

Can mindfulness-based interventions improve outcomes in cognitive-behavioural therapy for chronic insomnia disorder in the general population? Systematic review and meta-analysis

Manuel de Entrambasaguas¹  | Cintia Díaz-Silveira²  |
Francisco A. Burgos-Julián³  | Miguel A. Santed³ 

¹Sleep Unit, Clinical Neurophysiology, Hospital Clínico Universitario de Valencia, Valencia, Spain

²Department of Psychology, Health of Sciences Campus, Universidad Rey Juan Carlos, Alcorcón, Spain

³Faculty of Psychology, Universidad Nacional de Educación a Distancia (UNED), Madrid, Spain

Correspondence

Cintia Díaz-Silveira, Psychology department, Campus de Ciencias de la Salud. Avd. de Atenas s/n. 28922. Alcorcón, Universidad Rey Juan Carlos.

Email: cintia.diazsilveira@urjc.es

Abstract

Cognitive-behavioural therapy for insomnia (CBT-I) is the recommended first-line therapy for adults with chronic insomnia disorder (ID), which is characterized by hyperarousal. Mindfulness-based interventions (MBIs) are protocols aimed at stress reduction based on non-judgmental attention control in the present moment. However, MBIs have been increasingly used without a clear scientific basis. The objective of this analysis was to examine if MBIs could be useful as a component of the CBT-I therapeutic system through a systematic review and meta-analysis of randomized controlled trials (RCTs) and non-randomized studies (NRS) searched in PubMed, PsycINFO, Cochrane and WoS. The Insomnia Severity Index (ISI) was the primary outcome, while the Pittsburgh Sleep Quality Index (PSQI) and a composite sleep variable (CSV) were secondary outcomes. Thirteen articles corresponding to nine studies (three pragmatic RCTs, three explanatory RCTs and three NRS) were included. The omnibus test found that MBIs had a small to medium effect size on ISI nearing significance when comparing active control groups in the pretest–posttest period [$\Delta = 0.44$, $p = 0.07$], a medium, non-significant, effect size on PSQI [$\Delta = 0.52$, $p = 0.18$], and a significant though small effect size on CSV [$\Delta = 0.05$, $p < 0.01$]. No heterogeneity was found. The analysis could not demonstrate that MBIs, combined with CBT-I components in some studies, positively affected ID in the general adult population. This was probably due to the lack of pragmatic designs and suitable measuring instruments. Recommendations are made for designing further studies to address these issues.

KEYWORDS

cognitive-behavioural therapy, insomnia, meta-analysis, mindfulness, sleep, stress

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1 | INTRODUCTION

The prevalence of chronic insomnia disorder (ID) is rising and now affects around 10% of the European general adult population (Riemann et al., 2022). This disorder is related to cardiovascular and metabolic diseases and neurological and mental disorders. It involves considerable costs that often go unrecognized, as most are indirect, such as increased healthcare utilization and reduced work output (Kessler et al., 2011; Riemann et al., 2017).

Sleep is regulated by an endogenous circadian rhythm that alternates between promoting sleep or wakefulness in 24-h cycles and sleep homeostasis, which influences sleep drive depending on previous sleep deprivation or daytime napping (Borbély & Achermann, 1999; Scammell et al., 2017). Social requirements like work schedules influence both. However, genome-wide analysis has not found a relationship between insomnia and the circuitry that regulate sleep, but a substantial overlap between insomnia and depression, anxiety, and neuroticism instead, that is, circuitry involved in emotion regulation, as well as cardiometabolic traits, restless legs and sleep duration (Lane et al., 2019; Van Someren, 2021).

Insomnia may refer to three different clinical categories. *Insomnia symptoms* include difficulty initiating sleep, difficulty maintaining sleep or waking up involuntarily earlier than desired. *Insomnia syndrome* describes daytime impairment related to these night symptoms, which are clinically meaningful when both occur at least three times per week. *ID* describes an insomnia syndrome that is not better explained by an inadequate opportunity for sleep, another sleep disorder, medical conditions, mental disorders or due to substance use. It is chronic when it has been present for at least 3 months. ID results from genetic and early life stress-induced neurobiological vulnerability, with symptoms often triggered by life events lingering physiological, cognitive and emotional hyperarousal, REM sleep instability and maladaptive behaviours (Riemann et al., 2022).

The central nosological systems for sleep disorders now use standard diagnostic criteria for ID, although there are minor differences between them (American Psychiatric Association & American Psychiatric Association, 2013; American Academy of Sleep Medicine, 2014; World Health Organization, 2018). However, insomnia symptoms may appear in the clinical spectrum of a variety of health issues with different pathophysiology, so ID is comorbid with these conditions when they do not adequately explain the chief complaint of insomnia, which probably occurs more frequently than in isolation (Riemann et al., 2022). In such cases, treatment should target both ID and the comorbid condition, for example, major depression, chronic pain or sleep apnea, as addressing the elements that promote insomnia along with the underlying condition may improve sleep (Morin et al., 2021).

Previously, ICD-9 and ICD-10 distinguished between organic and non-organic insomnia, while DSM-III and DSM-IV differentiated between primary and secondary insomnia. This lumping approach attempted to differentiate insomnia as a sleep disorder from insomnia due to other health issues (Ellis, 2021). Meanwhile, ICSD-2 tried a splitting approach describing primary insomnia subtypes such as psychophysiological, paradoxical, idiopathic or inadequate sleep hygiene.

Key Practitioner Message

- The few RCTs found, only half of which were pragmatic, limited our conclusions about the actual efficacy of MBIs within CBT-I, so we suggest some future directions to address this issue.
- The overall estimate suggests an absence of effects of the MBIs in CBT-I in reducing the symptoms of insomnia in the general population.
- Caution is advised when interpreting MBI effects to determine their efficacy in ID. These interventions may incorporate mindfulness measures to know if dispositional mindfulness or mindfulness trait is increased.

However, these subtypes showed poor reliability and validity, possibly due to significant overlap with comorbid insomnia subtypes (Edinger et al., 2011).

Insomnia is characterized by hyperarousal, which appears in other mental disorders, including anxiety and depression. Insomnia patients show a restless rapid eye movement (REM) sleep that prevents the normal locus coeruleus silencing and consolidated noradrenalin time-out exclusive of this sleep stage, which alters synaptic plasticity and adaptation in limbic and salience circuits. This failing overnight relief of emotional memory distress may account for abiding hyperarousal and the relationship between insomnia and other mental disorders (Van Someren, 2021). Sleep onset and stabilization require physiological and cognitive de-arousal and emotional neutrality. These optimal conditions are achieved through a behavioural consolidation that generates adaptive conditioning that facilitates sleep (Espie, 2023).

Cognitive-behavioural therapy for insomnia (CBT-I) is the recommended first-line treatment for all adults with chronic ID and has received the most substantial level of endorsement (strong recommendation, high-quality evidence) (Morin et al., 2021; Qaseem et al., 2016; Riemann et al., 2017). Evaluated endpoints from meta-analyses on the efficacy of CBT-I included global outcomes (sleep questionnaires) and sleep outcomes (sleep parameters). Sleep questionnaires included the Insomnia Severity Index (ISI), a brief instrument designed to assess the severity of both nighttime and daytime components of insomnia that is sensitive to treatment response in clinical patients (Morin et al., 2011), and the Pittsburgh Sleep Quality Index (PSQI), which is aimed at measuring sleep quality, though different cut-offs have been proposed for insomnia screening in different demographic and clinical populations (Mollayeva et al., 2016). Sleep parameters included sleep onset latency (SOL), wakefulness after sleep onset (WASO), total sleep time (TST) and sleep efficiency (SE), which is the ratio of TST compared to the total amount of time spent in bed (TIB) trying to sleep. These parameters can be obtained objectively from polysomnography (PSG), which is the comprehensive recording of several physiological parameters during sleep including electroencephalography (Rundo & Downey, 2019), indirectly from actigraphy, which is the recording of limb movement activity over

time (Smith et al., 2018), and subjectively from sleep diaries, which is the self-recording of sleep on a night-to-night basis for at least 1 week (Carney et al., 2012). CBT-I is a multicomponent therapeutic intervention that includes educational, cognitive and behavioural strategies and may also include relaxation techniques.

This therapy system is tailored to each patient's characteristics through a stepped-care approach (Baglioni et al., 2020). CBT-I usually comprises sleep hygiene, a cognitive reappraisal of erroneous beliefs about sleep, cognitive control through dedicated worry time, paradoxical intention, stimulus control, sleep restriction or compression, and relaxation methods such as progressive muscle relaxation, autogenic training, imagery training and meditation. Mindfulness is a type of meditation that has become increasingly popular in the last decade.

Mindfulness-based interventions (MBI) are not usually listed as standard components of CBT. However, mindfulness could benefit standard CBT-I protocols by targeting emotions and emotional regulation skills, as these directly impact hyperarousal (Baglioni, 2022). Mindfulness practice is a psychological process of self-regulation based on non-judgmental attention control in the present moment, emotional regulation and self-awareness, with the ability to approach one's experiences with openness and acceptance (Tang et al., 2015). This practice was first standardized in a clinical program called mindfulness-based stress reduction (MBSR), which has been the model for ensuing protocols like mindfulness-based cognitive therapy (MBCT) aimed at the prevention of relapses in depression (Creswell, 2017).

MBIs include two primary techniques. Focused attention involves directing and sustaining attention on an object (i.e., the sensations of one's breathing), noticing when it drifts off to distractors (i.e., mind wandering or rumination), and warmly reminding to disengage from them and shift back to the object. This technique facilitates emotional regulation by reducing the perceived intensity of physical and psychological symptoms. Open monitoring consists in being non-reactively aware of the moment-to-moment flow of cognition, emotions and sensations. It promotes psychological distancing through acceptance and curiosity of one's perceptual and cognitive process and thus enhances resilience rather than resistance. It is suggested that the first technique creates a foundation of mental stability that allows for the development of the second, which is grounded in metacognition. In this sense, through the practice of mindfulness, a relaxation response and a new personal disposition of awareness and equanimity can be produced with everyday experiences and objects (Ngan & Cheng, 2022; Schuman-Olivier et al., 2020).

The underlying neural mechanisms involved in mindfulness meditation include the salience network (SN) regarding external attentional regulation, the default mode network (DMN) regarding interoceptive regulation of the whole consciousness process and DMN-central executive network connectivity for the non-reactive, self-related processing (Ngan & Cheng, 2022). Mindfulness practice also seemingly targets internetwork SN-DMN connectivity (Rahrig et al., 2022). MBIs have shown some mental and physical health benefits in different settings, including healthcare, school, and the workplace. However,

systematic reviews and meta-analyses on this issue have indicated the low quality of included studies (Zhang et al., 2021). A few meta-analyses have investigated the effect of MBIs on insomnia. However, inclusion criteria for eligible randomized controlled trials (RCTs) were heterogeneous or outcomes not specific to ID. Rash et al. (2019) included ID, comorbid insomnia and 'sleep disturbance' as defined by sleep questionnaires or sleep diaries. Although they could not assess the effect of MBIs compared with active treatments, MBIs were significantly better than waitlist control, and effects seemed to be durable 3 months after the intervention. Wang et al. (2020) investigated ID but did not include ISI as an outcome. They concluded that MBIs affected sleep quality as measured by PSQI positively. Finally, Chen et al. (2020) investigated MBSR alone and included ID and poor sleep quality as defined by PSQI. They concluded that MBSR significantly improved sleep quality.

The heterogeneity of RCTs included in these meta-analyses could be due to the scarcity of available studies. When a new therapeutic approach lacks sufficient RCTs to perform a quantitative synthesis, non-randomized studies (NRS) are often included in the analysis. However, results may be biased as treatment effects are overestimated. Becker (1988) addressed the problem of including NRS in meta-analyses by developing a method that separates the analysis for experimental and control groups, thus allowing the imputation of a fair value in studies without a comparison group.

This systematic review and meta-analysis aimed to assess the efficacy of MBIs in chronic ID to explore their potential value as another component of CBT-I. For this reason, we restricted this investigation to chronic ID as defined by international classification systems in the general adult population since treatment guidelines endorsing CBT-I specifically address this sleep disorder and this population. Also, because of this, the preferred endpoints were those described above for endorsing CBT-I. Finally, NRS were not excluded from the analysis to obtain as many eligible studies as possible since Becker's procedure could tackle bias issues.

2 | METHOD

2.1 | Search strategy

The search was performed in December 2022 and used the Boolean operators ('mindfulness') AND ('insomnia' OR 'insomnia disorder' OR 'chronic insomnia') AND ('intervention' OR 'randomized controlled trial') AND ('Insomnia Severity Index' OR 'ISI') for all languages in PubMed, PsycINFO, Central Register of Controlled Trials (Cochrane) and Web of Science (WoS) databases. Results from this search were downloaded into EndNote X9 (Clarivate Analytics, Philadelphia, PA, USA) for deduplication electronically and manually. Keywords 'mindfulness' and 'insomnia' were also used to examine the references cited in systematic reviews, meta-analyses and literature reviews thus identified to check for possible missing studies.

2.2 | Eligibility criteria

We followed the PICO acronym from the PRISMA-P 2015 protocol to describe the stated objective of this study and reporting elements (Moher et al., 2015). Participants (P): the general adult population (18 years old or older) with chronic ID according to international diagnostic criteria. Intervention (I): MBIs provided by a therapist, either face-to-face or online, with a description of the program. No requirements for follow-up time were established. Comparison (C): with other therapeutic interventions for insomnia or no direct intervention such as self-assessment or waiting list. Outcomes (O): global outcomes (sleep questionnaires) and sleep outcomes (sleep parameters) used for CBT-I endorsement. Case reports, book chapters, theses, dissertations and abstracts were excluded. Since few RCTs were expected to be found, NRS were not excluded, as described before. The inclusion of conflicting studies was discussed between the authors according to eligibility criteria.

2.3 | Data extraction

Two reviewers (FABJ and MdeE) independently extracted the data to a spreadsheet. This information included authors, professional background and year of publication, diagnostic criteria, description of MBI protocols, trial arms and controls, duration and follow-up, information on participants including demographics and location of recruitment, global and sleep outcomes plus source in the latter, related raw data, and information needed to assess the risk of bias. Multiple reports by the same authors were joined into single studies.

2.4 | Risk of bias assessment

The risk of bias was assessed by two authors independently (CD-S and MdeE) using the Revised Cochrane risk-of-bias tool for randomized trials (Higgins et al., 2022). Discrepancies were discussed with a third author (MAS) until a consensus was reached.

2.5 | Meta-analysis

Global outcomes included ISI as the primary outcome, while the second was PSQI. The sleep outcome was called *composite sleep variable* (CSV) and resulted from combining the sleep parameters included in the studies using Borenstein's aggregation method (Borenstein et al., 2010). The overall effect size for each variable was calculated using Becker's method, which provides a fair value by including RCT and NRS designs in the quantitative synthesis (Becker, 1988). The heterogeneity of included studies was calculated using Q test, which was supplemented with the prediction interval (PI; Higgins et al., 2009). A meta-regression analysis was used to assess potential moderators of variables appearing in at least five studies. Subgroup analysis was used to compare effect size estimates with and without imputed

values in the NRS designs. Publication bias was assessed by inspection of funnel plots inspection and Egger's test (Egger et al., 1997) with at least five studies and corrected by the trim-and-fill method in the presence of effects (Duval & Tweedie, 2000). The packages 'MAAd' (Del Re et al., 2014) and 'meta' (Schwarzer, 2007) for 'R' (Core Team, 2014) were used for statistical analysis.

3 | RESULTS

3.1 | Description of the studies

Figure 1 shows the literature search and selection flow, which included 13 articles corresponding to nine studies, including six RCTs (nine articles) and three NRS, that is, non-controlled pretest–posttest studies (four articles). Table 1 describes the main characteristics of these nine studies included. MBI protocols were MBSR (Gross et al., 2011; Ong et al., 2008, 2009, 2014, 2016, 2018) and MBCT (Lee et al., 2018; Wong et al., 2016), two adaptations of them that included CBT-I elements, respectively named mindfulness-based therapy for insomnia (MBTI) (Ong et al., 2014, 2016, 2018) and mindfulness-based cognitive therapy for insomnia (MBCT-I) (Heidenreich et al., 2006; Larouche et al., 2015; Wong et al., 2017), and free MBI protocols (Siritienthong et al., 2018; Vanhuffel et al., 2018). Duration of MBIs ranged between 6 and 8 weeks. It included home meditations, while one study did not describe the protocol details (Siritienthong et al., 2018), and another only named it (Heidenreich et al., 2006). The two RCTs that followed MBSR included a 6-h retirement. Follow-up varied from the end of therapy to 8 months or 1 year. All the studies except two (Heidenreich et al., 2006; Siritienthong et al., 2018) justified the training of the therapists responsible for MBIs.

Regarding outcomes, Table 1 also shows that ISI was included in all but one RCT and one NRS. PSQI was included in all RCTs except two and was not recorded by any NRS. Additionally, the Dysfunctional Beliefs and Attitudes about Sleep Scale (DBAS) (Morin et al., 2007) was included in five studies, the Pre-Sleep Arousal Scale (PSAS) (Nicassio et al., 1985) was reported by two research groups, and six other different global outcomes were listed in individual studies. The number of reported sleep outcomes ranged from one to four, most of which were obtained from sleep diaries. Only two studies recruited participants exclusively among patients attending a sleep unit (Heidenreich et al., 2006; Vanhuffel et al., 2018), while the rest enrolled them through advertisements in healthcare, research, education or general public settings. The median age of participants was around 50 years old, and women outnumbered men.

3.2 | Pragmatic RCTs

Three RCTs were pragmatic and compared MBIs with validated therapies for ID. Gross et al. (2011) found no differences between MBSR and the benzodiazepine-related drug eszopiclone 3 mg in global and

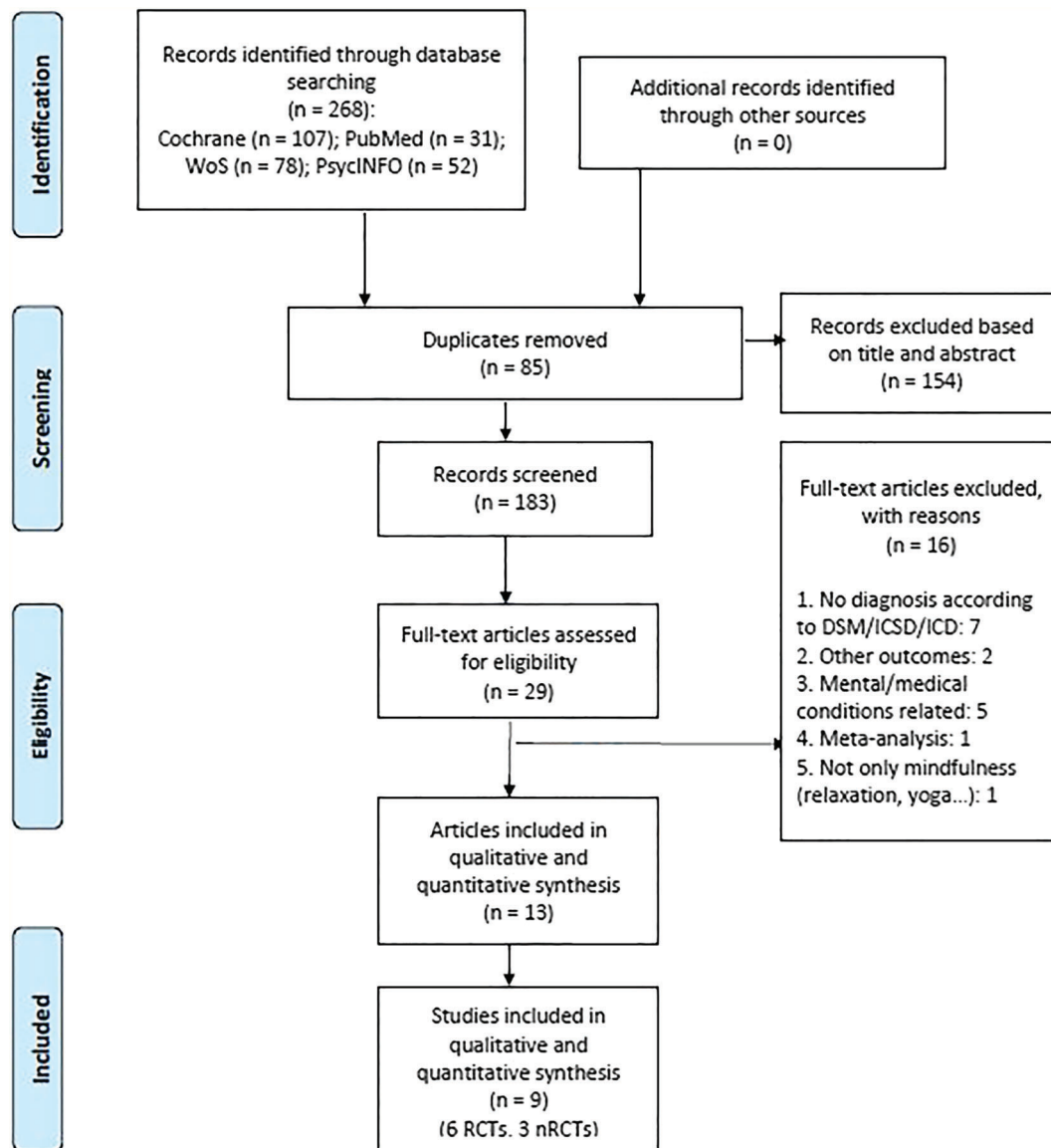


FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) study flow diagram.

sleep outcomes at the end of therapy and 5 months later. The sample size did not allow for establishing the non-inferiority of MBSR to eszopiclone. Vanhuffel et al. (2018) found a significant improvement in WASO at 6 weeks in CBT-I with added MBI ($p = 0.009$, no size effect provided) when compared to CBT-I only, despite the plus-MBI group being older ($p = 0.044$), having significant somatic comorbidity ($p = 0.041$) and larger pre-treatment WASO ($p = 0.026$). The remaining outcomes showed no differences. Sirtienthong et al. (2018) described their study as quasi-randomized and found no differences between CBT-I and MBI in the reported outcomes.

3.3 | Explanatory RCTs

The other three RCTs were explanatory, and they compared a combination of MBI and CBT-I elements with non-standard therapeutic interventions for ID. Ong et al. (2014, 2016, 2018) also used a

behavioural therapy for insomnia devoid of cognitive restructuring and relaxation techniques as a comparator. They found a significant improvement in ISI when comparing MBSR ($p < 0.05$) and MBTI ($p < 0.01$) to self-monitoring with weekly sleep diaries. At the same time, at 3 months follow-up, only MBTI was superior ($p < 0.05$), and at 6 months, no differences were found in MBSR, and MBTI groups showed no differences in remission or minimal response (reduction of ISI > 7 points) post-treatment or follow-up. PSAS showed a significant improvement in the combined MBSR and MBTI groups ($p = 0.002$, effect size 0.58) and individually ($p < 0.01$) at post-treatment but not at follow-up. MBTI showed a significant improvement compared to self-monitoring after treatment in questionnaires measuring hyperarousal, sleep effort, and beliefs and attitudes about sleep, and was not inferior to behavioural therapy as described earlier. Sleep diaries showed an improvement of total wake time (TWT = SOL + WASO + terminal wakefulness) in the combined MBI protocols when compared to self-monitoring ($p = 0.004$) and also individually for MBSR

TABLE 1 Description of the studies.

Study (authors, year, country)	Diagnostic criteria	Comparator	Follow-up	Population N, age, mean (SD); range y.o.* %female (F)	Global outcomes	Sleep outcomes (source)
Pragmatic RCTs						
Gross et al., 2011 USA	Chronic primary insomnia DSM-IV	Eszopiclone ad libitum	End of therapy 5 months later	N = 30, 19–65 y.o., F = 73.3%, MBSR = 20, 47; 21–65 y.o. (analysed = 18) Eszopiclone = 10, 53.5; 29–59 y.o. (analysed = 9)	ISI PSQI DBAS SSES	SL WASO TST SE (SD, act)
Explanatory RCTs						
Ong et al., 2014, 2016, 2018, USA	Chronic primary insomnia psychophysiological insomnia ICSD-2	MBTI versus MBSR versus self-monitoring, later BT-1	End of therapy 3 and 6 months later	N = 54, 42.9 (12.2); F = 74.1%, MBTI = 19 (analysed = 13) MBSR = 19 (analysed = 15) Self-monitoring = 16 (analysed = 16, then allocated to BT-1, analysed = 12)	ISI DBAS GSES HAS PSAS	TWT TST SE (SD, act, PSG)
Wong et al., 2016 Lee et al., 2018 Australia	Chronic primary insomnia DSM, ICD	CBT-1 + MBCT versus CBT-1 + CT-1	End of therapy 3 months later	N = 64, 21–66 y.o. (analysed = 57) + MBCT = 31; 50 (12.6); F = 65.5% + CT = 26; 49 (13.4); F = 61.3%	ISI PSQI APSQ DBAS SAMI SRBQ	TST (SD, act)
Wong et al., 2017 Hong Kong, China	Chronic primary insomnia DSM-IV, ICD-10	PEEC	2, 5, and 8 months after therapy	N = 216 (analysed = 196) MBCT-I = 111; 55.6 (9.1); F = 82% (analysed = 101) PEEC = 105; 56.6 (9.7); F = 74.3% (analysed = 95)	ISI	SOL WASO TST SE (SD)
Study (authors, year, country)						
NRS (pretest-posttest studies)						
Heidenreich et al., 2006 Germany	Chronic primary insomnia DSM-IV	None	End of therapy	N = 14; 48.6; F = 57%	None	SOL TST (SD)
Ong et al., 2008, 2009 USA	Chronic primary insomnia psychophysiological insomnia ICSD-2	None	End of therapy 6 and 12 months later	N = 30; 30 (36.4); 19–61 y.o. F = 60%; (analysed = 27, N = 21 in 2009); N = 21, 38.7 (13.6); 21–62 y.o. F = 52%	ISI HAS PSAS	SOL WASO TST SE (SD)

TABLE 1 (Continued)

Study (authors, year, country)	Diagnostic criteria	Comparator	Follow-up	Population N; age; mean (SD); range y. o.*; %female	Global outcomes	Sleep outcomes (source)
Larouche et al., 2015 Canada	Chronic primary insomnia psychophysiological insomnia ICSD-2 DSM-IV	None	End of therapy 3 months later	N = 12 54 (9.8); F = 100%	ISI DBAS PSAS	SOL WASO TST SE (SD, act)

Note: DSM: Diagnostic and Statistical Manual of Mental Disorders. ICD: International Classification of Diseases ICS: International Classification of Sleep Disorders. Protocols. MBI: Mindfulness-based Interventions, MBCT: Mindfulness-based Cognitive Therapy. MBSR: Mindfulness-based Stress Reduction. CBT: Cognitive-Behavioural Therapy. CT: Cognitive Therapy. BT: Behavioral Therapy. I: Insomnia. MBTI: Mindfulness-based Therapy for Insomnia. PEEC: Psycho-Education with Exercise Control. ISI: Insomnia Severity Index. PSQI: Pittsburgh Sleep Quality Index. APSQ: Anxiety and Preoccupation about Sleep Questionnaire. DBAS: Dysfunctional Beliefs and Attitudes about Sleep Scale. SAMI: Sleep Associated Monitoring Index. SRBQ: Sleep-Related Behaviors Questionnaire. GSES: Glasgow Sleep Effort Scale. HAS: Hyperarousal Scale. PSAS: Pre-Sleep Arousal Scale. SSES: Sleep Self-Efficacy Scale. SOL: Sleep Onset Latency. WASO: Wake After Sleep Onset. TST: Total Sleep Time. SE: Sleep Efficiency. TWT: Total Wake Time. SD: Sleep Diary. Act: Actigraphy. PSG: Polysomnography.
*some data may be missing/not reported.

($p < 0.05$) and MBTI ($p < 0.01$) but not at follow-up. Actigraphy showed an improvement of the combined MBI protocols in TWT ($p < 0.05$) and TST ($p < 0.01$) but not at follow-up. PSG outcomes showed no significant differences.

Wong et al. (2016) and Lee et al. (2018) found no differences between CBT-I with added MBCT and CBT-I with added cognitive therapy in both global and sleep outcomes. Wong et al. (2017) compared MBCT-I to an intervention with daily stretching and muscle-strengthening exercises called PEEC (for psychoeducation with exercise control). Both groups included sleep education, hygiene, stimulus control and regular rising time, but sleep restriction was limited to the MBCT-I group only. They found an improvement of ISI in the MBCT-I group at 2 months follow-up ($p = 0.023$, effect size -0.360) but none at 5 and 8 months. WASO also improved in this group at 2 months ($p = 0.049$, effect size -0.499) and 5 months ($p = 0.033$, effect size -0.430) but not at 8 months follow-up, while the remaining sleep outcomes showed no significant improvement.

3.4 | Non-RCTs

Three non-controlled pretest–posttest studies complete the included studies. Heidenreich et al. (2006) studied sleep outcomes with sleep diaries and found a significant improvement in SL ($p < 0.05$) and TST ($p < 0.01$) but not in WASO and SE after MBCT-I. Ong et al. analysed outcomes at posttest (2008), 6 and 12 months (2008, 2009), and found that treatment benefits were maintained throughout the follow-up period for ISI, PSAS, SE and TWT, and additionally for PSAS at 6 months. However, no significant results were found for TST. Larouche et al. (2015) found a significant improvement in ISI both after MBCT-I and 3 months later ($p < 0.01$) but not in PSAS. Sleep diaries found an improvement in TST at 3 months ($p < 0.05$), WASO after treatment ($p < 0.01$) and 3 months ($p < 0.05$), and SE ($p < 0.05$ and $p < 0.01$, respectively), but not in SOL. When collected from actigraphy, none of these sleep outcomes significantly improved.

3.5 | Risk of bias

The Table S1 describes the risk of bias. Regarding global outcomes, Siritienthong et al. (2018) did not include ISI, Heidenreich et al. (2006) provided none, and the other two NRS missed PSQI. However, all studies provided at least one sleep outcome. Overall, RCTs were assessed as having a low risk of bias, while NRS caused some concerns due to the lack of randomization.

3.6 | Meta-analysis

3.6.1 | Preliminary analysis

ISI was analysed in seven studies ($n = 399$), five of which were RCTs. Analysis of the control conditions showed an effect size of $g_+ = 0.95$,

$p < 0.01$, 95% CI (0.29, 1.61) with high effect sizes and no significant heterogeneity [Q (4) = 390.21, $p > 0.01$, 95% PI (−1.57, 3.47)] for pretest–posttest time points. The omnibus test was not calculated for follow-up measures due to the small number of studies available ($k < 3$). CSV was analysed in nine studies ($n = 478$), six of which met the treatment control condition. Independent analysis of the latter found an aggregate effect size of $g_+ = 0.56$, $p < 0.01$, 95% CI (0.33, 0.79) for pretest–posttest time points, with a moderate effect size and no significant heterogeneity [Q (7) = 331.77, $p > 0.01$, 95% PI (−0.28, 1.41)]. Three-month follow-up measures showed aggregate effect sizes with statistically significant differences $g_+ = 0.78$, $p < 0.01$, 95% CI (0.49, 1.07) and no significant heterogeneity [Q (4) = 252.20, $p > 0.01$, 95% PI (−2.81, 4.37)]. Since PSQI was analysed in only four studies, the previous imputation procedure was not applied. Control groups in this variable showed high effect sizes [$g_+ = 0.93$, $p < 0.01$, 95% CI (0.50, 1.36)] with no significant heterogeneity [Q (4) = 18.86, $p > 0.01$, 95% PI (−1.06, 2.92)].

3.6.2 | ISI

The effect of MBIs on ISI was checked with the omnibus test in seven studies ($n = 399$) comparing active control groups in the

pretest–posttest period (Figure 2). Results showed a small to medium effect size that was close to signification [$\Delta = 0.44$, $p = 0.07$, 95% CI (−0.05, 0.93)] with no heterogeneity [Q (6) = 274.81, $p < 0.01$, 95% PI (−1.25, 2.13)] and MBIs showing slightly higher values than active control conditions. The effect at 3-month follow-up was not analysed due to insufficient studies (<5).

3.6.3 | PSQI

The effect of MBIs on PSQI was checked with the omnibus test in four studies ($n = 152$) comparing active control groups in the pretest–posttest period (Figure 3). Results showed a medium effect size, non-significant [$\Delta = 0.52$, $p = 0.18$, 95% CI (−0.24, 1.28)] with no heterogeneity [Q (3) = 33.85, $p < 0.01$, 95% PI (2.96, 3.99)].

3.6.4 | Effects of the Composite Sleep Variable

The CSV included SOL, WASO, TST, SE and TWT as reported measures. The effect of MBIs on CSV was checked with the omnibus test in nine studies ($n = 478$) comparing active control groups in the pretest–posttest period (Figure 4). Results showed a significant

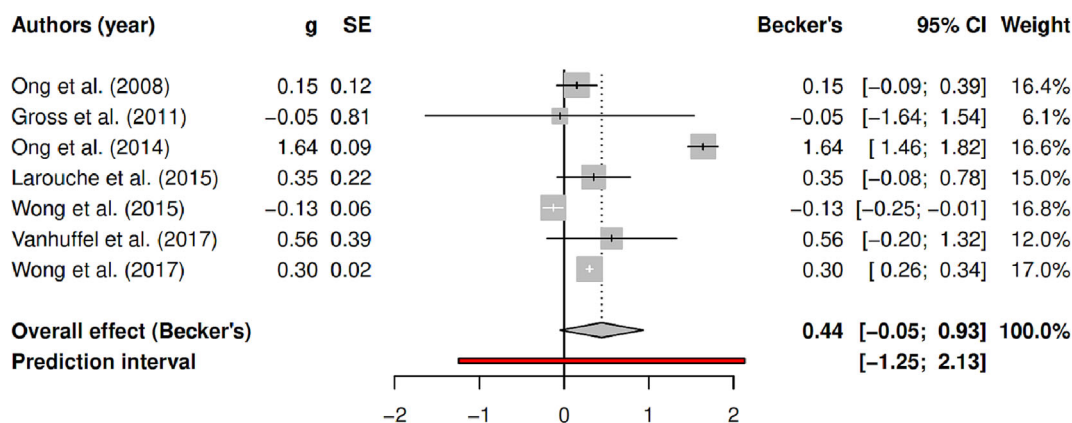


FIGURE 2 Forest plot meta-analysis of the Insomnia Severity Index (ISI) effects in the pretest–posttest period. Random effects model via the restricted maximum likelihood (REML) estimation method.

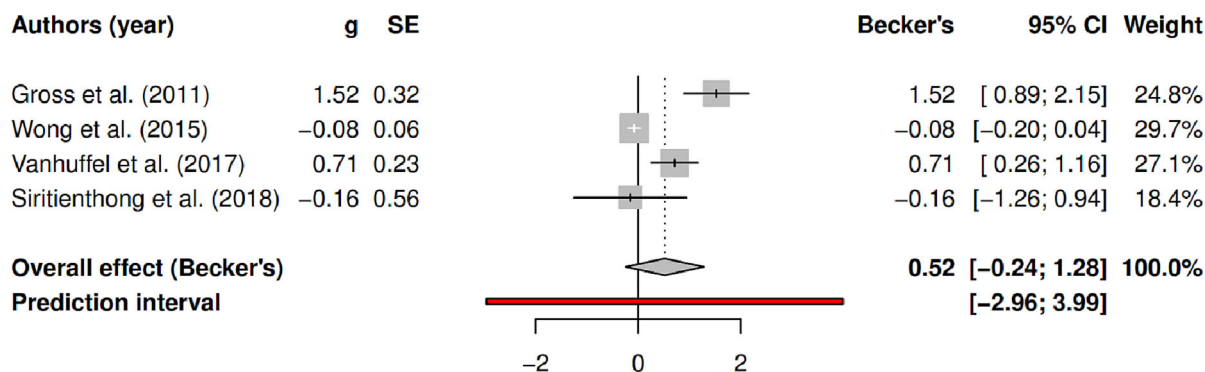


FIGURE 3 Forest plot meta-analysis of the Pittsburgh Sleep Quality Index (PSQI) effects in the pretest–posttest period. Random effects model via the restricted maximum likelihood (REML) estimation method.

though small effect [$\Delta = 0.05$, $p < 0.01$, 95% CI (-0.09, 0.19)] with no heterogeneity [$Q(8) = 70.61$, $p < 0.01$, 95% PI (-0.44, 0.54)], indicating the absence of superiority of MBIs over comparison conditions. Four studies ($n = 154$) were included in the omnibus test for follow-up at 3 months. Results showed no significant differences [$\Delta = -0.10$, $p = 0.31$, 95% CI (-0.30, 0.09)] with no heterogeneity [$Q(3) = 40.55$, $p < 0.01$, 95% PI (-0.98, 0.77)] and small effect sizes (Figure 5).

3.6.5 | Moderation analysis

The Table S2 shows that the meta-regression analysis found no moderating effects of ISI and CSV (pretest–posttest) on age, sex, therapy modality, risk of bias, dropout rate and type of comparison group.

3.6.6 | Publication bias

Visual inspection of the funnel plot and Egger's test found that the effect sizes of the omnibus test were not influenced by publication

bias for ISI pretest–posttest measures (Figure 6), Egger's test [$t(5) = 0.39$, $p = 0.71$] and CSV pretest–posttest measures (Figure 7) Egger's test [$t(7) = -2.04$, $p = 0.08$]. PSQI could not be evaluated as it only appeared in four studies.

4 | DISCUSSION

This systematic review and meta-analysis assessed the efficacy of MBIs in chronic ID, as defined by international classification systems, using the endpoints described to endorse CBT-I as first-line treatment for all adults presenting ID. The analysis failed to demonstrate that MBIs, combined with some CBT-I components in several studies, positively affected chronic ID in the general adult population: ISI [$\Delta = 0.44$, $p = 0.07$], PSQI [$\Delta = 0.52$, $p = 0.18$], CSV [$\Delta = 0.05$, $p < 0.01$]. This result calls for a thorough discussion, as from a theoretical point of view, MBIs should help treat ID. In all cases, no heterogeneity was found, which can be interpreted as the range of 95% of the actual Hedges' g expected in similar studies.

Our design required that participants were diagnosed with chronic ID and not insomnia symptoms or insomnia comorbid with

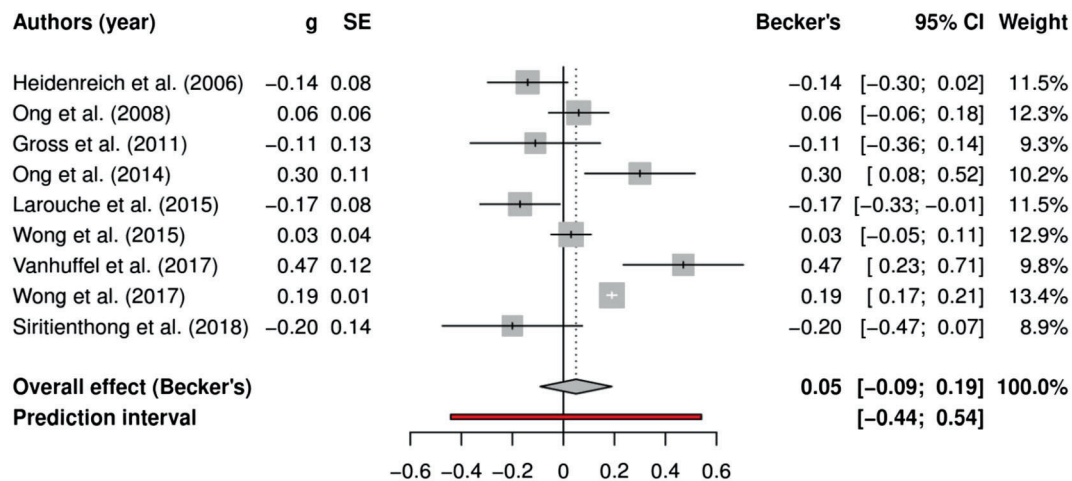


FIGURE 4 Forest plot meta-analysis of the effects of the composite sleep variable (CSV) in the pretest–posttest period. Random effects model via the restricted maximum likelihood (REML) estimation method.

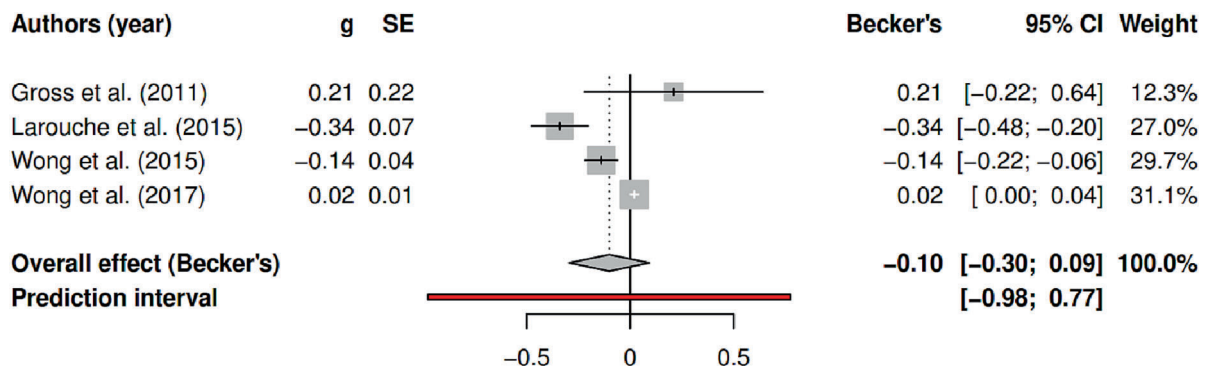


FIGURE 5 Forest plot meta-analysis of the composite sleep variable (CSV) effects in the follow-up period +3 months. Random effects model via the restricted maximum likelihood (REML) estimation method.

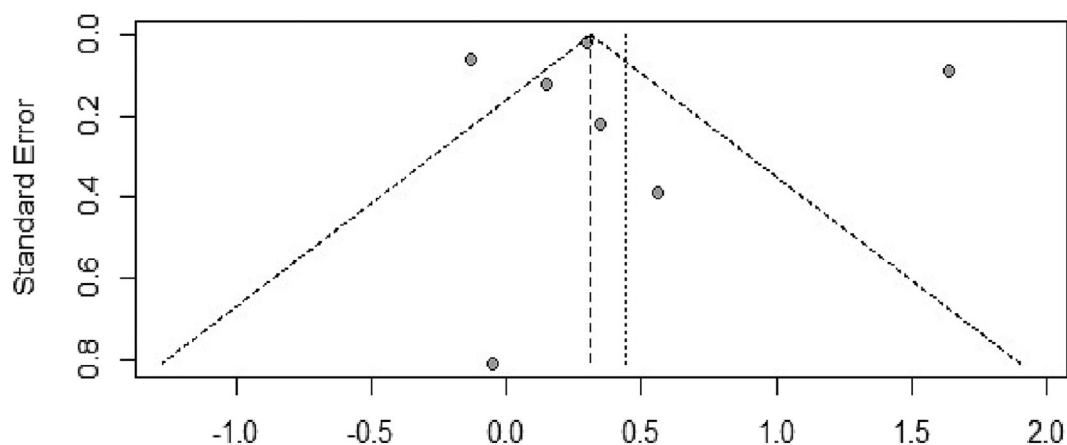


FIGURE 6 Funnel plot for the Insomnia Severity Index (ISI, pretest–posttest).

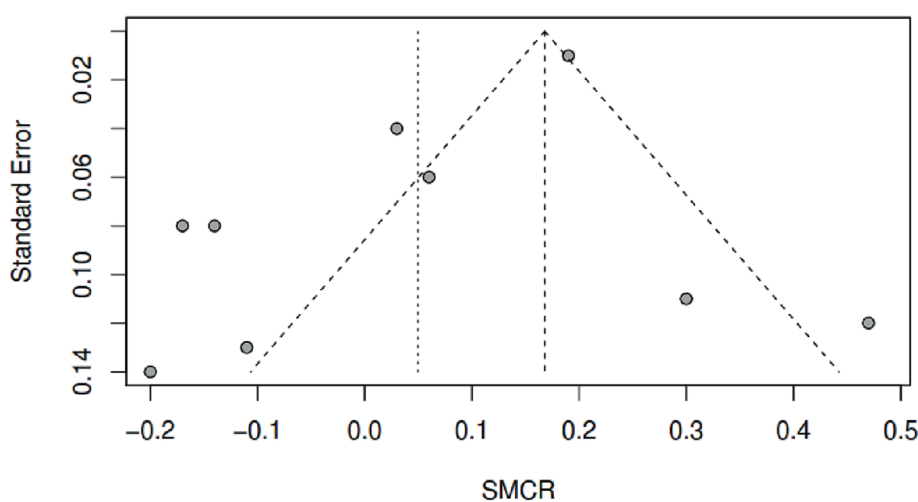


FIGURE 7 Funnel plot for the composite sleep variable (CSV, pretest–posttest).

another sleep disorder, medical condition or mental disorder. This requirement sought consistency in the pathophysiological mechanisms driving this complex sleep disorder, which must be targeted in any treatment. Although most studies followed the previous edition of the classification systems, diagnosis of primary or psychophysiological insomnia served this purpose. Participants were also required to represent the general population, as different sociodemographic variables may influence patients' attitudes toward insomnia, including consultation and treatment use (Leggett et al., 2016; Xiang et al., 2008). On the other hand, mindfulness has recently become increasingly popular as a form of personal development and a therapeutic tool in clinical psychology and integrative medicine (Harrington & Dunne, 2015). However, despite chronic ID being the most prevalent sleep disorder and MBIs becoming commonplace, the number of studies found was small and showed high heterogeneity. Research on MBIs has raised some concerns regarding the characterization of such interventions and the methodology of studies conducted for clinical purposes (Van Dam et al., 2018). Most studies included in the analysis provided a good characterization of the MBIs, and professionals delivered them with mindfulness training.

However, only three RCTs were pragmatic, that is, they reflected a realistic clinical environment where controls received other endorsed treatments for ID, namely eszopiclone (Gross et al., 2011) and CBT-I (Sirtienthong et al., 2018; Vanhuffel et al., 2018). On the other hand, the three explanatory RCTs developed MBI protocols that blended mindfulness and CBT-I elements. This design could not clarify whether the outcomes were due to the CBT-I contribution or the mindfulness component. Moreover, these MBIs were not compared with CBT-I, the first-line treatment. Wong et al. (2016) and Lee et al. (2018) included CBT-I both in the experimental and control groups. Ong et al. (2014, 2016, 2018) compared MBTI with CBT-I deprived of cognitive restructuring and relaxation techniques but did not justify using this blunted CBT-I protocol. Wong et al. (2017) compared MBCT-I with muscle stretching and exercise, which is not a standard therapy for insomnia. They also included CBT-I elements in both groups but limited sleep restriction, which is the most effective component of CBT-I (Riemann et al., 2022), to the mindfulness group.

The addition to the meta-analysis of NRS complying with eligibility criteria was not a source of bias but only incorporated three more studies. However, even with the drawbacks in the design of these

studies, the omnibus test found that MBIs had a small to medium effect size on ISI close to significance when comparing active control groups in the pretest–posttest period. On the other hand, MBIs did not result in better sleep quality than controls as measured by PSQI. However, unlike ISI, PSQI may not be an appropriate outcome measure for CBT-I (Chen et al., 2017). Individual sleep measures were combined into a composite sleep outcome since all the studies did not universally report them. An effective insomnia therapy would increase SE and TST due to a reduction in SOL, WASO or TWT, but MBIs were not superior to the other conditions in this regard.

At this point, it is essential to remember that the multi-component nature of CBT-I allowed its strong recommendation as a treatment for chronic ID in adults. At the same time, the single-component delivery of several components was only granted a conditional recommendation (Edinger et al., 2021). Flexibility is the great advantage of CBT-I, as it allows treatment tailoring for each patient according to their needs. Therefore, the design of each CBT-I intervention should focus on identifying which elements contribute to perpetuating ID in a given patient (Riemann et al., 2022) and which tools from the CBT-I toolbox are most appropriate for that work in that patient (Boland et al., 2019).

Following this reasoning, we therefore propose that trials investigating the efficacy of MBIs in ID incorporate outcomes that can assess treatment response in those areas where MBIs may be helpful. They would include improving emotion regulation by reducing cognitive (e.g., disengaging from mental wandering or rumination) and physiological hyperarousal (being aware of sympathetic nervous system activation and focusing on calming sensations) so that emotional stress is reduced. Thus, relaxation, acceptance and resilience could unfold, bearing in mind the patient's personality and lifestyle. Such a design would also require a previous assessment of the patient's meditative skills, as this intervention may be complex for some people. Scales such as Five Facet Mindfulness Questionnaire (FFMQ, Baer et al., 2008) or Mindfulness Attention Awareness Scales (MAAS, Brown & Ryan, 2009), Cognitive Affective Mindfulness Scale (CAMS, Hayes & Feldman, 2004), Kentucky Inventory of Mindfulness Skills (KIM, Baer et al., 2004) and Freiburg Mindfulness Inventory (FMI, Walach et al., 2006) may be helpful for these purposes.

These scales could be used to assess whether mindfulness is helpful in improving hyperarousal in insomnia and to identify those patients with difficulty or ease in meditating, which could influence outcomes.

5 | CONCLUSION

This systematic review and meta-analysis on the effectiveness of MBIs in treating chronic ID in adults found few studies. Although MBIs had a small to medium effect size on ISI close to significance, the analysis could not demonstrate that MBIs, combined with CBT-I components in several investigations, had a positive effect on chronic ID.

5.1 | Implications and future directions

Addressing the question of whether mindfulness can improve CBT-I outcomes in the adult general population would require specifically designed RCTs. First, the clinical inclusion criterion should be chronic ID as defined by the international classification systems. Second, CBT-I including mindfulness should be compared with CBT-I without this component. Third, outcome measures should include those used to endorse CBT-I but also validated scales and questionnaires to determine, on the one hand, if there is a positive response to the mindfulness component within the CBT-I system and, on the other hand, to identify patients with difficulty or ease with meditation. Fourth, these studies should have sufficient follow-up over time to determine the persistence of favourable changes and the frequency of relapse. Finally, therapists who include mindfulness as a component of CBT-I should have adequate training in this practice.

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

The data supporting this study's findings are openly available by email to psico.fburgos@gmail.com.

ORCID

Manuel de Entrambasaguas  <https://orcid.org/0000-0001-9531-2792>

Cintia Díaz-Silveira  <https://orcid.org/0000-0003-1087-6797>

Francisco A. Burgos-Julián  <https://orcid.org/0000-0001-7142-9435>

Miguel A. Santed  <https://orcid.org/0000-0002-3753-4511>

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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