care setting. The review included RCTs that delivered any CBT to adults with tinnitus.

Study Identification

To identify existing relevant systematic reviews, published and ongoing trials the following electronic databases were searched from inception to December 2019: MEDLINE, CINAHL, Web of Science: Core Collection, CENTRAL ClinicalTrials.gov and PROSPERO. There were no restrictions on the publication language. Database searching was supplemented with internet searching (e.g. Google Scholar), and forward and backward citation tracking from systematic reviews and included studies. Key terms used to search databases included: (*tinnitus OR cochlear disease* OR vestibulocochlear nerve disease**) AND (*insomnia OR sleep disorder* OR sleep disturbance* OR sleepless**), see supplementary material S2 search strategy for example of MEDLINE full search strategy. Search results were downloaded to Endnote, duplicate citations were removed, and titles and abstracts screened independently by two reviewers against the inclusion criteria. Where studies could not be excluded based on title and abstract, the reviewers assessed full papers for relevance independently. Any discrepancies were resolved through discussion.

Data Abstraction

We developed, tested and refined a structured data extraction template. One reviewer extracted data about each study which was then cross-checked for accuracy by a second reviewer. The extracted data included information about: trial characteristics and design (title, author, aim of study, country, design, inclusion/exclusion criteria, recruitment, randomisation, blinding of participants and study team, allocation concealment), participants (sample size, age, gender, tinnitus severity and duration), intervention components (description, target, CBT components, comparator, mode of delivery, dose, time to follow up) and key findings (primary and secondary outcomes).

Risk of Bias Assessment

Two reviewers independently assessed risk of bias using the Cochrane Risk of Bias assessment tool on key dimensions which included: random sequence generation, allocation concealment, blinding, and incomplete outcome data. Each domain was classified as adequate (low risk of bias), inadequate (high risk of bias) or unclear (not possible to determine risk of bias). Two reviewers independently examined and agreed on the risk of bias of the included studies. An overall study risk of bias was not assessed and data for each domain are presented for readers to interpret in context with review findings. Risk of bias assessment was not used as a reason for exclusion.

Data Analysis

All analyses were conducted using Review Manager (RevMan) version 5.3. The primary outcome was a mean difference in sleep as measured by the Insomnia Severity Index (ISI) questionnaire. The summary measure of treatment effect was the between groups difference in the post intervention ISI scores expressed as a mean difference (MD).

Random-effects models were used in all meta-analyses, as they are more conservative than the fixed effects models since, by incorporating within- and between-study variance, the confidence intervals for the summary effect are wider. Statistical heterogeneity was assessed using the I^2 test, which described the percentage of variability among effect estimates beyond that expected by chance. Sources of clinical and methodological diversity were explored where I^2 values were $\geq 40\%$.

Results

The search strategy identified 3,028 distinct citations, of which 2,759 were excluded during the first screening phase (see figure 1). Full text papers were ordered for the remaining 57

citations. Five studies [17, 15, 18, 19, 20] met the inclusion criteria for the systematic review and four of those provided data for statistical analysis.

Figure 1 Flow diagram of study selection [16].

Characteristics of Included Studies

The five included studies were conducted between 2005 and 2017. Four of the studies [15, 18, 19, 20] were included in the meta-analysis as they included ISI as an outcome measure. Andersson et al. [17] met the inclusion criteria for the systematic review, however they did not include ISI as their measure of sleep so could not be included in the data synthesis (see table 1). Participants in this trial rated their quality of sleep on visual analogue scales from 'much pleased' to 'not at all pleased'. The four studies included in the meta-analysis randomised 470 participants, 43 of whom were not included in the analysis as they formed a third arm (group based CBT) in the study by Jasper et al. [18]. The internet CBT arm was selected for inclusion as it best matched the other intervention groups within the included studies, and it is not appropriate to include more than one study data set in the meta-analysis. Participant age ranged from 22 to 83 years with both male and female participants in the included studies.

The interventions were internet-based except for Andersson et al. [17] which involved group sessions, and Kaldo et al. [19] who delivered treatment via a self-help book. The interventions all targeted tinnitus distress. Sleep management and/or guidance was an additional optional module in the studies. Tinnitus distress was the primary outcome in all of the studies with sleep disturbances and insomnia reported as secondary outcomes. Two of the studies had wait-list control groups [15, 19], and two included online discussion forums [18; 20]. Three studies [18, 19, 20] based their interventions on the same well-established CBT

self-help manual [21], one study [15] based theirs on a self-help program developed by Andersson and Kaldo [22], and one study [17] based theirs on earlier work of Andersson [23]. None of the CBT based interventions report the inclusion of other any theoretical approaches (e.g. ACT, MBCT) and would therefore be considered 2nd wave CBT [24]. Participants were required to be over 18 years in all studies, to have tinnitus for 6 months or longer in three studies [18; 19, 20] and 3 months or longer in one study [15]. The studies included participants with moderate tinnitus severity assessed with different tinnitus questionnaires; i.e. a score of ≥ 25 on the Tinnitus Functional Index [15], ≥ 8 on the Mini-Tinnitus Questionnaire (Mini-TQ) [18], ≥ 10 or above on the Tinnitus Reaction Questionnaire (TRQ) [19], and ≥ 38 on the Tinnitus Handicap Inventory (THI) or ≥ 13 on the Mini-Tinnitus Questionnaire (Mini-TQ) [20].

The sleep outcome measure that four of the five included studies had in common was the ISI. The ISI is a seven-item questionnaire assessing sleep duration, sleep quality, and negative impact on daily functioning [25]. The items are scored on a scale from 0 to 4 where 0 corresponding to having no and 4 to very severe symptoms. The item scores are summed together to provide a total insomnia score (0–7 = No clinically significant insomnia, 8–14 = Subthreshold insomnia, 15–21 = Clinical insomnia: moderate severity, 22–28 = Clinical insomnia: severe). The mean pre-intervention ISI scores for the intervention and control groups in the included studies all fell within the subthreshold category for insomnia.

Table 1 Study characteristics

Study (country)	Sample size	Intervention, frequency, duration and components	comparison	Sleep outcome measure, endpoint, study finding
*Andersson et al., 2005 ¹⁷ Sweden	Intervention: 12 control: 11	CBT group sessions, 2 hours weekly for six weeks. Tinnitus information, applied relaxation (four sessions), cognitive restructuring, behavioural activation, positive imagery, sound enrichment using environmental sounds, exposure to tinnitus, hyperacusis advice, hearing tactics, relapse prevention and management of sleep	Waiting list control group	Sleep quality: visual analogue scale (0-100mm, anchors ‘much pleased’ – ‘not at all pleased’). Diary recordings over a week at 5 weeks. No significant interaction.
Beukes et al., 2017 ¹⁵ United Kingdom	Intervention: 73 control: 73	Internet delivered audiologist guided CBT based self-help program , 2-3 modules released weekly over 8 weeks with weekly therapist contact via a secured online messaging system. 16 recommended modules & 5	Weekly monitoring control group	ISI, post intervention. Significant improvement in intervention compared to control (3.8±2.7)

		optional (including sleep module). Applied relaxation, thought analysis, cognitive restructuring, imagery and exposure techniques		
Jasper et al., 2014 ¹⁸ Germany	Intervention: 41 control: 44	Internet delivered CBT based self-help program, 12 mandatory and 6 optional text modules (including sleep module) and weekly therapist contact via a secured online messaging system. 10 week intervention. Applied relaxation, positive imagery, focus exercises, exposure to tinnitus, cognitive restructuring, and avoidance behaviour.	Web-based discussion forum	ISI, post assessment. Pre-post Cohen's d (95% CI) 0.68 (0.22-1.14). change score 2.3 (0.9-3.8)
Kaldo et al., 2007 ¹⁹ Sweden	Intervention: 34 control: 38	CBT based self-help book guided by brief telephone support. 7 weekly phone calls over 6 weeks. Tinnitus information, defining goals, applied relaxation, positive imagery, focus exercises, exposure to tinnitus, sound enrichment, hypersensitivity to sounds, hearing tactics, cognitive restructuring, sleep management,	Wait-list control group	ISI, post treatment. Significant interaction favouring intervention effect [$F(1, 69)=11.2$; $P<.001$]

		concentration management, treatment summaries & evaluation, planning maintenance of positive effects and relapse prevention.		
Weise et al., 2016 ²⁰ Sweden	Intervention: 62 control: 62	Internet delivered audiologist guided CBT self-help program, 12 mandatory, and 6 optional modules and weekly therapist contact via a secured online messaging system. 10 week intervention. Applied relaxation, positive imagery, focus exercises, exposure to tinnitus, cognitive restructuring, sleep management and avoidance behaviour.	Online discussion forum	ISI, maximum of 4 weeks post treatment. Significant improvement in intervention compared to control. Hedges g (95% CI) 0.66 (0.30-1.02)

*not included in meta-analysis,

Meta-analysis of four studies [15, 18, 19,20] demonstrated a statistically significant between groups difference in ISI score following CBT based interventions (-3.28, 95% CI -4.51, -2.05, $P < 0.001$), which equates to a moderate effect size (0.5). There was no evidence of statistical heterogeneity $I^2 = 0\%$ (Fig 2).

Fig 2 Between groups difference in insomnia severity index scores: a meta-analysis

Randomisation sequence generation, allocation concealment and selective outcome reporting processes were found to be well described and risk of bias was found to be low for all trials based on reviewers' judgements. Due to the nature of the intervention it was not possible to blind study participants or personnel from knowledge of which intervention a participant received. Blinding of outcome assessment was described in only one trial where the data analyst was masked to the groups [15]. Risk of bias was unclear for incomplete outcome data in one trial which did not adequately report control group attrition [19]. Risk of bias was low across all studies for selective outcome reporting (see table 2).

Table 2 Risk of Bias

Study ID	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting
Andersson 2005 ¹⁷	low	unclear	high	unclear	low	low
Beukes 2017 ¹⁵	low	low	high	low	low	low
Jasper 2014 ¹⁸	low	low	high	unclear	low	low
Kaldo 2007 ¹⁹	low	low	high	unclear	unclear	low
Weise 2016 ²⁰	low	low	high	unclear	low	low

Discussion

Five trials evaluating the effect of CBT based interventions on tinnitus reported sleep outcomes, with four of those trials providing data for a meta-analysis. None of the identified interventions targeted insomnia as a primary outcome. Synthesised data demonstrated a statistically significant difference (-3.28) in ISI scores following tinnitus CBT based interventions. There was no statistical heterogeneity evident.

Discussion of findings

The interventions in the included studies were all aimed at improving tinnitus, with sleep being reported among the secondary outcomes. The results from the data synthesis of the four trials included within the meta-analysis showed a statistically significant between groups difference in ISI scores even though the interventions were not primarily targeting insomnia. Whilst further research is warranted to define optimal cut off values in different patient populations, Morin [26] suggest a 7-point reduction would be the minimally important difference (MID), and Yang et al., [27] recommend a 6-point reduction in ISI would translate into a clinically meaningful improvement in insomnia. The between group differences (fig 2) for included studies were all below these values, and none of the primary studies reported meeting the MID in change scores post intervention, except for Beukes et al [15] who observed that 22% of the intervention and 4% of the control group participants did achieve clinically meaningful change scores (>9.8). Due to the association between these conditions, and considering that tinnitus and insomnia are likely to influence the perceived symptom severity of each other [7, 28], any indication of an improvement in sleep warrants further investigation in this population. Indicative of the potential benefit of CBTi in adults with tinnitus, Marks et al., [12] demonstrated a significant reduction in ISI score (10.1 [$P < 0.01$])

following a face-to-face intervention targeting tinnitus related insomnia. Significant effects were also reported for tinnitus related distress, psychological distress and anxiety and depression in agreement with previous studies suggesting CBT to be an effective intervention for tinnitus related psychological symptoms [13, 14]. Whilst the studies in the current review offered optional CBT sleep modules, data in relation to uptake of these modules was unavailable so it is not possible to attribute any improvement in insomnia to this.

The importance of sleep in both health and chronic conditions is becoming more widely recognised [29]. This is particularly relevant in the context of tinnitus as it is thought that tinnitus and insomnia not only share several underlying physiological mechanistic pathways (i.e. hyperarousal of the sympathetic nervous system) but also the aspects of the burden imposed by either of these conditions overlap significantly; i.e. compromised daily living, depression and anxiety [7]. Evidence that CBT interventions targeting tinnitus also alleviate insomnia, and potentially vice versa [7, 12], further supports the bidirectional nature of the relationship between these two distressing conditions.

It is not clear whether the interventions included in the present systematic review improved sleep directly or indirectly via changes in perceived tinnitus and related distress. Patients with tinnitus report that tinnitus can prevent them from falling asleep, and tinnitus perception and annoyance can also depend on the quality of the nights sleep [5]. Those with tinnitus and sleep difficulties have more severe tinnitus than patients who experience tinnitus without insomnia, suggesting that alleviation of insomnia could lead to the alleviation of tinnitus [30, 31, 32]. However, Hesser et al., [33] also observed that CBT targeting tinnitus had significant effects on secondary outcomes such as measures of anxiety and depression, indicative of the complex interaction between tinnitus and these mental health conditions which are also associated with the severity of insomnia [7, 4].

Another important finding in the present study was that the CBT based interventions were effective overall when delivered via the internet in three studies and a self-help book in one. CBT is considered an effective treatment option for tinnitus [33, 14], however resource availability can limit its application in practice [1]. Internet CBT is a useful alternative to face-to-face therapies, and a recent systematic review and meta-analysis concluded that internet-delivered CBTi was as effective as in-person therapy with a trained therapist for improving sleep in adults with insomnia [34]. It can be cost effective and overcomes many perceived barriers such as travelling time or the potential stigma of seeing a therapist [18]. It has also been shown to be an effective treatment in adults with primary insomnia [35].

Strengths and weaknesses of study

To limit the potential for bias this study adhered to the PRISMA reporting guidelines and a rigorous pre-specified protocol (PROSPERO). A comprehensive search for published and unpublished work, which included multiple electronic databases, scanning of bibliographies and contact with authors, identified five published studies. A strength of this review is that it presents the first meta-analysis synthesising the effects of behavioural interventions on sleep problems in tinnitus.

The absence of data from unpublished studies is a potential limitation. It is recognised that effects estimated from the included studies may be inflated due to bias from the non-publication of studies with null effects. All of the included studies reported significant effects of the intervention for their primary outcomes and many of their secondary outcomes.

However, there were not enough individual study estimates to conduct a funnel plot for the detection of bias.

A further potential limitation was the small number of studies, with just five meeting the inclusion criteria and four providing data for the meta-analysis, and none of which were

powered to detect differences in measures of sleep. All of the individual study estimates were in the same direction (favouring the intervention) with no evidence of statistical or clinical heterogeneity. The Jasper [18] and Weise [20] studies delivered the same CBT based interventions [21]. It is likely that the smaller non-significant point estimates observed for the Jasper and Kaldo studies [18, 19] may be in part attributable to reduced power to detect differences due to sample size. None of the participants in the included studies met the threshold for insomnia. Consequently, any improvements cannot be said to reduce in insomnia, but to improve sleep, and any improvements in sleep would only be expected to be small.

Risk of bias was presented for each domain for interpretation and was considered low for the majority. It is not possible to eliminate potential bias due to study designs which lacked blinding of participants and personnel, so this limitation was considered high for all studies.

A strength of the present review was the measure of insomnia used in the studies included in the meta-analysis was the ISI which is a reliable and valid instrument used to quantify perceived insomnia severity, and is commonly used as an outcome measure in insomnia treatment research due to its ease of application [25]. It has been used in a wide range of populations and is a useful subjective measure that captures not only information about the symptoms and consequences of insomnia, but also the degree of concerns or distress caused by these which are all important factors when quantifying the effects of insomnia.

Practice points

Available evidence from randomised controlled trials suggests that CBT based interventions for tinnitus improve both tinnitus and sleep.

Research agenda

Considering the significant overlap in mechanistic pathways and symptomology between these two conditions, treatment options for tinnitus related insomnia warrant further investigation.

Robust randomised controlled trials (adhering to CONSORT guidelines) are needed, specifically targeting tinnitus related insomnia.

Future trials should explore digital CBTi in this population.

Trials examining the effects of treatments on tinnitus related insomnia should recruit individuals who meet clinically significant thresholds for insomnia and report on clinically meaningful difference.

In preparing this review the authors identified one ongoing trial with a planned completion date of December 2019: A Comparison of CBTi and Usual Treatment for Tinnitus Related Insomnia [36].

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Conflicts of interest

The authors do not have any conflicts of interest to disclose.

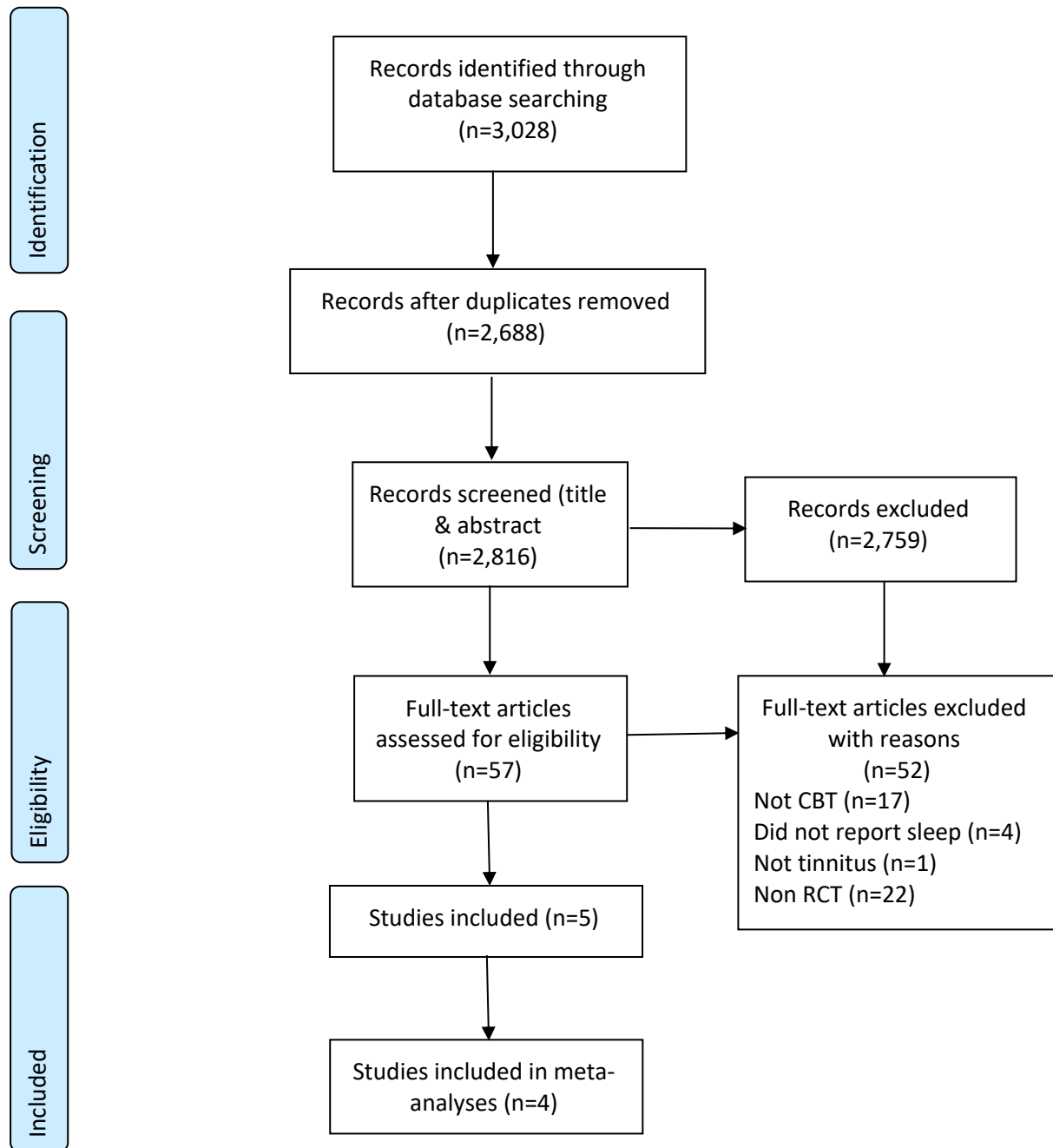
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