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CLINICAL REVIEW

A systematic review of cognitive behavioral therapy for insomnia implemented in primary care and community settings

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SUMMARY

The advent of stepped-care and the need to disseminate cognitive behavioral therapy for insomnia (CBT-I) has led to novel interventions, which capitalize on non-specialist venues and/or health personnel. However, the translatability of these CBT-I programs into practice is unknown. This review evaluates the current state of CBT-I programs that are directly implemented in primary care and/or community settings. A literature search was conducted through major electronic databases (N = 840) and through snowballing (n = 8). After removing duplicates, 104 full-texts were extracted and evaluated against our initial inclusion criteria. Twelve studies including data from 1625 participants were subsequently evaluated for its study design and methodological quality. CBT-I program components varied across studies and included cognitive therapy (n = 6), relaxation (n = 7), sleep restriction therapy (n = 9), stimulus control therapy (n = 11) and sleep psychoeducation (n = 12). The respective interventions produced small to moderate post-treatment weighted effect sizes for the Insomnia Severity Index (0.40), Pittsburgh Sleep Quality Index (0.37), sleep efficiency (0.38), sleep onset latency (0.38), and wake time after sleep onset (0.46) but total sleep time (0.10) did not reach statistical significance. While non-specialist community settings can potentially address the demands for CBT-I across clinical contexts, intervention heterogeneity precluded the full impact of the 12 CBT-I programs to be evaluated.

Introduction

Insomnia is one of the most prevalent sleep complaints in the general community population [1]. Despite a mounting body of evidence advocating the use of cognitive behavioral therapy for insomnia (CBT-I) as first-line treatment [2,3], current practice do not necessarily reflect these recommendations [4]. In primary care, treatment options for insomnia are generally limited to the use of pharmacotherapy and/or general sleep hygiene education [5,6], making CBT-I dissemination a key research priority in sleep medicine.

Issues precluding access to CBT-I include logistic barriers such as limited service providers, high up-front patient costs, ineffective referral pathways and constraints within the practice environment (e.g., limited consultation time) [7,8]. The conceptualization of 'stepped-care' as applied to the insomnia care pathway has provided much pragmatic appeal for addressing many of the aforementioned barriers [9,10]. Stepped-care organizes CBT-I into different tiers of treatment intensity and allocates patients to different levels of care based on insomnia severity to increase patient reach while economizing on the limited specialist CBT-I resources. Within the stepped-care framework, the lower tiers of "abbreviated" CBT-I interventions capitalize on the readily accessible venues of basic healthcare where patients with insomnia might directly seek help without a referral (e.g., general practice [11], community pharmacy [12] or workshops held in the community to promote sleep health [13,14]). More recently, the application of CBT-I has cross-disseminated to various comorbid conditions such as cancer, cardiovascular disease [15], post-traumatic stress disorder [16] and schizophrenia [17]. Even within the community/primary care setting, there is an increased

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Abbreviations

AIS	Athens insomnia scale
CASP	critical appraisal skills program
CBT-I	cognitive behavioral therapy for insomnia
CENTRAL	cochrane central register of controlled trials
DSM	diagnostic and statistical manual of mental disorders
ES	effect size
GP	general practitioner
ISI	insomnia severity index
ICSD	international classifications of sleep disorders
NAWK	number of awakenings
PSQI	Pittsburgh sleep quality index
PWP	psychological wellbeing practitioners
PRISMA	preferred reporting items for systematic reviews and meta-analyses
PROSPERO	international prospective register of systematic reviews
RCT	randomized control trial
SCI	sleep condition indicator
SCT	stimulus control therapy
SD	standard deviation
SE	sleep efficiency
SOL	sleep onset latency
SRT	sleep restriction therapy
TAU	treatment as usual
TST	total sleep time
WASO	wake time after sleep onset

emphasis of targeting vulnerable patient groups that could benefit from low-tiered CBT-I treatments such as older patients with osteoarthritis [18] or individuals with mental health conditions [19].

Despite the advancements in the various modes of CBT-I delivery, the prescribing rates for sedative hypnotics and related medications continue to increase in primary care [20]. Furthermore, the extent to which these newer CBT-I interventions can be translated or its impact in the broader community remains unclear. In fact, similar concerns have been raised about community-based interventions in closely related domains of health such as smoking cessation and weight loss [21]. Recent synthesis of the CBT-I literature has shifted its focus away from the therapeutic aspects of CBT-I to other external factors that impact on outcome such as the role of adherence [22] and the impact of Internet delivery/human interaction in CBT-I [23]. With the renewed interest for integrating behavioral health interventions into primary care [24,25] and the broader community, perhaps the venue of intervention implementation is another important factor to consider in tandem with the therapeutic components of CBT-I, particularly within the lower tiers of the stepped-care framework.

Indeed, many community-based CBT-I studies developed within a stepped-care framework strive for a sampling frame that is representative of patients who present with insomnia in the general community. This is achieved through soliciting participants via radio, community networks or primary care settings. However, the majority of such interventions are still developed and implemented in highly controlled (academic) research environments away from the constraints of 'real-world' practice settings, which may in part explain the current research-practice gap in the uptake of CBT-I [26]. Furthermore, the current shift towards adopting pragmatic clinical trial designs [27] and a focus on 'real-world' transferability also affords a timely opportunity to reappraise the evidence of community-based CBT-I programs and future implications for program development and dissemination. Therefore, the aim of this systematic review is to synthesize the current state of the science for CBT-I programs directly implemented in primary care and/or community settings and to gauge sleep outcomes in the context of practice constraints.

Method

The current systematic review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [28] and is registered on the PROSPERO international prospective register of systematic reviews (CRD42017068206).

Search strategy

A literature search was conducted using major biomedical databases: MEDLINE, PsychINFO, PubMed, CINHAL, Scopus, and the Cochrane Central Register of Controlled Trials (CENTRAL). The following MesH terms and related sub-headings were combined iteratively to generate our search strategy: '**insomnia**' as a major focus, '**cognitive behavioral therapy for insomnia**', 'relaxation therapy', 'stimulus control therapy', 'sleep restriction therapy', 'cognitive therapy', 'biofeedback' 'sleep hygiene', 'sleep education', '**primary care',** 'general practitioner', 'family physician', 'pharmacist', 'community pharmacy services', 'community health', 'nurse clinics', 'self-care'. Articles were limited to those in the English language and study populations of human adults, but no date limits were applied in order to obtain comprehensive search results. In addition, a backward (snowballing) search was conducted using the reference list of the identified articles and earlier reviews until no additional relevant articles were found. Reviews, case reports and editorials/commentaries were excluded from the review. Potentially relevant but unpublished studies/ongoing trials were identified through screening abstracts from recent scientific sleep meetings (i.e., annual scientific meeting of Associated Professional Sleep Societies 2017 and World Sleep Congress 2017) and Clinicaltrials.gov. Additional information about the status of the trials was obtained through contacting the primary investigators.

Inclusion criteria

Publications meeting the following criteria were included in the final review:

1) Study sample of adults with insomnia.
2) Interventions comprised of cognitive and/or behavioral treatment strategies aimed at treating insomnia containing any combination of stimulus control therapy(SCT), sleep restriction therapy (SRT), cognitive therapy (CT), relaxation therapy (RL) and/or psychoeducation.
3) Venue of intervention implementation must be in a primary care/community setting. This setting encompasses basic healthcare venues where patients might seek help directly for their insomnia, and that is readily accessible as a first point of care without a referral (e.g., primary care clinics, pharmacy, community health centers) and public spaces (e.g., local libraries, workplace settings). For this reason, studies in which treatment was provided within academic settings and specialist care facilities (e.g., oncology clinics) were excluded from this review.

4) Interventions targeted at potentially vulnerable patient populations (e.g., insomnia in the context of chronic pain) were not excluded provided that the study focused on insomnia management.
5) Treatment implementation is also operationalized as involving a care provider guiding patients' treatment plan to enable continuity of care and discourage self-treatment. Therefore, self-help interventions with minimal provider contact (e.g., internet-delivered treatment where the patients' home is the main care setting) were excluded from the current review. Notably, studies were not excluded on the basis of the type of intervention provider.
6) Study design included randomized controlled trial (RCT) or pragmatic clinical trial with pre-and post-treatment data for both intervention and control groups.
7) One or more sleep outcome(s) including: self-reported metrics of insomnia severity (e.g., ISI) or sleep quality (e.g., PSQI). Sleep diary measures including sleep onset latency (SOL), wake after sleep onset (WASO), sleep efficiency (SE) and total sleep time (TST).
8) Written in the English language.
9) Published in a peer–reviewed journal.

Article selection process

The title and abstract of the articles generated from the search strategy were first screened by JMYC. In line with the notion of stepped-care, articles deemed relevant at this stage were those that explicitly investigated a CBT-I intervention that had been adapted to a specific clinical setting (e.g., general practice, pharmacy, online CBT-I, etc.) or CBT-I adapted for another clinical disease state (e.g., chronic pain). After removing duplicate articles, the full text of these references were subsequently retrieved. The focus on venue implementation for this review also necessitated the retrieval of more full texts than would otherwise be expected. Full texts were independently screened by two authors (JMYC and AB) paying close attention to *patient recruitment* and the *site of intervention implementation* outlined in the methods section of the respective articles. Any discrepancies were discussed with the second author (DCJ) until a consensus was reached. Where necessary, corresponding authors were contacted via email to clarify the setting of intervention implementation for the respective studies included.

Study quality and risk of bias assessment

A quality assessment was conducted for the final 12 articles included for review using the Critical Appraisal Skills Program (CASP) checklist for RCTs [29]. For consistency, two authors (JMYC and OB) independently conducted the quality assessment for the 12 articles against the CASP checklist. While developers of the CASP checklist do not suggest a scoring system, an arbitrary scoring system was used for this review to allow inter-rater reliability to be computed (i.e., yes = 2, no = 1, can't tell = 0). Items seven[1] and eight[2], although discussed in research meetings, were omitted from the calculation as they do not represent discrete ratable items. Any discrepancies were resolved through discussion with DCJ until a consensus was reached. Search strategies were updated to identify new publications since the initial inception of the review. Evidence of bias was assessed using the Cochrane Collaboration's Risk of Bias tool [30] and tabulated using Review Manager Software 5.3.

Data extraction

Studies that fulfilled the inclusion criteria were read in full to extract and record study details on a standardized extraction form to collect details relating to sample characteristics, CBT-I features, design, and clinical outcome measures. Sample characteristics considered patient demographics, and the inclusion/exclusion criteria of the patient population and existing comorbidities. Interventions were evaluated for several features: treatment program components, venue of delivery (e.g., community pharmacy) and mode of delivery (i.e., group vs. individual). The dose (i.e., number of hours of intervention, frequency of consultation visits) and duration of the respective treatment program was also evaluated along with the treatment provider and level of CBT-I training received. Study design and type of control group were also evaluated. Collection of sleep measures were evaluated based on the mode of collection and the intervals for collection at post-treatment and, where reported, follow-up intervals. The primary outcome variable of interest was self-reported metrics of sleep such as the ISI, PSQI or Sleep Condition Indicator (SCI). Secondary outcomes of interest were sleep diary measures (e.g., SOL, WASO, SE, TST).

Computing effect size scores

Key outcome variables of the studies included for review were then analyzed using effect size (ES) scores to compare the post-treatment effects between the intervention and control group.[3] ES uses standard deviation (SD) units to quantify the magnitude of change between two groups where change is defined as small (0.2), medium (0.5) and large (>0.8) [31]. Individual, Cohen's *d* was calculated using the formula $d = \overline{X}_E - \overline{X}_C / SD_{Pooled}$, where $\overline{X}_E$ is the mean of the experimental group and $\overline{X}_C$ is the mean of the control group. The pooled standard deviation was determined using the equation $SD_{Pooled} = \frac{\sqrt{(n_E-1)*SD_E^2 + (n_C-1)*SD_C^2}}{(n_E-1)+(n_C-1)}$ where n_E and SD_E is the number of participants and the standard deviation of the experimental group respectively. n_C and SD_C is the number of participants and the standard deviation in the control group. When only the standard error of the mean (SEM) was provided, SD was determined by the formula $SD = SEM^*\sqrt{N}$. To correct for bias in studies with very small samples sizes (i.e., <40), all ES were expressed in terms of Hedge's g using the following equation: $g \cong d\left(1 - \frac{3}{4N-9}\right)$ where N is the total sample size of the study at post-treatment. To ensure consistency in the interpretation of the different outcome measures, where necessary, mean differences between intervention and control were multiplied by −1 to ensure a positive direction of effect for measures, where lower scores are indicative of improved disease control (i.e., ISI, PSQI, SOL and WASO). The ES were weighted to account for individual sample sizes by using the inverse variance method [32]. The overall weighted ES (g+) for the respective measures were obtained by dividing the sum of the weighted g by the sum of the weights using the following equation: $g+ \; = \frac{\sum[w_i * g_i]}{\sum w_i}$. The weight is derived by taking the reciprocal of the variance. In addition, forest plots were generated to visually assess the standardized mean difference using Review Manager Software 5.3.

[1] How large was the treatment effect?
[2] How precise was the estimate of treatment effect?

[3] Studies which only compared active treatment groups for treatment were not included in the effect size calculations.

Results

Description of studies included for review

The initial literature search resulted in 840 articles (MEDLINE = 177, PsychINFO = 340, PubMed = 71 and SCOPUS = 235, CINAHL = 13, CENTRAL = 4) spanning between 1981 and 2017. Eight articles were retrieved from manual snowballing. After reading titles and abstracts of these studies, 160 were deemed relevant against our initial inclusion criteria. After removing duplicates (n = 56), 104 full texts articles were retrieved for in-depth review. Authors were contacted for seven studies where information about the site of intervention implementation was unclear in the published manuscript [33–38]. Clarification of implementation site was not available for one study [39]. Studies were excluded because the venue of implementation was not in primary care or studies were not RCTs (e.g., case reports). Fig. 1 outlines the flow chart of the literature selection process. A total of 12 articles were included in the final review (Table 1).

Quality assessment of studies

All 12 studies were assessed independently by two reviewers (JMYC and OB) using the CASP checklist (Table S1). Inter-rater reliability of the assessment of study quality occurred in three iterative rounds until agreement was reached. Initial assessments were found to be fair (Cohen's Kappa = 0.373). The second round of assessments and discussion resulted in moderate reliability scores (Cohen's Kappa = 0.550). A third and final round of discussion took place to resolve any further discrepancies resulting in an almost perfect agreement between reviewers (Cohen' Kappa = 0.979).

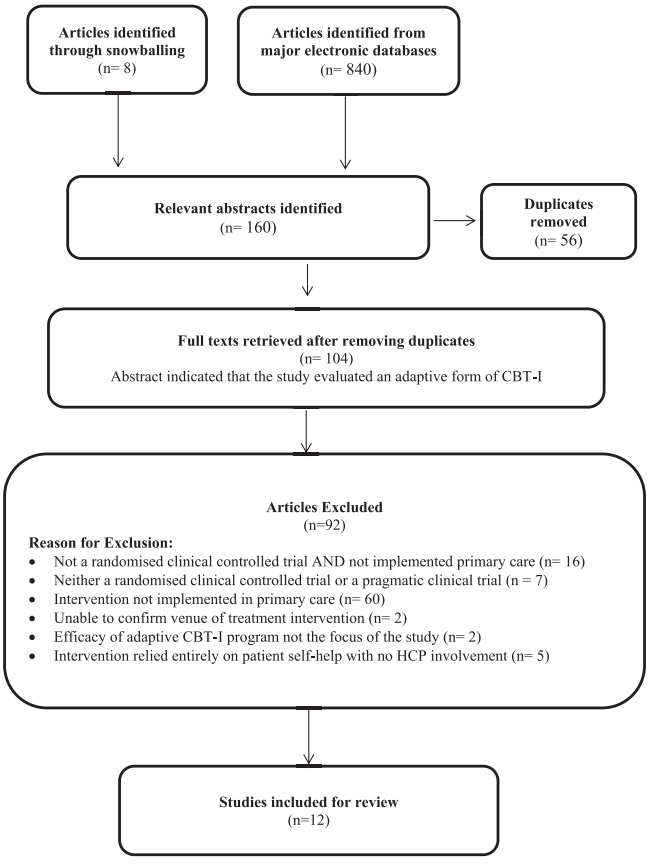

Fig. 1. Flow chart outlining the process of study selection for the studies included in the review.

Quality assessment scores are presented in (Table 1). For the 12 included studies, the mean total quality score was six (SD = 1.48; Score Range: 4 to 8) out of a possible nine assessment criteria. The original developers of the CASP checklist do not suggest a formal scoring system to define study quality. All studies met the criteria for having a clear research question, randomization process and patient accountability at the conclusion of trial. Based on CASP criteria, studies included in this review all met criteria for result validity. However, studies with higher CASP scores were more comprehensive in their coverage/reporting of clinical outcomes, group comparability at baseline and in treatment conditions.

Assessment of publication bias

From the risk of bias summary (Fig. 2), all 12 RCTs reported an adequate randomization method; nine studies (75%) reported a sufficient allocation concealment procedure. The main source of bias stemmed from the lack of participant/personnel blinding (n = 9, 75%) due to the pragmatic nature of these studies and the inherent challenges of providing controls for psychotherapy interventions. The greatest source of uncertainty came from detection bias (n = 6, 50%), as the assessor/assessor duties for these studies were not always clearly stated.

In terms of attrition bias, eight studies (67%) provided adequate statistical handling of missing data, while three studies were deemed to carry a high risk of attrition bias due to the absence of statistical handling for missing data [12,40,41]. Attrition bias risk was unclear for one study [42]. Reporting bias was low across the 12 studies, as studies either reported key outcomes (i.e., insomnia severity/sleep quality and/or SE) or decided on a set of *a priori* sleep measures. Other sources of bias were observed in three studies (35%). There was potential recruitment bias in two of the three cluster RCTs, which did not have counter measures to abate risk (e.g., double-blinding) [12,40] and potential sample contamination in one study where all participants worked in the same location [43].

Study design, randomization and controls

Of the 12 studies, four conducted standard RCTs [42–45] and three studies were cluster RCTs [12,18,40]. In the latter group, provider membership determined participants' treatment allocation. Four studies adopted a pragmatic clinical trial design [19,41,46,47]. A comparative study design of CBT-I delivery methods was investigated in one study [48]. All 12 studies used well-defined randomization procedures. Active controls included treatment as usual (TAU) in the context of pharmacy [12], primary care mental health [19] and general practice [46]. Three studies used an education control [18,42,45], one study used a self-monitoring control [41] and two studies did not have a '*control*', as active treatments were directly compared [48,40]. Only three studies employed wait-list controls in their study design [43,44,47]. Except for one study being conducted in Japan [43], the other studies were all conducted in western countries (Table 1). Interestingly, studies also commented on the concessions made to the study design to facilitate treatment delivery at the respective venues. The scope of these concessions included the use of retrospective sleep outcome estimates in place of sleep diaries.

Participant characteristics

Twelve studies published between 2001 and 2016 were included in this review. In total, there were 1625 participants (study range: 20 to 367 participants) with a mean age range of 37.5 to 77.2

Table 1
Sleep health outcomes.

Study	Year	Enrolled Participants[a]	Study Design	Sleep Medication Use Permitted	Diagnostic Criteria for Insomnia	Sleep Outcomes	Δ Sleep Outcomes at Post −Treatment	Δ Sleep Outcomes at Follow-Up	Country	Attrition[b]	CASP Quality Assessment[c]
Bothelius et al. [47]	2013	66 adults (mean age = 50.7) with chronic insomnia	Pragmatic clinical trial	Yes	Research diagnostic criteria for chronic insomnia	ISI, Sleep Diary (SOL, WASO, NWAK, SE, TIB, TST, SQ)	At 9 weeks: • ↓ISI (p = 0.001); • ↓ SOL (p = 0.027), ↓ WASO (p = 0.027) • no significant Δ for NWAK, SE, TST & SQ	At 18 month[d]: • ↑ISI (p = 0.001) • ↓ SOL (p = 0.027), ↑WASO (p = 0.006)	Sweden	34/66 = 51.5%	4/9 = 44.4%
Cape, et al. [19]	2016	239 adults (mean age = 42.2) with insomnia + comorbid mental health condition	Pragmatic parallel-group RCT	Yes	Symptoms[e]	SCI, (SE, SOL, WASO, TST) -calculated from retrospective estimation of prior 2 weeks	At 5 weeks[f]: • ↑SCI • ↑SE, ↑TST ↓SOL, ↓WASO,	At 20 wk: • ↑SCI, • ↑SOL ↓SE, ↓WASO, ↓TST	United Kingdom	62/239 = 25.9%	6/9 = 66.7%
Espie et al. [41]	2001	139 adults (mean age = 51.4) with chronic insomnia	RCT	Yes[g]	ICSD (insomnia symptoms ≥4 nights/week for ≥ 3 months) + PSQI ≥5	Sleep diary/ actigraphy[h] (SOL, WASO, TST, # wakenings)	At 6 weeks: • ↓SOL (p<0.001), ↓WASO (p<0.01), • little effect on TST (p=0.052)	At 12 mo: • ↓SOL (p < 0.001), • little effect on TST, ↑WASO (p = 0.160)	United Kingdom	30/139 = 21.6%	6/9 = 66.7%
Espie et al. [46]	2007	201 adults (mean age = 54.3) with chronic insomnia	Pragmatic clinical trial	Yes	ICSD-R and DSM-IV (≥3 nights/week for ≥ 6 months) + PSQI	PSQI, Sleep diary + actigraphy[i] (SOL, WASO, TIB, SE)	At 5 weeks: • ↓PSQI (P= 0.045), • ↓SOL (p=0.004), ↓WASO (p=0.10), ↑ SE (p=0.045), ↑TST (p > 0.05)	At 6 mo: • ↓PSQI (P:= 0.002), • ↓SE, ↑SOL, ↑WASO, ↑TST (P= 0.094); improvements not maintained	United Kingdom	58/201 = 28.9%	8/9 = 88.9%
Falloon et al. [45]	2015	97 adults (mean age = 53.6) with primary insomnia	Parallel design RCT	No	Self-reported insomnia symptoms[j]	ISI, PSQI, Sleep Diary + Actigraphy (SE, SOL, WASO, TST)	At 3 mo: ↓ PSQI (p <0.0001), ↓ ISI (p = 0.001) at 3 mo. Quantitative sleep measures not reported.	At 6 mo: • ↑PSQI (p<0.0001), ↓ ISI (p = 0.001) • ↑SE (p = 0.006); • ↓SOL,↑ WASO ↑TST but p > 0.05	New Zealand	3/97 = 3.0%	8/9 = 88.9%
Fuller et al. [12]	2016	46 adults (mean age = 53.7) with insomnia symptoms	Cluster-RCT	No	ISI ≥7	ISI, Sleep Diary (TST, SOL, WASO, SE)	At 3 mo: ↓ISI (p = 0.05) all sleep diary variables (p > 0.05)	Long-term follow-up data not collected	Australia	14/46 = 30.4%	4/9 = 44.5%
Holmqvist al. [48]	2014	73 adults with chronic insomnia; no information provided about age	RCT (non-inferiority trial)	Yes	Research diagnostic criteria for insomnia	ISI, Sleep Diary (TST, SOL, SE, NWAK, WASO)	At 6 weeks: ↓ISI, ↑ TST, ↓SOL, ↓NWAK, ↓WASO, (comparable results across the different delivery formats)	Treatment benefits maintained at 8 wks.	Canada	19/73 = 26.0%	8/9 = 88.9%
Katofsky et al. [40]	2012	96 adults (mean age = 51.5) with primary insomnia	RCT (factorial trial)	Yes	DSM-IV (primary insomnia)	PSQI, Sleep Diary (TST, SOL, WASO)	At 6 weeks: • ↓PSQI (p = 0.039)	At 6 mo[k]: • ↓PSQI (p = 0.026)	Germany	20/96 = 20.8%	6/9 = 66.7%

(*continued on next page*)

Table 1 (*continued*)

Study	Year	Enrolled Participants[a]	Study Design	Sleep Medication Use Permitted	Diagnostic Criteria for Insomnia	Sleep Outcomes	Δ Sleep Outcomes at Post −Treatment	Δ Sleep Outcomes at Follow-Up	Country	Attrition[b]	CASP Quality Assessment[c]
							• ↑TST, ↓SOL, ↓ WASO ($p < 0.001$)	• Improvements in TST, SOL & WASO maintained ($p<0.01$)			
McCrae et al. [42]	2007	20 elderly adults (mean age = 77.2) with chronic insomnia	RCT	Yes (inferred)[l]	Self-reported insomnia symptoms ≥ three nights/week for ≥ 6 months + daytime impairment	Sleep diary (SOL, NWAK WASO, TST)	At 8 weeks: • ↓SOL, ↑SE ($p < 0.01$).	Long-term follow-up data not collected	United States of America	1/20 = 5.0%	6/9 = 66.7%
Swift et al. [44]	2012	151 adults (mean age = 55.75) with self-reported sleep complaint	RCT	Yes	Self-reported insomnia (aimed to be as inclusive as possible)	ISI, Sleep diary (SE, SOL, WASO)	No assessments made at the end of CBT-I workshop	• ↓ ISI ($p = 0.000$) • ↑ SE ($p < 0.01$), ↓ WASO (<0.001) at 3 mo.	United Kingdom	25.8%[m]; 31.3% (sleep diary data)	6/9 = 66.7%
Vitiello et al. [18]	2013	367 elderly adults (mean age = 73.1) with clinically significant OA pain and insomnia	Double-blind controlled, cluster-RCT	Yes	Research diagnostic criteria for insomnia	ISI, Sleep diary + actigraphy (SE)	At 7 weeks[n]: For both intervention arms: • ↓ ISI ($p < 0.001$) • ↑ SE ($p < 0.05$)	Effects maintained at 9 mo.	United States of America	26/367 = 7.1%	8/9 = 100%
Yamamoto et al. [43]	2016	130 working adults (mean age = 37.7 years) with insomnia	RCT	Yes	AIS ≥ 6	ISI	No assessments made at the end of the session	At 3 mo: • No significant ↓ ISI ($p = 0.25$) • Objective sleep measures not collected during intervention	Japan	21/130 = 16.2%	5/9 = 55.6%

AIS = Athens Insomnia Scale.
ICSD = International classification of sleep disorders.
ISI = Insomnia Severity Index.
NWAK = Number of awakenings during the night. OA= Osteoarthritis
SE = Sleep efficiency.
SCI = Sleep Condition Indicator (higher scores indicative of better outcomes). SQ= Sleep quality
TASO = Time awake after sleep onset.

[a] Number of participants meeting inclusion criteria, enrolled into the study at baseline.
[b] Attrition is calculated as a proportion of participants (both intervention and control) at the final point of follow-up relative to the number of participants randomized at baseline.
[c] Only 9 out of 11 items on the CASP checklist has been included in the scoring.
[d] Only follow-up data for the intervention group was computed as the wait-list control group was offered treatment.
[e] Difficulty with sleep initiation and/or maintenance of at least 3 months duration.
[f] Measures collected at the end of a 5-week intervention and reported as a standardized mean difference.
[g] Inferred − sleep medication use included as a covariate in the analyses.
[h] Actigraphy was only used for five nights to gather actigraphy data.
[i] Actigraphy was used to objectively measure sleep 14 nights before and after treatment.
[j] Verified with sleep diary measures 2 weeks prior to commencement of trial.
[k] This study included a follow-up period at 6-week and 6-month, only 6-month follow-up is reported in this table.
[l] Only individuals stabilized on medications for 6 weeks.
[m] Attrition rate varied: 25.8% based on ISI and BDI data and 31.3% for sleep diary data.
[n] Assessments performed at two visits to participants' homes one week apart.

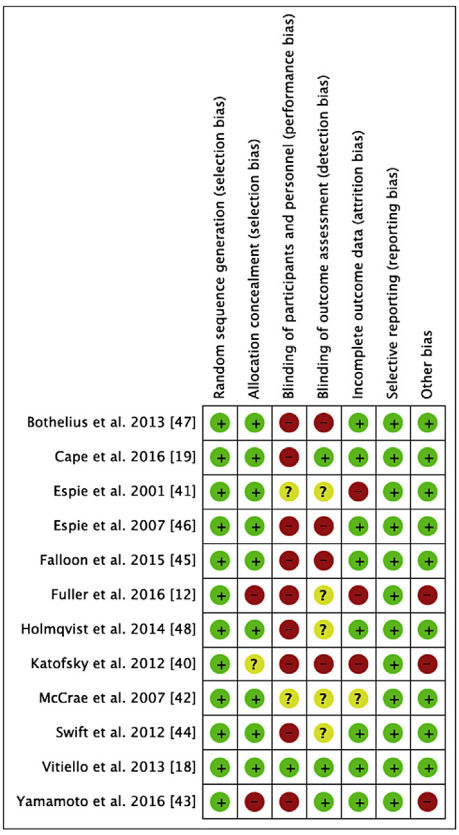

Fig. 2. Risk of bias assessment summary.

years. All studies reported a larger proportion of female[4] (n = 1073) to male (n = 526) participants. Five studies comprised of interventions delivered in conventional primary care settings such as general practice [40,41,45–47] and community pharmacy [12]. The remaining seven studies delineated potential vulnerable patient groups presenting to community/primary care and could potentially benefit from a lower-tiered CBT-I intervention such as older adults with osteoarthritis [18], individuals with mental health comorbidities [19], receiving care in rural health settings [42,48], psychological distress in the workplace [43] and sleep health promotion in the wider community [44].

Participant screening

Participants were typically self-referred or physician-referred into the study. Confirmation of insomnia status varied across studies ranging from relatively liberal self-reports of insomnia symptoms to more extensive nosological inclusion criteria. Two studies relied on self-reported measures such as the ISI (cut-off score ≥ seven) [12] and the Athens Insomnia Scale (AIS) (cut-off score ≥ six) [43] as part of the eligibility screening process. Studies also relied on participants' self-reported symptoms of insomnia (i.e., difficulty with the sleep initiation and/or maintenance for at least three months) [19,44] or the presence of insomnia symptoms ≥ three nights/week confirmed through sleep diary [45]. Three studies [18,47,48] used research diagnostic criteria for insomnia [49]. Nosological assessments required participants to meet Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria for primary insomnia [40], another study required patients to meet International Classification of Sleep Disorders 1st edition for (ICSD) insomnia in addition to obtaining a PSQI score ≥ five [41]. One study drew on diagnostic criteria of both ICSD-R[5] and the DSM-IV [46]. However, concomitant hypnotic medication use was not an exclusion criterion for participation except for two studies, which excluded for patients using prescription insomnia medication [12] or those not willing to cease medication during the trial [45].

CBT-I characteristics

Treatment components for the respective CBT-I programs varied based on the target patient population and the therapeutic goals of the intervention. Treatment programs typically included at least two components within the CBT-I treatment repertoire (Table 2). Across the 12 studies, only six provided a multicomponent CBT-I program consisting of at least one behavioral, one cognitive and an educational component [19,41,42,44,46,47]. Collectively, cognitive therapy was included in six studies [19,40,41,44,46,47]. Nine studies included SRT [12,18,19,40,43–45,47,50], 11 studies included SCT [12,18,19,40,41,43,44,46–48,50] and seven studies included a relaxation component [19,40,43,44,46–48]. All 12 studies included a psychoeducational component in the intervention covering sleep physiology/sleep hygiene. Additional treatment components such as maintenance and relapse prevention [47], goal setting/action planning [12,44], progressive medication tapering [48], and daily sleep monitoring [18] were also included.

Treatment venue and treatment provider

Interventions were implemented in a wide range of settings, which included general practice [40,41,45–47], community pharmacy [12] and rural health clinics [42,48]. Studies also illustrated the emergence of new care venues such as classroom spaces for health education purposes [18], the use of community spaces (i.e., town hall, libraries and leisure centers) [19,44] and the workplace [43].

The provider of CBT-I across studies came from diverse clinical disciplines such as pharmacists [12], occupational health physicians [43], general practitioners [40,45], primary care nurses [41,46], psychological wellbeing practitioners[6]/recent psychology graduates [19] and specialists in CBT-I/behavioral sleep medicine [44,48]. A subset of studies also involved multidisciplinary care teams consisting of primary care nurses and a social worker [47], (health) counselors and social workers [40] and a team of psychologists and counselors [18]. Treatment provision in conventional healthcare settings occurred in one of two ways: co-locating the provider at an existing health venue [18,41,42,46–48] or having the provider directly deliver the intervention as part of routine patient care [12,40,45].

Intervention format

The time frame for intervention implementation ranged from one day to three months. The number of sessions ranged from a single-day workshop to weekly sessions over eight weeks (Mean = 4.4 sessions). While day-long workshops required several

[4] Only the number of female/male participants completing the study was reported.

[5] International Classification of Sleep Disorders-Revised.

[6] Psychological Wellbeing Practitioners (PWP) is an accredited a role that evolved out of the Improving Access to Psychological Therapy in the UK. PWP's scope of practice involves assessing and supporting people with common mental health problems (i.e., anxiety disorders and depression). PWPs typically work alongside clinicians to facilitate the delivery of evidence-based psychological therapies, delivered face-to-face via telephone or online.

Table 2
Description of CBT-I interventions.

Study	Year	Venue	Referral	Provider of Intervention	CBT-I Training Provided	Treatment (Intervention) vs. control	Treatment Fidelity Measures	Format	No. of Sessions	Duration of Session	Time Frame of Program
***Bothelius et al.* [47]**	2013	General medical practice	Consecutive referrals	Primary care nurse + social worker	2 day training for using treatment manual	(SRT, SCT, RL,CT, PE) vs. WLC	N/A	Group	5	60–90 mins	9 weeks
***Cape, et al.* [19]**	2016	Town center/ library	GP referral + self-referral	Psychological Wellbeing Practitioners[a] + recent graduates	eight web-delivered 90-min teaching sessions or half-day teaching session	(SRT,SCT,RL,CT, PE) vs. TAU	N/A	Group	5	90 mins	9 weeks
***Espie et al.* [41]**	2001	General medical practice	Consecutive referrals from GP	Health visitors[b]	Sessional teaching of treatment components; practicum and consultancy from senior author	(SCT,CT,PE) vs. SMC	Adherence to treatment manual	Group	6	50 mins	6 weeks
***Espie et al.* [46]**	2007	General medical practice	Referred by GP	Health visitors	Participation in a short CBT course, practical learning opportunities, ongoing mentoring by clinical psychologist	(SCT, RL, CT, PE) vs. TAU	Strict adherence to treatment manual + audiotaped sessions for appraisal, participants/research personnel to not share treatment materials	Group	5	60 mins	5 weeks
***Falloon et al.* [45]**	2015	General medical practice	Referrals from 14 GP practices	GP	Reviewing literature and CBT-I evidence	(SRT, PE) vs. EC	Standardized delivery by one GP.	Individual	2	Extended GP consultation	3 months
***Fuller et al.* [12]**	2016	Community pharmacy	Patient presenting with insomnia/ requesting product	Community pharmacist	Self-study manual & face-to-face workshops	(SRT, SCT, PE) + goal setting vs. TAU	Staff visits to pharmacies during sessions and auditing paperwork	Individual	3	23.5 mins[d]	3 months
***Holmqvist al.* [48]**	2014	Rural health clinic	Physician referral to the clinic or responding to advertisement	CBT-I expert	N/A	(SCT,RL, PE) + medication tapering: web-based vs. telehealth vs. in-person CBT-I	Attendance to treatment sessions, practice of HW ≥ four nights/week	Group + Individual	6	1.5 hrs[e]	6 weeks
***Katofsky et al.* [40]**	2012	General medical practice	Presenting to GP with sleep problems	GP	Training workshop with case examples	(SRT, SCT,RL,CT, PE) vs. EC	Information on treatment fidelity not collected to limit GP workload	Individual	8	Common GP consultation	8 weeks
***McCrae et al.* [42]**	2007	Rural health clinic	Physician referral + self-referral	Mental health counsellor, social worker and provisionally licensed counselor	2-day training workshop	(SRT, SCT & PE) vs. EC	N/A	Individual + telephone	4	40 mins[f]	8 weeks
***Swift et al.* [44]**	2012	Leisure centre, Library	Self-referral	CBT-I Expert	N/A	(SRT, SCT,RL, CT, PE) vs. WLC	Couples, friends and acquaintances randomized in pairs	Group	1	7 hrs	1 day
***Vitiello et al.* [18]**	2013	Group health primary care clinics	Existing members of a health maintenance organization	Master's level counselor and PhD psychologist	6-week training program by expert clinical psychologist co-investigators [g]	(SRT, SCT & PE) + daily sleep monitoring vs. EC	**Fidelity Assessment**[g]: Supervision, reviewing audiotaped sessions, participant post session	Group	6	90 mins	6 weeks

Yamamoto et al. [43]	2016	Workplace	Email invitation to employees at an IT company	Occupational health physician	10 h training from sleep medicine expert	(SRT, SCT, RL, PE) vs. WLC	N/A	rating, participant checklists	Group + Individual	2	45 mins[h]	2 weeks

SCT= Stimulus control therapy.
RL = Relaxation therapy.
CT= Cognitive therapy.
SRT= Sleep restriction therapy.
PE= Psychoeducation: various components including educating patients about the physiology of sleep and sleep hygiene.
HW = Homework.
SMC = Sleep monitoring control.
TAU = Treatment as usual.
WLC = Wait-list control.
EC = Education control.
GP = General Practitioner.
[a] Individuals trained in the assessment of anxiety disorders and depression and in supporting people using self-help approaches such as CBT-informed self-help books.
[b] Community nurses with post-qualification training and certification, generally based in primary care teams.
[d] Mean duration across three separate sessions (33 min, 21 min and 17 min).
[e] 1.5 h for telehealth and not specified for the web-based group.
[f] Mean duration across four sessions (2 x in-person sessions (50 min) and 2 x telephone sessions (30 min)).
[g] Group Interventions for Co-Morbid Insomnia and Osteoarthritis Pain in Primary Care: The Lifestyles Cluster Randomized Trial Design.[51]
[h] Mean duration across two sessions (Session 1: 60 min and session 2: 30 min).

hours, multi-session interventions ranged from 17 to 90 min per session with initial sessions taking more time compared to follow-up sessions. Two studies described session duration to be within the confines of a general consultation with a family physician [40,45]. Interventions were either exclusively group-based [18,19,41,46,47], individual sessions [12,40,42,45] or a combination of group and individual sessions [43,44,48]. All 11 studies involved some face-to-face interactions as part of the treatment intervention with the exception of one study comparing the efficacy between telehealth and web-based CBT-I delivery [48]. The nature of the telehealth intervention involved real-time provider interaction with the patient group as opposed to being fully automated. However, the latter study did include an in-person comparison group in their secondary analyses.

Treatment fidelity

Treatment fidelity was ensured through various measures such as close adherence to a treatment manual, auditing paperwork, visiting research sites, supervising treatment delivery and reviewing audio-taped treatment sessions. For the e-health/telehealth intervention, treatment fidelity was assessed based on attendance of sessions and completion of homework modules [48]. Other strategies to maintain treatment fidelity involved randomizing participants who were in pairs (e.g., friends/couples) to avoid compromising the intervention arms [44] or restricting the sharing of content from different intervention arms among participants and between providers/research personnel and participants [18,46]. One study explicitly reported not assessing treatment fidelity to minimize GP workload [40].

CBT-I training

The level of training required to up-skill treatment providers and the detail provided also varied across studies. Training typically centered on a CBT-I treatment manual combined with other components such as didactic workshops, case studies, practical observation and supervised practice along with ongoing feedback [19,40–42,46,47]. A similar training protocol was adopted by Vitiello, McCurry [18], published in a separate paper [51]. Self-directed study either through treatment manuals or self-devised training programs (e.g., studying the literature) was another important part of the up-skilling process [12,45]. One study did not describe the exact training content but stated '10 h of CBT-I training from an expert' [43]. Two studies involved psychologists with pre-existing expertise in CBT-I [44] and behavioral sleep medicine [48], and therefore no additional training was required.

Treatment outcome assessment

SE (n = 11) and subjective sleep questionnaires [ISI (n = 7), PSQI (n = 3), SCI (n = 1)] were the main primary outcome measures reported across the 12 studies. Only one study reported psychological distress as their primary outcome [43]. Insomnia severity and/or sleep quality were not reported in two studies [41,50]. The sleep parameters SOL, TST and WASO were treated as secondary outcomes and mostly collected using sleep diaries (n = 10). Four studies used actigraphy data to verify sleep diary data [18,41,45,46]. However, data loss due to equipment failure was reported by one study [18]. One study used retrospective accounts of participant self-reported estimates of their sleep over the previous two-week period in place of a daily sleep diary [19]. Another study did not collect any formal quantitative sleep measures during the trial period and relied on retrospective self-report of sleep patterns for baseline assessment

Table 3
Post-treatment effects of CBT-I interventions.

	K[b]	N	Hedge's g	95% CI	P-value
Measures of Sleep Quality					
Insomnia Severity Index [a]	6	700	0.40	0.24, 0.55	<0.001
Pittsburgh Sleep Quality Index [a]	4	687	0.37	0.22, 0.52	<0.001
Sleep Diary Measures					
Sleep Onset Latency [a]	9	935	0.38	0.25, 0.51	<0.001
Wake time After Sleep Onset [a]	8	693	0.46	0.32, 0.60	<0.001
Total Sleep Time	9	1130	0.10	−0.02, 0.22	0.09
Sleep efficiency	8	1021	0.38	0.25, 0.51	<0.001

K = number of studies included in the analysis.
ES = Hedge's g. Conventions: small (0.2), medium (0.5) and large (0.8).
[a] Effect sizes were corrected for the direction of effect, since lower scores are indicative of improvements in sleep parameters such as the ISI, PSQI, SOL and WASO.
[b] Discrepancies in the number of studies (K) between Tables 1 and 3 is due to the exclusion of studies which did not use a control arm or the data for the specific measure was not explicitly reported in the study results or could not be obtained from the author.

[43]. Additional sleep measures were requested and retrieved from Vitiello, McCurry [18] and Bothelius, Kyhle [47].

Post-treatment assessments were carried at intervals of five weeks [19,46] six weeks [40,41,48], seven weeks [18], eight weeks [42], nine weeks [47] and three months [12,45]. Workshop interventions did not immediately evaluate post-treatment effects [43,44]. Pre-to-post treatment decreases on subjective questionnaire measures were observed (e.g., the ISI [12,18,43–45,47,48], PSQI [40,45,46], and (SCI)[7] [19]). From Table 3, ES calculated for ISI (0.40, 95% CI: 0.24,0.55) and PSQI (0.37, 95% CI: 0.22, 0.52) were small to moderate. For sleep diary measures, a small to moderate ES was reported for SE (0.38, 95% CI: 0.25, 0.51), SOL (0.38, 95% CI: 0.25, 0.51) and WASO (0.46, 95% CI: 0.32, 0.60), but TST did not reach statistical significance. Forest plots are provided for ISI and SE (Figs. 3 and 4).

Discussion

The primary aim of this review was to synthesize the current state of the science for CBT-I programs directly implemented in community settings. Twelve studies met the initial inclusion criteria and were further assessed using the CASP checklist for RCTs [29]. In evaluating CBT-I implementation in community settings, preliminary evidence demonstrates improved sleep outcomes from the respective interventions. However, the full impact of the respective treatment programs cannot be evaluated due to heterogeneity in program, provider, setting and the use and collection of outcomes/assessments. Recommendations for unifying these study design components and implications for translation into practice are further discussed.

The ES computed for the available studies were smaller in comparison to those typically reported in meta-analyses, which tend to be moderate to large [23,52]. However, given that studies in this review were selected on the basis of implementation under typical practice rather than experimental conditions, this smaller magnitude of treatment effect is not surprising. It is well-established that controlling for the confounders that are an inherent part of clinical practice (e.g., limited consultation times) tends to inflate the true benefit of treatment [53,54]. However, albeit the smaller magnitude in effect size, the greatest improvements were observed for sleep measures that were denoted as key primary endpoints by the respective studies (i.e., ISI, PSQI and SE). These findings provide preliminary evidence on the applicability of CBT-I programs implemented in community settings for improving sleep health outcomes. However, there are several caveats and limitations with respect to these findings, warranting further discussion about study design and CBT-I implementation in community settings within a stepped-care framework.

Inconsistencies in the reporting of the respective sleep outcome measures across the 12 studies was an important factor limiting the strength of our findings. Consequently, the magnitude of treatment effect cannot be fully assessed. Sleep questionnaire measures, when used, tended to have greater consistency. Of the sleep questionnaires, the ISI was preferentially used compared to other measures of insomnia/sleep quality. The popularity of this measure (i.e., 7 out of 12 studies), suggests that its brevity and clear cut-off scores has pragmatic appeal in diverse clinical settings and could be easily integrated at the practice interface [55]. In comparison, sleep diary measures for our primary (e.g., SE) and secondary (e.g., WASO, SOL) endpoints exhibited greater inconsistencies both in the collection and reporting procedures. Since 10 out of 12 studies utilized a sleep diary (with additional actigraphy included in four studies), this is a surprising finding. Indeed sleep diary formats may differ between study sites [56] but they are designed to collect a standard set of sleep parameters (i.e., SOL, WASO, TST, etc.). The inconsistencies may reflect pragmatic considerations to simplify study protocols but given the infancy of community-based CBT-I programs, a comprehensive dataset using standardized measures and reporting procedures needs to be prioritized. Perhaps capitalizing on technology through the use of web-based forms/smart-phone applications would be a more effective strategy for balancing between protocol rigor and practice constraints [27].

Patient heterogeneity reflects similar issues raised in the aforementioned sleep outcome measures. The insomnia status of the individual was verified differently across studies, ranging from self-reported symptoms alone, single measures alone (e.g., ISI or AIS), extensive clinical interviews against nosological criteria to a combination of these methods. This poses a problem when profiling the type of patient to which the findings might be generalizable to or the extent to which the patient populations under evaluation are comparable when aggregating results [54]. If the goal of community-based CBT-I programs is translation into practice, there is a need to better outline which candidates are better suited to the various community-based CBT-I programs available from a health policy and funding perspective. So far, the stepped-care framework provides a theoretical model of how patients might move between the different tiers of treatment based on need [9]. However, reiterating similar sentiments to Edinger [57] and Manber, Simpson [58], the appropriateness of an 'entry' CBT-I program have not been definitively mapped out against insomnia severity. Furthermore, the sustained interest in understanding the link between insomnia patient phenotypes and treatment response [59], provides a timely opportunity to devise a consistent assessment standard for defining and profiling the insomnia patient at the outset of evaluating lower-tiered CBT-I programs.

The CBT-I intervention also varied considerably across the 12 studies ranging from single-session workshops to comprehensive group treatment programs elapsing over several weeks. Treatment components also ranged from a single behavioral strategy to multicomponent programs. Importantly, some studies draw on published treatment manuals (e.g., Morin and Espie [60], Edinger and Carney [61] and Troxel, Germain [11]) as the basis for intervention development. However, the empirical premise for studies to include/exclude CBT-I components or modify established strategies remains unclear. In one study, a modified sleep restriction program was proposed with the initial sleep window set at 'the average total sleep duration plus 50% of the total time spent awake in bed (minimum of 5 h)' followed by sleep window titration intervals of 30 min [45]. Without adequate empirical testing, it is difficult to evaluate the extent to which a modified sleep restriction

[7] A brief (8-item, range 0–32), reliable (α = 0.83) patient-reported outcome measure for insomnia disorder based on DSM-5.

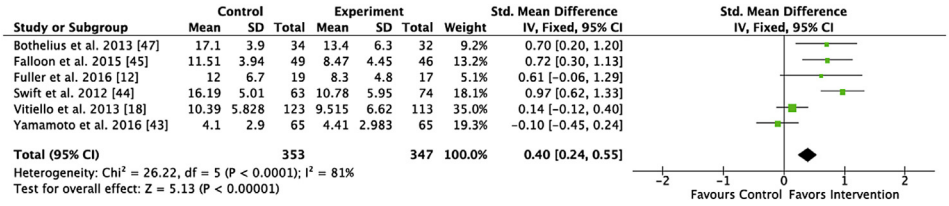

Fig. 3. Forest plot of post-treatment effect sizes for insomnia severity based on the ISI.

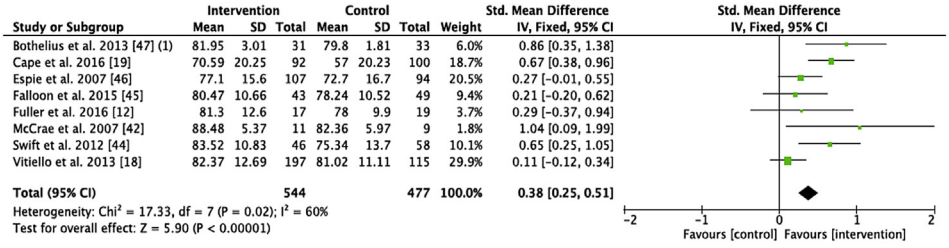

Fig. 4. Forest plot of post-treatment effect sizes for sleep efficiency.

protocol is comparable to conventional SRT [62] or sleep compression [63]. This problem is further complicated by the addition of auxiliary components (e.g., goal setting) in some of these treatment programs. It is also important to note that the studies selected for review are often 'proof-of-concepts' interventions, extrapolated from the broader CBT-I evidence base and evaluated within a piloting framework, highlighting the need to direct greater research efforts to establish a firm evidence-base within a stepped-care framework of CBT-I delivery.

Upon reflecting on the 12 studies included for review, an important question arises: to what extent can CBT-I be abbreviated and/or diluted? Akin to the study conducted by Edinger, Wohlgemuth [64], systematically investigating the dose–response of lower-tiered CBT-I programs represents an important research agenda. The relevance of dose-response is apparent in this review where it is difficult to conclusively compare a one-day workshop program to a multi-session program. Establishing minimum standards of effective treatment (i.e., CBT-I components and the number and duration of sessions) could provide greater guidance on the future development of CBT-I programs for dissemination into the broader community space. Indirectly, the notion of a minimum effective-dose will have important implications in the development of training structures for up-skilling diverse groups of non-sleep specialists. Across the 12 studies evaluated, the training descriptions ranged from detailed session-by-session outlines to general statements such as '10 h of CBT-I training from an expert' [43] or 'reviewing the literature' [45], posing challenges in comparing these training programs or to identify the core competencies that the respective programs sought to impart to the non-sleep specialist. Many of the real-world challenges of training described by Manber, Carney [65] in the context of the Veterans Health Administration (e.g., practitioner workload, practice structure and funds) also resonate with the challenges of intervention implementation in the community space, as highlighted in the aforementioned study design concessions. Therefore, a key developmental direction within the stepped-care framework would be to strategically align key training competencies with what is feasible with respect to the practitioners' scope of practice and constraints if CBT-I is to be routinely offered to patients as a first-line treatment option.

Diverse settings and providers of CBT-I pose new challenges at the dissemination and practice front, particularly the notion of TAU. TAU plays an important role in pragmatic clinical trials for comparing interventions to routine practice [66]. However, the involvement of different (health)care providers, each regulated under a separate practice jurisdiction, means that the spectrum of treatments and level of care access within the scope of TAU will inevitably vary from setting to setting and provider to provider [67]. One key source of treatment variability observed in the selected studies is the availability/non-availability of prescribed sleep medications as part of TAU. Ten out of 12 studies allowed participants to continue the use of their sleep medications during the trial period. This makes it difficult to discern the extent to which improvements observed are attributable to the intervention, the medication or the combined effects of the two [68]. As the pragmatic clinical trial becomes increasingly used across different practice settings, these sources of variability need to be accounted for in the study design and perhaps there is a need to adopt minimum reporting standards for describing the TAU condition in future clinical trials [69].

Strengths and limitations

The current review appraised 12 RCTs evaluating CBT-I interventions in the community setting, which omits a large proportion of the literature that would otherwise be contextualized within a stepped-care framework. Furthermore, the heterogeneity of treatment programs/structure and the inconsistencies in the reporting of sleep outcome measures made it difficult to draw conclusions relating to effectiveness of the respective interventions, as reflected in the extensive discussion needed for item agreement, and thus, warrants the need for more well-designed studies to be conducted and added to the evidence base. Importantly, our team of reviewers with diverse disciplinary backgrounds (e.g., psychology, medicine and pharmacy) and healthcare system experiences in different countries (i.e., Australia, Canada, France and Hong Kong) had different implicit understandings of clinical concepts such as primary care, giving rise to the lower initial Kappa scores. This observation has important implications given the field's interest in the cultural adaption of CBT-I, which will be further discussed below. Nonetheless, the computed ES offer insight on the extent of the impact of CBT-I programs delivered in real-world settings. From a translational standpoint, this review is limited to only synthesizing the tangible elements of the respective programs (e.g., number of

sessions, duration of sessions) and it was not possible to evaluate clinician attitudes despite its central role for integrating new practice protocols [70]. With renewed interest and reforms to integrate behavioral health services in primary care [24] and the community at large, targeted interventions that facilitate clinician behavior changes would be an important area of research development when new services are integrated into practice [71].

Additionally, all 12 studies included in this review were conducted in developed countries, 11 of which were western countries with comparable healthcare systems, hindering the overall generalizability of our findings to developing countries. Differences in healthcare access and cultural perceptions of health can bring about a different set of clinical constraints and challenges for disseminating CBT-I programs within a stepped-care framework. Given the already scarce CBT-I expertise in developing countries, the dissemination of CBT-I programs into the broader community is perhaps a more pressing matter. Together with increased interest in the cultural adaptation of CBT-I, the need for directing greater research effort in these underrepresented countries is apparent.

Conclusion

The primary objective of this review was to synthesize the evidence on the current state of the science for CBT-I programs implemented in community settings. While the small to moderate ES scores can be attributed to practice constraints, improvements were still observed for key outcome measures that studies sought to improve (i.e., insomnia severity). These findings, albeit inconclusive, illustrate the feasibility and utility of providing lower-tiered CBT-I programs, as first-line treatment in community settings. However, in order to draw firmer conclusions about the impact of these lower-tiered CBT-I treatment programs implemented in the community space, there is a need to standardize reporting measures, patient assessments and address the potential confounding effects of concomitant hypnotic use in the control arms. Unifying these elements of CBT-I programs developed within a stepped-care framework represents an important future research agenda as insomnia care is increasingly delivered in multidisciplinary teams and extending into various public community spaces such as the workplace.

Practice Points

1. Current evidence indicates that CBT-I produces clinically meaningful improvements in insomnia symptoms when implemented in various primary care/community venues as envisioned by the initial conceptualization of stepped-care.
2. Studies reflect a high and unmet demand for CBT-I across clinical settings. Different iterations of CBT-I programs further highlight new avenues for treatment dissemination and patient engagement such as the workplace and various community spaces.
3. Insomnia is encountered across broad clinical contexts and reflect the need to embed CBT-I training both in the teaching curriculum of the different health professions and as part of ongoing professional development.
4. Practice constraints limit the magnitude of treatment effects of community-based CBT-I programs. However, improvements in primary outcomes measures suggests that such programs could still play an important role in realigning patient beliefs/behaviors in the early stages of the help-seeking process.

Research Agenda

1. Implementing well-designed pragmatic clinical trials to evaluate programs at the practice interface, which helps to inform and establish minimum standards for reporting treatment outcomes, patient assessment and training needs, particularly in developing countries.
2. Given the proliferation of community-based CBT-I programs of varying lengths and structures, it is important to establish a 'minimum effective dose' (i.e., minimum number and duration of sessions) and essential treatment components for a program to be clinically meaningful.
3. The interdisciplinary provision of CBT-I involves diverse groups of health professionals, each practicing under a different jurisdiction. These differences lead to heterogeneity in terms of the types of treatment that is/is not available in the TAU control arm. Standardizing and refining TAU protocols is necessary with the increased use of pragmatic clinical trials.
4. Additional treatment components (e.g., goal setting) could play a role in improving patient self-efficacy in adhering to the necessary sleep behavior changes. This may potentiate the therapeutic effects of CBT-I and warrants further investigation as the field continues to evolve.

Conflicts of interest

JMYC, DCJ, OB and AB have no further potential conflicts of interest to declare. CMM has served as a consultant for Cereve, Philips and Merck and served as a speaker for Eisai and Merck.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.smrv.2018.11.001.

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