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Cognitive Behavioral Therapy for Insomnia in People With Chronic Disease
A Systematic Review and Meta-Analysis

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IMPORTANCE Insomnia is highly prevalent among individuals with chronic disease (eg, chronic pain, cardiovascular disease, and cancer) and results in poorer disease outcomes and quality of life. Cognitive behavioral therapy for insomnia (CBT-I) is recommended as first-line treatment for insomnia. However, concerns remain about its applicability and efficacy in people with chronic disease.

OBJECTIVE To evaluate the nature, efficacy, and acceptability of CBT-I in adults with chronic disease, and to identify moderators of treatment outcomes.

DATA SOURCES Systematic searches were conducted in PsycINFO, Medline, Embase, and CENTRAL from database inception to June 5, 2025. Additional records were identified from reference lists of relevant reviews and studies.

STUDY SELECTION Eligible studies were randomized clinical trials (RCTs) involving adults (aged ≥18 years) with chronic disease and insomnia. Studies using CBT-I with measured sleep outcomes were included.

DATA EXTRACTION AND SYNTHESIS Two assessors extracted data from RCTs. Hedges *g* was used to calculate effect sizes, and random effects meta-analyses were conducted. Heterogeneity was assessed via I^2. Subgroup analyses examined whether outcomes varied by delivery format, chronic condition type, or control group.

MAIN OUTCOMES AND MEASURES Primary outcomes included insomnia severity, sleep efficiency, and sleep onset latency. Secondary outcomes included treatment acceptability and adverse effects.

RESULTS Sixty-seven RCTs (5232 participants) met inclusion criteria, including chronic diseases such as cancer, chronic pain, irritable bowel syndrome, and stroke. CBT-I was associated with significantly improved outcomes for insomnia severity (g = 0.98; 95% CI, 0.81-1.16) and moderate effect sizes regarding sleep efficiency (g = 0.77; 95% CI, 0.63-0.91) and sleep onset latency (g = 0.64; 95% CI, 0.50-0.78). Subgroup analyses revealed some sample, treatment, and methodological moderators (eg, longer treatment yielded better outcomes for sleep efficiency and sleep onset latency). Satisfaction with CBT-I was high, with a mean dropout rate of 13.3%. Treatment-related adverse effects were rare.

CONCLUSIONS AND RELEVANCE This systematic review and meta-analysis showed that CBT-I demonstrated strong efficacy and acceptability in chronic disease populations, with moderate to large effect sizes that appear comparable to those in non–chronic disease populations. Efficacy of CBT-I was similar across a range of disease subgroups. Future research should explore the role and nature of treatment adaptations for specific populations and increase access to CBT-I in medical settings.

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Supplemental content

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Approximately 10% to 15% of adults experience chronic insomnia, characterized by a consistent pattern of difficulties initiating and/or maintaining sleep.[1] Among people with chronic diseases, the rates of insomnia disorder are significantly higher. For example, 60% and 70% of people with cancer and chronic pain, respectively, report clinically significant insomnia.[2,3] Insomnia and chronic disease share a close relationship, with poor sleep exacerbating disease outcomes, such as increased pain[4] and heightened risk of hypertension and type 2 diabetes.[5,6] Conversely, chronic disease often disrupts sleep through mechanisms such as physical discomfort, pain, or fatigue.[7,8] Given this relationship, it is critical to develop treatments that target insomnia in people with chronic disease.

Cognitive behavioral therapy for insomnia (CBT-I) is a nonpharmacological treatment that targets the psychological and behavioral factors that maintain insomnia, using strategies such as stimulus control, sleep restriction, and cognitive restructuring. Its efficacy in the general insomnia population is well established,[9] with randomized clinical trials (RCTs) showing greater long-term benefits than sleep medication.[10] However, applying CBT-I in chronic disease populations presents unique challenges. People with chronic disease experience symptoms such as pain, fatigue, and cognitive impairment that may interfere with implementing core behavioral components like stimulus control and sleep restriction. For example, patients may struggle to get out of bed during nighttime awakenings because of mobility limitations. Clinicians may also be concerned that temporary sleep restriction could exacerbate symptoms or trigger adverse health events, particularly in certain populations (eg, those with epilepsy, cardiovascular disease, or immunosuppression). These clinical realities raise questions about the feasibility, acceptability, and efficacy of CBT-I in these contexts.[11,12]

Preliminary evidence suggests that CBT-I achieves good efficacy in chronic disease populations.[13] Specifically, a 2015 meta-analysis examined CBT-I in populations with psychiatric and medical comorbidity and found that 36% of participants receiving CBT-I achieved remission from insomnia compared with 17% in control groups. However, the authors observed larger effect sizes in the studies conducted in people with psychiatric disorders (g = 0.20; $P \leq .001$). This leaves some uncertainty about whether CBT-I is as efficacious in studies of people with chronic physical disease. Since 2015, a substantial number of trials have been conducted among chronic disease populations. This provides an opportunity to update efficacy estimates and examine key subgroup effects (eg, disease type, delivery format) as well as explore whether and how CBT-I is modified or adapted to address the more complex needs of chronic disease populations. This systematic review and meta-analysis aimed to explore the nature, acceptability and efficacy of CBT-I in chronic disease populations.

Key Points

Question Is cognitive behavioral therapy for insomnia (CBT-I) effective and acceptable for treating insomnia in individuals with chronic disease?

Finding This systematic review and meta-analysis of 67 randomized clinical trials including 5232 participants found that CBT-I was significantly associated with improved insomnia severity, sleep efficiency, and sleep onset latency with moderate to large effect sizes. Treatment associations were moderated by a variety of sample, treatment, and methodological factors, and treatment acceptability and satisfaction were high.

Meaning These findings suggest that CBT-I is an acceptable and efficacious intervention for managing insomnia in chronic disease populations, supporting its use as a first-line treatment across diverse patient groups.

Methods

The current systematic review and meta-analysis was prospectively registered on Open Science Framework.[14] We conducted this study according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guideline.

Search Strategy

Searches were conducted across PsycINFO, Medline, Embase, and the Cochrane Central Register of Randomized Controlled Trials (CENTRAL) from database inception to June 5, 2025. Terms focused on insomnia, RCT methodology, and CBT-I treatment components. Studies were limited to those published in English. The study protocol[14] includes the detailed search strategies. Reference lists of relevant systematic reviews and included studies were also screened to identify additional eligible studies.

Study Selection

Two authors independently screened titles and abstracts, followed by full-text articles, for inclusion. Disagreements were resolved through consensus. Briefly, studies were RCTs in people with chronic disease (defined as any condition expected to persist for >3 months) and insomnia disorder or clinically significant insomnia symptoms. No trials were designed to recruit individuals with primary psychiatric disorders, though some studies allowed incidental comorbidity. Studies that explicitly excluded severe psychiatric conditions (eg, psychosis, bipolar disorder) were retained. eTable 1 in Supplement 1 provides further information about inclusion and exclusion criteria.

Data Extraction

Data were extracted into a spreadsheet covering the following domains: trial characteristics, sample characteristics, interventions, treatment modifications, and control condition. Two independent assessors (A.J.S., A.B.C., M.R., S.C., and A.I.H.) coded each study, and differences were discussed by the team until consensus was reached.

Outcome Variables

Outcome data included self-report measures of insomnia severity (the Insomnia Severity Index [ISI]; possible scores range from

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0 to 28, with higher scores indicating more severe insomnia)[15] as well as either self-report or objectively-measured sleep efficiency (SE; defined as the percentage of time spent in bed asleep) or sleep onset latency (SOL; defined as the amount of time taken to fall asleep). These outcomes reflect what is commonly reported in RCTs.[9] For data synthesis, outcomes were extracted as either the mean (SD) of relevant scores pre- and posttreatment or the mean (SD) change between pre- and posttreatment, enabling the calculation of a standardized Hedges *g*. Effect sizes were interpreted using the following widely accepted thresholds: 0.2 was considered small, 0.5 medium, and ≥0.8 large.[16] When mean data was unavailable, effect sizes were calculated from other reported statistics (eg, F-tests, *t* tests, or *P* values) following established conversion methods.[17] Where effect size data were not compatible with effect size calculation or transformation, corresponding authors were e-mailed on 2 occasions with requests for data. Finally, pooled remission rates were calculated on the basis of recognized cut-offs (ie, the number of participants scoring below 8 on the ISI).[18] We also calculated the odds ratio for remission compared with control conditions.

Data Synthesis and Analysis

Data regarding treatment development, modification, and acceptability or satisfaction were qualitatively synthesized. Quantitative analyses were conducted in Comprehensive Meta-Analysis, version 3 (Biostat, Inc), and forest plots for study effect sizes and the overall effect were generated using the ggpllot2 package in R, version 4.2.2 (R Foundation).[19] Random-effects models were used to account for variability between studies. Statistical heterogeneity was examined using the I^2 statistic. Sensitivity analyses removing outliers were also performed, whereby we removed any effect sizes whose 95% CIs did not overlap with the 95% CIs of the overall effect and recalculated the overall effect size with such studies removed.[20] Results were considered statistically significant when $P < .05$ (2 sided).

Subgroup analyses were conducted using mixed effects models and only when at least 5 studies contributed to each subgroup. We examined moderators including chronic disease type, delivery format (digital or face-to-face), number of sessions (0-4, 5-8, or ≥9), risk of bias (high, some concerns, or low), and study size (n >20 vs n <20 per arm). Control groups were categorized as inactive (no education or contact), active (some education or contact), and matched active (equivalent therapist time). This distinction helped separate minimal-contact conditions (eg, pamphlets) from more intensive ones (eg, multisession programs). For studies reporting SOL or SE, we examined whether outcome measurement (self-report vs actigraphy or polysomnography) moderated effects. We also tested whether dropout rate was associated with outcomes via metaregression.

Study Quality and Risk of Bias

The Cochrane Risk of Bias (RoB) 2 tool was used to assess study quality. This tool assesses risk of bias across 5 domains regarding the randomization process, deviations from the intervention, outcome data handling, outcome measurement, and selective reporting.[21] Because double-blinding is impossible in psychotherapy research, domain 4 (bias due to outcome measurement) was modified in line with past research.[22]

Table 1. Study Characteristics Summary

Characteristic	No. (%)
Study country	
US	36 (54)
UK	5 (7)
Australia	4 (6)
Sweden	4 (6)
Canada	3 (4)
Spain	3 (4)
Other[a]	12 (18)
Chronic disease	
Cancer	18 (27)
Chronic pain	17 (25)
Traumatic brain injury	6 (9)
Cardiovascular disease	5 (7)
Renal disease	5 (7)
Type 2 diabetes	3 (4)
Mixed chronic diseases	3 (4)
Stroke	2 (3)
Irritable bowel syndrome	2 (3)
Other[b]	7 (9)
Delivery method	
Individual therapy (face-to-face)	29 (43)
Group therapy (face-to-face)	21 (31)
Self-guided digital therapy	6 (9)
Clinician-guided digital therapy	8 (12)
Other	4 (6)
No. of control arms	
1	61 (91)
≥2	6 (9)
Control group type (of 73 control arms)	
Inactive (eg, waitlist, treatment as usual)	25 (34)
Active	17 (25)
Active, structurally equivalent	25 (34)
Risk of bias	
Low risk	10 (15)
Some concerns	38 (57)
High risk	19 (28)

[a] Other countries included China (n = 2), Denmark (n = 2), Iran (n = 1), Netherlands (n = 2), New Zealand (n = 1), Portugal (n = 1), South Korea (n = 1), and Taiwan (n = 2).

[b] Other diseases (all n = 1) included concussion, chronic obstructive pulmonary disease, epilepsy, Gulf War illness, hearing impairment, multiple sclerosis, and tinnitus.

Publication Bias

Publication bias was assessed using funnel plots to detect asymmetry.[23] Egger weighted regression test was used as a statistical test for funnel plot asymmetry, as well as Duval and Tweedie trim and fill, which provides an estimate of the number of missing studies, and an updated estimate of the effect size should those missing studies be included.[24]

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Table 2. Meta-Analysis and Subgroup Analyses Results

Subgroup	Insomnia severity						Sleep efficiency						Sleep onset latency					
	Comparisons, No.	g (95% CI)	I^2	T^2	*P* value		Comparisons, No.	g (95% CI)	I^2	T^2	*P* value		Comparisons, No.	g (95% CI)	I^2	T^2	*P* value	
All studies	55	0.98 (0.81-1.15)	77	0.31	NA		51	0.78 (0.63-0.92)	72	0.18	NA		38	0.64 (0.50-0.78)	63	0.11	NA	
No outliers	49	0.85 (0.69-1.01)	67	0.21	NA		47	0.68 (0.54-0.81)	67	0.13	NA		37	0.58 (0.45-0.71)	55	0.07	NA	
Measurement																		
Objective[a]		NA	NA	NA	NA		21	0.50 (0.26-0.74)	78	0.23	.02		12	0.65 (0.32-0.98)	75	0.23	.78	
Subjective[b]		NA	NA	NA			45	0.83 (0.68-0.98)	69	0.16			37	0.60 (0.46-0.73)	62	0.10		
Type of disease		NA																
Cancer	16	1.04 (0.71-1.38)	88	0.40			13	0.67 (0.46-0.88)	61	0.09			10	0.46 (0.32-0.60)	1	0		
Cardiovascular	5	0.64 (0.41-0.85)	0	0.00	.10		3	NA	NA	NA	.06		2	NA	NA	NA	.22	
Chronic pain	14	0.90 (0.57-1.23)	81	0.28			15	0.82 (0.50-1.13)	78	0.27			10	0.69 (0.35-1.04)	73	0.21		
Delivery format																		
Digital	12	1.05 (0.61-1.49)	89	0.53			7	0.90 (0.61-1.18)	51	0.07			7	0.59 (0.36-0.83)	42	0.04		
Face-to-face	39	0.98 (0.79-1.17)	78	0.25	.39		41	0.73 (0.58-0.89)	68	0.16	.53		30	0.66 (0.49-0.83)	68	0.14	.84	
No. of sessions																		
0 to 4	8	0.88 (0.49-1.23)	75	0.46			9	0.49 (0.25-0.74)	39	0.05			7	0.45 (0.07-0.82)	69	0.40		
5 to 8	44	0.99 (0.80-1.19)	84	0.35	.76		37	0.81 (0.64-0.99)	74	0.19	.04		27	0.63 (0.49-0.78)	47	0.06	.001	
≥9	3	-NA	NA	NA			4	NA	NA	NA			3	NA	NA	NA		
Control group																		
Active	19	0.84 (0.58-1.09)	75	0.21			17	0.88 (0.58-1.18)	76	0.26			9	0.50 (0.23-0.78)	57	0.09		
Matched active	16	0.60 (0.43-0.77)	49	0.05	<.001		19	0.55 (0.38-0.72)	46	0.06	.02		19	0.60 (0.41-0.79)	60	0.10	.27	
Inactive	20	1.37 (1.08-1.66)	81	0.33			15	0.92 (0.66-1.17)	74	0.18			10	0.82 (0.54-1.11)	70	0.14		
<20 Participants per arm																		
No	30	0.81 (0.58-1.02)	88	0.33	<.001		27	0.70 (0.52-0.89)	80	0.18	.25		22	0.55 (0.40-0.69)	63	0.07	.06	
Yes	25	1.23 (1.03-1.44)	36	0.10			24	0.89 (0.65-1.12)	50	0.17			16	0.88 (0.57-1.19)	60	0.24		
Risk of bias																		
High risk	13	0.89 (0.61-1.17)	72	0.15			17	0.76 (0.53-0.99)	72	0.15			14	0.70 (0.43-0.98)	72	0.18		
Low risk	9	1.18 (0.57-1.80)	95	0.83	.85		6	0.77 (0.35-1.20)	83	0.23	.99		4	NA	NA	NA	.76	
Some concerns	33	0.91 (0.72-1.10)	68	0.18			28	0.78 (0.58-0.99)	68	0.19			20	0.61 (0.42-0.80)	59	0.10		

Abbreviation: NA, not applicable.

[a] Objective measurement constitutes sleep measured via actigraphy or polysomnography.

[b] Subjective measurement constitutes sleep measured via sleep diary.

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Figure 1. Forest Plot of Insomnia Severity

Source	Hedges *g* (95% CI)
Zachariae et al,[54] 2018	1.21 (0.95 to 1.48)
Ymer et al,[69] 2021	0.29 (-0.28 to 0.87)
Yang and Jun,[76] 2022	1.28 (0.73 to 1.84)
Wiklund et al,[75] 2022	0.35 (-0.22 to 0.92)
Vitiello et al,[40] 2013	0.21 (-0.04 to 0.46)
Tang et al,[39] 2012	2.85 (1.63 to 4.07)
Smith et al,[47] 2015	0.38 (-0.01 to 0.77)
Siengsukon et al,[64] 2020 cohort b	2.19 (1.11 to 3.27)
Siengsukon et al,[64] 2020 cohort a	2.36 (1.25 to 3.48)
Siebmanns et al,[68] 2021	0.64 (0.07 to 1.21)
Savard et al,[44] 2014 cohort b	0.72 (0.33 to 1.11)
Savard et al,[44] 2014 cohort a	1.17 (0.77 to 1.57)
Savard et al,[28] 2005	0.68 (0.16 to 1.21)
Ritterband et al,[38] 2012	1.81 (0.92 to 2.71)
Redeker et al,[73] 2022	0.60 (0.30 to 0.90)
Redeker et al,[46] 2015	0.73 (0.14 to 1.32)
Pigeon et al,[37] 2012 cohort b	1.56 (0.23 to 2.89)
Pigeon et al,[37] 2012 cohort a	1.70 (0.40 to 2.99)
Palesh et al,[63] 2020	0.52 (0.05 to 1.00)
Palesh et al,[52] 2018	0.63 (0.16 to 1.10)
Oswald et al,[71] 2022	1.29 (0.52 to 2.06)
Nhu et al,[83] 2024	0.35 (-0.26 to 0.96)
Nguyen et al,[57] 2019	1.44 (0.34 to 2.54)
Nguyen et al,[49] 2017	1.21 (0.36 to 2.06)
Morgan et al,[36] 2012	0.34 (0.06 to 0.63)
Mehrotra et al,[82] 2024	0.10 (-0.32 to 0.52)
McCurry et al,[67] 2021	0.79 (0.55 to 1.03)
Matthews et al,[43] 2014	0.45 (-0.08 to 0.97)
Marks et al,[80] 2023 cohort b	2.36 (1.74 to 2.97)
Marks et al,[80] 2023 cohort a	1.45 (0.91 to 1.98)
Malarkey et al,[86] 2024	0.65 (0.19 to 1.11)
Ludwig et al,[91] 2024	1.83 (1.01 to 2.64)
Latocha et al,[79] 2023	2.18 (1.55 to 2.80)
Kapella et al,[33] 2011	0.91 (-0.02 to 1.83)
Jungquist et al,[31] 2010	1.44 (0.59 to 2.30)
Javaheri et al,[61] 2020	0.54 (-0.13 to 1.21)
Jansson-Fröjmark et al,[35] 2012	1.25 (0.51 to 1.99)
Heffner et al,[50] 2018	1.33 (0.56 to 2.11)
Harris et al,[55] 2019	0.83 (0 to 1.65)
Hall et al,[70] 2022	0.89 (0.26 to 1.53)
Garland et al,[81] 2024	1.99 (1.57 to 2.40)
Ford et al,[78] 2023	0.58 (0.04 to 1.13)
Fleming et al,[77] 2023	0.54 (0.11 to 0.98)
Edinger et al,[26] 2005 cohort b	0.75 (-0.01 to 1.50)
Edinger et al,[26] 2005 cohort a	0.73 (0.07 to 1.39)
Dirksen and Epstein,[89] 2008	0.60 (0.12 to 1.08)
Dickerson et al,[85] 2024	0.12 (-0.21 to 0.46)
Dean et al,[60] 2020	0.91 (0.26 to 1.56)
Clara et al,[88] 2025	2.57 (2.15 to 3.00)
Chao et al,[66] 2021	0.22 (-0.21 to 0.64)
Casault et al,[45] 2015	1.32 (0.60 to 2.04)
Bothelius et al,[87] 2024	0.16 (-0.26 to 0.58)
Ballou et al,[59] 2020	1.39 (0.48 to 2.29)
Alshehri et al,[65] 2021	1.39 (0.59 to 2.20)
Alshehri et al,[58] 2020	1.39 (0.55 to 2.22)
Overall	0.98 (0.81 to 1.16)

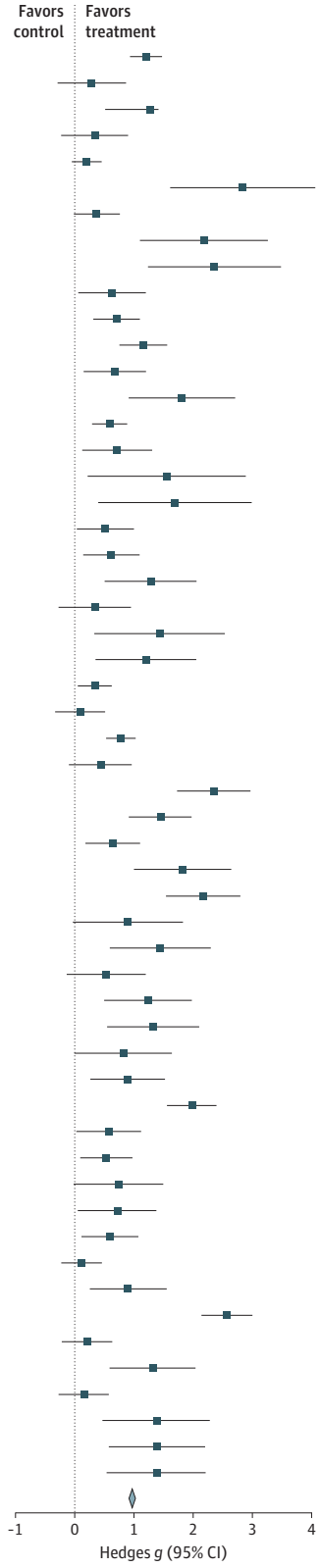

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Figure 2. Forest Plot of Sleep Efficiency

Source	Hedges *g* (95% CI)
Alshehri et al,[58] 2020	1.46 (0.61 to 2.31)
Alshehri et al,[65] 2021	1.46 (0.64 to 2.28)
Ballou et al,[59] 2020	1.47 (0.56 to 2.39)
Casault et al,[45] 2015	1.07 (0.38 to 1.77)
Chao et al,[66] 2021	0.89 (0.44 to 1.34)
Chen et al,[32] 2011	0.65 (0.18 to 1.12)
Clara et al,[88] 2025	1.26 (0.91 to 1.60)
Dean et al,[60] 2020	0.35 (-0.27 to 0.98)
Dickerson et al,[85] 2024	0.66 (0.31 to 1.02)
Edinger et al,[26] 2005 cohort a	0.35 (-0.30 to 1.00)
Edinger et al,[26] 2005 cohort b	0.51 (-0.23 to 1.25)
Groeneveld et al,[84] 2024	0.06 (-0.45 to 0.57)
Hall et al,[70] 2022	0.26 (-0.35 to 0.87)
Harris et al,[55] 2019	0.88 (0.05 to 1.70)
Hou et al,[41] 2014	1.19 (0.76 to 1.62)
Jungquist et al,[31] 2010	1.68 (0.80 to 2.57)
Kapella et al,[33] 2011	0.54 (-0.36 to 1.44)
Lami et al,[51] 2018	0.17 (-0.27 to 0.60)
Latocha et al,[79] 2023	2.28 (1.64 to 2.91)
Marks et al,[80] 2023 cohort a	1.12 (0.61 to 1.63)
Marks et al,[80] 2023 cohort b	1.32 (0.80 to 1.84)
Martínez et al,[42] 2014	0.65 (0.14 to 1.17)
Matthews et al,[43] 2014	0.37 (-0.15 to 0.90)
McCrae et al,[56] 2019 cohort a	0.45 (0 to 0.91)
McCrae et al,[56] 2019 cohort b	0.60 (0.14 to 1.06)
Mehrotra et al,[82] 2024	0.19 (−0.23 to 0.62)
Morgan et al,[36] 2012	1.46 (1.14 to 1.77)
Oswald et al,[71] 2022	0.68 (-0.04, 1.40)
Paardekooper et al,[62] 2020	0.12 (-0.73 to 0.96)
Padron et al,[72] 2022	0.14 (-0.51 to 0.79)
Pigeon et al,[37] 2012 cohort a	1.67 (0.38 to 2.96)
Pigeon et al,[37] 2012 cohort b	2.24 (0.74 to 3.75)
Redeker et al,[46] 2015	0.45 (-0.13 to 1.02)
Redeker et al,[73] 2022	0.27 (-0.03 to 0.56)
Ritterband et al,[38] 2012	0.95 (0.16 to 1.74)
Rybarczyk et al,[25] 2002 cohort a	0.84 (0.02 to 1.66)
Rybarczyk et al,[25] 2002 cohort b	1.61 (0.61 to 2.61)
Rybarczyk et al,[27] 2005	0.81 (0.39 to 1.24)
Savard et al,[28] 2005	0.50 (-0.02 to 1.03)
Savard et al,[44] 2014 cohort a	0.59 (0.20 to 0.97)
Savard et al,[44] 2014 cohort b	0.41 (0.03 to 0.79)
Siengsukon et al,[64] 2020 cohort a	1.93 (0.90 to 2.96)
Siengsukon et al,[64] 2020 cohort b	0.96 (0.07 to 1.85)
Smith et al,[47] 2015	0.17 (-0.22 to 0.57)
Smitherman et al,[48] 2016	0.41 (-0.27 to 1.10)
Tang et al,[39] 2012	1.96 (0.92 to 3.00)
Theadom et al,[53] 2018	0.22 (-0.69 to 1.13)
Vitiello et al,[40] 2013	0.28 (0.02 to 0.54)
Wiklund et al,[75] 2022	1.03 (0.44 to 1.63)
Ymer et al,[69] 2021	0.29 (-0.28 to 0.87)
Zachariae et al,[54] 2018	1.11 (0.85 to 1.37)
Overall	0.77 (0.63 to 0.91)

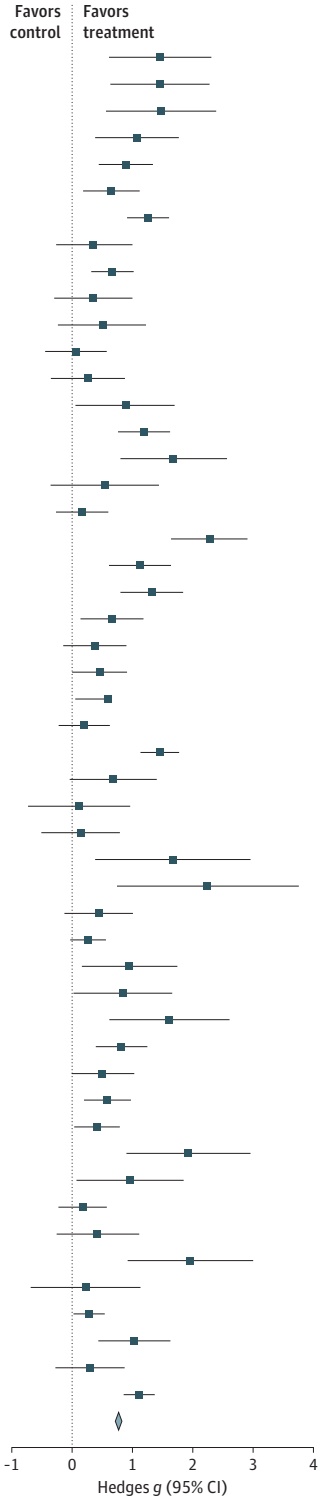

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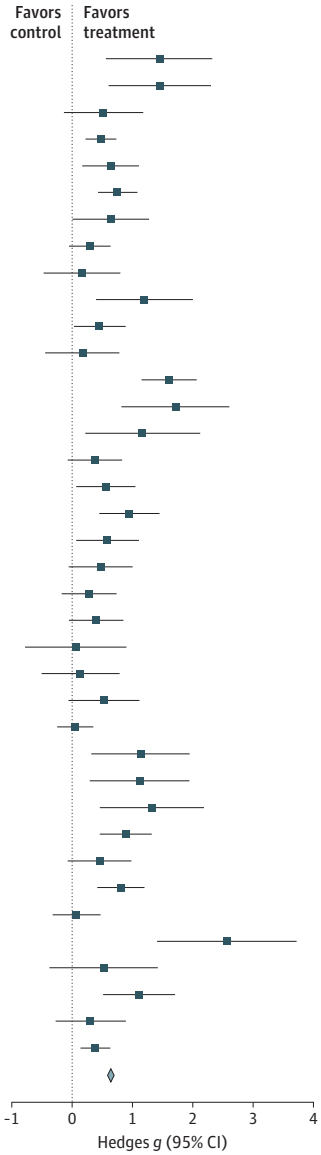
Figure 3. Forest Plot of Sleep Onset Latency

Source	Hedges *g* (95% CI)
Alshehri et al,[58] 2020	1.45 (0.57 to 2.32)
Alshehri et al,[65] 2021	1.45 (0.60 to 2.29)
Casault et al,[45] 2015	0.51 (−0.15 to 1.17)
Chao et al,[66] 2021	0.48 (0.22 to 0.73)
Chen et al,[32] 2011	0.63 (0.17 to 1.10)
Clara et al,[88] 2025	0.75 (0.42 to 1.07)
Dean et al,[60] 2020	0.64 (0 to 1.27)
Dickerson et al,[85] 2024	0.29 (−0.05 to 0.63)
Edinger et al,[26] 2005 cohort a	0.16 (−0.48 to 0.80)
Edinger et al,[26] 2005 cohort b	1.19 (0.40 to 1.99)
Fleming et al,[77] 2023	0.45 (0.02 to 0.88)
Hall et al,[70] 2022	0.17 (−0.44 to 0.78)
Hou et al,[41] 2014	1.61 (1.16 to 2.06)
Jungquist et al,[31] 2010	1.71 (0.82 to 2.60)
Kapella et al,[33] 2011	1.17 (0.21 to 2.12)
Lami et al,[51] 2018	0.37 (−0.07 to 0.81)
Marks et al,[80] 2023 cohort a	0.56 (0.07 to 1.04)
Marks et al,[80] 2023 cohort b	0.95 (0.45 to 1.45)
Martínez et al,[42] 2014	0.58 (0.07 to 1.10)
Matthews et al,[43] 2014	0.47 (−0.05 to 1.00)
McCrae et al,[56] 2019 cohort a	0.28 (−0.17 to 0.73)
McCrae et al,[56] 2019 cohort b	0.40 (−0.05 to 0.85)
Paardekooper et al,[62] 2020	0.06 (−0.78 to 0.90)
Padron et al,[72] 2022	0.13 (−0.51 to 0.78)
Redeker et al,[46] 2015	0.53 (−0.05 to 1.11)
Redeker et al,[73] 2022	0.05 (−0.24 to 0.35)
Ritterband et al,[38] 2012	1.13 (0.32 to 1.94)
Rybarczyk et al,[25] 2002 cohort a	1.12 (0.29 to 1.94)
Rybarczyk et al,[25] 2002 cohort b	1.32 (0.46 to 2.18)
Rybarczyk et al,[27] 2005	0.89 (0.46 to 1.31)
Savard et al,[28] 2005	0.46 (−0.06 to 0.98)
Shareh et al,[74] 2022	0.81 (0.42 to 1.19)
Smith et al,[47] 2015	0.07 (−0.32 to 0.47)
Tang et al,[39] 2012	2.56 (1.41 to 3.72)
Theadom et al,[53] 2018	0.52 (−0.37 to 1.42)
Wiklund et al,[75] 2022	1.11 (0.52 to 1.70)
Ymer et al,[69] 2021	0.31 (−0.27 to 0.89)
Zachariae et al,[54] 2018	0.38 (0.14 to 0.63)
Overall	0.64 (0.50 to 0.78)



Results

Trial Flow

Database searches yielded 13 734 articles, with 10 200 remaining after duplicate removal. Following title and abstract screening, 160 full texts were reviewed, and 67 met inclusion criteria (5232 participants) (eTable 1 in Supplement 1).[25-91] Of these, 64 (5044 participants) were eligible for meta-analysis.

Study Characteristics

Table 1 summarizes the study characteristics, and eTable 2 in Supplement 1 lists individual study details and characteristics. Studies were published between 2002 and 2025. Most were conducted in the US (n = 36),[25-27, 30, 31, 33, 37, 38, 40, 43, 46-48, 50, 52, 55, 56, 58-61, 63-67, 70-73, 81, 82, 85, 86, 89, 91] and the most studied chronic diseases were cancer (n = 17)[23, 28-30, 38, 44, 45, 52, 54, 60, 63, 70-72, 81, 85, 89] and chronic pain (n = 17).[26, 27, 31, 34, 37, 39, 40, 42, 47, 48, 50, 51, 56, 67, 75, 79, 83, 87] Five studies were conducted in cardiovascular disease,[46,55,61,68,73] kidney disease,[32,41,74,82,90] and traumatic brain injury.[49,53,69,78,86] Other populations included chronic obstructive pulmonary disease,[33] epilepsy,[62] irritable bowel syndrome,[59] and tinnitus.[80] Three studies were conducted in populations with mixed chronic diseases.[25,27,36] Treatment delivery included individual face-to-face treatment (n = 30),[23, 26, 30, 31, 33, 37, 43, 44, 47-50, 52, 55-60, 63-67, 69, 72, 81-83, 85, 91] group face-to-face treatment (n = 21),[25, 27-29, 32, 34, 35, 39-42, 46, 51, 62, 73, 74, 76, 79, 80, 89, 90] internet-delivered CBT-I (n = 13),[38,53,54,61,68,70,75,77,78,84,86-88] and blended delivery (n = 4).[36,44,45,78]

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Qualitative Data Synthesis

Intervention Development

eTable 3 in Supplement 1 provides descriptions of each study and its development, adaptation, acceptability, and adverse effects. Most reported developing their intervention from a recognized, evidence-based protocol (eg, Perlis et al,[92] Morin and Espie,[93] Edinger and Carney[94]) and/or theory (eg, Spielman et al[95] and Harvey[96]).

Intervention Adaptation for Chronic Disease

Thirty-one studies reported no changes or adaptations to standard treatment.[23,26,27,29-32,35-38,40,41,47,48,50,54,55,58-61,65,66,71,83-86,89,90] Of those that reported adaptations, most modified their initial psychoeducation session to incorporate information about the chronic disease (n = 15) (eTable 3 in Supplement 1).[28,34,42,44,46,52,53,63,67-69,73,74,78,91] Five studies supplemented CBT-I with fatigue strategies (eg, activity pacing).[44,49,57,69,75] Five studies modified advice around naps (eg, permitting naps during chemotherapy.[52,57,64,77,82] Some studies modified stimulus control for those with mobility restrictions, by encouraging participants to sit up in bed instead of leaving it.[64,77] One study in epilepsy[62] set a minimum sleep window of 6 hours to reduce the risk of seizures due to sleep deprivation.[62] Studies conducted in chronic pain populations incorporated both insomnia and pain management strategies.[37,56] Finally, some studies adapted materials for cognitive impairments by using pictorial cues and simplified content.[49,57]

Acceptability

Twenty-one studies administered measures of acceptability and satisfaction (eTable 3 in Supplement 1).[27,29,33,35,39,40,45-48,52,56,59,67,70-72,74,75,80,85] However, the measure and method of assessment varied considerably. Overall, data regarding participant satisfaction indicate moderate to high satisfaction (eg, satisfaction ratings of around 7-8 out of 10).[46,59] The acceptability of treatment was supported by a low mean dropout rate of 12.7% (range, 0% to 45%).

Adverse Effects

Twenty-two studies provided adverse effect (AE) reporting, with varying findings (eTable 3 in Supplement 1).[29,31,32,39,46-48,52,54,58,61,67,74,75,77,79-82,85,87,90] Seven studies reported no AEs,[32,39,48,54,61,74,77] and 8 reported AEs related and unrelated to treatment.[46,47,65,67,79,81,88,90] Of these, 1 study reported 1 AE (increased anxiety) attributed to CBT-I,[79] and 1 study[81] identified 31 AEs linked to CBT-I and noted 3 withdrawals due to treatment. The remaining studies found no AEs attributable to CBT-I.

Quantitative Data Synthesis

Overall Effect of CBT-I

CBT-I resulted in significant positive effects across all 3 treatment outcomes (**Table 2**). Regarding insomnia severity, a large effect was observed (g = 0.98; 95% CI, 0.81-1.16) (**Figure 1**). Moderate effects were observed for SE (g = 0.77; 95% CI, 0.63-0.91) (**Figure 2**) and SOL (g = 0.64; 95% CI, 0.50-0.78) (**Figure 3**). All effects were slightly smaller after removal of outliers. Heterogeneity was substantial, as indicated by I^2 values between 63% and 77%. Eight studies reported rates of remission across treatment and control groups. The overall pooled prevalence of remission in treatment groups was 54.0% (95% CI, 40.3%-67.0%) compared with 18.0% (95% CI, 11.9%-26.5%) in control. The odds ratio for remission between treatment and control was 5.35 (95% CI, 2.66-10.75).

Method of Measurement

Sleep diaries were the most common measurement of sleep (with 45 and 37 comparisons available for SE and SOL, respectively). However, numerous studies utilized actigraphy or polysomnography data alongside self-report (21 comparisons for SE; 12 comparisons for SOL). Regarding SE, significantly larger effect sizes were observed when outcomes were measured via sleep diary (g = 0.83 [95% CI, 0.68-0.98]) vs actigraphy or polysomnography (g = 0.50 [95% CI, 0.26-0.74]) (P = .02). Method of measurement did not moderate SOL.

Type of Chronic Health Condition

There were enough studies to compare the effect sizes of CBT-I treatment between populations with cancer (16 comparisons), cardiovascular disease (5 comparisons), and chronic pain (14 comparisons). Subgroup analyses showed no significant difference in effect size across any outcome.

Delivery Format and Number of Sessions

No significant differences were observed between studies conducted face-to-face vs digitally across any outcome. Additionally, number of sessions did not moderate the efficacy of CBT-I regarding insomnia symptom severity, but significant outcomes were observed regarding SE and SOL. In both instances, smaller effect sizes were observed in brief treatments (0-4 sessions; g = 0.49 [95% CI, 0.25-0.74] for SE and g = 0.45 [95% CI, 0.07-0.82] for SOL) compared with standard-length treatments of 5 to 8 sessions (g = 0.81 [95% CI, 0.64-0.99] for SE and g = 0.63 [95% CI, 0.49-0.78] for SOL) (P = .04 for SE and P = .001 for SOL).

Type of Control Group

Control group type significantly moderated the effect sizes of CBT-I for insomnia symptom severity and SE. For both outcomes, higher treatment effect sizes were observed when CBT-I was compared to inactive control (symptom severity: g = 1.37 [95% CI, 1.08-1.66]; P < .001; SE: g = 0.92 [95% CI, 0.66-1.17; P = .02). Smaller effect sizes were observed for those with active controls.

Small Studies and Study Dropout

There was a moderating effect whereby smaller studies observed significantly larger treatment effects regarding insomnia severity (<20 participants per arm: g = 1.23 [95% CI, 1.03-1.44]; ≥20 participants: g = 0.81 [95% CI, 0.58-1.02]; P < .001). There was no moderation effect regarding small studies for SE or SOL.

Metaregression analyses found no significant association between study dropout rates and any of the 3 outcomes.

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Risk of Bias

eTable 2 in Supplement 1 lists individual domain ratings for all studies. Most studies (37 [58%]) were rated as having some concerns, 21 (33%) were rated as high risk of bias, and 9 (14%) were rated as low. Overall, studies performed well regarding the conduct and reporting of randomization (57% low risk, 3% high risk), as well as potential bias due to deviations from intended interventions (88% low risk, 3% high risk). In comparison, bias due to missing outcome data (domain 3) was the poorest-performing domain (51% low risk, 28% high risk), often arising from not conducting intent-to-treat analyses or failing to appropriately handle missing data. Risk of bias rating did not moderate study outcomes.

Publication Bias

Funnel plots indicated moderate asymmetry for insomnia severity, with smaller studies absent on the left of the mean, suggesting publication bias (n = 47; regression test: $t = 3.64$; $P < .002$). Trim-and-fill estimated 15 missing studies, with an adjusted g of 0.63 (95% CI, 0.56-0.69). SE showed mild asymmetry but a nonsignificant test, with 5 missing studies and an adjusted $g = 0.68$ (95% CI, 0.61-0.75). SOL displayed some asymmetry (n = 34; regression test: $t = 3.36$; $P = .002$), with 7 missing studies and an adjusted g of 0.51 (95% CI, 0.34-0.81).

Discussion

The aim of this meta-analysis was to examine CBT-I in populations with chronic diseases. A 2015 meta-analysis among studies conducted in people with insomnia and either psychiatric or chronic medical disorders found that that CBT-I produced high rates of remission compared to control.[13] Since then, 41 additional RCTs among people with chronic diseases have been conducted. This allowed us to comprehensively examine CBT-I in chronic diseases and explore its effects within key subgroups.

Our results show large overall effects on insomnia severity and moderate effects on SE and SOL. These effects are comparable to those observed in populations without comorbid conditions.[9] An average of 54% patients were found to meet remission criteria, a higher figure than was reported by Wu and colleagues.[13] Encouragingly, no significant differences in outcomes were observed between the disease groups examined. This provides evidence for the widespread efficacy of CBT-I among chronic disease populations. It is nonetheless noteworthy that heterogeneity was substantial, and we observed variations in effect sizes depending on a variety of factors.

As expected, effect sizes varied by control group; effects were smaller when controls included treatment elements (eg, education, therapist contact) and larger with inactive controls (eg, waiting list control, treatment as usual). Importantly, CBT-I still showed a moderate effect size when compared with matched active controls, reinforcing the efficacy of core components, such as sleep restriction therapy and cognitive restructuring, beyond general therapeutic factors. This supports CBT-I as a targeted, mechanism-driven intervention for insomnia.

We also observed larger SE and SOL with longer treatments, suggesting a dose-response relationship. Lengthier interventions may allow more time for behavioral components, which may require extended support to implement effectively. This aligns with research examining participant feedback following brief behavioral treatments (4 weeks), where some reported the duration was insufficient for lasting change.[97]

Our subgroup analyses also found no significant difference in efficacy between digital and face-to-face CBT-I, suggesting that digital formats may be a viable and efficacious treatment option. This is encouraging in the context of limited access to CBT-I.[98]

Around half of the studies included employed standard CBT-I protocols with no modifications for chronic disease populations. Among those reporting adaptations, studies typically added psychoeducational content about the specific chronic disease (eg, fatigue after TBI,[69] the interaction of gastrointestinal symptoms and sleep[76]), while leaving core CBT-I components unchanged. Some studies added strategies (eg, fatigue management or memory aids). Modification to behavioral components (eg, stimulus control, sleep restriction therapy) was only reported by 1 study.[62] Overall, the finding that moderate to high treatment effects were achieved even when CBT-I was largely unmodified is promising and suggests that the core components of CBT-I retain their efficacy in people who are medically unwell. It is possible that modest additions (eg, adding disease-specific psychoeducation) may help support clinician confidence when treating these populations.

Indicators of acceptability and tolerability were encouraging. Participant satisfaction with CBT-I was high, and average dropout (12.7%) was lower than rates typically seen in psychotherapy (eg, 19.9% for depression).[99] Of the few studies reporting treatment-related AEs, results suggested that AEs were typically minor and unrelated to treatment. However, regular AE monitoring and more consistent reporting is recommended for future research.

Strengths and Limitations

This study has several strengths, including a comprehensive search, rigorous screening and data extraction, and use of robust meta-analytic techniques. Sensitivity analyses suggested that while larger or more rigorous studies reported smaller effects, CBT-I consistently demonstrated moderate to large effect sizes. Despite these strengths, the observed heterogeneity highlights the need for caution in interpreting pooled estimates, particularly given the evidence of publication bias and missing small studies with nonsignificant effects. These findings also point to a broader need for greater standardization in future trials, including consistent use of recognized outcomes (eg, ISI remission criteria) and robust handling of missing data. We also included studies with varying methods for identifying insomnia and chronic disease, including self-report, which may have introduced misclassification bias.

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Conclusion

This meta-analysis provides strong evidence that CBT-I is an effective and acceptable intervention for insomnia in chronic disease populations. Despite variability in study outcomes and some evidence of publication bias, the overall findings reinforce the efficacy of CBT-I in this population. Efforts should now shift toward broadening access and evaluating its potential benefits beyond insomnia to improve outcomes for those with chronic diseases.

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Concept and design: Scott, Bisby, Dear.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Scott, Rahimi, Dear.
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Statistical analysis: Scott.
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Administrative, technical, or material support: Scott, Bisby, Rahimi, Heriseanu, Dear.
Supervision: Scott, Dear.

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