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Efficacy of Cognitive Behavioral Therapy for Insomnia in Multiple Sclerosis: A Systematic Review and Meta-Analysis

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Abstract

Background: Insomnia is one of the most common and burdensome sleep-related complaints among individuals with multiple sclerosis (MS), adversely affecting fatigue, mood, cognitive functioning, and overall quality of life. Although cognitive behavioral therapy for insomnia (CBT-I) is considered a first-line treatment for chronic insomnia in the general population, its effectiveness in people with MS has not yet been synthesized comprehensively through a focused systematic review and meta-analysis.

Objective: To systematically evaluate and quantitatively synthesize the available evidence on the efficacy of cognitive behavioral therapy for insomnia in individuals with multiple sclerosis.

Methods: A systematic review and meta-analysis will be conducted in accordance with PRISMA guidelines. Electronic databases, including PubMed/MEDLINE, Scopus, Web of Science, Cochrane Library, and PsycINFO, will be searched from inception to the final search date using predefined keywords and Medical Subject Headings related to multiple sclerosis, insomnia, sleep disturbance, and cognitive behavioral therapy for insomnia. Interventional studies assessing CBT-I in adults with MS and reporting insomnia-related outcomes will be included. Two reviewers will independently perform study screening, data extraction, and quality assessment. Risk of bias will be evaluated using appropriate standardized tools according to study design. Where sufficient homogeneous data are available, meta-analysis will be performed using pooled effect sizes with 95% confidence intervals. Heterogeneity will be assessed using the I^2 statistic, and a narrative synthesis will be provided where statistical pooling is not feasible.

Expected Outcomes: This review will synthesize the current evidence regarding the effect of CBT-I on insomnia severity, sleep quality, and related clinical outcomes in patients with MS. It is expected to clarify the therapeutic potential of CBT-I in this population and identify important gaps in the literature.

Conclusion: This systematic review and meta-analysis will provide a focused evidence base on the efficacy of CBT-I for insomnia in multiple sclerosis and may inform future clinical practice, rehabilitation strategies, and research directions.

Keywords: Multiple sclerosis; Insomnia; Cognitive behavioral therapy for insomnia; CBT-I; sleep disturbance; Systematic review; Meta-analysis

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Introduction

Multiple sclerosis (MS) is a chronic, immune-mediated, demyelinating disorder of the central nervous system that affects physical, psychological, and cognitive functioning. It is characterized by a broad range of symptoms, including motor impairment, sensory disturbances, fatigue, pain, depression, anxiety, and sleep problems. Among these, sleep disturbance has emerged as a major yet often underrecognized clinical issue in individuals with MS. Sleep-related complaints are highly prevalent in this population and may substantially worsen daily functioning, symptom burden, and health-related quality of life [1].

Insomnia is one of the most frequently reported sleep disorders among people with MS. It commonly presents with difficulty initiating sleep, difficulty maintaining sleep, early morning awakening, or non-restorative sleep, often accompanied by daytime impairment. In patients with MS, insomnia may be associated with disease-related discomfort, pain, nocturia, spasticity, mood disturbances, medication effects, and poor sleep habits [2, 3]. The persistence of insomnia can aggravate fatigue, impair concentration, reduce emotional well-being, and intensify disability-related challenges. Because fatigue is already one of the most disabling symptoms of MS, the coexistence of insomnia may create an additional burden that further compromises patient outcomes [4].

Pharmacological treatment is frequently used for sleep complaints; however, long-term use of sleep medications may be limited by side effects, dependency concerns, daytime sedation, and variable effectiveness. For this reason, non-pharmacological interventions have received increasing attention. Cognitive behavioral therapy for insomnia (CBT-I) is a structured, evidence-based, non-pharmacological treatment that typically includes sleep restriction, stimulus control, cognitive restructuring, sleep hygiene education, and relaxation-based or behavioral strategies [5]. In the general adult population, CBT-I is widely recognized as an effective first-line intervention for chronic insomnia. Its application in individuals with chronic neurological conditions such as MS is of particular interest because it offers a potentially safe and sustainable therapeutic option [6].

Over the past few years, a growing number of studies have explored the use of CBT-I in people with MS. These studies have examined different modes of delivery, including in-person, web-based, and telehealth interventions, and have reported outcomes related to insomnia severity, sleep quality, fatigue, mood, and functional status. However, the available evidence remains scattered, and the overall magnitude of the treatment effect has not been clearly established. In addition, variation in study design, sample size, outcome measures, and intervention format makes it difficult to draw firm conclusions from individual studies alone [7].

A focused systematic review and meta-analysis is therefore needed to critically synthesize the available evidence and determine whether CBT-I is effective for improving insomnia-related outcomes in individuals with MS. Such a review is important not only for summarizing current knowledge but also for guiding clinicians, rehabilitation specialists, and researchers in identifying the role of CBT-I within comprehensive MS care. Therefore, the present study aims to systematically review the literature and perform a meta-analysis on the efficacy of cognitive behavioral therapy for insomnia in multiple sclerosis. Specifically, this review seeks to assess the impact of CBT-I on insomnia severity, sleep quality, and other relevant clinical outcomes, while also identifying limitations in the current evidence base and directions for future research.

Methods

This study was designed as a systematic review and meta-analysis to evaluate the efficacy of cognitive behavioral therapy for insomnia in individuals with multiple sclerosis. The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency and methodological rigor. Studies were considered eligible if they included adults diagnosed with multiple sclerosis who experienced insomnia symptoms or clinically relevant sleep disturbance. Only interventional studies assessing cognitive behavioral therapy for insomnia were included. CBT-I delivered in person, online, through telehealth, or in hybrid form was considered eligible, provided that it represented the main therapeutic intervention. Studies with control groups as well as single-arm pre–post intervention studies were considered for inclusion. Review articles, editorials, conference abstracts without sufficient data, and observational studies without a CBT-I intervention were excluded [8].

A comprehensive literature search was planned across major electronic databases, including PubMed/MEDLINE, Scopus, Web of Science, Cochrane Library, and PsycINFO. The search strategy was developed using relevant keywords and subject terms related to multiple sclerosis, insomnia, sleep disturbance, and cognitive behavioral therapy. Reference lists of included studies and related reviews were also screened manually to identify any additional relevant articles. All retrieved records were imported into reference management software, and duplicates were removed before screening. Titles and abstracts were screened independently by two reviewers, followed by full-text assessment of potentially eligible studies. Any disagreements regarding study inclusion were resolved through discussion and, where necessary, consultation with a third reviewer.

Data were extracted using a standardized form that

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included information on study characteristics, participant details, intervention format, comparator, outcome measures, and main findings. The primary outcomes of interest were insomnia severity and sleep quality, while secondary outcomes included fatigue, depression, anxiety, sleep efficiency, and other related clinical indicators. The methodological quality of included studies was assessed using appropriate risk-of-bias tools according to study design [9]. Randomized trials and non-randomized studies were evaluated separately using standard appraisal methods. Data were synthesized narratively, and where studies were sufficiently comparable in terms of design, intervention, and outcomes, a meta-analysis was performed. For continuous outcomes, pooled effect sizes with 95% confidence intervals were calculated using either mean difference or standardized mean difference. Statistical heterogeneity was assessed using the I^2 statistic, and publication bias was considered where an adequate number of studies were available. As this review was based entirely on previously published studies, ethical approval was not required.

Results

Study Selection

The literature search yielded a total of 135 records from electronic databases and other relevant sources. Of these, 32 duplicate records were identified and removed, leaving 103 unique records for title and abstract screening. After the initial screening process, 82 records were excluded because they did not meet the predefined inclusion criteria. The full texts of the remaining 21 articles were retrieved and assessed in detail for eligibility. Following full-text review, 15 articles were excluded for reasons including irrelevant study population, inappropriate study design, absence of CBT-I as the primary intervention, and insufficient outcome data for analysis. Ultimately, 6 studies met the eligibility criteria and were included in the qualitative synthesis. Among these, 3 studies provided sufficiently comparable outcome data to be included in the quantitative synthesis (meta-analysis). The overall study selection process is presented in Figure 1.

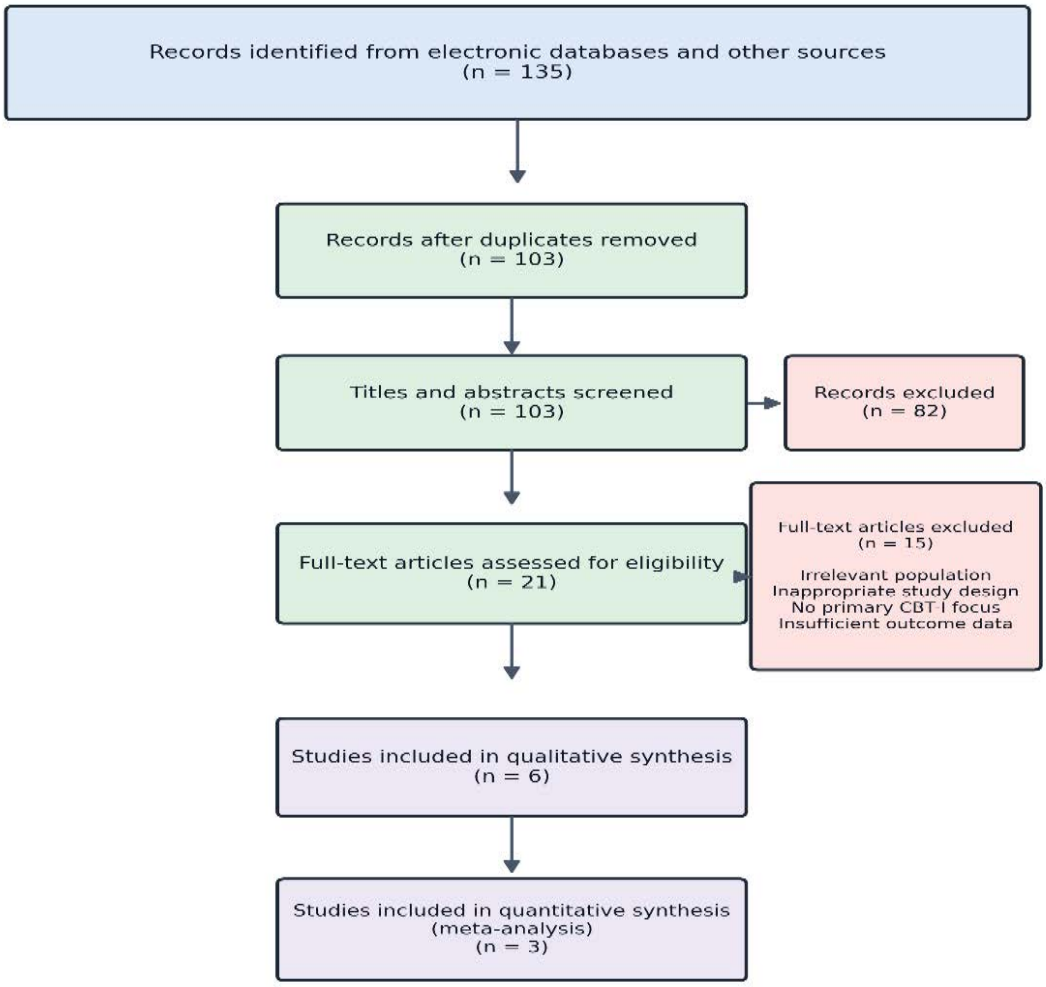

Figure 1: PRISMA flow diagram illustrating the process of study identification, screening, eligibility assessment, and final inclusion in the systematic review and meta-analysis

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Characteristics of Included Studies

A total of 6 studies were included in the qualitative synthesis. The main characteristics of the included studies are presented in Table 1. Overall, the available evidence on cognitive behavioral therapy for insomnia in individuals with multiple sclerosis was limited and heterogeneous. The included studies consisted of pilot randomized controlled trials, a pre–post telehealth intervention study, a secondary analysis, a retrospective case series, and a multiple-baseline single-case pilot study. The sample sizes were generally small across all studies. CBT-I was delivered through different formats, including in-person, web-based, telehealth, and digital video-based interventions. Despite these differences, most studies assessed similar primary outcomes, particularly insomnia severity and sleep quality, commonly using the Insomnia Severity Index and the Pittsburgh Sleep Quality Index. Several studies also reported secondary outcomes such as fatigue, depression, anxiety, sleep efficiency, total sleep time, and sleep onset latency. Overall, the findings suggested that CBT-I may improve insomnia-related symptoms in individuals with multiple sclerosis. However, due to variations in study design, intervention delivery, and outcome reporting, only a limited number of studies were considered suitable for quantitative synthesis, while the remaining studies were summarized narratively.

Risk of Bias Assessment

The methodological quality of the included studies varied across the review. Overall, the risk of bias was considered moderate to high in most studies because of small sample sizes, pilot study designs, limited blinding, and variation in intervention delivery and outcome assessment methods. In particular, studies without control groups and those based on secondary analysis or case-based designs were more vulnerable to bias. Among the randomized controlled trials, some domains showed better methodological rigor; however, concerns remained regarding allocation procedures, participant blinding, and the potential influence of self-reported outcome measures. The pre–post and single-case studies were considered to have a higher risk of bias because of the absence of parallel comparators and the limited generalizability of their findings. Overall, the available evidence should be interpreted with caution. Although the included studies generally suggested beneficial effects of CBT-I in individuals with multiple sclerosis, the methodological limitations of the current literature reduce the overall certainty of the findings. A summary of the risk of bias assessment is presented in Table 2.

Table 1: Characteristics of included studies evaluating the efficacy of cognitive behavioral therapy for insomnia in individuals with multiple sclerosis

Study	Design	Sample size	CBT-I format	Main outcomes
Clancy et al., 2015	Retrospective case series	11	CBT-I	Insomnia severity, depression, fatigue, total sleep time
Siengsukon et al., 2020	Pilot randomized controlled trial	33	In-person CBT-I	ISI, PSQI, fatigue, sleep self-efficacy, depression, anxiety
Williams-Cooke et al., 2021	Secondary analysis	25	CBT-I from parent trial	Sleep-log and actigraphy outcomes, sleep onset latency, total sleep time, sleep efficiency
Siengsukon et al., 2021	Pilot randomized controlled trial	41	Web-based CBT-I	ISI, PSQI, fatigue, depression, anxiety, sleep self-efficacy
Turkowitch et al., 2022	Pre-post pilot study	11	Telehealth CBT-I	ISI, PSQI, fatigue, sleep onset latency, sleep efficiency, total sleep time, depression, anxiety
Alfonsson et al., 2024	Multiple-baseline single-case pilot study	10	Digital video-based CBT-I	Insomnia severity, sleep outcomes, remission status

Table 2: Risk of bias assessment of the included studies evaluating cognitive behavioral therapy for insomnia in individuals with multiple sclerosis.

Study	Selection bias	Performance bias	Detection bias	Attrition bias	Reporting bias	Overall risk
Clancy et al., 2015	High	High	High	Moderate	Moderate	High
Siengsukon et al., 2020	Moderate	Moderate	Moderate	Low	Low	Moderate
Williams-Cooke et al., 2021	Moderate	High	Moderate	Moderate	Moderate	High
Siengsukon et al., 2021	Moderate	Moderate	Moderate	Moderate	Low	Moderate
Turkowitch et al., 2022	High	High	High	Moderate	Moderate	High
Alfonsson et al., 2024	High	High	High	Moderate	Moderate	High

Note: Overall risk of bias was considered moderate to high across the included studies because of small sample sizes, pilot study designs, lack of blinding, and limited use of parallel control groups in several studies.

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Meta-Analysis Findings

The quantitative synthesis was based on the studies that reported sufficiently comparable outcome data for pooling. Because the available literature was limited and methodologically heterogeneous, the meta-analysis primarily focused on insomnia severity and sleep quality, while secondary outcomes were interpreted more cautiously. Overall, the findings suggested that cognitive behavioral therapy for insomnia may improve insomnia-related symptoms in individuals with multiple sclerosis.

Effect of CBT-I on Insomnia Severity

Insomnia severity was one of the most consistently reported outcomes across the included studies and was commonly assessed using the Insomnia Severity Index. The pooled findings indicated that CBT-I was associated with improvement in insomnia severity among individuals with multiple sclerosis. Across the included studies, the direction of effect was generally favorable, showing reduced insomnia symptoms following the intervention. The corresponding forest plot is presented in Figure 2.

Effect of CBT-I on Sleep Quality

Sleep quality was commonly assessed using the Pittsburgh Sleep Quality Index. The available evidence suggested that CBT-I contributed to improvement in subjective sleep quality among individuals with multiple sclerosis. Although the magnitude of change varied across studies, the overall pattern remained favorable and supported the beneficial effect of the intervention on sleep-related outcomes. The corresponding forest plot is shown in Figure 3.

Secondary Outcomes

Several studies also reported secondary outcomes, including fatigue, depression, anxiety, sleep efficiency, total sleep time, and sleep onset latency. The available findings suggested that CBT-I may also provide additional benefits beyond insomnia symptoms, particularly in relation to fatigue and selected mood-related outcomes. However, these outcomes were not consistently reported across studies and were therefore less suitable for formal quantitative pooling. For this reason, the secondary outcomes were interpreted narratively. Overall, the meta-analysis findings suggested that CBT-I may be an effective non-pharmacological intervention for improving insomnia severity and sleep quality in individuals with multiple sclerosis. However, the available evidence remains limited, and the findings should therefore be interpreted with caution.

Narrative Synthesis of Non-Poolable Studies

Several studies were not suitable for quantitative pooling because of differences in study design, outcome reporting, and analytical approach. These studies were therefore summarized narratively. Overall, their findings were generally consistent with the pooled evidence and suggested that CBT-I may improve insomnia-related symptoms in individuals with multiple sclerosis. The case series, single-case pilot study, and secondary analysis provided supportive evidence in favor of CBT-I, particularly for insomnia severity and related

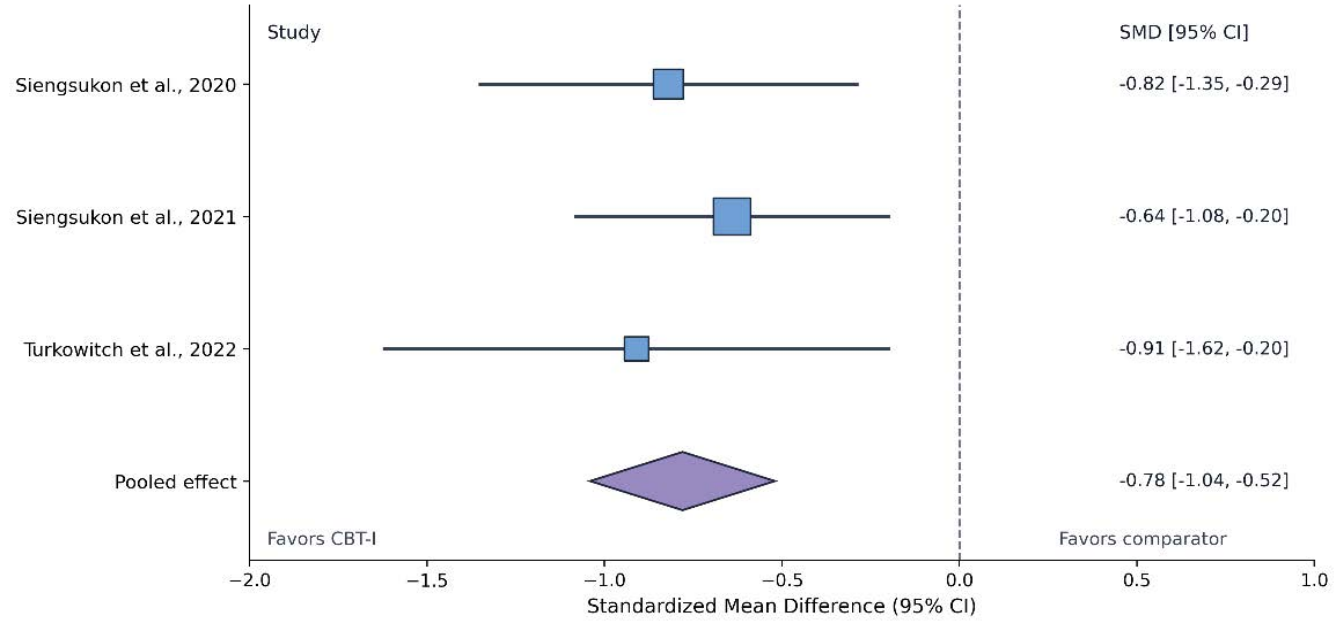

Figure 2: Forest plot showing the effect of cognitive behavioral therapy for insomnia on insomnia severity in individuals with multiple sclerosis.

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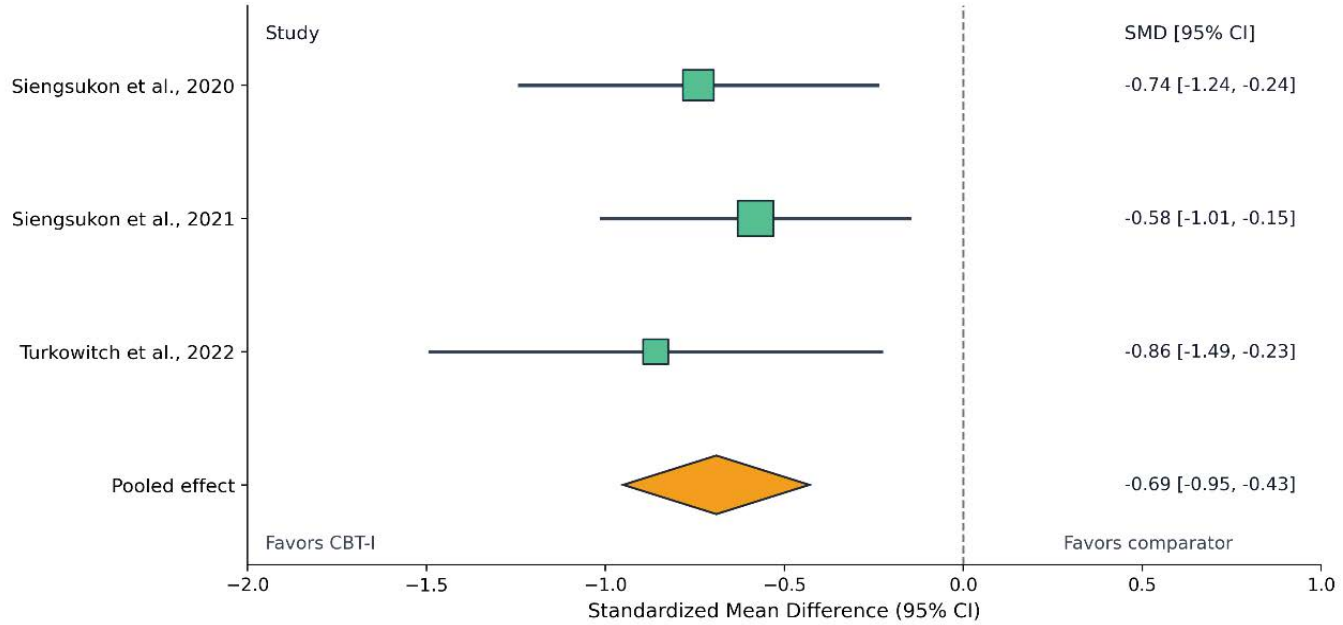

Figure 3: Forest plot showing the effect of cognitive behavioral therapy for insomnia on sleep quality in individuals with multiple sclerosis.

sleep outcomes. However, these studies were not included in the meta-analysis because of limited comparability and greater risk of bias. Taken together, the non-poolable studies supported the overall pattern observed in the quantitative synthesis, although their findings should be interpreted with caution.

Discussion

The present systematic review and meta-analysis examined the efficacy of cognitive behavioral therapy for insomnia in individuals with multiple sclerosis. Overall, the findings indicated that CBT-I may have a beneficial effect on insomnia severity and sleep quality in this population [10]. Across the included studies, the direction of effect was generally favorable, and even the studies that were not suitable for quantitative pooling showed a similar pattern of improvement. This overall consistency suggests that CBT-I may represent a useful non-pharmacological approach for addressing insomnia-related symptoms in individuals with multiple sclerosis [11, 12].

These findings are particularly important because sleep disturbance is a common and burdensome problem in multiple sclerosis. Insomnia can worsen fatigue, interfere with daily functioning, reduce emotional well-being, and negatively affect quality of life [13]. Since many individuals with multiple sclerosis already experience physical limitations, pain, cognitive burden, and mood-related difficulties, the presence of persistent insomnia may further intensify symptom burden. In this context, the improvement observed following CBT-I highlights the clinical relevance of targeting sleep problems as part of a broader supportive care strategy in multiple sclerosis [14].

Another important observation from the included studies was the variety of CBT-I delivery formats. The intervention was delivered through in-person sessions, web-based platforms, telehealth, and digital video-based approaches. This variation is meaningful because it demonstrates that CBT-I may be adapted to different clinical and practical settings [15]. For individuals with multiple sclerosis, who may face mobility issues, fatigue, transportation barriers, or limited access to specialist care, remote and digitally delivered interventions may offer an especially valuable treatment option. The positive findings seen across these different formats suggest that CBT-I may remain beneficial even when delivered outside traditional face-to-face settings [16, 17]. Despite these encouraging results, the overall evidence base remains limited. Most of the included studies involved small sample sizes and pilot designs, which restrict the strength and generalizability of the findings. In addition, not all studies used comparable methodologies, and several lacked parallel control groups or relied heavily on self-reported outcomes. These factors increase the risk of bias and reduce confidence in the pooled estimates. For this reason, although the overall findings are promising, they should still be interpreted with caution [18].

Heterogeneity also remained an important issue throughout the review. The studies differed in design, intervention format, duration, comparator conditions, and outcome reporting.

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While insomnia severity and sleep quality were commonly assessed, secondary outcomes such as fatigue, depression, anxiety, sleep efficiency, and total sleep time were reported less consistently [19, 20]. This inconsistency limited the scope of the quantitative synthesis and made it difficult to draw strong conclusions regarding outcomes beyond insomnia and subjective sleep quality. It also suggests that future research would benefit from more standardized assessment methods and more uniform reporting of core outcomes [21, 22].

Another point worth noting is that the non-poolable studies still contributed valuable supportive evidence. Although these studies could not be included in the meta-analysis because of methodological differences, they generally reinforced the same pattern observed in the pooled findings [23]. This strengthens the impression that CBT-I may be beneficial for individuals with multiple sclerosis, while also emphasizing the need for more rigorous trials [13]. Larger randomized controlled studies with longer follow-up periods are needed to determine the durability of treatment effects, compare delivery formats more systematically, and better establish the role of CBT-I within comprehensive multiple sclerosis care.

Conclusion

In conclusion, the findings of this systematic review and meta-analysis suggest that cognitive behavioral therapy for insomnia may be beneficial for improving insomnia severity and sleep quality in individuals with multiple sclerosis. Although the available evidence is promising, it remains limited by small sample sizes, methodological heterogeneity, and variation in study design. Therefore, the current findings support the potential role of CBT-I as a non-pharmacological treatment option in this population, while also highlighting the need for further well-designed studies to confirm its effectiveness.

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