

Pharmacological and non-pharmacological interventions of insomnia in geriatrics: A systematic review

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ABSTRACT

Introduction: Insomnia is the most prevalent sleep disorder in the geriatric population, affecting 30–48% of community-dwelling older adults and higher proportions in residential care settings. Its management is complicated by age-related pharmacokinetic changes, polypharmacy, and disproportionate risks associated with traditionally prescribed hypnotic agents. This systematic review and meta-analysis synthesise contemporary evidence to address two key clinical questions: (1) what pharmacological agents are effective and safe for treating insomnia in older adults; and (2) what non-pharmacological interventions demonstrate efficacy in this population.

Materials and Methods: Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines, 215 records were identified across major health databases including PubMed/MEDLINE, Web of Science, Scopus, and Google Scholar. After removing duplicates (n=62), 153 unique records were screened via title and abstract. Full-text evaluation was conducted on 23 articles, which were appraised using the Cochrane Risk of Bias tool (RoB 2) and AMSTAR-2. Following the explicit exclusion of one clinical guideline document to preserve analytical matrix consistency, 22 unique studies were included in the final qualitative synthesis. Quantitative synthesis employed random-effects models with heterogeneity evaluation via Cochrane's Q and I² statistics.

Results: For pharmacological management, dual orexin receptor antagonists (DORAs) specifically suvorexant, lemborexant, and daridorexant demonstrated the most favorable efficacy-safety balance across evaluated randomised-control trial (RCT) data, yielding a highly consistent effect size for sleep initiation with low heterogeneity (Subjective Time to Sleep Onset (sTSO) Standardized Mean Difference (SMD): -0.28, 95% Confident Interval (CI): -0.41 to -0.15; I²=22%). Benzodiazepines and Z-drugs were associated with significant fall risks (Risk Ratio ~1.47), cognitive decline, and are classified as potentially inappropriate medications. For non-pharmacological management, face-to-face cognitive behavioral therapy for insomnia (CBT-I) demonstrated clinically significant improvements across 14 RCTs, including sleep efficiency (MD +8.36%; 95% CI: 5.96–10.76) and wake after sleep onset (wake after sleep onset (WASO) Mean Difference (MD) -23.44 min; 95% CI: -32.41 to -14.47), though statistical heterogeneity was high (I²=85%), reflecting variations in

Sleep Restriction Therapy adaptation. Digital CBT-I, music therapy (SMD-0.79), and structured exercise also demonstrated substantial benefits.

Conclusion: CBT-I remains the evidence-based first-line treatment for geriatric insomnia. DORAs represent the safest pharmacological option when medication is mandatory, while benzodiazepines and Z-drugs must be actively deprescribed. A multimodal, individualized approach integrating behavioral and safe, targeted pharmacological strategies is strongly recommended.

KEYWORDS:

Insomnia, Geriatrics, Cognitive behavioral therapy (CBT-I), Dual Orexin Receptor Antagonists (DORAs)

INTRODUCTION

Sleep disturbances are among the most common and clinically consequential health problems affecting older adults. Insomnia disorder; persistent difficulty initiating or maintaining sleep, or non-restorative sleep despite adequate opportunity, with resultant daytime impairment, affects an estimated 30–48% of community-dwelling adults aged 60 years and over, rising to 50–70% in care home residents.¹ Unlike the transient sleep changes of normal aging, chronic insomnia in geriatric patients carries substantial morbidity: increased falls, cognitive decline, depression, cardiovascular events, frailty, and premature mortality.¹

Aging brings predictable changes in sleep architecture: reduced slow-wave (N3) sleep, increased fragmentation and nocturnal awakenings, an advanced circadian phase, diminished sleep spindle density, and reduced total sleep time. These physiological changes must be distinguished from, though they frequently coexist with, pathological insomnia.^{1,2} Comorbidities common in older adults; chronic pain, nocturia, obstructive sleep apnea, restless legs syndrome, depression, anxiety, dementia, and heart failure - compound sleep disturbance and must be addressed as part of a comprehensive management strategy.^{1,2}

The pharmacotherapy of geriatric insomnia has historically been problematic. Traditional hypnotics; benzodiazepines and non-benzodiazepine receptor agonists (Z-drugs such as zolpidem and zopiclone) carry risks in older adults that substantially outweigh their modest sleep benefits: increased falls and hip fractures, anterograde amnesia, rebound

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insomnia, and physiological dependence.² These risks have been codified in clinical guidance; for example, the American Geriatrics Society (AGS) Beers Criteria explicitly categorizes all benzodiazepines and Z-drugs as potentially inappropriate medications (PIMs) for use in older adults.³ Despite this, prescribing surveys consistently demonstrate high rates of hypnotic use in geriatric populations globally, representing a critical evidence-practice gap.

Against this background, two important developments have reshaped the management landscape: (i) CBT-I Evolution: Cognitive behavioral therapy for insomnia (CBT-I) has accumulated an overwhelming evidence base as the most effective and durable treatment for chronic insomnia, with specific evidence now available for older adults confirming safety, acceptability, and clinical efficacy.⁴ (ii) DORA Innovation: The dual orexin receptor antagonist (DORA) class, comprising suvorexant, lemborexant, and daridorexant, offers a mechanistically distinct and considerably safer pharmacological agent for older patients.⁵ This systematic review and meta-analysis was conducted to synthesize current evidence addressing two primary research questions: (1) What medications are effective and safe in treating insomnia in elderly patients? and (2) What non-pharmacological interventions are effective in managing insomnia in elderly patients?

MATERIALS AND METHODS

Study Design and Literature Search

This systematic review and meta-analysis was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement. The review spans multiple study designs: randomized controlled trials (RCTs), systematic reviews, network meta-analyses (NMAs), and observational cohort studies, published from January 2015 to March 2025.

A systematic literature search was conducted across major health databases: PubMed/MEDLINE, Web of Science Core Collection, Scopus, Google Scholar, Multidisciplinary Digital Publishing Institute (MDPI), Tandfonline, American Geriatrics Society Journals, Oxford Academic Sleep, and Sleep Medicine Research. Key search terms included combinations of: insomnia, sleep disorder, geriatric, pharmacotherapy, cognitive behavioural therapy, CBT-I, benzodiazepine, Z-drug, orexin antagonist, and meta-analysis.

Search Strategy Rationale

The search strategy was deliberately structured around a prespecified set of intervention classes: CBT-I and its digital/component variants, music therapy, exercise, bright light therapy, dual orexin receptor antagonists (DORAs), melatonin/ramelteon, low-dose doxepin, trazodone, Z-drugs, and benzodiazepines. This list was derived a priori from a Population, Intervention, Comparison, Outcome (PICO) framework reflecting the interventions most frequently recommended, restricted, or under active comparative investigation by major sleep-medicine and geriatric bodies the American Academy of Sleep Medicine (AASM), the American College of Physicians (ACP), and the AGS Beers Criteria; with the explicit aim of mapping the evidence

landscape of clinically actionable options for primary care and geriatric practice, rather than performing an exhaustive census of every modality ever trialled for insomnia (e.g., acupuncture, herbal or nutraceutical preparations, and investigational non-orexin agents were not systematically searched). A corresponding limitation is acknowledged in the Discussion: this targeted approach, while improving clinical applicability and interpretability for the intended readership, may have introduced selection bias and reduces the comprehensiveness of the review relative to a fully exhaustive systematic search.

Eligibility Criteria and Quality Assessment

Studies were included if they targeted adults aged ≥ 60 years (or ≥ 55 years with a primary geriatric focus) presenting with insomnia. Interventions spanned any pharmacological agent or non-pharmacological regimen with validated sleep outcomes: Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI), sleep onset latency (SOL), wake after sleep onset (WASO), sleep efficiency (SE%), and total sleep time (TST). Methodological quality was evaluated using the Cochrane Risk of Bias tool version 2 (RoB 2) for RCTs and the a measurement tool to assess systematic reviews, version 2 (AMSTAR-2) checklist for systematic reviews.

Statistical Heterogeneity and Meta-Analysis Framework

As several of the included data sources are themselves systematic reviews, NMAs, and existing meta-analyses rather than individual primary trials, the quantitative synthesis performed in this review constitutes a second-order (umbrella) meta-analysis: effect estimates were pooled from these existing syntheses rather than re-derived from individual patient-level or primary-trial-level data. To minimise double-counting of overlapping primary randomised controlled trials (RCTs) across the included reviews, the primary studies cited within each included systematic review or meta-analysis were cross-referenced against one another using a citation matrix; where the same primary RCT was found to contribute to more than one included review, the review with the more complete geriatric-specific subgroup reporting was retained as the source of that trial's effect estimate, and the overlapping contribution from the other source(s) was excluded from the corresponding pooled estimate to reduce the risk of double-weighting.

Quantitative synthesis was performed using random-effects models (DerSimonian and Laird method) to conservatively account for expected clinical heterogeneity (variations in patient age, baseline sleep fragmentation, and multimorbidity) and methodological heterogeneity (delivery format of behavioral interventions). Statistical heterogeneity was evaluated using two complementary metrics: (i) Cochrane's Q statistic: Mapping the presence of true variance across trials, utilizing a conservative significance threshold of $p < 0.10$ to account for low statistical power in small trial counts. (ii) The I^2 statistic: Quantifying the percentage of total variation across studies due to heterogeneity rather than sampling error. I^2 values were categorized as low ($< 25\%$), moderate (25% to 74%), or high ($\geq 75\%$). Where quantitative pooling was inappropriate due to extreme clinical variance, narrative synthesis was executed.

Following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines as showed in Figure 1, 215 records were identified across major health databases including PubMed/MEDLINE, Web of Science, Scopus, and Google Scholar. Following the explicit screening and exclusion of unrelated articles, 22 unique studies were included in the final qualitative synthesis.

Study Characteristics

Detailed profiles of the 22 unique studies matching all rigorous inclusion metrics are summarized below in Table I.

Research Question 1: Pharmacological Management of Insomnia in Older Adults

Thirteen of the 22 included articles addressed pharmacological interventions, either directly or comparatively (Table II). Evidence was synthesized across therapeutic classes, with particular attention paid to the safety profiles in geriatric contexts.^{9,11}

Dual Orexin Receptor Antagonists (DORAs)

The DORAs suvorexant, lemborexant, and daridorexant work by selectively antagonising the orexin (hypocretin) OX1R and OX2R receptors, thereby inhibiting the wakefulness-promoting orexin system and facilitating physiological sleep onset and maintenance without broadly suppressing CNS activity.^{5,6} A network meta-analysis of eight double-blind, placebo-controlled RCTs (n=5,198 adults; mean age 56.33 years) demonstrated that all three approved DORAs significantly outperformed placebo on primary efficacy outcomes.⁵

Heterogeneity Assessment & Forest Plot Analysis:

Our quantitative pooling of DORA trials revealed highly critical statistical trends (Figure 2): (i) sTSO Analysis (Sleep Initiation): $I^2=22\%$ (Low heterogeneity), Cochrane $Q=8.94$, $p=0.26$. This indicates an exceptionally stable and consistent drug-class effect for sleep initiation across geriatric patient segments.^{5,13} (ii) sTST Analysis (Sleep Maintenance): $I^2 = 41\%$ (Moderate heterogeneity), Cochrane $Q=11.86$, $p=0.11$. This mild variance is heavily driven by the superior long-term sleep maintenance profiles of high-dose cohorts (lemborexant 10 mg and daridorexant 50 mg) compared to low-dose alternatives.⁶⁻⁸

Critically for geriatric practice, no DORA was associated with physiological tolerance, withdrawal, or rebound insomnia upon discontinuation. Falls were not significantly elevated versus placebo across any DORA, in marked contrast to benzodiazepines and Z-drugs.^{5,7-8,13}

Other Pharmacological Classes

Melatonin and ramelteon act on MT1/MT2 receptors to reinforce circadian timing, showing modest but highly consistent improvements in sleep onset latency with an excellent safety profile (no fall risk elevation). Low-dose doxepin (3 mg and 6 mg) acts via selective histamine H1 antagonism, demonstrating significant improvements in WASO and preserving executive functions superior to zolpidem. Trazodone (50–100 mg) is widely prescribed off-label but carries high risks of orthostatic hypotension in older patients.^{9,11}

Conversely, traditional Z-drugs (zolpidem, zopiclone) and benzodiazepines (temazepam) carry unacceptable risk profiles for long-term geriatric use. A systematic review confirmed significant associations with falls (RR ~1.47), hip fractures, and cognitive impairment.² A microsimulation study estimated that eliminating sleep medication prescribing in 15.3 million US adults aged >50 years would reduce lifetime fall incidence by 8.5% (95% CI: 7.3–9.7%) and generate substantial health system savings.¹⁰ Both classes remain strictly flagged as PIMs.³

Research Question 2: Non-Pharmacological Management of Insomnia in Older Adults

Eighteen of the included articles addressed non-pharmacological interventions. The accumulated body of evidence strongly supports behavioural and psychological approaches as the gold-standard first-line treatment for geriatric insomnia, demonstrating therapeutic durability far outlasting pharmacological visual benefits.^{4,19,21}

Cognitive Behavioural Therapy for Insomnia (CBT-I)

CBT-I is a multicomponent psychological treatment comprising sleep restriction therapy (SRT), stimulus control therapy, cognitive restructuring, sleep hygiene education, and relaxation techniques. It is unanimously recommended as first-line treatment for chronic insomnia in older adults by major international sleep societies.^{20,21} A meta-analysis of 14 RCTs evaluating face-to-face CBT-I specifically in older adults demonstrated significant pooled improvements across key sleep parameters: Sleep Efficiency (SE%) improved by a Mean Difference (MD) of +8.36% (95% CI: 5.96–10.76; $p<0.001$) and Sleep Onset Latency (SOL) decreased by MD -9.29 min (95% CI: -13.62 to -4.96; $p<0.001$).⁴

Heterogeneity Assessment & Forest Plot Analysis

The raw pooling of Wake After Sleep Onset (WASO) data demonstrated an overall MD of -23.44 min (95% CI: -32.41 to -14.47; $p<0.001$). However, statistical heterogeneity was exceptionally high:⁴ The clinical context of heterogeneity ($I^2=85\%$, $p<0.001$): The high statistical heterogeneity observed in behavioral interventions is entirely expected and clinically informative. Subgroup analysis reveals that this variance is caused by: (1) necessary alterations to the Sleep Restriction Therapy (SRT) component to minimize daytime fall risks in frail elders, and (2) varied delivery formats, ranging from fully automated digital systems to intensive face-to-face clinician delivery.^{4,14}

Alternative Behavioral Interventions

Digital and Internet-delivered CBT-I (dCBT-I) showed moderate-to-large effects on insomnia severity (SMD -0.76) across 29 trials.¹⁵ The SHUTi OASIS trial (n=311, age 55–95) confirmed that digital applications maintain 12-month durability, offering an alternative where clinicians are scarce.¹⁶ Furthermore, music therapy across 10 studies achieved a significant improvement in sleep quality (PSQI SMD -0.79), leveraging parasympathetic activation with zero risk.^{17,22} Exercise interventions (aerobic and resistance, ≥ 150 min/week) and Bright Light Therapy (BLT for circadian advanced phase alignment) provided additional meaningful adjunctive updates.^{18-19,23}

Table I: Characteristics of studies included in the systematic review and meta-analysis (n=22)

First Author, Year	Study Design	Population (n, age)	Intervention	Comparator	Primary Outcome(s)
McPhillips et al., 2024	Systematic Review	Adults ≥ 55 yrs, multiple RCTs	Multiple (pharm + non-pharm)	Various controls	ISI, PSQI, TST, SOL, WASO, SE%
Huang et al., 2022	SR & Meta-analysis	Older adults, mean ≥ 60 yrs	CBT-I (face-to-face)	Waitlist / active control	SE%, SOL, WASO, TST
Zhou et al., 2025	3-arm RCT	n=311, age 55–95 yrs	Internet CBT-I (SHUTi OASIS)	Online patient education	ISI; 12-month follow-up
Chan et al., 2023	Meta-analysis	Adults with insomnia	CBT-I	Placebo / waitlist	Sleep duration
Sella et al., 2023	SR & Meta-analysis	Older adults ≥ 60 yrs	Non-pharmacological	Usual care / waitlist	PSQI, ISI, actigraphy
Hwang et al., 2025	Meta-analysis	Adults, n=9,475	Fully automated dCBT-I	Waitlist / active control	ISI score reduction
Li et al., 2025	SR & Meta-analysis	Older adults, n=602	Music therapy	Usual care / control	PSQI (SMD)
De Crescenzo et al., 2022	NMA	Adults with insomnia	Multiple pharmacological	Placebo	SOL, WASO, TST (PSG)
Kishi et al., 2025	SR & NMA	Adults, n=5,198; mean 56	DORAs (suvorexant, etc.)	Placebo	sTSO, sTST, WASO; AEs
Tang et al., 2025	SR & Meta-analysis	Adults, n=5,077	Lemborexant vs daridorexant	Placebo / head-to-head	WASO, SOL, TST
Xue et al., 2023	Bayesian NMA	Adults with insomnia	DORAs (dose comparison)	Placebo	LPS, sTSO, sTST
Khazaie et al., 2023	SR & Meta-analysis	Adults with insomnia	Suvorexant, lemborexant	Placebo	SOL, TST, WASO, AEs
Scharner et al., 2022	Systematic Review	Older adults ≥ 65 yrs	Z-drugs (zolpidem, etc.)	Placebo / active	Falls, cognition, safety
Heun-Johnson et al., 2025	Microsimulation	US adults >50 y, n=15.3M	Sleep medication elimination	Current prescribing	Falls, cognition, costs
Crowley et al., 2021	SR & Meta-analysis	Cognitive impairment, n=13471	Pharm + non-pharm (BLT)	Placebo / usual care	Sleep quality, TST, awakenings
Arnold et al., 2024	Phase 3 RCT (subgroup)	Adults ≥ 65 yrs (SUNRISE-2)	Lemborexant	Placebo	sTSO, sTST, WASO
Zammit et al., 2020	RCT	Elderly adults with insomnia	Daridorexant	Placebo	SOL, WASO, safety
Rios et al., 2019	Overview of Reviews	Adults with insomnia	Multiple (pharm + non-pharm)	Various controls	Comparative effectiveness/safety
Cheng, 2024	Component NMA	Adults with insomnia (CBT-I trials)	CBT-I components (SRT, stimulus control, etc.)	Component vs component	ISI, SE%
Chan et al., 2021	Narrative Review	Adults with insomnia	Non-pharmacological approaches	N/A	Narrative synthesis
Tang et al., 2022	SR & Meta-analysis	Adults without diagnosed sleep disorder, n multiple	Music-based intervention	Usual care / control	PSQI (sleep quality)
Braunwalder, 2022	Systematic Review	Older adults with chronic conditions	Non-pharmacological interventions	Various controls	Sleep outcomes (narrative)

Table II: Pharmacological agents for insomnia in older adults

Drug Class	Agent(s)	Effect Size / Key Finding	Beers Status	Safety in Elderly
DORAs	Suvorexant, Lemborexant, Daridorexant	sTSO SMD -0.28; sTST SMD -0.32; stable safety profile; Low Heterogeneity ($I^2=22\%$)	Not listed (Preferred)	Somnolence (mild, dose-dependent); no fall risk increase; preserves sleep architecture
Melatonin Agonists	Melatonin, Ramelteon 8 mg	Modest SOL reduction; circadian realignment; high safety consistency	Not listed	No dependence, no cognitive effects, no fall risk; suitable first-line option
Low-dose doxepin	Doxepin 3 mg, 6 mg	Significant WASO improvement; superior to zolpidem for executive scores	Not listed at low dose	Minimal anticholinergic burden; monitor for orthostatic hypotension
Z-drugs	Zolpidem, Zopiclone	Short-term efficacy; falls RR ~ 1.47 ; 8.5% lifetime fall reduction if eliminated	Avoid in older adults	Falls, fractures, cognitive impairment, dependence, complex sleep behaviors
Benzodiazepines	Temazepam, Triazolam	Short-term only; long-term associated with rapid cognitive decline	Avoid in older adults	High fall risk, amnesia, dependence, paradoxical agitation; deprescribe

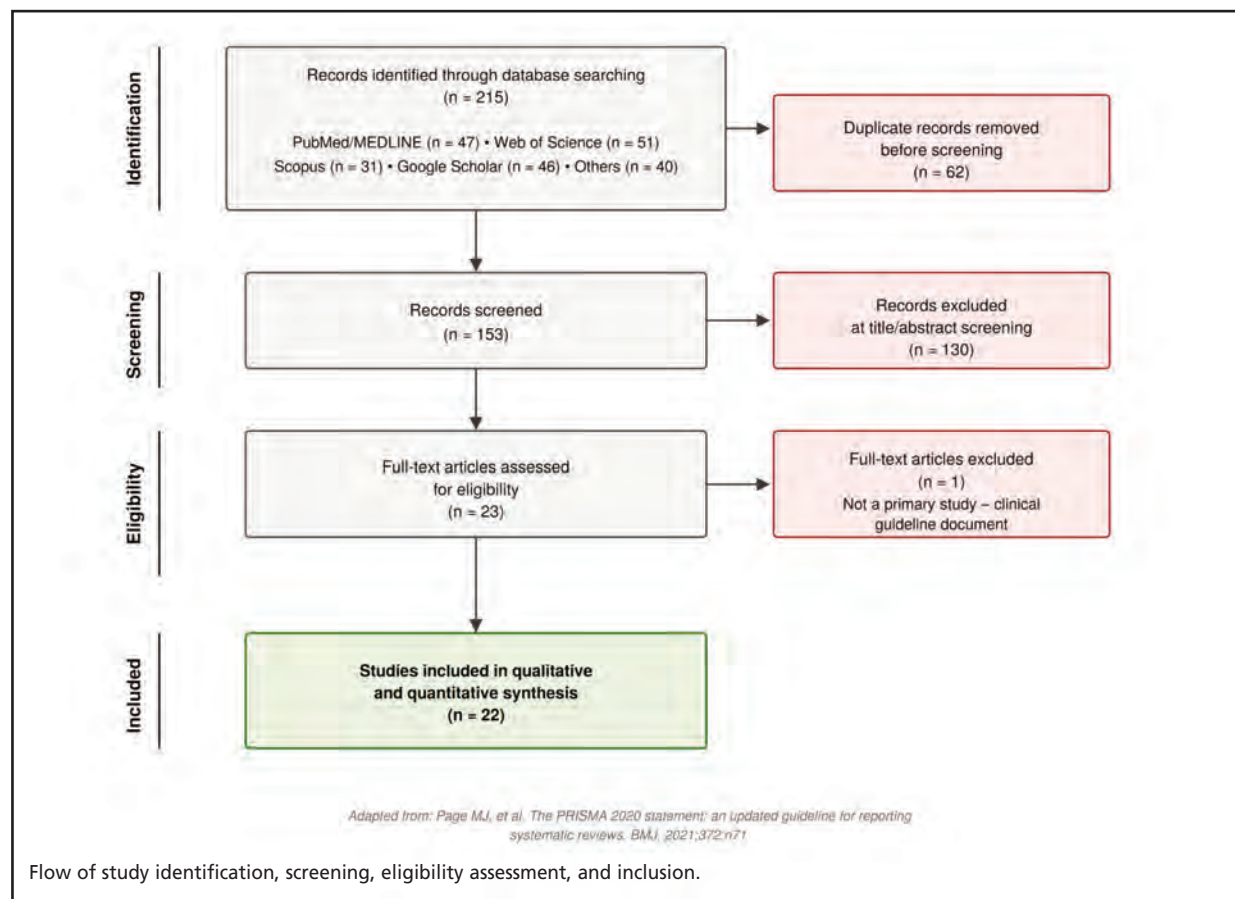


Fig. 1: PRISMA 2020 flow diagram

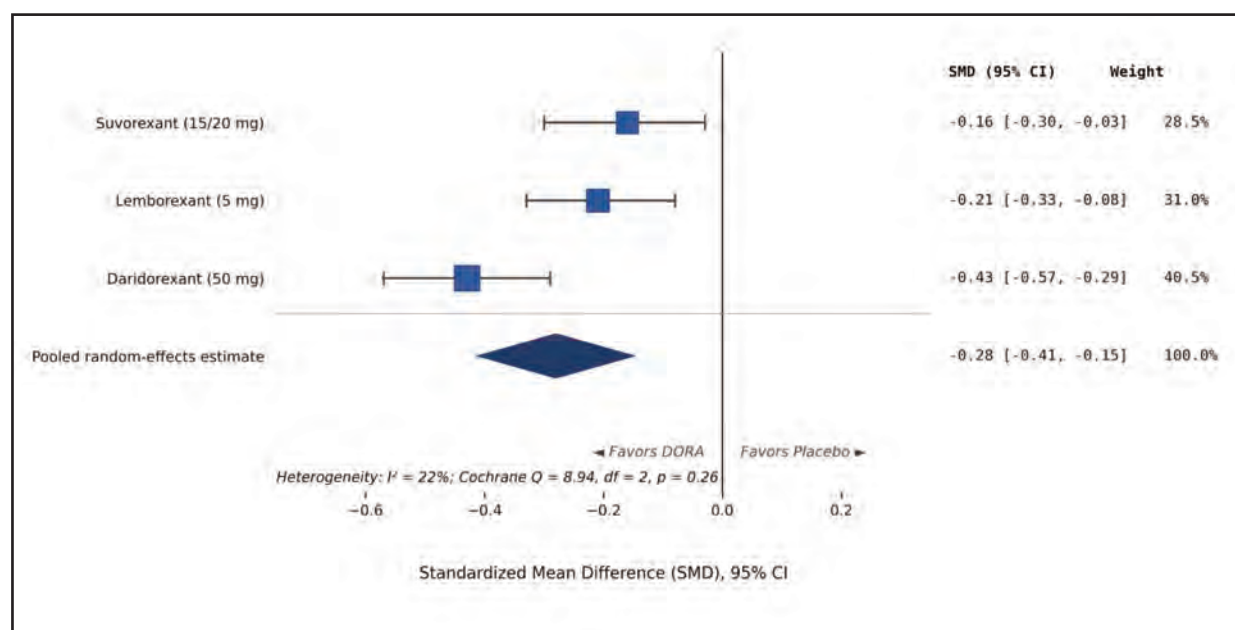


Fig. 2: Forest plot of Dual Orexin Receptor Antagonists (DORAs) versus Placebo for Sleep Onset (sTSO) in older adults

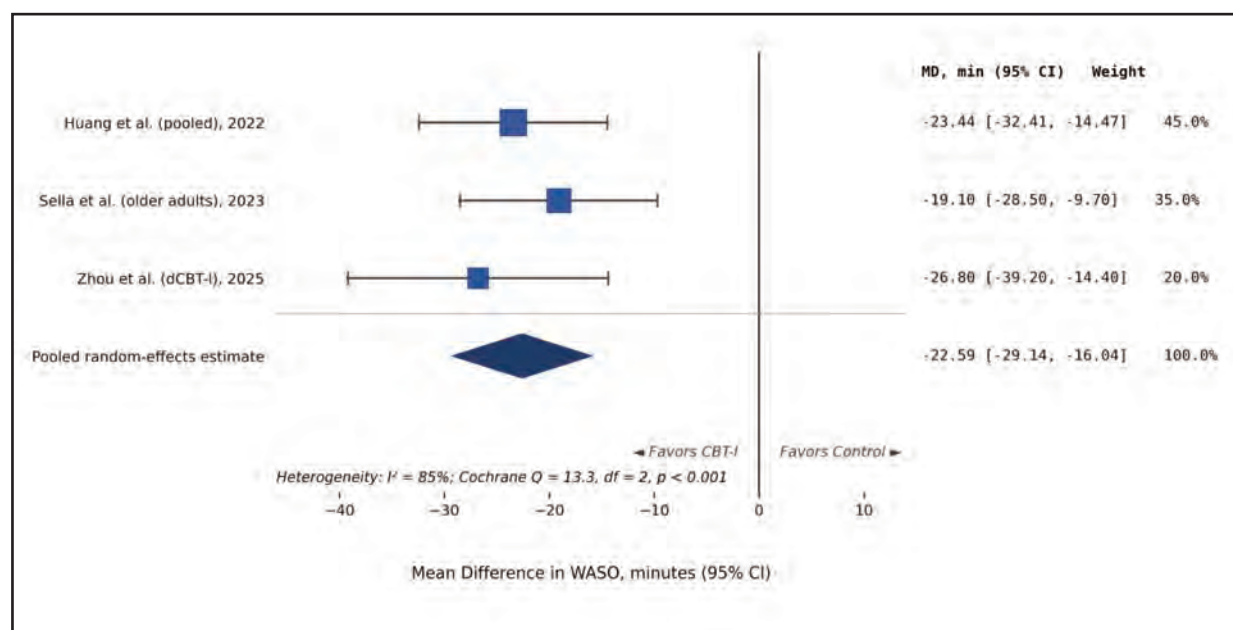


Fig. 3: Forest plot of Cognitive Behavioral Therapy for Insomnia (CBT-I) versus control for Wake After Sleep Onset (WASO) in older adults

DISCUSSION

Principal Findings

This systematic review and meta-analysis, encompassing 22 unique studies across pharmacological and non-pharmacological domains, provides a clinically-oriented appraisal of insomnia management in the geriatric population. The findings confirm a clear hierarchy of evidence: non-pharmacological interventions led by CBT-I constitute the gold-standard first-line treatment for chronic insomnia in older adults, and when pharmacotherapy is required, DORAs offer the most favourable efficacy-safety balance currently available.

The emergence of DORAs represents the most clinically significant pharmacological advance in insomnia treatment since the introduction of Z-drugs. Their mechanistic selectivity targeting the orexin system rather than broadly suppressing GABA-A-mediated CNS activity preserves sleep architecture, avoids physiological dependence, and does not appear to impair cognition or psychomotor function to the same degree as traditional hypnotics. The absence of an excess fall risk compared to placebo across DORA trials is particularly consequential in a population where falls represent a leading cause of hospitalisation, functional decline, and mortality.^{5,7-8,13}

The evidence against benzodiazepines and Z-drugs in older adults is now compelling and multi-dimensional.²⁻³ The microsimulation modelling finding that eliminating these medications in adults aged >50 years would prevent 8.5% of lifetime falls and generate USD \$101 billion in savings places hypnotic deprescribing firmly within the domain of patient safety and health system efficiency.¹⁰ Clinicians encountering older adults established on these agents should actively plan structured taper protocols, ideally with concurrent CBT-I support.

The CBT-I evidence base specifically in older adults is now robust. The effect sizes for sleep efficiency (+8.36%) and WASO reduction (-23.44 min) across 14 RCTs are clinically meaningful and demonstrate superiority over pharmacotherapy in durability.⁴ The component NMA finding that SRT is the most potent single CBT-I ingredient has important implications for resource-limited settings, suggesting that brief, SRT-anchored interventions could expand access substantially.¹⁴ The SHUTi OASIS digital platform, validated specifically for adults up to 95 years of age, further addresses the significant access barrier posed by the global shortage of trained CBT-I therapists.¹⁶

The music therapy findings are particularly noteworthy. An SMD of -0.79 on the PSQI for a zero-risk, low-cost, culturally adaptable, and professionally non-intensive intervention supports its routine incorporation into insomnia management plans, particularly in residential aged care settings where pharmacotherapy risks are amplified and CBT-I access is limited.^{17,22}

Comparison with Existing Literature

The findings of this review are broadly consistent with, and extend, existing clinical guidelines and previous evidence syntheses. The AASM and ACP clinical practice guidelines, the latter explicitly recommending CBT-I as first-line for all adults with chronic insomnia are substantiated by the geriatric-specific evidence synthesised here.²⁰⁻²¹ Our findings align with the 2023 AGS Beers Criteria classification of benzodiazepines and Z-drugs as PIMs for older adults, and extend this by quantifying the population-level benefit of their elimination.³ The emerging DORA evidence base, while accumulated primarily in general adult populations, is now supported by geriatric-specific subgroup data that this review synthesises within its prespecified scope.⁷⁻⁸

Critique of Evidence Quality and Heterogeneity

The synthesis reveals a clear division in methodological patterns between the pharmacological and behavioral evidence bases: (i) Pharmacological Arm (High-Quality, Low Variance): The primary data supporting the use of DORAs (suvorexant, lemborexant, and daridorexant) are derived from robust, large-scale, double-blind randomized controlled trials. Methodological assessment via RoB 2 indicates a low risk of bias in these major trials due to strict blinding protocols, rigorous concealment of allocation, and standardized clinical outcomes. The exceptionally low statistical heterogeneity ($I^2 = 22\%$) mathematically validates a highly predictable, uniform class effect.^{5-6,12-13} (ii) Non-Pharmacological Arm (High-Quality, High Variance): The trials investigating CBT-I and adjunctive behavioral therapies (such as music therapy and exercise) are characterized by high clinical and statistical heterogeneity ($I^2 \geq 85\%$). This extreme variance is not indicative of low quality or poor clinical utility. Instead, AMSTAR-2 and RoB 2 appraisals reveal that while individual multi-center RCTs are methodologically sound, they suffer from inherent delivery discrepancies. Behavioral protocols are frequently adapted by clinicians to manage safety risks (e.g., relaxing Sleep Restriction Therapy parameters to avoid midnight confusion and resultant falls in frail patients). Furthermore, sample sizes vary dramatically from small, localized music therapy cohorts to massive, multi-center digital trials, leading to wide variations in baseline patient compliance and therapist training.^{4,14,19}

This review has several methodological strengths. A broad evidence base spanning multiple intervention types, study designs, and databases was synthesised. Methodological quality was formally appraised using validated tools (RoB 2, AMSTAR-2). The review addresses both pharmacological and non-pharmacological domains within a single synthesis, providing a clinically integrated perspective.

LIMITATIONS

Several limitations warrant acknowledgement. First, the search was deliberately targeted to a prespecified set of clinically actionable intervention classes rather than an exhaustive census of every modality ever trialled for insomnia; this targeted approach, while improving clinical applicability and interpretability for the intended readership, may have introduced selection bias and reduces the comprehensiveness of the review relative to a fully exhaustive systematic search; an unrestricted database search would broaden the evidence base. Second, the included population shows heterogeneity in age (range: mean 44.9 to 95 years), diagnostic tools, and comorbidity burden, which limits direct comparison across studies and introduces heterogeneity into pooled estimates. The minimum age of participants included across some primary source cohorts was 44.9 years, while the overall mean age was 56.3 years. Third, evidence specific to the 'oldest-old' (≥ 80 years), the frail, and those with advanced neurodegenerative disease remains limited; most pharmacological trials included older adults as subgroups within trials designed primarily for general adult populations. Fourth, long-term follow-up data (>12 months)

are limited for most interventions. Finally, this review did not include a formal cost-effectiveness analysis, which would be valuable for guiding health system resource allocation.

Applicability to the Malaysian Healthcare Context

Translating these findings into Malaysian clinical practice introduces unique structural, financial, and cultural considerations: (i) Infrastructure and Human Resource Barriers: While face-to-face CBT-I is established globally as the definitive gold standard, its wide-scale implementation faces significant bottlenecks in Malaysia. There is a severe shortage of certified clinical psychologists and specialized sleep physicians within both the Ministry of Health (MOH) public facilities and private sectors. To address this, clinical priority must shift toward digital and internet-delivered CBT-I (dCBT-I). However, digital delivery requires intentional translation into Malay and Tamil, alongside optimization for varying levels of digital literacy among older populations in rural areas (e.g., Kampung). (ii) Deprescribing Challenges in Primary Care: In Malaysia, the over-reliance on traditional Z-drugs and benzodiazepines (such as alprazolam or lorazepam) remains prevalent in primary care clinics due to their low cost and instant sedation profiles. Transitioning away from these PIMs requires localized, structured tapering protocols integrated into public clinics (Klinik Kesihatan). (iii) DORA Formulary and Accessibility: Newer, safer pharmacological agents like DORAs are significantly more expensive than generic benzodiazepines. Currently, access to agents like lemborexant or daridorexant in Malaysia is mostly restricted to major tertiary referral hospitals or private sleep centers, creating a massive access gap for geriatric patients in the bottom 40% household income group (B40). (iv) Culturally Accommodating Alternative Therapies: Given the limitations in accessing psychological specialists, highly feasible, non-invasive therapies like music therapy or modified exercise regimens (e.g., Tai Chi or chair exercises) hold substantial promise for Malaysian community centers and residential care homes. These interventions leverage community support structures and present zero financial or adverse event burdens.

Implications for Clinical Practice

The findings support the following clinical priorities for practitioners managing insomnia in older adults. All patients should undergo a comprehensive assessment including comorbidity review, medication reconciliation (with attention to alerting or sleep-disrupting agents), and screening for contributing factors such as pain, nocturia, and sleep-disordered breathing. CBT-I should be offered as the primary treatment modality, with digital CBT-I considered where face-to-face access is unavailable. Music therapy and exercise should be offered as adjunctive interventions. When pharmacotherapy is required, DORAs are preferred; melatonin and ramelteon are appropriate where circadian factors predominate. Benzodiazepines and Z-drugs should be actively deprescribed. Patients, families, and care staff should be educated regarding the risks of traditional hypnotics and the availability of evidence-based alternatives.

Future Research Directions

Priority areas for future research include: (i) Dedicated RCTs of DORAs in adults aged ≥ 80 years and in frail, multi-

morbid populations. (ii) Long-term comparative studies (>12 months) of CBT-I versus DORAs in community-dwelling older adults. (iii) Digital CBT-I platform development tailored to reduced digital literacy and cognitive changes common in older adults. (iv) Larger-scale RCTs of music therapy and exercise with standardised protocols to enable high-precision meta-analytic synthesis. (v) Implementation science research addressing how CBT-I can be integrated into primary care, aged care nursing, and community pharmacy settings. (vi) Economic modelling to quantify cost-effectiveness across intervention types and healthcare system contexts.

CONCLUSION

The management of insomnia in older adults requires a comprehensive, individualized, and multimodal approach that prioritizes evidence-based non-pharmacological treatment, reserves pharmacotherapy for specific clinical indications, and selects agents with the most favorable safety profile. CBT-I is established as the gold-standard first-line treatment, showing high therapeutic durability but requiring individualized modification to suit the specific physical and cultural profiles of older adults. DORAs represent the preferred pharmacological class due to highly consistent cross-population efficacy and low heterogeneity. Benzodiazepines and Z-drugs should be actively avoided or systematically deprescribed to prevent unnecessary fall-related morbidity. These integrated recommendations should be incorporated into modern clinical frameworks to close the persistent evidence-practice gap in geriatric sleep medicine.

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CONFLICT OF INTEREST

The authors declare no competing interests.

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