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CLINICAL REVIEW

# Cognitive and behavioral therapies in the treatment of insomnia: A meta-analysis

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SUMMARY

Insomnia is a major public health problem considering its high prevalence, impact on daily life, comorbidity with other disorders and societal costs. Cognitive behavioral treatment for insomnia (CBTI) is currently considered to be the preferred treatment. However, no meta-analysis exists of all studies using at least one component of CBTI for insomnia, which also uses modern techniques to pool data and to analyze subgroups of patients. We included 87 randomized controlled trials, comparing 118 treatments (3724 patients) to non-treated controls (2579 patients). Overall, the interventions had significant effects on: insomnia severity index ($g = 0.98$), sleep efficiency ($g = 0.71$), Pittsburgh sleep quality index ($g = 0.65$), wake after sleep onset ($g = 0.63$) and sleep onset latency (SOL; $g = 0.57$), number of awakenings ($g = 0.29$) and sleep quality ($g = 0.40$). The smallest effect was on total sleep time ($g = 0.16$). Face-to-face treatments of at least four sessions seem to be more effective than self-help interventions or face-to-face interventions with fewer sessions. Otherwise the results seem to be quite robust (similar for patients with or without comorbid disease, younger or older patients, using or not using sleep medication). We conclude that CBTI, either its components or the full package, is effective in the treatment of insomnia.



## Introduction

Insomnia is a major public health problem. The prevalence of insomnia, which may be characterized by difficulty initiating or maintaining sleep, with significant distress and impairments of daytime functioning, is high: about a third of the population suffers from insomnia symptoms, and about 10% fulfills the criteria for a sleep disorder [1,2]. Insomnia has a high burden of disease, which impacts daily life in different domains [3,4] and often persists for many years [5]. The societal costs are substantial: poor sleepers cost society about ten times as much as good sleepers [6]. These societal costs are due to increased health care consumption but especially caused by reduced work productivity and increased work absenteeism [6,7].

In addition, insomnia is strongly associated with other somatic and mental health problems as well as with an increased mortality rate [8–10]. Most notable is the association with cardiovascular diseases [11–13] and with depression [14–16]. The nature of these associations is still not clear but it has been suggested that hyperarousal and the chronic activation of stress responses is a possible pathway between insomnia, depression and cardiac disease [13]. There are also indications that insomnia is a mediator in the increased mortality rates after depression [17].

Treatment of insomnia is highly desirable, mostly to decrease the burden of insomnia itself. But it might also contribute to a decrease of the associated somatic and mental health problems such as depression and cardiovascular risk.

Several meta-analyses have shown that benzodiazepine-receptor agonists are effective in enhancing sleep in the short run, but with risks of negative side effects and limited evidence for their long-term efficacy [18–20]. Various non-pharmacological treatments have been developed as alternatives. These non-pharmacological treatments can be classified as educational (psycho-education, sleep hygiene), behavioral (relaxation, sleep

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**List of abbreviations**

| | |
|---|---|
| AASM | American Academy of Sleep Medicine |
| AT | autogenic training |
| BT | behavioral therapy |
| CBTI | cognitive behavioral therapy for insomnia |
| CD | cognitive distraction |
| CMI | comorbid insomnia |
| CT | cognitive therapy |
| DSM | diagnostic and statistical manual of mental disorders |
| DSISD | Duke structured interview for sleep disorders |
| ICSD | International classification of sleep disorders |
| F2F | face-to-face |
| ISI | insomnia severity index |
| NWAK | number of awakenings |
| PE | psycho-education |
| PI | primary insomnia |
| PR | progressive relaxation |
| PSQI | Pittsburgh sleep quality index |
| RDC | research diagnostic criteria |
| RCTs | randomized controlled trials |
| SC | stimulus control |
| SD | standard deviation |
| SE | sleep efficiency |
| SH | sleep hygiene |
| SIS-D | structured interview for sleep disorders for DSM-III-R |
| SOL | sleep onset latency |
| SR | sleep restriction |
| TST | total sleep time |
| WASO | wake after sleep onset |
| WLC | wait-list control |

restriction, stimulus control, paradoxical intention) or cognitive (identifying and challenging dysfunctional thoughts and excessive worries about sleep; [21–26]). Since the 1990s it has become popular to offer these non-pharmacological treatments in (various) combinations. These combinations are usually referred to as cognitive behavioral therapy for insomnia (CBTI).

Several excellent (systematic) reviews and meta-analyses have been written on CBTI; they conclude that CBTI is effective [27–33] in primary [34] and comorbid [35,36] insomnia and CBTI is at least as effective as pharmacotherapy [37,38]. As a result, the American College of Physicians recently recommended CBTI as the initial treatment for all adults with insomnia [39]. Even though some of these reviews pooled the data of individual studies [e.g., [28,29,35]], to our knowledge, no recent meta-analysis exists that includes all CBTI studies and that uses modern techniques to pool data and to analyze the subgroups of patients which might benefit most from CBTI.

The aim of this meta-analysis is to quantify the effects of educational, behavioral and cognitive therapies for insomnia, based on all available randomized controlled trials, and to perform subgroup analysis as a function of several potential moderators (e.g., comorbidity, sleep medication, year of publication) of treatment outcomes.

## Method

### *Search strategy*

We carried out a comprehensive literature search in PubMed, PsycINFO, EMBASE and the Cochrane central register of controlled trials. We combined terms indicative of insomnia (e.g., insomnia, sleep disorders, sleep initiation and maintenance disorders) with those of psychological treatment (e.g., psychotherapy, cognitive therapy, behavior therapy). For example for PsycINFO we used (DE=("sleep disorders" or "insomnia")) and (DE=("psychotherapy" or "behavior therapy" or "cognitive behavior therapy" or "cognitive therapy")). We searched all literature up to December 2015. Titles and abstracts were screened by one person (AvS, TvdZ, AK or JL). Only those records that were definitely not suitable (e.g., not a randomized trial, a biological or medical treatment) were excluded in this phase. We retrieved the full papers of the remaining 196 references. Those papers were examined independently by two of the four researchers (AvS, TvdZ, AK or JL). In case of disagreement the paper was discussed with the third and fourth reviewer until consensus was achieved.

### *Inclusion criteria*

We used the following inclusion criteria: 1) the study had to be a randomized controlled trial (RCT), 2) investigating CBTI or at least one component of it, 3) for adults of 18 y or older, 4) with insomnia, 5) in comparison with a non-active control group (e.g., waitlist control, care-as-usual, or a minimal intervention such as psychoeducation about sleep or sleep hygiene information), 6) reporting on sleep diary outcomes. We identified the following treatments as being part of CBTI: relaxation, sleep restriction, stimulus control, paradoxical intention, and identifying and challenging dysfunctional thoughts (about sleep). We excluded all other therapies such as interpersonal therapy, bright light therapy, exercise and biofeedback. Cognitive distraction was also excluded because it only encompassed advice on topics to think about (e.g., a recipe or a plot of a television show) or things to do (e.g., to read a book or watch television). We also excluded studies: aimed at children or adolescents, at tapering of medication, which used outcomes such as fatigue instead of sleep, or which were aimed at treating another mental health disorder and reported insomnia as a secondary outcome. We also excluded studies with insufficient information to calculate the effect size (e.g., those presenting scores in a plot without providing means, standard deviations or other relevant statistics).

### *Data extraction*

We coded the following characteristics of the studies: 1) year of publication, 2) setting where patients were recruited (community, primary care, other care facilities, university), 3) the definition of insomnia that was used, 4) co-morbidity (e.g., insomnia in chronic pain patients), 5) age group (young adults, older adults or all adults), 6) the treatment format (individual, group or self-help), 7) the number of treatment sessions, 8) the use of sleep medication (allowed, not allowed or not reported), 9) the type of control group (e.g., waitlist, no treatment), 10) the number of patients included in the treatment and control group, and 11) type of intervention. We distinguished four categories of interventions: a) full CBTI which had to include an educational component as well as a behavioral and cognitive one, b) behavioral therapy which had to include both stimulus control and sleep restriction (with or without an educational component), c) relaxation, and d) "other" which included e.g., stimulus control only or paradoxical intention only. Two independent assessors coded each study and differences were

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discussed by the review team until consensus was reached (AvS, TvdZ, AK, or JL).

*Quality assessment*

We assessed the validity of the studies using the criteria suggested by the Cochrane handbook [40]: 1) adequate sequence generation, 2) concealment of allocation, 3) adequate handling of incomplete outcome data, and 4) selective reporting of data. We did not assess the blinding of patients or therapists since this is impossible in psychotherapy research nor did we assess blinding of outcome assessors since all reported outcomes are based on self-report. Two reviewers conducted the quality assessment independently of each other (AvS, TvdZ, AK, or JL).

*Meta-analyses*

We examined the effects as observed immediately after treatment (post-test). We calculated between group effect sizes for all individual studies using Hedges' *g*. This is the standardized mean differences (or Cohen's *d*) after adjusting for small sample sizes [41,42]. The effect size represents the difference between two groups in number of standard deviations. Effect sizes of 0.56–1.2 can be assumed to be large, while effect sizes of 0.33–0.55 are moderate, and effect sizes of 0–0.32 are small [43]. To calculate those effect sizes, we used the available statistics as published in the papers (e.g., means and standard deviations, mean difference score and 95% confidence interval).

To calculate the individual effect sizes as well as the pooled mean effect size we used the computer program Comprehensive meta-analysis (CMA) version 3.3.070 for Windows, developed for support in meta-analysis (www.metaanalysis.com). We first performed the analyses on all studies and then checked for outliers. An outlier was defined as a study in which the 95% confidence interval around the effect size did not overlap with the 95% confidence interval around the pooled effect size. We then repeated the analysis without the identified outliers.

As we expected considerable heterogeneity, we calculated pooled effect sizes with the random effects model. We tested heterogeneity under the fixed effects model using $I^2$ which describes the variance between studies as a proportion of the total variance. A value of 0% indicates no observed heterogeneity and larger values show increasing heterogeneity. We calculated 95% confidence intervals (CI) around $I^2$, using the non-central Chi squared-based approach within the heterogi module for Stata.

We tested for publication bias by visually inspecting the funnel plot and by conducting the Egger's test of the intercept. We used the Duval and Tweedie [44] trim and fill procedure to estimate the effect size after the publication bias had been taken into account. It also provides an estimate of the number of missing studies.

In addition, we performed univariate subgroup analyses on three different outcome variables: sleep onset latency (SOL), sleep efficiency (SE) and insomnia severity index (ISI). We chose SOL because this was the most frequently used outcome variable, SE because this is often described as the preferred primary outcome in insomnia research and ISI because this questionnaire is gaining popularity rapidly as an outcome and is much easier to collect than a sleep diary. For these three variables we tested whether the effect size was significantly related to treatment, patient or study variables. We used the mixed effects model, which pools studies within subgroups with the random effects model, but tests for significant differences between subgroups with the fixed effects model. Lastly, we conducted multivariate meta regression analysis. We only included variables that were univariate associated with the outcome with a p-value of 0.25 or less. Two variables were excluded because of collinearity: type of treatment (which was collinear with yes/no full CBTI treatment) and number of sessions (which was collinear with treatment format since self-help interventions cannot be divided into discrete sessions). We entered all the variables in the model simultaneously and calculated standard regression coefficients. Finally, we reported the overall proportion of the total between-study variance which is explained by the model (*R* square).

## Results

*Selection of studies*

The titles and abstracts of 1727 references were screened (after removal of 290 duplicates). We excluded 1503 references and retrieved full-text papers of the remaining 224 references. A total of 137 papers did not fulfill our inclusion criteria (Fig. 1). We included 87 papers on RCTs in which (a component of) CBTI was examined in comparison to a non-treatment control group [45–131]. Some studies had more than two arms and examined different active interventions in comparison to a control. Of the 87 studies, 63 examined one intervention, 18 examined two interventions, five studied three interventions and one studied four interventions. The total number of comparisons was therefore 118. There were 6.303 patients included in the studies, 3.724 in the intervention groups and 2.579 in the control groups.

*Characteristics of included studies*

The first studies were published in 1974 but the majority of studies ($n = 62$; 71%) were published in or after the year 2000 (Table 1). Most studies recruited people from the general population ($n = 59$; 68%). A minority of the studies recruited people through care facilities (primary care or specific care settings, $n = 20$; 23%) and many of those studies additionally recruited via general media. The remaining eight studies (9%) recruited participants through universities. Some studies excluded older patients (n = 18; 21%), while others specifically focused on the elderly ($n = 20$; 23%). The remaining studies either included both younger and older adults ($n = 30$; 34%) or did not specify which age categories were eligible for the study ($n = 19$; 22%). Some studies specifically examined insomnia in the context of another somatic disorder ($n = 15$; 17%) or a mental disorder ($n = 5$; 6%) but most studies aimed to examine primary insomnia and therefore excluded patients with mental or somatic illnesses ($n = 45$; 52%). For the remaining studies comorbidities were allowed but it was not always clear whether or not they excluded patients with severe illnesses ($n = 22$; 25%). About half of the studies allowed the use of sleep medication during the study ($n = 40$; 46%), while in the other half of the studies sleep medication was either not allowed ($n = 37$; 43%) or it was not reported how the use of sleep medication was handled ($n = 10$; 11%).

Out of the 118 interventions included in this meta-analysis 51 (43%) consisted of full CBTI (educational component as well as a behavioral and cognitive one), 13 (11%) of behavioral therapy (stimulus control and sleep restriction but no cognitive element), 23 (19%) of relaxation (without any other treatment element) while the remaining 31 interventions (26%) consisted of "other" treatments such as paradoxical intention only, or stimulus control only. About a third of the treatments ($n = 35$; 30%) was offered in group format, about half ($n = 57$; 48%) was offered as individual face-to-face therapy while the remaining studies examined self-help treatments (either through books, audio or the internet, $n = 26$; 22%). The individual or group treatments typically took up to six sessions ($n = 71$; 60%). Of the 87 studies, 41 used a waitlist control

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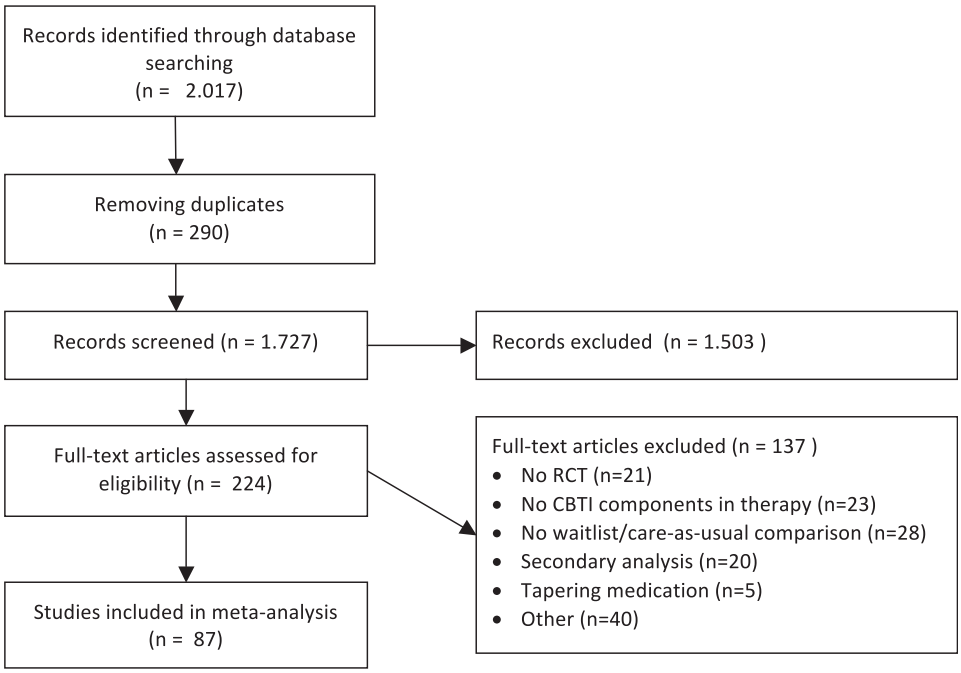


**Fig. 1.** Flow-chart of studies included in the meta-analysis on psychological treatment for insomnia (inception to 10 january 2016).

(47%), 14 no treatment (16%), 20 placebo (mostly quasi-desensitization; 23%) and 12 offered psycho-education (14%).

*Quality assessments*

Out of all 87 studies 38 (44%) reported an adequate sequence generation for their randomization while the remaining 49 studies did not report how they handled this. Only 23 studies (26%) reported that their random allocation had been concealed. For the other 64 studies (74%) this remained unclear. About half of the studies ($n$ = 45; 52%) handled their missing data well by performing intention-to-treat analyses. For another 24 studies (27%) it was clear that missing cases had been dropped from their analysis. For the other 18 studies (21%) it remained unclear how many patients were randomized, how many patients had dropped out and how missing data were handled.

We used self-report sleep diary data to extract our outcome data. Many different variables might be extracted from a sleep diary and this was reflected in the included studies. Of all the 118 comparisons 108 calculated SOL. This is the time it takes to fall asleep after going to bed and turning the lights out/attempting to sleep. The SE, the percentage of time having slept while being in bed, was calculated for 79 comparisons, total sleep time (TST) for 91, the time being awake after sleep onset (WASO) for 71, sleep quality (SQ) for 40 and the number of awakenings during the night (NWAK) for 36 comparisons. Out of all 87 studies 38 also included the insomnia severity index (ISI [132]) as an outcome measure and 19 included the Pittsburg sleep quality index (PSQI [133]).

*Overall effects*

The CBTI interventions had positive statistically significant effects on all reported sleep outcomes (Table 2). The ISI showed the largest effect ($g$ = 0.98) but large effects were also obtained for SE ($g$ = 0.71), PSQI ($g$ = 0.65), WASO ($g$ = 0.63) and SOL ($g$ = 0.57). Small to moderate effect sizes were observed for NWAK ($g$ = 0.29) and SQ ($g$ = 0.40). The smallest effect was on TST ($g$ = 0.16). Since there were studies with extremely high effect sizes as well as studies with extremely low effect sizes, deleting the outliers did not influence the effect sizes substantially. It did reduce the percentage of heterogeneity ($I^2$). Heterogeneity remained quite high for the ISI and the SQ but was small to moderate for all outcomes based on sleep diaries. Of the 87 studies, 24 (28%) examined more than one treatment while using only one control group for each study. This means that the comparisons from these studies were not independent of each other which may have resulted in an artificial reduction of heterogeneity. We examined the possible effects by conducting sensitivity analyses in which we included only one comparison per study. First, we included only the comparison with the largest effect size from that study and then we conducted another analysis in which we included only the smallest effect size. The resulting effect sizes and heterogeneity statistics were highly comparable with the ones found in the overall analyses (Table 2) and therefore not shown.

*Association between effect and treatment, patient and study variables*

We studied the association between the effect size on SOL, SE and ISI on the one hand and different treatment, patient and study variables on the other (Table 3). Overall the results were mixed and depended on the outcome variable.

First, we describe the results for SOL. SOL was significant ($p < 0.05$) related to type of treatment, age, and year of publication: effect sizes were higher for relaxation and “other” treatments than for CBTI or behavioral treatments and higher for young adults than for older adults. There seems to be a U-shape association between SOL and the year of publication: the oldest studies have the highest effect sizes, but after the 90s the effect sizes start to increase again. There were also significant associations for the use of sleep medication and concealment of allocation. In these cases effect sizes were higher for studies that did not report the use of sleep

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**Table 1**
Characteristics of the included studies on (elements of) CBT for insomnia.

| Study | Recruitment | Definition insomnia | Co-morbidity | Age | Interv | Format | F2F sessions | $N_{EXP}$ | Control group | $N_{ctrl}$ |
|---|---|---|---|---|---|---|---|---|---|---|
| Alperson, 1979 [45] | Comm | SOL ≥ 30 min | Allowed | 17–54 | Relax + SC | Group | 2 | 7 | WL | 7 |
| Arnedt, 2011 [46] | Care | SOL ≥ 30 min, ≥ 3 n/wk, ≥ 1 mo + ISI ≥ 8 | Alcohol | 18–65 | CBTI | Indiv | 4 | 9 | Plac | 8 |
| Arnedt, 2013 [47] | Care | Wake time > 60 min + SE < 85% | Excluded | 18–65 | CBTI | Phone | 4–8 | 18 | PE | 15 |
| Ascher, 1979 [48] | Comm | SOL ≥ 60 min, ≥ 3 n/wk | Excluded | 18+ | Pdox | Indiv | 4 | 8 | - | 9 |
| Ascher, 1980 [49] | Comm | No criteria | Excluded | 18+ | Pdox A | Indiv | 4 | 10 | WL | 10 |
| | | | | | Pdox B | Indiv | 4 | 10 | | |
| Borkovec, 1976 [50] | Univ | Average SOL ≥ 30 min | Allowed | – | Relax | Group | 4 | 12 | - | 12 |
| Bothelius, 2013 [51] | Care | Poor sleep > 1 m mo + daytime imp | Excluded | 18+ | CBTI | Group | 5 | 32 | WL | 34 |
| Broomfield, 2003 [52] | Univ | SOL ≥ 30 min, > 3 n/wk + PSQI > 5 | Excluded | 16–65 | Pdox | SHp | n/a | 17 | - | 17 |
| Buysse, 2011 [53] | Care | DSM-IV and ICSD-2 insomnia diagnosis | Allowed | elderly | Behavioral | Indiv | 2 | 42 | PE | 40 |
| Carr-Kaffashan, 1979 [54] | Comm | Average SOL ≥ 30 min, ≥ 6 mo | Allowed | 18+ | Relax | Indiv | 4 | 16 | Plac | 14 |
| Creti, 2005 [55] | Comm | No criteria | Excluded | 55+ | Relax | SHp | n/a | 14 | - | 13 |
| Currie, 2000 [56] | Care | DSM-III insomnia diagnosis with SIS-D and ICSD diagnosis | Pain | <60 | CBTI | Group | 7 | 32 | WL | 28 |
| Currie, 2004 [57] | Care | SOL ≥ 30 min, ≥ 3 n/wk | Alcohol | 18+ | CBTI | Indiv | 5 | 20 | WL | 20 |
| | | | | | CBTI | SHp | n/a | 20 | | |
| Edinger, 2001 [58] | Comm | Mean WASO ≥ 60 min, ≥ 6 mo | Excluded | 40–80 | Behavioral | Indiv | 6 | 25 | Plac | 25 |
| | | | | | Relax | Indiv | 6 | 25 | | |
| Edinger 2005 [59] | Comm | Mean WASO ≥ 60 min | Fibromyalgia | 21–65 | Behavioral | Indiv | 6 | 18 | - | 11 |
| Edinger, 2003 [60] | Primary care | Difficulty initiating or maintaining sleep ≥ 1 mo + daytime imp | Excluded | – | BT | Indiv | 2 | 10 | plac | 10 |
| Edinger, 2007 [61] | Comm | Mean WASO ≥ 60 min, ≥ 6 mo | Excluded | 40–75 | Behavioral | Indiv | 1 | 16 | WL | 11 |
| | | | | | Behavioral | Indiv | 2 | 18 | | |
| | | | | | Behavioral | Indiv | 4 | 24 | | |
| | | | | | Behavioral | Indiv | 8 | 17 | | |
| Edinger, 2009 [62] | Care | Mean SOL + WASO ≥ 60 min | Excl (PI) | – | Behavioral | Indiv | 4 | 20 | PE | 40 |
| | | | Allow (CMI) | | Behavioral | Indiv | 4 | 21 | | |
| Ellis, 2015 [63] | Comm | Difficulty initiating or maintaining sleep or early morning awakening, ≥ 3 n/wk, < 3 mo | excluded | – | CBTI | Indiv | 1 | 20 | WL | 20 |
| Epstein, 2007 [64] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 2 wk + daytime imp | Cancer | 18+ | Behavioral | Group | 4 | 40 | PE | 41 |
| Epstein, 2012 [65] | Comm | SOL or WASO ≥ 45 min, ≥ 3 n/wk, ≥ 6 mo + day-time imp | Excluded | 55+ | PE + SR | Group | 4 | 44 | WL | 50 |
| | | | | | PE + SC | Group | 4 | 44 | | |
| | | | | | PE + SC + SR | Group | 4 | 41 | | |
| Espie, 1989 [66] | Care | Mean SOL ≥ 30 min, ≥ 1 y | Excluded | – | SC | Group | 8 | 14 | - | 13 |
| | | | | | Relax | Group | 8 | 14 | | |
| | | | | | Pdox | Group | 8 | 15 | | |
| Espie, 2001 [67] | Care | ICSD difficulty falling/maintaining sleep, ≥ 4 n/wk, ≥ 3 mo + PSQI ≥ 5 | Excluded | – | CBTI | Group | 6 | 74 | WL | 65 |
| Espie, 2007 [68] | Care | ICSD/DSM-IV criteria of insomnia | Allowed | – | CBTI | Group | 5 | 107 | - | 94 |
| Espie, 2008 [69] | Care | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 3 mo + PSQI ≥ 5 | Cancer | 18+ | CBTI | Group | 5 | 100 | - | 50 |
| Espie, 2012 [70] | Comm | poor sleep ≥ 3 n/wk, ≥ 3 mo + daytime imp + SE < 80% | Excluded | 18+ | CBTI | SHp | n/a | 55 | WL | 54 |
| Freedman, 1976 [71] | Univ | SOL ≥ 60 m, ≥ 4 n/wk, ≥ 6 mo | Excluded | – | Relax | Indiv | 6 | 6 | PE | 6 |
| Friedman, 2000 [72] | Comm | SE < 80%, SOL >30 min, TST < 6h, WASO > 30 min, ≥ 5 n/2wk | Excluded | 55+ | SC + SR | Indiv | 5 | 16 | PE | 11 |
| Harris, 2012 [73] | Comm | SOL > 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 18–65 | SC | Indiv | 5 | 20 | PE | 20 |
| Haynes, 1974 [74] | Univ | NR | – | 18–21 | Relax | Group | 6 | 7 | plac | 7 |
| Ho, 2014 [75] | Comm | SOL or WASO ≥ 3 n/wk, ≥ 3 mo + daytime imp | Allowed | 18+ | CBTI | SHp+ | n/a | 103 | WL | 105 |
| | | | | | CBTI | SHp– | n/a | 104 | | |
| Irwin, 2014 [76] | Comm | SOL or WASO ≥ 3 n/wk, ≥ 3 mo + daytime imp | Excluded | 55+ | PE + SC + CT + relax | group | 16 | 50 | PE | 25 |
| Jacobs, 2004 [77] | Comm | SOL > 60 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 25–64 | CBTI | Indiv | 4 | 15 | Plac | 15 |
| Jansson, 2012 [78] | Care | SOL or WASO > 30 m, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Hearing problems | 18–65 | CBTI | Indiv | 7 | 17 | WL | 15 |
| Jernelov, 2012 [79] | Comm | ISI > 10 + poor sleep ≥ 4 wk | Excluded | 18+ | CBTI | SHp | N/A | 44 | WL | 44 |
| | | | | | CBTI | SHp | N/A | 45 | | |
| Jungquist, 2010 [80] | Care | SOL or WASO > 30 min, > 3 n/wk, > 6 mo | Pain | 25+ | CBTI | Indiv | 8 | 19 | Plac | 9 |
| Kaldo, 2015 [81] | Comm | Difficulty initiating or maintaining sleep + daytime imp + ISI > 10 | Excluded | 18+ | CBTI | SHp | n/a | 73 | Plac | 75 |
| Kapella, 2011 [82] | Comm | Difficulty initiating or maintaining sleep, waking up too early or poor quality sleep | COPD | 45+ | CBTI | Indiv | 6 | 9 | plac | 9 |
| Lacks, 1983a [83] | Comm | SOL ≥ 30 min, ≥ 1 n/w, ≥ 6 mo | Excluded | 17–59 | Relax | Group | 4 | 19 | Plac | 16 |
| | | | | | SC | Group | 4 | 15 | | |
| | | | | | Pdox | Group | 4 | 14 | | |
| Lacks, 1983b [84] | Comm | WASO ≥ 30 min, ≥ 1 n/wk, ≥ 6 mo | Excluded | 17–59 | SC | Group | 4 | 7 | Plac | 8 |

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**Table 1** (*continued*)

| Study | Recruitment | Definition insomnia | Co-morbidity | Age | Interv | Format | F2F sessions | $N_{EXP}$ | Control group | $N_{ctrl}$ |
|---|---|---|---|---|---|---|---|---|---|---|
| Lancee, 2012 [85] | Comm | SE < 85% + SLEEP-50 ≥ 19 | Allowed | 18+ | CBTI | SHp | N/A | 205 | WL | 202 |
| | | | | | CBTI | SHp | N/A | 216 | | |
| Lancee, 2015 [86] | Comm | SOL or WASO > 30 min, ≥ 3 n/wk, ≥ 3 mo + daytime imp + ISI > 10 | Excluded | 18+ | CBTI | SHp | n/a | 36 | WL | 27 |
| Lancee, 2016 [87] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 3 mo + ISI ≥ 10 | Excluded | 18+ | CBTI | SHp | n/a | 30 | WL | 30 |
| | | | | | | Indiv | 6 | 30 | | |
| Lichtstein, 1999 [88] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 6 mo | Excluded | – | Relax | Indiv | 3 | 10 | WL | 10 |
| Lichtstein, 2000 [89] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Illness | 58+ | Relax + SC | Indiv | 4 | 23 | WL | 21 |
| Lichtstein, 2001 [90] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 59+ | Relax | Indiv | 6 | 27 | Plac | 23 |
| | | | | | SR | Indiv | 6 | 24 | | |
| Lick, 1977 [91] | Comm | Average SOL ≥ 50 min | Excluded | – | Relax+ | Indiv | 6 | 10 | - | 10 |
| | | | | | Relax− | Indiv | 6 | 10 | | |
| Lovato, 2014 [92] | Comm | WASO > 30 min, ≥ 3 n/wk, > 6 mo + daytime imp | Exluded | Older | CBTI | Group | 4 | 86 | WL | 32 |
| Manber, 2008 [93] | Comm | SOL or WASO ≥ 30 min, TST ≤ 6.5 h, ≥ 3 n/wk | Depression | 18–75 | CBTI | Indiv | 7 | 15 | Plac | 15 |
| McCrae, 2007 [94] | Comm | SOL > 31 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 65+ | SC + SR | Indiv | 2 | 11 | PE | 11 |
| Means, 2000 [95] | Univ | SOL or WASO ≥ 30 min + poor sleep ≥ 2 mo + daytime imp | Excluded | – | Relax | Indiv | 3 | 28 | - | 29 |
| Mimeault, 1999 [96] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 1 mo + daytime imp | Excluded | 18+ | CBTI | SHp | N/A | 18 | WL | 18 |
| | | | | | CBTI | SHp | N/A | 18 | | |
| Morawetz, 1989 [97] | Comm | SOL or WASO > 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 18–60 | SR + relax | SHp | N/A | 16 | WL | 18 |
| | | | | | SR + relax | Group | 5 | 16 | | |
| Morin, 1988 [98] | Comm | WASO > 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 55+ | SC | Group | 6 | 9 | WL | 10 |
| Morin, 1993 [99] | Comm | WASO > 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 60+ | CBTI | Group | 8 | 12 | WL | 12 |
| Morin, 1999 [100] | Comm | SOL or WASO ≥ 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 55+ | CBTI | Group | 8 | 18 | Plac | 20 |
| Morin, 2005 [101] | Comm | Poor sleep ≥ 3 n/wk | Allowed | 18+ | CBTI | SHp | n/a | 96 | - | 96 |
| Nicassio, 1974 [102] | Comm | Average SOL ≥ 30 min | Allowed | – | Relax A | Indiv | 4 | 8 | - | 7 |
| | | | | | Relax B | Indiv | 4 | 8 | | |
| Norell-Clarke, 2015 [103] | Comm | Insomnia symptoms > 3 n/wk + ISI > 10 | Depression | – | CBTI | Group | 4 | 32 | Plac | 32 |
| Pigeon, 2012 [104] | Care | SOL or WASO > 30 min, ≥ 3 n/wk, ≥ 6 mo | Pain | 35–75 | CBTI | Indiv | 10 | 6 | WL | 4 |
| Riedel, 1995 [105] | Comm | SOL > 30 min, ≥ 3 n/wk, ≥ 12 mo | Excluded | 60+ | PE + SR | Group | 4 | 25 | WL | 25 |
| Riedel, 1998 [106] | Comm | SOL or WASO or early awakening > 30 min, ≥ 3 n/wk, ≥ 6 mo | Excluded | 19–80 | SC | Indiv | 2 | 11 | WL | 10 |
| Riley, 2010 [107] | Comm | SOL or WASO or early awakening > 30 min, ≥ 3 n/wk, ≥ 6 mo | Excluded | 18–65 | SC + SR | SHp | n/a | 57 | PE | 33 |
| Ritterband, 2009 [108] | Comm | Poor sleep ≥ 3 n/wk, ≥ 6 mo + daytime imp | Allowed | 18–65 | CBTI | SHp | n/a | 22 | WL | 23 |
| Ritterband, 2012 [109] | Comm | Poor sleep ≥ 3 n/wk, ≥ 6 mo + daytime imp + average TST ≤ 6.5 h | Cancer | 21+ | CBTI | SHp | n/a | 14 | WL | 14 |
| Rybarczyk, 2002 [110] | Care | SOL ≥ 45 min or WASO ≥ 60 min or TST ≤ 5 h, ≥ 3 n/wk | Illnesses | 55+ | CBTI | Group | 8 | 16 | WL | 13 |
| | | | | | Relax | SHp | n/a | 18 | | |
| Rybarczyk, 2005 [111] | Care | SOL ≥ 30 min/WASO ≥ 60 min/ TST ≤ 6.5 h, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Illness | 55+ | CBTI | Group | 8 | 46 | Plac | 46 |
| Savard, 2005 [112] | Comm | SOL or WASO > 30 min, SE < 85%, ≥3 n/wk, ≥ 6 mo + daytime imp | Cancer | 18+ | CBTI | Group | 8 | 27 | WL | 30 |
| Savard, 2014 [113] | Care | ISI ≥ 8 or ≥ 2 nights of sleepmedication in last 2 wk | Cancer | 18–75 | CBTI | Indiv | 6 | 81 | - | 81 |
| | | | | | CBTI | SHp | n/a | 80 | | |
| Sivertsen, 2006 [114] | Comm | Poor sleep ≥ 3 mo + daytime imp | Allowed | 55+ | CBTI | Indiv | 6 | 18 | Plac | 12 |
| Smith, 2015 [115] | Care | SOL or WASO > 30 min, ≥ 2 n/wk, > 1 mo | Knee osteoarthritis | – | CBTI | Indiv | 8 | 50 | Plac | 50 |
| Soeffing, 2008 [116] | Comm | SOL or WASO > 30 min, ≥ 3 n/wk, ≥ 6 mo + daytime imp | Excluded | 50+ | CBTI | Indiv | 8 | 20 | Plac | 27 |
| Stanton 1989 [117] | Comm | Average SOL > 30 min, ≥ 6 mo | Allowed | – | Relax | Indiv | 4 | 15 | Plac | 15 |
| | | | | | SC | Indiv | 4 | 15 | | |
| Steinmark, 1974 [118] | Univ | Average SOL > 30 min, ≥ 6 mo | Allowed | – | Relax A | Group | 4 | 12 | WL | 12 |
| | | | | | Relax B | Group | 4 | 12 | | |
| Strom, 2004 [119] | Comm | SOL/WASO/early awakening > 30 min, ≥ 3 n/wk, ≥ 3 mo + daytime imp | Excluded | 18+ | CBTI | SHp | n/a | 54 | WL | 55 |
| Swift, 2012 [120] | Comm | No in- or exclusion criteria | Allowed | 18+ | CBTI | Group | 1day | 75 | WL | 76 |
| Talbot, 2014 [121] | Comm | ISI > 14 + difficulty initiating or maintaining sleep + daytime imp | PTSD treatment | 18–65 | CBTI | Indiv | 8 | 29 | WL | 16 |
| Taylor, 2010 [122] | Care | Average SE < 85%, ≥6 mo + regular use of sleep medication | Excluded | 18+ | SR | Indiv | 8 | 24 | WL | 22 |
| Taylor, 2014 [123] | Univ | SOL or WASO > 30 min, ≥ 3 n/wk, ≥ 3 mo + daytime imp | Allowed | 18–27 | CBTI | Indiv | 6 | 17 | WL | 17 |

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**Table 1** (*continued*)

| Study | Recruitment | Definition insomnia | Co-morbidity | Age | Interv | Format | F2F sessions | $N_{EXP}$ | Control group | $N_{ctrl}$ |
|---|---|---|---|---|---|---|---|---|---|---|
| Turner, 1979 [124] | Comm | Not reported | Allowed | – | Relax | Indiv | 4 | 10 | - | 10 |
| | | | | | Pdox | Indiv | 4 | 10 | | |
| | | | | | PR | Indiv | 4 | 10 | | |
| Van Straten, 2009 [125] | Comm | SOL/WASO/early awakening > 30 min, ≥ 3 n/wk, ≥ 1 mo | Allowed | 18+ | CBTI | SHp | n/a | 126 | WL | 121 |
| Van Straten, 2013 [126] | Comm | SOL > 30 min, ≥ 3 n/wk, ≥ 3 mo | Allowed | 18+ | CBTI | SHp | n/a | 59 | WL | 59 |
| Vincent, 2009 [127] | Comm | SOL or WASO > 30 min, ≥ 4 n/wk, ≥ 6 mo + daytime imp | Allowed | 18+ | CBTI | SHp | n/a | 59 | WL | 59 |
| Waters, 2003 [128] | Comm | SOL and (WASO > 30 min or NWAK > 3) for ≥ 4 nights wk for ≥ 1 mo | Excluded | 18–59 | Relax | Indiv | 4 | 13 | PE | 16 |
| | | | | | SC + SR | Indiv | 4 | 14 | | |
| Woolfolk, 1983 [129] | Comm | Average SOL ≥ 50 min, ≥ 6 mo | Excluded | 18+ | Relax A | Group | 4 | 8 | WL | 7 |
| | | | | | Relax B | Group | 4 | 10 | | |
| | | | | | Relax C | Group | 4 | 9 | | |
| Wu, 2006 [130] | Comm | SOL or WASO ≥ 30 min, ≥ 6 mo + daytime imp | Excluded | – | CBTI | Group | 16 | 19 | Plac | 19 |
| Zwart, 1979 [131] | Univ | Average SOL ≥ 30 min | Allowed | – | SC | Group | 4 | 9 | WL | 8 |

Abbreviations: AASM = American Academy of Sleep Medicine; AT = autogenic training; CD = cognitive distraction; CMI = comorbid insomnia; Comm = community; CT = cognitive therapy; DSISD = Duke structured interview for sleep disorders; F2F = face-to-face; ICSD = International classification of sleep disorders; imp = impairment; indiv = individual; ISI = insomnia severity index; $N_{EXP}$ = number of patients in experimental condition; $N_{ctrl}$ = number of patient in control condition; NWAK = number of awakenings; NR = not reported; PE = psycho-education; PI = primary insomnia; plac = placebo; PR = progressive relaxation; PSQI = Pittsburgh sleep quality index; RDC = research diagnostic criteria; relax = relaxation; SC = stimulus control; SE = sleep efficiency; SHp = self-help; SIS-D = structured interview for sleep disorders for DSM-III-R; SOL = sleep onset latency; SR = sleep restriction; TST = total sleep time; univ = university; WASO = wake after sleep onset; WL = waitlist.

medication and for studies that did not report allocation concealment. There were borderline significant ($p < 0.10$) associations for SOL with treatment format (individual and group treatments yielded higher effect sizes than self-help), number of sessions (longer treatments yielded better effect sizes than shorter treatments), recruitment population (non-community samples yielded higher effect sizes), and type of control (no treatment had highest effect size). Overall, heterogeneity seemed to be moderate.

Second, we describe the results for SE. Some of the results for SE were comparable to those of SOL. This means that there was a (borderline) significant association with: type of treatment (higher effect sizes for "other" treatment than for CBTI or behavioral treatments), treatment format (higher effect sizes for individual and group therapy than for self-help), number of sessions (higher effect sizes for five or more sessions than for one to four), age (higher effects for younger people than for older people), recruitment population (higher effect sizes for patients recruited in other ways than general media/community) and year of publication (the most recent publications yielded the highest effect sizes). There were also some differences between the results for SOL and SE because SE was also (borderline) significantly associated with comorbidity (people with comorbid disorders obtained higher effects) and ITT (intention to treat) analysis (studies using ITT analysis showed higher effects than studies which did not report this).

Third, we describe the results for ISI. ISI was significantly related only to the type of control: studies with waitlist controls showed higher effects than studies with other type of control groups. There was furthermore a borderline significant association with allocation concealment: studies not reporting this yielded higher effect sizes (Table 3).

We examined a number of variables which might be related to each other (e.g., studies examining self-help might have included younger people than studies examining individual therapy). Therefore, we also performed a multivariate analysis (Table 4). The multivariate model showed significant relations with SE and ISI for treatment format. Self-help interventions performed worse than individual face-to-face interventions. Two other significant associations were related to study quality: studies that did not report allocation concealment had higher effects on SOL and ISI, and studies that did not report age had higher effects on SE and ISI. Finally, two significant associations were related to study design: studies with a waitlist control showed higher effect sizes on ISI than studies with an information control (or other minimal interventions) and more recent studies showed higher effect sizes on SE than older studies.

**Table 2**
Main post-test effects of insomnia treatments.

| Outcome | $N_c$ | Hedges *g* (95% CI) | $I^2$ (95% CI) | NNT |
|---|---|---|---|---|
| Insomnia severity index | 38 | 0.98 (0.82–1.15) | 74 (63–80) | 1.95 |
| Without seven outliers[a] | 31 | 0.92 (0.79–1.06) | 51 (19–67) | 2.07 |
| Sleep efficiency (SE) | 79 | 0.71 (0.61–0.82) | 70 (61–75) | 2.60 |
| Without 14 outliers[b] | 65 | 0.68 (0.60–0.74) | 34 (5–51) | 2.70 |
| Pittsburgh sleep quality index[c] | 19 | 0.65 (0.51–0.79) | 39 (0–64) | 2.82 |
| Wake after sleep onset (WASO) | 71 | 0.63 (0.53–0.73) | 60 (46–68) | 2.91 |
| Without nine outliers[d] | 62 | 0.66 (0.57–0.74) | 40 (14–55) | 2.78 |
| Sleep onset latency (SOL) | 108 | 0.57 (0.50–0.65) | 48 (33–58) | 3.18 |
| Without nine outliers[e] | 99 | 0.55 (0.48–0.61) | 27 (3–43) | 3.31 |
| Sleep quality (SQ) | 40 | 0.40 (0.24–0.56) | 74 (64–80) | 4.50 |
| Without six outliers[f] | 34 | 0.45 (0.31–0.59) | 49 (17–65) | 4.00 |
| Number of awakenings (NWAK) | 36 | 0.28 (0.16–0.40) | 29 (0–52) | 6.41 |
| Without nine outliers[g] | 34 | 0.28 (0.17–0.38) | 11 (0–42) | 6.41 |
| Total sleep time (TST) | 91 | 0.16 (0.08–0.24) | 47 (30–58) | 11.11 |
| Without nine outliers[h] | 82 | 0.17 (0.11–0.24) | 14 (0–35) | 10.42 |

95% CI = 95% confidence interval; $N_c$ = number of comparisons; NNT = number needed to treat.
[a] Three lower and four higher; [b] Seven lower and seven higher; [c] No outliers present; [d] Six lower and three higher; [e] Three lower and six higher; [f] Four lower and two higher; [g] One lower and one higher; [h] Six lower and three higher.

### *Publication bias*

Visual inspection of the funnel plot seemed to indicate that there was publication bias and this was confirmed by Egger's test ($p < 0.01$ for SOL, SE and ISI). This means that there are studies which are not published because of their small effects. Duval and Tweedie have developed a method (implemented in CMA) which is able to estimate how many studies are missing and what their effect size would have been [44]. It re-calculates the pooled effect size

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**Table 3**
Post-test effects of insomnia treatment on SOL, SE and ISI: subgroup analyses.

| | Sleep onset latency (SOL) | | | | | Sleep efficiency (SE) | | | | | Insomnia severity index (ISI) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | $N_C$ | *g* (95% CI) | $I^2$ | (95% CI | p | $N_C$ | *g* (95% CI) | $I^2$ | (95% CI | p | $N_C$ | *g* (95% CI) | $I^2$ | (95% CI | p |
| **Treatment variables** | | | | | | | | | | | | | | | |
| Full CBTI | | | | | | | | | | | | | | | |
| Yes | 44 | 0.47 (0.41–0.53) | 51 | (27–65) | 0.25 | 47 | 0.63 (0.56–0.69) | 70 | (58–77) | 0.41 | 34 | 0.82 (0.74–0.91) | 75 | (65–81) | 0.98 |
| No | 64 | 0.61 (0.52–0.70) | 44 | (20–58) | | 32 | 0.69 (0.58–0.79) | 70 | (55–78) | | 4 | 1.03 (0.79–1.26) | 48 | (0–81) | |
| Type of treatment | | | | | | | | | | | | | | | |
| CBTI | 44 | 0.47 (0.41–0.53) | 51 | (27–65) | 0.03 | 47 | 0.63 (0.56–0.69) | 70 | (58–77) | <0.01 | 34 | 0.82 (0.74–0.91) | 75 | (65–81) | 0.67 |
| Behavioral | 12 | 0.38 (0.20–0.55) | 45 | (0–70) | | 13 | 0.68 (0.50–0.85) | 67 | (32–80) | | 2 | 0.90 (0.53–1.26) | 80 | n/a[d] | |
| Relaxation | 22 | 0.63 (0.46–0.80) | 35 | (0–60) | | 5 | 0.18 (−0.09–0.45) | 0.0 | (0–64) | | – | – | – | – | |
| Other | 30 | 0.72 (0.59–0.84) | 42 | (0–62) | | 14 | 0.87 (0.71–1.03) | 72 | (47–82) | | 2 | 1.12 (0.81–1.42) | 0 | n/a[d] | |
| Treatment format | | | | | | | | | | | | | | | |
| F2F individual | 50 | 0.61 (0.51–0.71) | 50 | (27–63) | 0.07 | 37 | 0.66 (0.56–0.77) | 47 | (17–64) | 0.03 | 14 | 1.11 (0.94–1.28) | 68 | (37–80) | 0.21 |
| F2F group | 33 | 0.59 (0.49–0.68) | 42 | (3–61) | | 17 | 0.90 (0.78–1.01) | 79 | (65–85) | | 9 | 0.98 (0.82–1.13) | 48 | (0–74) | |
| Self help | 25 | 0.42 (0.34–0.49) | 42 | (0–63) | | 25 | 0.52 (0.44–0.59) | 71 | (54–80) | | 15 | 0.68 (0.58–0.79) | 78 | (62–85) | |
| Number of sessions[a] | | | | | | | | | | | | | | | |
| 1–4 | 41 | 0.49 (0.38–0.60) | 44 | (13–61) | 0.06 | 16 | 0.54 (0.39–0.69) | 12 | (0–52) | 0.01 | 4 | 1.03 (0.79–1.27) | 40 | (0–79) | 0.44 |
| 5–6 | 26 | 0.66 (0.56–0.76) | 49 | (11–67) | | 22 | 0.84 (0.73–0.95) | 76 | (63–83) | | 10 | 1.12 (0.96–1.29) | 52 | (0–75) | |
| 7 or more | 16 | 0.68 (0.52–0.84) | 43 | (0–67) | | 16 | 0.88 (0.72–1.04) | 57 | (13–74) | | 9 | 0.89 (0.68–1.10) | 74 | (40–85) | |
| n/a (self help) | 25 | 0.42 (0.34–0.49) | 42 | (0–63) | | 25 | 0.52 (0.44–0.59) | 71 | (54–80) | | 15 | 0.68 (0.58–0.79) | 78 | (62–85) | |
| **Patient variables** | | | | | | | | | | | | | | | |
| Population | | | | | | | | | | | | | | | |
| Community | 79 | 0.47 (0.41–0.53) | 51 | (34–62) | 0.10 | 59 | 0.60 (0.54–0.66) | 70 | (61–77) | 0.10 | 26 | 0.82 (0.73–0.91) | 78 | (68–84) | 0.59 |
| Other | 29 | 0.64 (0.54–0.74) | 29 | (0–54) | | 20 | 0.77 (0.66–0.88) | 64 | (37–77) | | 12 | 0.93 (0.78–1.08) | 54 | (0–74) | |
| Comorbidity | | | | | | | | | | | | | | | |
| Yes | 20 | 0.63 (0.52–0.75) | 36 | (0–62) | 0.38 | 20 | 0.87 (0.75–0.99) | 55 | (16–72) | 0.03 | 14 | 0.90 (0.76–1.05) | 68 | (37–80) | 0.65 |
| No | 88 | 0.49 (0.43–0.55) | 49 | (33–60) | | 59 | 0.58 (0.52–0.64) | 70 | (61–77) | | 24 | 0.82 (0.73–0.91) | 77 | (65–83) | |
| Sleep medication | | | | | | | | | | | | | | | |
| Allowed | 51 | 0.46 (0.40–0.52) | 49 | (25–63) | <0.01 | 41 | 0.58 (0.52–0.65) | 70 | (57–77) | 0.22 | 25 | 0.77 (0.68–0.86) | 76 | (64–83) | 0.13 |
| Not allowed | 4710 | 0.59 (0.49–0.68) | 48 | (22–62) | | 35 | 0.76 (0.66–0.87) | 69 | (55–77) | | 11 | 1.06 (0.89–1.22) | 62 | (10–79) | |
| Not reported | | 0.93 (0.69–1.17) | 0 | (0–53) | | 3 | 0.99 (0.65–1.32) | 0 | (0–73) | | 2 | 1.58 (0.91–2.25) | 0 | n/a[d] | |
| Age[b] | | | | | | | | | | | | | | | |
| Younger adults only | 21 | 0.70 (0.57–0.84) | 0 | (0–41) | 0.02 | 13 | 0.99 (0.84–1.15) | 0 | (0–49) | <0.01 | 10 | 1.02 (0.84–1.19) | 72 | (38–84) | 0.16 |
| All adults | 36 | 0.42 (0.35–0.49) | 52 | (24–66) | | 29 | 0.55 (0.49–0.63) | 71 | (56–79) | | 19 | 0.73 (0.63–0.84) | 78 | (65–85) | |
| Older adults only | 24 | 0.52 (0.40–0.64) | 48 | (7–67) | | 27 | 0.82 (0.71–0.94) | 72 | (58–80) | | 6 | 1.11 (0.92–1.31) | 0 | (0–61) | |
| Not reported | 27 | 0.63 (0.51–0.75) | 52 | (17–68) | | 10 | 0.34 (0.18–0.50) | 0 | (0–53) | | 3 | 0.68 (0.41–0.95) | 35 | (0–81) | |
| **Study variables** | | | | | | | | | | | | | | | |
| Year of publication | | | | | | | | | | | | | | | |
| 1970–1979 | 16 | 1.03 (0.80–1.27) | 0 | (0–45) | <0.01 | – | – | – | – | <0.01 | – | – | – | – | 0.82 |
| 1980–1989 | 16 | 0.73 (0.53–0.92) | 52 | (0–72) | | – | – | – | – | | – | – | – | – | |
| 1990–1999 | 6 | 0.35 (0.07–0.64) | 0 | (0–61) | | 7 | 0.56 (0.30–0.83) | 55 | (0–79) | | 2 | 1.15 (0.66–1.64) | 0 | n/a[d] | |
| 2000–2009 | 37 | 0.41 (0.32–0.49) | 9 | (0–39) | | 38 | 0.46 (0.38–0.55) | 58 | (37–70) | | 8 | 0.71 (0.54–0.89) | 82 | (62–89) | |
| 2010+ | 33 | 0.53 (0.46–0.60) | 64 | (46–75) | | 34 | 0.77 (0.70–0.85) | 74 | (62–80) | | 28 | 0.87 (0.78–0.96) | 73 | (58–80) | |
| Type of control | | | | | | | | | | | | | | | |
| No treatment | 21 | 0.66 (0.54–0.77) | 53 | (13–70) | 0.09 | 9 | 0.57 (0.44–0.70) | 77 | (50–86) | 0.27 | 3 | 0.63 (0.45–0.81) | 88 | (50–94) | 0.03 |
| Waitlist | 54 | 0.49 (0.43–0.56) | 53 | (33–65) | | 43 | 0.68 (0.61–0.75) | 76 | (68–82) | | 25 | 0.95 (0.85–1.04) | 76 | (64–83) | |
| Placebo | 20 | 0.47 (0.34–0.61) | 50 | (5–69) | | 15 | 0.60 (0.45–0.74) | 51 | (0–72) | | 8 | 0.79 (0.60–0.97) | 32 | (0–69) | |
| PE/other | 13 | 0.45 (0.28–0.62) | 0 | (0–49) | | 12 | 0.59 (0.42–0.77) | 0.0 | (0–50) | | 2 | 0.41 (−0.07–0.90) | 0 | n/a[d] | |
| Allocation sequence | | | | | | | | | | | | | | | |
| Adequate | 43 | 0.49 (0.43–0.55) | 62 | (44–72) | 0.51 | 46 | 0.67 (0.60–0.73) | 76 | (67–81) | 0.13 | 27 | 0.86 (0.77–0.94) | 78 | (68–84) | 0.53 |
| Not reported | 65 | 0.57 (0.48–0.65) | 33 | (4–50) | | 33 | 0.56 (0.44–0.67) | 53 | (25–68) | | 11 | 0.79 (0.60–0.98) | 56 | (0–76) | |
| Allocation concealed | | | | | | | | | | | | | | | |
| Yes | 26 | 0.39 (0.32–0.47) | 53 | (2–~69) | <0.01 | 26 | 0.58 (0.50–0.65) | 73 | (58–81) | 0.54 | 14 | 0.67 (0.56–0.78) | 74 | (52–84) | 0.08 |
| Not reported | 82 | 0.63 (0.56–0.70) | 38 | (16–53) | | 53 | 0.71 (0.63–0.79) | 67 | (55–75) | | 24 | 1.03 (0.92–1.15) | 67 | (46–77) | |
| Study drop-out | | | | | | | | | | | | | | | |
| Unknown | 11 | 0.71 (0.46–0.97) | 61 | (7–78) | 0.62 | 2 | 0.13 (−0.44–0.69) | 0 | n/a[d] | 0.21 | – | – | – | – | 0.25 |
| 0–9% | 34 | 0.58 (0.47–0.70) | 14 | (0–44) | | 28 | 0.66 (0.54–0.78) | 10 | (0–44) | | 13 | 0.90 (0.73–1.08) | 65 | (26–79) | |
| 10–19% | 47 | 0.50 (0.43–0.57) | 57 | (37–68) | | 32 | 0.68 (0.61–0.76) | 80 | (73–85) | | 17 | 0.95 (0.94–1.05) | 77 | (62–85) | |
| 20% or more | 16 | 0.46 (0.34–0.57) | 52 | (0–71) | | 17 | 0.55 (0.44–0.66) | 73 | (54–82) | | 8 | 0.61 (0.46–0.75) | 68 | (13–83) | |
| ITT analyses | | | | | | | | | | | | | | | |
| Yes | 51 | 0.51 (0.44–0.57) | 62 | (47–71) | 0.67 | 50 | 0.66 (0.60–0.73) | 75 | (67–80) | 0.09 | 33 | 0.83 (0.75–0.91) | 74 | (63–81) | 0.67 |
| No/not reported | 57 | 0.54 (0.45–0.63) | 25 | (0–46) | | 29 | 0.55 (0.43–0.67) | 50 | (16–67) | | 5 | 1.08 (0.77–1.40) | 73 | (0–87) | |
| **Publication bias** | | | | | | | | | | | | | | | |
| Adjustment for publication bias[c] | Add 27<br>0.41 (0.33–0.50) | | Egger's regression<br>intercept p < 0.01 | | | Add 21<br>0.49 (0.37–0.61) | | Egger's regression<br>intercept p = 0.01 | | | Add 13<br>0.71 (0.54–0.89) | | Egger's regression<br>intercept p < 0.01 | | |

CBTI = cognitive behavioral treatment for insomnia; F2F = face-to-face; ITT = intention to treat; PE = psycho-education; WASO = wake after sleep onset.
[a] Self help treatments excluded.
[b] Studies not reporting inclusion range for age were excluded (WASO, n = 6; SQ, n = 3).
[c] Trim and fill procedure which estimates the number of missing studies (number that needs to be added) and produces the effect size after adding those studies.
[d] The 95% CI of $I^2$ cannot be calculated when the number of groups is lower than three.

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**Table 4**
Association between post-test treatment effects and treatment-, patient- and study variables (standardized regression coefficients of multivariate meta regression analyses).

| | Sleep onset latency (SOL) | | Sleep efficiency (SE) | | Insomnia severity index (ISI) | |
|---|---|---|---|---|---|---|
| | *g* (95% CI) | p | *g* (95% CI) | p | *g* (95% CI) | p |
| **Treatment variables** | | | | | | |
| Full CBTI | | | | | | |
| Yes | Ref | 0.56 | n/a | | n/a | |
| No | 0.08 (−0.18 to 0.33) | | | | | |
| Treatment format | | | | | | |
| F2F individual | Ref | 0.62 | Ref | 0.03 | Ref | 0.05 |
| F2F group | −0.04 (−0.23 to 0.16) | | 0.33 (0.04–0.62) | | −0.47 (−1.01 to 0.08) | |
| Self help | −0.13 (−0.38 to 0.13) | | −0.05 (−0.36 to 0.26) | | −0.56 (−1.01 to −0.11) | |
| **Patient variables** | | | | | | |
| Population | | | | | | |
| Community | Ref | 0.55 | Ref | 0.28 | n/a | |
| Other | 0.06 (−0.14 to 0.26) | | 0.16 (−0.13 to 0.45) | | | |
| Comorbidity | | | | | | |
| Yes | n/a | | Ref | 0.78 | n/a | |
| No | | | −0.05 (−0.36 to 0.27) | | | |
| Sleep medication | | | | | | |
| Allowed | Ref | 0.28 | Ref | 0.65 | Ref | 0.34 |
| Not allowed | 0.02 (−0.18 to 0.23) | | 0.13 (−0.15 to 0.41) | | −0.37 (−0.87 to 0.14) | |
| Not reported | 0.28 (−0.07 to 0.63) | | 0.06 (−0.56 to 0.69) | | −0.01 (−0.94 to 0.92) | |
| Age | | | | | | |
| Younger adults only | Ref | 0.42 | Ref | 0.01 | Ref | 0.02 |
| All adults | −0.17 (−0.41 to 0.08) | | −0.28 (−0.62 to 0.06) | | −0.61 (−1.07 to −0.14) | |
| Older adults only | −0.20 (−0.46 to 0.06) | | −0.22 (−0.58 to 0.14) | | −0.28 (−1.00 to 0.43) | |
| Not reported | −0.14 (−0.38 to 0.11) | | −0.70 (−1.13 to −0.27) | | −0.81 (−1.43 to −0.19) | |
| **Study variables** | | | | | | |
| Year of publication | −0.001 (−0.012 to 0.009) | 0.85 | 0.02 (−0.001 to 0.05) | 0.06 | n/a | |
| Type of control | | | | | | |
| No treatment | Ref | 0.16 | n/a | | Ref | <0.01 |
| Wait list | −0.10 (−0.34 to 0.14) | | | | 0.60 (0.03 to 1.17) | |
| Placebo | −0.27 (−0.55 to 0.01) | | | | 0.33 (−0.33 to 0.99) | |
| Info/other | −0.29 (−0.62 to 0.05) | | | | −0.99 (−1.91 to −0.08) | |
| Allocation sequence | | | | | | |
| Adequate | n/a | | Ref | 0.48 | n/a | |
| Not reported | | | 0.11 (−0.19 to 0.42) | | | |
| Allocation concealed | | | | | | |
| Yes | Ref | <0.01 | n/a | | Ref | 0.02 |
| Not reported | 0.27 (0.08–0.46) | | | | 0.45 (0.09–0.81) | |
| Study drop-out | | | | | | |
| 0–9% | n/a | | Ref | 0.80 | Ref | 0.35 |
| 10–19% | | | 0.09 (−0.16 to 0.35) | | 0.22 (−0.15 to 0.59) | |
| 20% or more | | | 0.13 (−0.17 to 0.42) | | 0.20 (−0.23 to 0.63) | |
| Unknown | | | −0.11 (−0.90 to 0.67) | | – | |
| ITT analysis | | | | | | |
| Yes | n/a | | Ref | 0.61 | n/a | |
| No/not reported | | | −0.07 (−0.33 to 0.19) | | | |
| R squared | 0.30 | | 0.32 | | | |

95% CI = 95% confidence interval; CBTI = cognitive behavioral treatment; F2F = face-to-face; *g* = hedges g; ITT = intention to treat; Ref = reference group.

while imputing the missing effect sizes. The results showed that 27 studies were missing for SOL, 21 for SE, and 13 for ISI. The effects remained statistically significant after re-calculation but became smaller ($g = 0.41$ for SOL, $g = 0.49$ for SE, and $g = 0.71$ for ISI; Table 3).

## Discussion

In this meta-analysis on 87 studies with 118 comparisons we examined the effects of educational, behavioral and/or cognitive treatments for insomnia. The overall effects were large on insomnia severity (ISI; $g = 0.98$), sleep efficiency (SE; $g = 0.71$), the Pittsburgh sleep quality Index (PSQI; $g = 0.65$), wake after sleep onset (WASO; $g = 0.63$) and sleep onset latency (SOL; $g = 0.57$). Small to moderate effect sizes were observed for number of awakenings (NWAK; $g = 0.28$) and sleep quality (SQ; $g = 0.40$). The smallest effect was on total sleep time (TST; $g = 0.16$). Heterogeneity was highest for self-reported outcomes (ISI and SQ) and more moderate for sleep diary variables. Multivariate analysis showed different associations for different sleep variables (SOL, SE and ISI). We found that face-to-face interventions perform better than self-help interventions (on SE and ISI but not on SOL), newer studies and studies with a waitlist control yielded higher effect sizes (on SE and ISI respectively), and studies that did not report age or allocation concealment reported higher effect sizes (SOL and ISI, and SE and ISI respectively).

The overall effects for insomnia treatments seem to be in line with psychological treatments for other disorders such as depression ($d = 0.78$ [134]), social phobia ($d = 0.70$ [135]), panic disorder with ($d = 0.78$) or without agoraphobia ($d = 1.04$ [136]). However, the magnitude of the effects varied between the different outcome parameters. Quite large effect sizes were obtained for scores on the questionnaires of insomnia severity and sleep quality (PSQI) even though there was considerable heterogeneity. The ISI and PSQI do not rate the nocturnal symptoms of insomnia alone but also their day-time consequences. However, it would be premature to conclude from this that insomnia treatments are effective in improving daytime functioning. We need studies examining

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day-time functioning in more detail (e.g., examining fatigue, work productivity, social activities) before we can make such a statement.

Several indices derived from the daily sleep diary (SE, WASO and SOL) also yielded high effect sizes, indicating that treatment was very effective for improving sleep continuity. As previously reported in other studies, the actual number of hours of sleep (TST) improved only modestly. Post-hoc analysis did not seem to indicate that TST was related to type of treatment indicating that TST was not (artificially) reduced because of sleep restriction. Thus, the findings indicate that treatment is mostly effective for improving sleep continuity/efficiency and sleep quality, with some evidence of improved daytime functioning as well. It must be noted, however, that not all outcomes were reported in all studies. This hampers the interpretation of the differences in effect sizes on the various measures. Our knowledge about insomnia and its treatments would be greatly enhanced if future randomized clinical trials used the same outcome measures to estimate treatment effects [137].

Overall, CBTI treatments for insomnia are effective but the next question is: can we explain the differences in effects between studies (the heterogeneity)? First we examined this by comparing the studies that used full CBTI to those who did not include all CBTI components. There were no statistically significant differences between the effects of those studies. Second we compared full CBTI to different (combinations of) components. Univariate analyses showed that relaxation works well for SOL and that “other” treatments work the best on all sleep outcomes. The high effects for “other” treatments compared with full CBTI are counterintuitive. One explanation might be that these studies tend to be older and these older studies tend to have poorer quality (no report on randomization sequence or randomization concealment). The effect sizes for the full CBTI package seem to be similar to those for behavioral techniques only. This brings into question the additional effect of the cognitive modules. One recent study was aimed at this question and compared behavioral treatment (BT) with cognitive treatment (CT) and full CBTI [138]. Even though this study did not demonstrate significant differences among the three treatments on the post-test continuous ISI scores, there were some indications that BT worked faster than CT but that the effects of CT lasted longer than those of BT. Therefore, to make use of both effects, the authors recommended full CBTI. Our current meta-analysis, which did not include long-term follow-ups, can neither endorse nor reject this recommendation.

Another reason for the failure to detect clear and consistent differences in effects between the different treatments is that there is considerable variety in the treatments within one category (e.g., full CBTI). This has been described previously with respect to sleep restriction treatment [139]: there was a great variability in the way the average number of hours asleep was calculated, the minimum number of hours in bed, how bed and rise times were positioned, what was the sleep efficiency criterion for extending the sleep window, for how many days this criterion should be reached before actually extending etc. In all likelihood, these variations also exist for the other CBTI elements. Our data support this idea since we demonstrated quite large 95% confidence intervals for heterogeneity within the different treatment subgroups. Ultimately we need to standardize our treatment components and examine differences in effect by direct comparisons. We recommend that more dismantling studies be performed.

The treatment format was significantly related to all studied sleep outcomes. More specifically: self-help interventions seem to perform worse than face-to-face interventions, especially on SE and ISI. This is in contrast to studies on other mental disorders which often yield a similar or quite similar effect size for self-help interventions compared with face-to-face interventions [140,141]. Moreover, some of the recent studies on self-help interventions demonstrated very high effect sizes, even those without any human support [64,98]. Since insomnia is so prevalent and self-help interventions are much easier to offer than face-to-face treatments against lower costs because of reduced therapeutic input, we conclude that self-help interventions are worthwhile as a first step of treatment. But sufficient face-to-face options need to be available for those who do not recover. Furthermore, we urgently need studies comparing the two treatment formats directly since two recent studies showed mixed results with one not finding differences in effect [142] and the other finding face-to-face treatment superior to online treatment [87].

It remains unclear to what extent the number of treatment sessions is important to obtain optimal effects. There are some indications from the univariate analysis that one to four session treatments yield lower effect sizes than treatments which are composed of more than four sessions. However, these results are not very robust and do not apply to the ISI. It was not possible to test the effect of the number of sessions in a multivariate analysis since the self-help interventions all had zero sessions and this caused collinearity. The only study that directly compared the treatment duration (one, two, four and eight sessions; [61]) concluded that a duration of four sessions was optimal. Since Edinger and colleagues [61] concluded that four sessions were optimal, and we have indications that five or more sessions are more effective, we conclude that one to three session treatments seem to be less effective than longer treatments. However, more studies directly comparing treatment length (and costs) are needed to establish optimal treatment length.

Interestingly, there seems to be an association between publication year and treatment effect. For SE the newest studies (after 2010) showed significantly higher effect sizes than those published between 1990 and 2010. There were no studies measuring SE before 1990. For SOL, there seemed to be a U-shaped association: the oldest studies showed the highest effects. Effect sizes then decreased over time but the newest studies yielded higher effects again. The association disappeared in the multivariate analysis but this might be because in this analysis we used the actual publication year instead of categories. Furthermore, we tested for a linear relationship and not for a U-curved relationship. A possible explanation for the U-curve in SOL is the variation in study design over time. The older studies (performed in the 1970s) more often used homogeneous samples (young, without comorbidity, without sleep medications). They were also smaller (fewer patients) and less methodologically rigorous and therefore more susceptible to different types of bias. These methodological shortcomings might have led to higher effects. This is also in line with some of the other results of the multivariate analysis: in studies of poorer methodological quality the interventions seemed to perform better. Studies that did not report age or did not report the way they concealed treatment allocation showed better results than those who did. However, it might still be possible that the treatments offered in the 1970s were truly more effective than those offered later on. The majority of these studies focused on either relaxation or paradoxical intention. Maybe these treatments are indeed effective but have been pushed aside by the current fashion of CBTI? After all, this also occurred in depression treatment where it has become state-of-the-art to offer CBTI even though there is no conclusive proof that CBTI actually works better than other treatments [134]. More research is needed in which older insomnia treatments are directly compared with newer ones.

The treatment effects were not significantly related to the presence of comorbidity, the allowance to use sleep medication, or to age. This is in line with previous reviews of insomnia treatments which argued that CBTI is effective for younger and older adults, for

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patients with and without comorbidities, for medication-free patients as well as for chronic hypnotic users [32].

An important limitation of this meta-analysis is that we only could include studies of which the results were published. There were indeed indications of publication bias. This suggests that the actual effects of CBTI on insomnia might be smaller although still significant. Another limitation is that not all of the studies used the same outcome measure. Differences in effects between outcomes might therefore reflect differences between studies rather than real differences in effect. Finally, many quality criteria were not met by the studies which might mean that we overestimate the true effectiveness.

Despite the limitations we conclude that CBTI, either its components or the full package, is effective in the treatment of insomnia. Face-to-face treatments and treatments of at least four sessions seem to be more effective than self-help interventions or face-to-face interventions with fewer sessions. Otherwise the results seem to be quite robust (similar for patients with or without comorbid disease, younger or older patients, using or not using sleep medication). We need more high quality research, comparing different treatment components directly with one another, to understand whether or not full CBTI is more effective than its separate components and whether or not there are other (older) treatments that are actually as effective as CBTI.

**Practice points**

- Cognitive behavioral treatment for insomnia is effective with large overall effects on insomnia severity, sleep efficiency, wake after sleep onset, and sleep onset latency. The magnitude of these effects is in line with psychological treatments for other disorders.
- The smallest effects of cognitive behavioral treatment for insomnia are found for total sleep time.
- Face-to-face treatments and treatments of at least four sessions seem to be more effective than self-help interventions or face-to-face interventions with fewer sessions.

**Research agenda**

Future studies on cognitive behavioral treatment for insomnia should focus on:

- Determining which treatment components are essential for delivering cognitive behavioral treatment for insomnia
- Comparing face-to-face treatments for insomnia with their online counterpart
- Evaluating the optimal treatment length for cognitive behavioral treatment for insomnia
- Directly comparing earlier insomnia interventions (e.g., relaxation) to newer ones (e.g., CBTI)

## Conflicts of interest

Prof. Van Straten, Ms van der Zweerde, dr. Kleiboer, prof. Cuijpers and dr. Lancee, declare that they have no competing interests. Prof. Morin has served as a consultant for Merck, Valeant, and Novartis and received research support from Novartis. We did not receive any financial support to write this meta-analysis.

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* The most important references are denoted by an asterisk.

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