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Cognitive behavioural treatment for insomnia in primary care:

a systematic review of sleep outcomes

Abstract

Background
Practice guidelines recommend that chronic insomnia be treated first with cognitive behavioural therapy for insomnia (CBT-I), and that hypnotic medication be considered only when CBT-I is unsuccessful. Although there is evidence of CBT-I's efficacy in research studies, systematic reviews of its effects in primary care are lacking.

Aim
To review the effects on sleep outcomes of CBT-I delivered in primary care.

Design and setting
Systematic review of articles published worldwide.

Method
Medline, PsycINFO, EMBASE, and CINAHL were searched for articles published from January 1987 until August 2018 that reported sleep results and on the use of CBT-I in general primary care settings. Two researchers independently assessed and then reached agreement on the included studies and the extracted data. Cohen's *d* was used to measure effects on sleep diary outcomes and the Insomnia Severity Index.

Results
In total, 13 studies were included. Medium-to-large positive effects on self-reported sleep were found for CBT-I provided over 4–6 sessions. Improvements were generally well maintained for 3–12 months post-treatment. Studies of interventions in which the format or content veered substantially from conventional CBT-I were less conclusive. In only three studies was CBT-I delivered by a GP; usually, it was provided by nurses, psychologists, nurse practitioners, social workers, or counsellors. Six studies included advice on withdrawal from hypnotics.

Conclusion
The findings support the effectiveness of multicomponent CBT-I in general primary care. Future studies should use standard sleep measures, examine daytime symptoms, and investigate the impact of hypnotic tapering interventions delivered in conjunction with CBT-I.

Keywords
chronic insomnia; cognitive behavioural therapy; family practice; primary health care; sleep disorders; sleep initiation and maintenance disorders.

INTRODUCTION

Insomnia is the most prevalent sleep disorder, affecting 10–15% of the adult population[1] and 19–44% of primary care patients worldwide.[2–4] Chronic insomnia disorder is defined as early-morning awakening or difficulty initiating or maintaining sleep that occurs at least 3 nights a week for at least 3 months and impairs functioning.[5] It is associated with numerous health problems[6,7] and a number of psychiatric illnesses, most notably depression.[8] As well as the demand this creates on health care, insomnia also burdens the economy through work absences and is associated with absenteeism and reduced productivity.[9,10]

For patients seeking professional help for insomnia, GPs are, by far, the health professionals most likely to be consulted.[11] Practice guidelines recommend cognitive behavioural therapy for insomnia (CBT-I) as the first-line treatment, with hypnotic medication to be considered only if CBT-I does not work.[12,13] Compared with pharmacotherapy, CBT-I has been shown to be superior in reducing symptoms of insomnia[14] and in maintaining sleep improvements for years.[15,16] Furthermore, non-pharmacological approaches are often preferred by patients, as they are considered to be better at improving daytime functioning and less likely to produce adverse side effects.[17] The components of CBT-I are typically:

- stimulus control — pairing the bed with sleep, leaving the bed when awake;
- sleep restriction — reducing time in bed to increase sleep pressure;
- cognitive therapy — challenging alerting thoughts about sleep loss; and
- relaxation training.

Although these components can be delivered individually, the therapy is most effective when all components are delivered together as full CBT-I.[18]

Despite abundant evidence for the efficacy of CBT-I, the approach is under-utilised.[19] GPs are often aware of the need to reduce hypnotic prescribing but have limited knowledge about, and access to, CBT-I.[20] In order to refer patients for CBT-I or provide it in their practice, GPs first need to know whether, and how well, it works in primary care specifically. Although much literature exists about the efficacy of CBT-I, systematic reviews focused on the effectiveness of its use in primary care are lacking. As such, this study was undertaken to review the effects of CBT-I on sleep outcomes in general primary care settings and provide a pragmatic overview of the results for general practice.

METHOD

Database searches

A systematic review was conducted with searches of the Medline (Ovid), PsycINFO (Ovid), EMBASE, and CINAHL databases.

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How this fits in

The primary care physician is the health professional most likely to be consulted by a patient with insomnia. Although cognitive behavioural therapy for insomnia (CBT-I) is the recommended first-line treatment, reviews of its effectiveness in the primary care setting are lacking. This review provides evidence that multicomponent CBT-I (group or individual) is effective at improving sleep outcomes for primary care patients with chronic insomnia.

Box 1. Search terms

Search terms used for all four databases. Words in each section combined with 'or'; each section combined with 'and' in order to search each combination of terms.

insomnia*
Sleep initiation
sleep maintenance
sleep disorder

psychotherap*
cognitive behavio* therap*
behavio* therapy
CBT
CBT-I
CBTI
cognitive therapy
sleep hygiene
stimulus control
sleep restriction
relaxation
imagery

primary care
general practice
family practice
family medicine

Search strategies combining indexing keywords relevant to CBT-I in primary care (Box 1) were used with each database. The initial search included articles published from January 1987 until 16 November 2017. Studies published in English or French were included. The results of the searches were combined and duplicates removed. Articles were reviewed by two authors to identify studies possibly suitable for inclusion based on their title and abstract. These articles were then reviewed in depth by the same authors to determine their relevance. The database searches and procedures used to identify relevant articles were repeated on 8 August 2018 using the exact terms as before, but with a date range of January 2017 to August 2018, to identify any new relevant articles.

To be included in the review, studies had to:

- report results of original research (not reviews, protocols, recommendations, conference abstracts, or clinical advice papers) on the effects of CBT-I;
- be based in a general primary care population;
- have at least 10 adult (≥18 years) patients; and
- have quantitative measures of sleep outcomes.

Participants could have medical or psychological comorbidity and could use hypnotic medication, and online or telephone therapy was included if the participants had been recruited in primary care. Randomised controlled trials (RCTs) and pre-post clinical case series were included; the latter's design — an important step between RCTs and direct clinical application of CBT-I — provides data on within-subject changes experienced by patients in their primary care setting.

Studies had to report Insomnia Severity Index (ISI) scores or at least one of the following outcomes derived from sleep diaries:

- sleep onset latency (SOL);
- wake after sleep onset (WASO);
- total sleep time (TST); or
- sleep efficiency (SE).

The ISI is a brief self-report measure of the severity of insomnia symptoms and their impact on functioning; it has been validated in primary care.[21] Higher scores reflect greater insomnia severity. As insomnia is defined by a complaint of sleep difficulty, sleep diaries[22] and the ISI are standard tools to assess insomnia and monitor response to treatment.

For the results to be maximally applicable to physicians in general practice settings, the focus was on general primary care; studies conducted in special settings (for example, universities, active military or veterans' treatment centres, community pharmacies) were excluded.

Study quality and risk of bias

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations on the reporting of systematic reviews[23] were followed. For each of the 13 studies, all three authors independently assessed the extent of sleep disorder screening and the risk of bias for common validity indicators.[23] The three then met and reached consensus on the values in bias tables (information available from the authors on request).

Data extraction

Information about participants, interventions, and results of the included studies were extracted for the evidence tables. Two researchers independently extracted data from the studies; when there was discrepancy they met to reach agreement on the final entries.

If not provided in the article, effect sizes were calculated based on reported sleep data, then checked by two researchers. Cohen's *d* was used as the standard measure of effect size and, in line with Cohen's suggestion, interpreted as small (0.20), medium (0.50), or large (0.80).[24] Although study designs varied and authors used various formulas for *d*, this review reported classical Cohen's *d* for all between-group studies in order to make effect sizes comparable, as outlined by Morris and DeShon.[25]

The formula was:

$$d = (M_1 - M_2)/SD_{pooled}$$

In the formula, M_1 and M_2 are the post-treatment means of the two groups, $SD_{pooled} = \sqrt{[(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2]/(n_1 + n_2)}$ and n and s are the sample size and standard deviation (SD) of each group. This gives an estimate of the effect of CBT-I relative to a control or comparator condition.

For clinical case series, within-subject effect sizes were reported; the following formula was used:

$$d_z = M_z/SD_z$$

In this formula, z = difference score, and M_z and SD_z are the mean and SD of the difference scores. Within-subject *d*s are useful here because they estimate the pre-post effect that would be expected for patients in regular practice.

For the description of studies, conventional CBT-I was defined as multicomponent treatment consisting of sleep restriction, stimulus control therapy, cognitive therapy, and relaxation delivered in 4–8 sessions. Low-impact control was defined as a control condition that was assumed to be relatively inactive compared with CBT-I and included wait list, self-monitoring, and/or sleep hygiene.[26] If prescription or withdrawal of hypnotic medication was combined with the CBT-I treatment, this information was noted as part of the intervention.

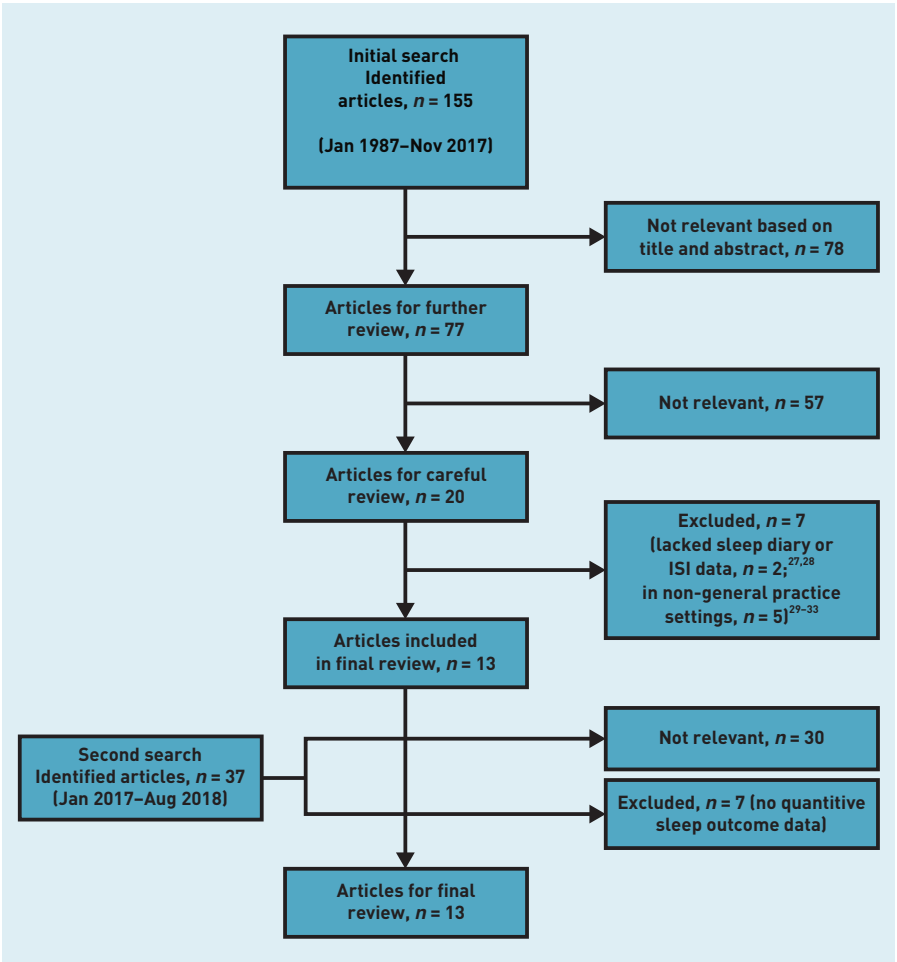

Figure 1. Flow diagram of article selection process. ISI = Insomnia Severity Index.

RESULTS

Figure 1 shows the steps in the evaluation and selection of studies. In total, 13 studies were included in the final review.[34–46]

Study quality and bias

Ten studies used a RCT design. There was one cluster randomised trial in which 31 physicians were randomly assigned to provide one of two treatments.[40] Two studies were case series.[45,46] The examination of sources of bias across studies raised questions about the impact on reported outcomes of the following factors: level of screening for sleep disorders; type of health professional; the provider's amount of CBT-I training; treatment fidelity; lack of blinding of patients, health providers, and analysts; and high rates of loss to follow-up in some studies (information available from the authors on request).

RCTs with mixed-age samples

Seven studies used an RCT design with mixed-age adult samples in primary care (Table 1). The samples were largely composed of females; the mean age was in the low–mid-50s. Four studies[34–37] used conventional CBT-I in group format provided by nurses or social workers; the other three[38–40] provided variations of CBT-I (Table 1).

CBT-I group studies. For the four CBT-I group studies,[34–37] the effect sizes for SOL were medium to large and those for WASO were small to medium. CBT-I was associated with a mean reduction of 9–30 minutes for SOL, and a mean reduction of 22–36 minutes for WASO; for controls, the mean reductions were 1–4 minutes and 6–8 minutes for SOL and WASO respectively. Effect sizes for TST were absent or small, while medium effects were found for SE, where reported.[36,37] Large effects were found for the ISI in the two studies that reported it;[34,37] CBT-I was associated with a mean ISI reduction of 6–8 points versus the 0–1 points for controls.

Table 1. Randomised controlled trials of CBT-I in general primary care with mixed-age adult samples

Study	Sample size, *n*	Sex, % female	Mean age, years	Country/ region	Intervention	Sessions, *n*	Session duration	Control condition	Intervention delivered by	Effect sizes, Cohen's *d*			
										SOL	WASO	TST	SE	ISI
Bothelius *et al* (2013)[34]	66	86.4	50.7	Sweden	CBT-I group, HT	5	60–90 mins	Wait list	Nurses, social workers	0.57	0.55	–	–	0.90
Espie *et al* (2001)[35]	139	68.3	51.4	UK	CBT-I group, HT	6	50 mins	Monitoring	Nurses	0.97	0.48	0.32	–	–
Espie *et al* (2007)[36]	201	68.2	54.3	UK	CBT-I group	5	60 mins	Treatment as usual	Nurses	0.58	0.35	0.13	0.68	–
Sandlund *et al* (2017)[37]	165	72.7	54.5	Sweden	CBT-I group, HT	7 (6 + 1-month follow-up)	120 mins	Treatment as usual	Nurses	0.51	0.39	0.40	0.62	1.23
Falloon *et al* (2015)[38]	94	77.3	53.5	New Zealand	Sleep restriction (brief), individual	2	Not specified, GP appointment	Sleep hygiene guidelines	GP	0.13	0.36	0.01	0.21	0.55
Wong *et al* (2017)[39]	216	78.2	56.1	Hong Kong	MBCT-I + sleep restriction + sleep-specific cognitive therapy, group	8	150 mins	Psychoeducation[a] + stretching	MBCT instructors/ physiotherapists	0.02	0.50	0.14	0.14	0.36
Katofsky *et al* (2012)[40]	80	77.5	51.5	Germany	Self-help CBT-I manual + 4-week lormetazepam start and taper, individual	6	Not specified, GP appointment	Short term lormetazepam	GPs	0.41	0.18	0.10	–	–

[a]*Included stimulus control therapy and sleep hygiene. Dashes signify not reported. CBT-I = cognitive behavioural therapy for insomnia. HT = hypnotic medication tapering. ISI = Insomnia Severity Index. MBCT = mindfulness-based cognitive therapy. SE = sleep efficiency. SOL = sleep onset latency. TST = total sleep time. WASO = wake after sleep onset.*

CBT-I variants. Falloon *et al*[38] studied the effects of a sleep restriction protocol, carried out within two GP appointments, compared with sleep hygiene. Post-treatment measures were reported 6 months after the second appointment. There were small effects for SOL and SE, a negligible effect for TST, and a medium effect for the ISI.

Wong *et al*[39] compared mindfulness-based cognitive therapy for insomnia (MBCT-I) with eight sessions of sleep psychoeducation — which included sleep hygiene and stimulus control therapy — plus stretching and strengthening exercises. MBCT-I was associated with a negligible effect for SOL, a medium effect for WASO, and small effects for TST, SE, and the ISI.

Katofsky *et al*[40] compared self-help CBT-I provided in 6 weekly chapters (of the self-help manual referred to in Table 1), plus short-term (introduced and tapered within 4 weeks) lormetazepam with short-term lormetazepam alone. GPs, rather than patients, were randomised to provide one of the two treatments. Small effect sizes were found for SOL, WASO, and TST.

RCTs with older primary care patients

Table 2 summarises the four studies that included RCTs of CBT-I in older patients in primary care. Approximately two-thirds to three-quarters of the samples were female, and participants' mean age was late 60s–late 70s. In the study by Vitiello *et al*,[44] patients also had osteoarthritis. All four studies used education or sleep hygiene as the control, and variations (both in content and format) of conventional CBT-I: two studies provided four treatment sessions, two of which were face-to-face and two of which were conducted over the telephone;[41,42] one study used mailed-out booklets;[43] and one used group CBT-I combined with cognitive behavioural therapy (CBT) for pain management.[44]

The studies by Buysse *et al*[41] and McCrae *et al*[42] found large effects for SOL, WASO, TST, and SE. Together, these studies found reductions in SOL and WASO of 23–25 minutes and 24–37 minutes respectively, versus the control reductions of 0–1 minutes and 3–18 minutes. Based on the ISI data, Morgan *et al*[43] found a medium-to-large effect for self-help booklets, while Vitiello *et al*[44] found a small effect for CBT-I combined with CBT for pain.

Clinical case series

Two studies[45,46] reported sleep outcomes in clinical case series studies. In both, patients received advice on tapering hypnotic medication, if relevant. In Baillargeon *et al*'s

Table 2. Randomised controlled trials of CBT-I with older patients in primary care

Study	Sample size, *n*	Sex, % female	Mean age, years	Country/ region	Intervention	Sessions, *n*	Session duration	Control condition	Intervention delivered by	Effect sizes, Cohen's *d*			
										SOL	WASO	TST	SE	ISI
Buysse *et al* (2011)[41]	79	68.3	71.6	US	Sleep restriction, SCT, sleep education; individual	4	45–60 mins face to face; 20 mins telephone; 30 mins face to face; 20 mins telephone	Education (articles), 10-mins telephone call	Mental health nurse practitioner	3.38	3.91	1.83	3.43	–
McCrae *et al* (2007)[42]	20	65.0	77.2	US	Sleep restriction, SCT relaxation; individual	4	2 × 50-min face to face; 2 × 30-mins telephone	Sleep hygiene education	Mental health workers or social workers	0.82	1.06	0.99	1.14	–
Morgan *et al* (2012)[43a]	193	66.3	66.7	UK	Self-help CBT-I booklets, HT info	6 booklets	Weekly booklet	Sleep hygiene sheet	Booklet	–	–	–	[b]	0.74
Vitiello *et al* (2013)[44c] (two of three study arms)	245	77.6	73.1	US	CBT for pain and insomnia; group	6	90 mins	Education on pain + sleep management	Counsellor, psychologist	–	–	–	[b]	0.40

[a] Patients had long-term conditions. [b] Reported but not based on sleep diaries. [c] Patients had osteoarthritis. Dashes signify not reported. CBT-I = cognitive behavioural therapy for insomnia. HT = hypnotic medication tapering. ISI = Insomnia Severity Index. SCT = stimulus control therapy. SE = sleep efficiency. SOL = sleep onset latency. TST = total sleep time. WASO = wake after sleep onset.

study,[45] GPs provided stimulus control therapy to 15 patients and recorded a large reduction in mean SOL (44 minutes; large effect size). Of note, the treatment was provided until SOL reached ≤30 minutes, or for 10 sessions, thereby potentially inflating the effect. In the study by Davidson *et al*,[46] 81 consecutive primary care patients were studied before and after group CBT-I was provided by a psychologist and a nurse practitioner or graduate student. Effect sizes were large for SOL, WASO, SE, and the ISI, and small for TST. The mean reductions in SOL, WASO, and the ISI were 31 minutes, 37 minutes, and nine points, respectively.

Adjunctive hypnotic medication interventions

In six of the 13 studies, the treatment protocols included advice on step-by-step reduction of hypnotic medication,[34,35,37,45] provided general information on sleep medication in booklet format,[43] or offered an adjunct programme of hypnotic withdrawal.[46] In an additional study, hypnotic medication was both started and then tapered within 4 weeks.[40] The remaining six studies did not mention interventions aimed at hypnotic medication use.

Follow-up data

Two studies found effects were somewhat reduced at 6 months[36] and 18 months[34] post-treatment, although follow-up outcomes were still superior to baseline. Otherwise, follow-up data (where available), showed good maintenance of therapeutic gains at 3 months,[39,43,45] 6 months,[40,41,43,45] 9 months,[44] and 12 months.[35,37]

DISCUSSION

Summary

The sleep outcomes of 13 studies of CBT-I set in general primary care were examined. Those studies that provided either full CBT-I, or an intervention that included stimulus control and sleep restriction in at least four sessions, showed the greatest effects on SOL, WASO, and the ISI. This was true for mixed-age samples and for older patients. Variations on conventional CBT-I were not as successful, for example, limiting the intervention to two brief appointments for sleep restriction[38] led to smaller effect sizes; adding self-help CBT-I booklets to medication led to only modest improvements over medication alone.[40] Methodological issues within the studies — including the use of a CBT-I component in the control condition,[39] the absence of sleep diary data,[43,44] and delayed collection of post-treatment data[38] — rendered the

results of non-conventional CBT-I less conclusive.

Strengths and limitations

Although CBT-I is recommended as the first-line treatment of chronic insomnia, to the authors' knowledge, this was the first systematic review of its use in primary care (since the current paper went to press, another review has appeared[47]).

This review also used methods in accordance with PRISMA standards. Limitations should be noted, however. First, the study focused on subjective sleep outcomes and not daytime symptoms (fatigue, functioning, mood), which are also important insomnia treatment outcomes. Second, the requirement of sleep diary or ISI data led to the exclusion of two large pragmatic studies.[27,28] Both found positive effects of CBT-I on non-standard sleep estimates and, as such, their exclusion does not appear to alter the main findings of this review. Third, the application of these results to clinical practice rests on the assumption that patients are carefully screened for other sleep disorders before doing CBT-I (based on the quality and bias analyses). Fourth, publication bias in the form of negative, unpublished trials cannot be ruled out. Finally, this review was limited to studies in general practice settings — the results do not necessarily represent special populations, such as university students or the military.

Comparison with existing literature

The results presented here converge with recent meta-analytic reviews of CBT-I in adults in general,[48–50] older adults,[51] and in patients with medical or mental comorbidity.[52–54] For example, the effect sizes for SOL, WASO, SE, and the ISI for conventional CBT-I found in this study were similar to those found by Trauer *et al*,[50] Koffel *et al*,[49] and Geiger-Brown *et* al.[52] They are somewhat lower than the large effect sizes for CBT-I at behavioural sleep medicine clinics.[55–57] Consistent with other studies,[49,52,55] TST did not increase substantially. Also consistent with the literature,[15,16] sleep improvements were generally well maintained at follow-up.

Implications for research and practice

For the primary care provider, the results of this review provide evidence that CBT-I (group or individual) is effective at improving sleep onset and maintenance in primary care patients with chronic insomnia. SOL can be expected to decrease by 9–31 minutes and WASO by 22–37 minutes. Sleep improvements are sustained 3–12 months after treatment. The effectiveness of interventions that deviate markedly in terms of content or number of sessions from the 4–6 session conventional CBT-I format are, as yet, unproven in this setting.

The best methods of integrating CBT-I into primary care services need to be identified. In only three of the 13 studies reviewed was the GP directly involved in administering the CBT-I intervention;[38,40,45] in the remaining 10 studies, other health professionals provided CBT-I, including nurses, nurse practitioners, social workers, mental health workers, and psychologists. In some cases, CBT-I involved support for the discontinuation of hypnotic medication, a component especially relevant to primary care settings. In two studies, the tapering schedule was designed by pharmacists.[35,46] Overall CBT-I appears to be finding a place within primary health systems that support interdisciplinary teamwork.

This review revealed some variation in the intervention components, sleep disorders screening, and in the health discipline and CBT-I training of the providers — all of these are potential moderator variables that warrant further research. Future studies should use standard measures of sleep,[22] measure daytime symptoms,[58] and examine the impact of hypnotic tapering interventions delivered as part of CBT-I programmes for primary care patients.

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