

Evidence Compass



Technical Report

What are effective interventions for veterans
with sleep disturbances?

A Rapid Evidence Assessment

September 2014



Australian Government
Department of Veterans' Affairs

Disclaimer

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Executive Summary

- Insomnia and related sleep disturbances commonly occur in veterans, with prevalence rates as high as 90% reported in some studies. Driving factors behind high rates of sleep disturbances in veterans include disruptions to sleep patterns as a result of military service, in particular on deployment. The high rate of psychiatric comorbidity amongst veterans also plays a role in the prevalence of sleep disturbance.
- The aim of this rapid evidence assessment (REA) was to review the effective interventions for veterans with sleep disturbances.
- Literature searches were conducted to collect studies published from 2004-2014 that investigated the efficacy of interventions for sleep problems in veterans. Studies were excluded if they did not have a majority sample of veterans, if they did not report on sleep outcomes, or if the inclusion criteria did not specify sleep problems/disorders. Studies were assessed for quality of methodology, risk of bias, and quantity of evidence, and the consistency, generalisability and applicability of the findings to the population of interest. These assessments were then collated for each sleep disturbance intervention to determine an overall ranking of level of support for each intervention.
- The ranking categories were 'Supported' –clear, consistent evidence of beneficial effect; 'Promising' – evidence suggestive of beneficial effect but further research required; 'Unknown' – insufficient evidence of beneficial effect; 'Not supported' – Clear, consistent evidence of no effect or negative/harmful effect.
- Eighteen studies met the inclusion criteria for review. All studies originated from the United States except for a single study from Israel.
- The majority of the studies investigated the effectiveness of cognitive behavioural therapy for insomnia (CBTi; n=10). Five studies investigated CBTi with an adjunctive psychotherapy, typically for PTSD-related sleep disturbances. One further study investigated sleep hygiene education (a component of CBTi) with pharmacotherapy. Two final studies investigated hypnotherapy and mind-body bridging, respectively. Overall, the quality of the studies was mixed, with some high and some poor quality studies.
- The key findings were that:

- The evidence for CBTi in treating sleep disturbances in veterans received a 'Promising' ranking.
 - The evidence for CBTi with adjunctive psychotherapy for PTSD-related sleep disturbances in treating veterans received a 'Supported' ranking.
 - The evidence for sleep hygiene education with pharmacotherapy in treating sleep disturbances in veterans received an 'Unknown' ranking.
 - The evidence for alternative psychological therapies (hypnotherapy and mind-body bridging) in treating sleep disturbances in veterans both received 'Unknown' rankings.
- Future research should address how to maximise clinical gains from CBTi while minimising cost and time factors to best suit the unique needs of veterans. Alternative psychological interventions need ongoing research to establish their effectiveness.

Introduction

Sleep disturbances can manifest in a range of ways and include sleep-related disorders such as insomnia, which is typically defined as problems with initiating sleep (more than 30 minutes to fall asleep), maintaining sleep (waking multiple times throughout the night; taking a long time to get back to sleep after waking; waking too early in the morning), and/or feeling unrefreshed when waking in the morning¹. These sleep disturbances occur despite the individual having ample opportunity and circumstances to have healthy sleep². Furthermore, the sleep disturbances experienced typically cause significant distress or impairment during the daytime. Insomnia sufferers also tend to have distorted perceptions about the quality of their sleep in that they overestimate how poorly they slept³. Insomnia can present as a secondary problem (comorbid insomnia), and commonly occurs with psychiatric disorders or alternatively, can occur as an independent disorder (primary insomnia)^{4,5}. Sub-types of insomnia can be defined by duration, with both acute and chronic types⁵.

Insomnia can have profound and severe consequences for the individual and society. Insomnia sufferers may have reduced quality of life, as fatigue affects memory, cognition and energy levels⁶. Research has shown that insomnia sufferers are at increased risk for accidents, utilise healthcare services more, experience lower work productivity, and experience interpersonal relationships as less satisfying^{2,5,7}. Furthermore, research has shown that insomnia is a risk factor for poor clinical outcomes for psychiatric disorders such as posttraumatic stress disorder (PTSD), depression and suicidality⁸. This relationship is bi-directional, in that sleep disturbance is an independent risk factor for developing depression⁹, suicidal ideation¹⁰ and posttraumatic psychiatric disorders¹¹.

Incidence of sleep disturbances in the community is relatively high. Symptoms of insomnia have been thought to affect approximately 30% of the general population¹² and rates of insomnia disorder have been estimated at 5-10%². Prevalence rates of sleep disturbances have been reported to be even higher in military samples. For example, in a large sample of US adults, lower rates of sleep duration and higher rates of insufficient rest or sleep were found among veterans compared to non-veterans¹³. In a sample of 375 US Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) service members and veterans, 89% were classified as poor sleepers¹⁴. Another study found rates as high as 94% in veterans who were experiencing multiple difficulties, such as pain, PTSD and traumatic brain injury¹⁵. Comparably, in a small sample of Australian Vietnam veterans, 90% of veterans had significant sleep disturbances¹⁶.

The higher rates of sleep disturbances in military samples may be due to a multitude of individual and environmental factors. Contributing factors to insomnia can include those that predispose an individual to the development of insomnia, such as adverse childhood events⁸. Other non-military related factors may include an individual's pre-military sleep patterns and physical health. Mental health problems such as depression and PTSD are also highly co-morbid with insomnia. Military personnel may be particularly vulnerable to the development of such psychological disorders¹⁷, which may place them at greater risk for developing insomnia. In addition to these factors, unique aspects of military life itself may make veterans vulnerable to insomnia, such as military culture, training and the experience of deployment. For example, sleep deprivation is common in military training^{18,19} and normal sleep patterns are significantly disrupted on deployment⁸. To compound this further, research into military culture has found that sleep is perceived by some to be a luxury or a weakness²⁰.

Normal sleep patterns are likely to be significantly disrupted during deployment⁸. During deployment, the physical sleep environment for an individual is changed completely, and the stress of both being away from home and being on deployment, compounded by frequent shift work and irregular sleep/wake cycles, can make the experience of deployment extremely disruptive to normal sleep patterns. As such, sleep disturbances have been one of the most frequently reported complaints from recently deployed veterans, reported by nearly a quarter of non-injured veterans and between 37-54% of injured US veterans returning from Iraq²¹. Furthermore, a large scale prospective study of 41,225 OEF/OIF personnel showed that those who were deployed or returned from deployment had shorter durations of sleep and reported more trouble sleeping than those who had not deployed²². It is important to note that this relationship was explained by combat exposure and mental health problems. It remains unclear if deployment exacerbates a previously undiagnosed sleep disorder or creates new sleep disorders in veterans²³.

The aim of the current REA was to examine the scientific literature for evidence of effective interventions for veterans with sleep disturbances. It is important to note that guidelines and several systematic reviews exist for the treatment of insomnia in adults e.g.,²⁴⁻²⁹. However, there are no specific guidelines or systematic reviews pertaining specifically to the treatment of sleep disturbances and/or insomnia in the broader veteran population. Veterans differ from community samples in that they have higher rates of psychiatric problems, including PTSD¹⁷. The higher rate of complex psychiatric presentation in veterans, combined with the likelihood that a veteran's sleep disturbance is influenced by military factors and military trauma-related experiences, means they may differ in response to treatment. Despite these differences between civilian and military population sleep disturbances, many of the

investigations into sleep interventions for veterans have applied those recommended for civilian adults. This trend reflects the emerging nature of research into effective interventions for sleep disturbances in veterans, and as such, an overview of current established and emerging interventions for the treatment of insomnia in (civilian) adults, and their respective levels of evidence support are discussed below.

Cognitive behavioural therapy for insomnia (CBTi)

CBTi is a multimodal intervention, that is designed to increase levels of relaxation at bedtime, decrease behaviours that contribute to poor sleep, and develop associations between bedtime and sleep³⁰. Many individuals with insomnia have developed maladaptive coping strategies to try to manage their sleep difficulties, such as using stimulants during the day, napping, or spending too much time in bed³¹. Unfortunately, these coping strategies often contribute to ongoing insomnia. In addition, insomnia sufferers often experience excessive worry and ruminations in the pre-sleep period, which contribute to physiological arousal and impede sleep onset³. Cognitive behavioural therapy for insomnia (CBTi) targets these negative or dysfunctional thoughts about sleep, typically in conjunction with behavioural therapy to improve poor associations between sleep and the environment (e.g., associating restlessness and distress with the bed) and poor sleep hygiene practices. CBTi can include one or any combination of the following interventions:

Cognitive therapy: involves identifying and resolving dysfunctional or negative thoughts about sleep.

Sleep hygiene education: involves education about good health and environmental practices that promote sleep^{26,32} (see Table 1 for details).

Stimulus control: involves limiting the association between the bedroom with sleep and sex only³². Reading, watching television, and other activities are banned from the bedroom. Individuals are taught to only go to bed when they feel tired, and to leave the bedroom if they have not fallen asleep or fallen back to sleep after waking within 15-20 minutes.

Sleep restriction: involves reducing the amount of time spent in bed awake in order to maximise sleep efficiency. After estimating average total sleep time (as compared to total time spent in bed), time spent in bed is restricted to this amount. As sleep efficiency improves, time in bed is gradually increased.

Relaxation therapy: involves use of several relaxation techniques in order to reduce arousal associated with bedtime in those with insomnia.

Table 1. *Sleep hygiene principles*³²

Avoid napping during the daytime
Avoid stimulants (caffeine, nicotine) and known sleep disrupters (alcohol) too close to bedtime
Exercise during the day, but not within four hours of bedtime
Avoid large meals close to bedtime
Make the sleep environment relaxing (temperature, lighting)
Establish a relaxing bedtime routine
Set a routine bedtime and wake time.

Barriers to CBTi include the cost and time involved in the treatment³². Clinicians require training in CBTi, particularly for the cognitive therapy component. However, because much of CBTi involves psychoeducation, components such as sleep hygiene education and stimulus control can be taught by practitioners without formal mental health qualifications³². An additional barrier is that the sleep restriction component may initially increase levels of sleepiness, as participants are reducing their time spent in bed in the initial stages of treatment³³.

CBTi is recommended by guidelines for the treatment of primary and secondary insomnia in adults^{27,29}. There is also evidence supporting long-term use of the components of CBTi in improving insomnia symptoms for up to two years³³. However, there is no established procedure for the selection of components to include in treatment of insomnia, or method for determining in which instances a single component of CBTi is sufficient²⁸. Researchers appear to select components of CBTi based on their available time and cost resources. While no systematic evaluation has been made to assess the effectiveness of individual CBTi components, guidelines have stated that sleep hygiene alone does not have sufficient evidence to support its effectiveness in treatment insomnia, and should only be used in combination with other components²⁷.

CBTi and adjunctive psychotherapies for PTSD-related sleep disturbances

Diagnostic criteria for PTSD includes two sleep-related disturbance symptoms: difficulty falling or staying asleep; and distressing trauma-related dreams, with the latter potentially creating fear of sleeping and contributing to sleep disturbance^{34,35}. Although insomnia has been shown to be highly co-morbid with PTSD, the relationship between PTSD and

insomnia is complex. Researchers have proposed that trauma-related sleep disturbances are inherently different to classic insomnia³⁶. Specifically, those with insomnia find sleep highly desirable and are apprehensive about their ability to achieve restful sleep, whereas those with trauma-related sleep disturbances, such as nightmares, may be fearful of sleep itself and tend to be sleep avoidant. As such, CBTi alone for trauma-related sleep disturbances, such as those seen in people with PTSD, may be insufficient. Given that PTSD-related nightmares create insomnia, and nightmares and insomnia can occur regardless of PTSD, researchers have investigated whether a combination treatment approach to nightmares and insomnia may be effective⁸. Imagery rehearsal therapy (IRT) and variants such as exposure, relaxation and rescripting treatment (ERRT) are interventions designed to treat the distressing nature of nightmares. Specifically, the interventions involve altering the distressing content of a nightmare to something non-distressing or pleasant, and rehearsing the newly rescripted nightmare in imagination before going to sleep³⁷. Research in veterans with PTSD has shown that IRT is highly effective in reducing nightmare frequency^{38,39} and it is currently recommended as best practice for the treatment of nightmare disorder³⁷. While IRT targets the nightmare-related sleep disturbances of PTSD, the 'pure' insomnia-related disturbances may require a different intervention. As such, recent research has proposed combining CBTi and IRT or similar psychotherapies to target the complex nightmare and insomnia-related sleep disturbances found in those with PTSD³⁶.

Alternative psychological interventions for the treatment of insomnia

Psychological therapies that are alternative to standard interventions, include mind-body interventions and hypnotherapy.

Hypnotherapy involves the therapist inducing hypnosis in an individual, an altered state of consciousness where the conscious mind becomes deeply relaxed while the subconscious mind remains focused. Once an individual enters this state, known as a 'hypnotic trance', they are especially responsive to ideas, images, or beliefs and render control of many cognitive systems to the hypnotist⁴⁰. Hypnotherapists often use hypnosis to change behaviours⁴¹. Hypnotism success can depend on the susceptibility of an individual to hypnosis, or their 'hypnotisability'⁴².

Mindfulness-based therapies focus on the connection between the mind and the body, and aim to build a set of strategies for dealing with internal states⁴³. These therapies focus on raising awareness of the current experience while remaining non-judgemental towards

what is currently unfolding. Specifically, awareness is raised by an individual paying attention to current sensory, cognitive and emotional experiences. Individuals are taught only to observe these experiences and not to judge any of them in a positive or negative way⁴⁴. Mindfulness-based therapies are driven by the theoretical assumption that the emotional, mental and spiritual state of the mind impacts on the physical state of the body^{41,45}. Common types of therapies include acceptance and commitment therapy, mindfulness-based stress reduction and mindfulness based cognitive therapy, but there are many other variants.

Pharmacotherapy

Pharmacotherapy is a common treatment for insomnia. Typically, sedative hypnotics are administered, but other treatments such as anti-depressants or anti-epileptic drugs are also used²⁷. Pharmacotherapy has side effects and risks associated with dependency and tolerance²⁹. Moreover, pharmacotherapy targets the symptoms of insomnia, and does not target the possible underlying causes, such as dysfunctional beliefs and behaviours regarding sleep, and negative associations with the sleep environment²⁸. While the effectiveness of pharmacotherapy alone was not investigated in this review, studies where pharmacotherapy was combined with other psychological interventions were investigated.

There is evidence supporting the use of pharmacotherapy (sedative hypnotics only) in the short-term to treat insomnia in adults in the general community³³. There is insufficient evidence to support the use of pharmacotherapy in the long-term treatment (over six months) of insomnia³³. Guidelines have recommended that short term pharmacotherapy treatment should be supplemented with psychotherapies when possible²⁷. Evidence has indicated that the short-term outcomes of pharmacotherapy or psychotherapy are comparable^{24,33}.

Measuring sleep disturbances

Regardless of the intervention method used, studies typically measure sleep disturbances in similar ways. Objective indicators of sleep quality and frequency, such as polysomnography (electrodes fitted to body to record physiological data during sleep) and actigraphy (small device worn on a limb to record movement during sleep) measure sleep/wake cycles and related physiological changes. While objective outcome measures are often considered the 'gold standard' in scientific research, the underlying theoretical basis of insomnia, in that it is caused by a *perceived* deficit in sleep quantity, quality and restfulness, means that subjective reports are often more reflective of an individual's sleep disturbances³³. As such,

while objective measures used to capture insomnia changes post-intervention may indicate an improvement in sleep disturbances, if subjective measures do not match up, then the individual will have ongoing problems. The opposite may also occur, with no improvements to objective indicators of sleep disturbances, but the individual may have subjective improvements. As such, objective measures of sleep disturbances are not considered routine when evaluating sleep disturbances²⁷. Consistent with this, the studies included in this review use subjective measures of sleep to evaluate treatment efficacy.

Subjective indicators of sleep disturbances include self-report psychometric scales such as the Pittsburgh Sleep Quality Index (PSQI)⁴⁶ that measures sleep quality, and the Insomnia Severity Index (ISI)⁴⁷ which measures insomnia severity. A sleep diary, completed by an individual each day, is regularly used to measure sleep variables, such as time gone to bed, sleep onset latency (SOL: time taken to fall asleep), number of awakenings, wake after sleep onset (WASO: the sum of wake times from sleep onset to the final awakening), time in bed (TIB: time from bedtime to getting out of bed for the day), total sleep time (TST: time in bed minus SOL and WASO), sleep efficiency percent (SE: equals $TST/TIB \times 100$)³². Sleep diaries can also be used to measure a subjective indicator of sleep quality, in addition to nightmare frequency and nightmare severity. Sleep diaries are often used to track progress over the course of treatment, particularly for CBTi, which aims to limit time in bed and to increase overall sleep efficiency. They are subject to the individual's perceptions of sleep rather than actual sleep, and individuals with insomnia tend to over-estimate how poorly they sleep³.

Method

This literature review utilised a rapid evidence assessment (REA) methodology. The REA is a research methodology which uses similar methods and principles to a systematic review but makes concessions to the breadth and depth of the process, in order to suit a shorter timeframe. The advantage of an REA is that it utilises rigorous methods for locating, appraising and synthesising the evidence related to a specific topic of enquiry. To make a REA rapid, however, the methodology places a number of limitations in the search criteria and in how the evidence is assessed. For example, REAs often limit the selection of studies to a specific time frame (e.g., last 10 years), and limit selection of studies to peer-reviewed published, English studies (therefore not including unpublished pilot studies, difficult-to-obtain material and/or non-English language studies). Also, while the strength of the evidence is assessed in a rigorous and defensible way, it is not necessarily as exhaustive as a well-constructed systematic review and meta-analysis. A major strength, however, is that

an REA can inform policy and decision makers more efficiently by synthesising and ranking the evidence in a particular area within a relatively short space of time and at less cost than a systematic review/meta-analysis.

Defining the research question

The components of the question were precisely defined in terms of the population, the interventions, the comparisons and the outcomes (PICO - refer to Appendix 1). Operational definitions were established for key concepts for each question, and from this specific inclusion and exclusion criteria were defined for screening studies for this REA. As part of this operational definition, the population of interest was defined as veterans with sleep disturbances, the intervention was defined as any psychological intervention, and the outcome was defined as sleep outcomes, such as quality or quantity.

Search strategy

To identify the relevant literature, systematic bibliographic searches were performed to find relevant trials from the following databases: EMBASE, MEDLINE (PubMed), PsychINFO, Cochrane, Clinical Guidelines Portal (Australia), and the National Guideline Clearinghouse (USA).

No guidelines, meta-analyses or systematic reviews were identified which covered effective interventions for veterans with sleep disturbances that met the inclusion/exclusion criteria of the current review.

Search terms

Search terms specific to sleep disturbances, psychological interventions and veterans were included in searching the Title/s, Abstract/s, MeSH terms, Keywords lists and Chemical: *insomnia, primary insomnia, sleep disturbance*, sleep problem*, sleep disorder*, psychological intervention, nonpharmacologic, behavi* therapy, cognitive therapy, psychotherapy, psychological therapy, clinical trial, control trial, treatment, effectiveness, therapy, treatment study, clinical study, control study, military, veteran*, defence, defense.*

An example of the search strategy conducted in the Embase database appears in the Appendix 2.

Paper selection

Papers were included in the review of the evidence if they met all of the following inclusion criteria.

Included:

1. Internationally and locally published peer-reviewed research studies
2. Research papers that were published from **1st January 2004** to **18th April 2014**
3. Trials with outcome data that assesses sleep disturbances or insomnia
4. Human Adults (i.e. ≥ 18 years of age)
5. English Language
6. The majority of the samples are veterans ($\geq 75\%$)

Excluded:

1. Non-English papers
2. Papers where a full-text version is not readily available
3. Validation study
4. Animal studies
5. Grey literature (e.g. media: websites, newspapers, magazines, television, conference abstracts, theses)
6. No quantitative outcome data reported
7. Papers where sleep disturbances or insomnia were only an outcome measure and not an inclusion criteria

Information management

A screening process was adopted to code the eligibility of papers acquired through search strategy. Papers were directly imported into the bibliographic tool Endnote X5, and then processed using Excel. All records that were identified using the search strategy were screened for relevance against the inclusion criteria. Initial screening for inclusion was performed by one reviewer, and was based on the information contained in the title and abstract. Full text versions of all studies which satisfied this initial screening were obtained.

In screening the full-text paper, the reviewer made the decision on whether the paper should be included or excluded, based on the pre-defined inclusion and exclusion criteria. If the paper met the criteria for inclusion, then it was subject to data abstraction. At this stage in

the information management process, 10% of the articles being processed were randomly selected and checked by a second independent reviewer. It was found that there was 100% inter-rater agreement between the two reviewers. The following information was extracted from studies that met the inclusion criteria: (i) study description, (ii) intervention description, (iii) participant characteristics, (iv) primary outcome domain, (v) main findings, (vi) bias and (vii) quality assessment.

Evaluation of the evidence

There were four key components that contributed to the overall evaluation of the evidence.

These components were:

- The **strength of the evidence base**, in terms of the quality and risk of bias, quantity of evidence, and level of evidence (study design)
- The **consistency** of the study results
- The **generalisability** of the body of evidence to the target population (e.g. veterans)
- The **applicability** of the body of the evidence to the Australian context

The first two components provided a gauge of the internal validity of the study data in support of efficacy for an intervention. The last two components considered the external factors that may influence effectiveness, in terms of the generalisability of study results to the intended target population, and applicability to the Australian context.

Strength of the evidence base

The strength of the evidence base was assessed in terms of the a) quality and risk of bias, b) quantity of evidence, and c) level of evidence.

- Quality and risk of bias** reflected how well the studies were conducted, including how the participants were selected, allocated to groups, managed and followed-up, and how the study outcomes were defined, measured, analysed and reported. An assessment was conducted for each individual study with regard to the quality and risk of bias criteria utilising a modified version of the Chalmers Checklist for appraising the quality of studies of interventions (see Appendix 3). Three independent raters rated each study according to these criteria, and together a consensus agreement was reached as to an overall rating of 'Good', 'Fair', or 'Poor'.
- Quantity** of evidence reflected the number of studies that were included as the evidence base for each ranking. The quantity assessment also took into account the number of participants in relation to the frequency of the outcomes measures (i.e. the statistical

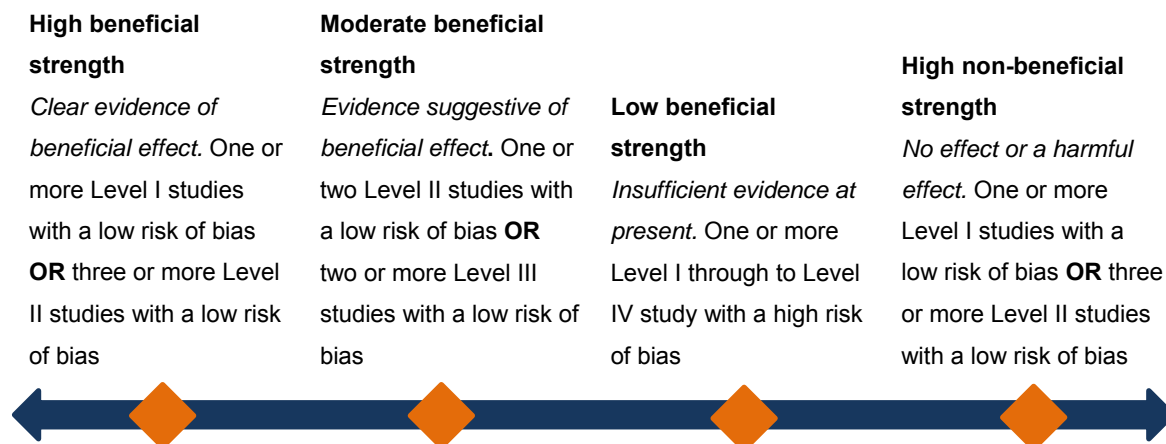
power of the studies). Small underpowered studies that were otherwise sound may have been included in the evidence base if their findings were generally similar- but at least some of the studies cited as evidence must have been large enough to detect the size and direction of any effect.

c) **Level of evidence** reflected the study design. The details of the study designs which are covered by each level of evidence are as follows:

- Level I: A systematic review of Randomised Controlled Trials (RCTs)
- Level II: An RCT
- Level III-1: A pseudo-randomised controlled trial (i.e. a trial where a pseudo-random method of allocation is utilised, such as alternate allocation).
- Level III-2: A comparative study with concurrent controls. This can be any one of the following:
 - Non-randomised experimental trial [this includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (i.e. utilise A vs B and B vs C to determine A vs C with statistical adjustment for B)]
 - Cohort study
 - Case-control study
 - Interrupted time series with a control group
- Level III-3: A comparative study without concurrent controls. This can be any one of the following:
 - Historical control study
 - Two or more single arm study [case series from two studies. This would include indirect comparisons utilise (i.e. A vs B and B vs C to determine A vs C where there is no statistical adjustment for B)]
 - Interrupted time series without a parallel control group.
- Level IV: Case series with either post-test or pre-test/post-test outcomes

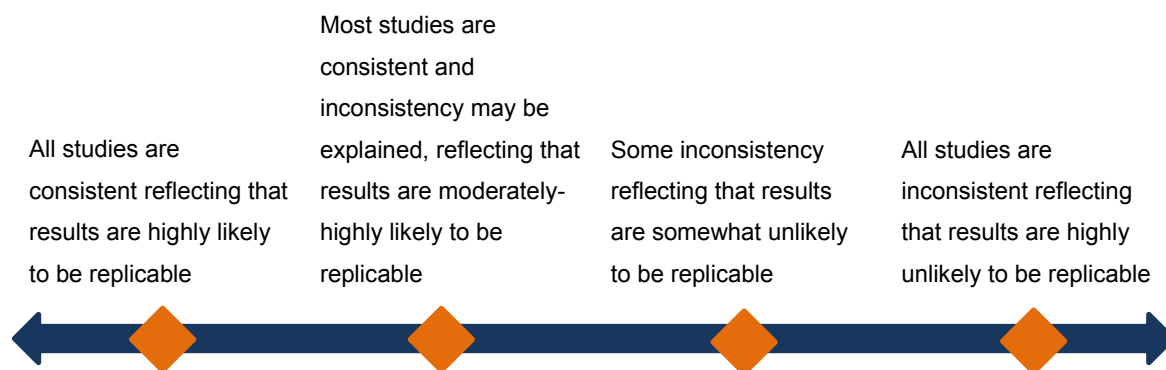
Overall strength

A judgement was made about the strength of the evidence base, taking into account the quality and risk of bias, quantity of evidence and level of evidence. Agreement was sought between three independent raters and consensus about the strength of the evidence based was obtained according to the categories below.



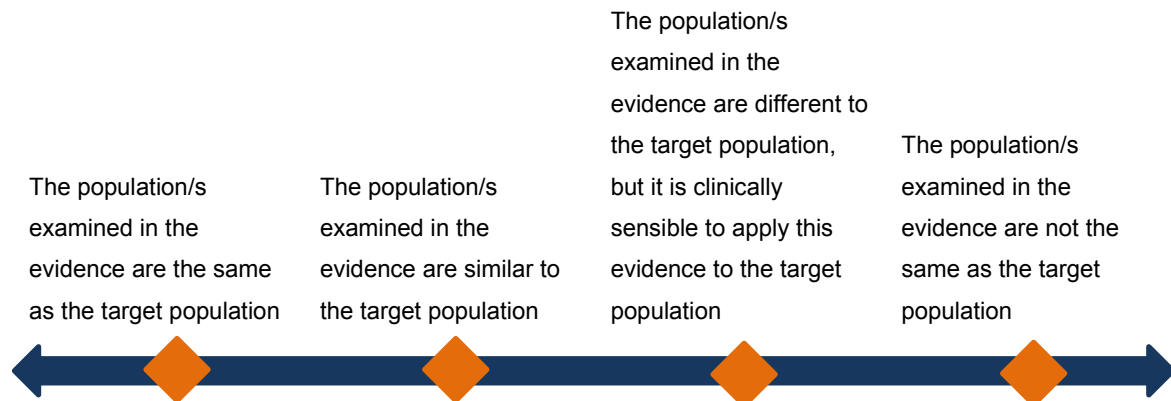
Consistency

The consistency component of the ranking system of the body of the evidence assessed whether the findings were consistent across the included studies (including across a range of study populations and study designs). It was important to determine whether study results were consistent to ensure that the results were likely to be replicable or only likely to occur under certain conditions.



Generalisability

This component covered how well the participants and settings of the included studies could be generalised to the target population. Population issues that might influence this component included gender, age or ethnicity, or level of care (e.g. community or hospital).



Applicability

This component addressed whether the evidence base was relevant to the Australian context, or to specific local settings (such as rural areas or cities). Factors that may reduce the direct application of study findings to the Australian context or specific local settings include organisational factors (e.g. availability of trained staff) and cultural factors (e.g. attitudes to health issues, including those that may affect compliance).



Ranking the evidence

On balance, taking into account the considerations of the strength of the evidence (quantity and risk of bias, quantity of evidence and level of evidence), consistency, generalisability and applicability, the total body of the evidence was then ranked into one of four categories: 'Supported', 'Promising', 'Unknown' and 'Not Supported' (see Figure 1). Agreement on ranking was sought between three independent raters. NOTE: If the strength of the evidence was considered to be low, the next steps of rating consistency, generalisability and applicability were not conducted and the evidence was rated as 'Unknown'.

Figure 1: Categories within the intervention ranking system

SUPPORTED	PROMISING	UNKNOWN	NOT SUPPORTED
Clear, consistent evidence of beneficial effect	Evidence suggestive of beneficial effect but further research required	Insufficient evidence of beneficial effect and further research is required.	Clear, consistent evidence of no effect or negative / harmful effect

Results

The following section presents figures pertaining to the volume of records identified at each stage of the rapid evidence assessment (Figure 2), the country of publication (Figure 3), and the year of publication (Figure 4). From all the sources searched, a total of 18 papers met the inclusion criteria and were included in the final report. Of the 18 studies, 95% originated from the USA and a single study originated from Israel. The year of publication for studies that were included in this rapid evidence assessment is presented in Figure 4. As can be seen, no studies were published between 2004 and 2007. The final full year of the search period (2013) resulted in 29% of the publications.

Figure 2: Flowchart representing the number of records retrieved at each stage of the rapid evidence assessment

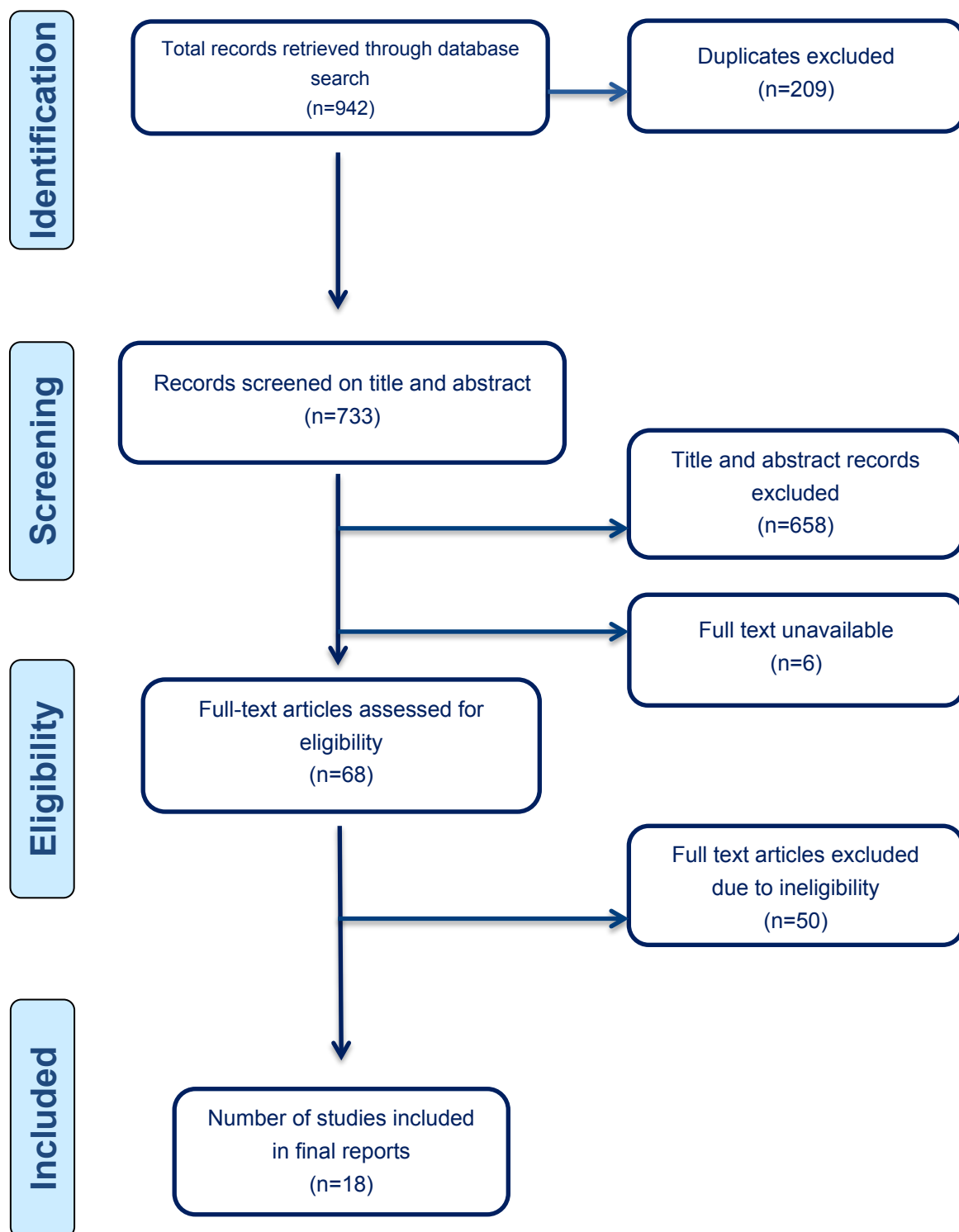


Figure 3. Country of publication of studies included in the rapid evidence assessment

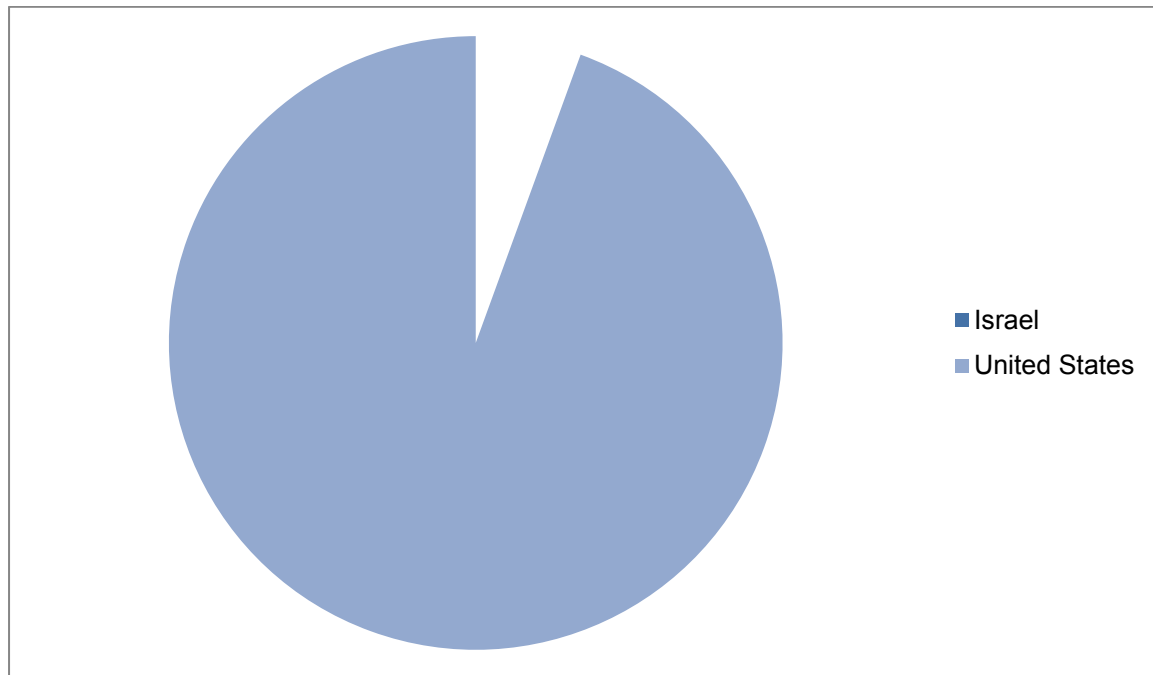
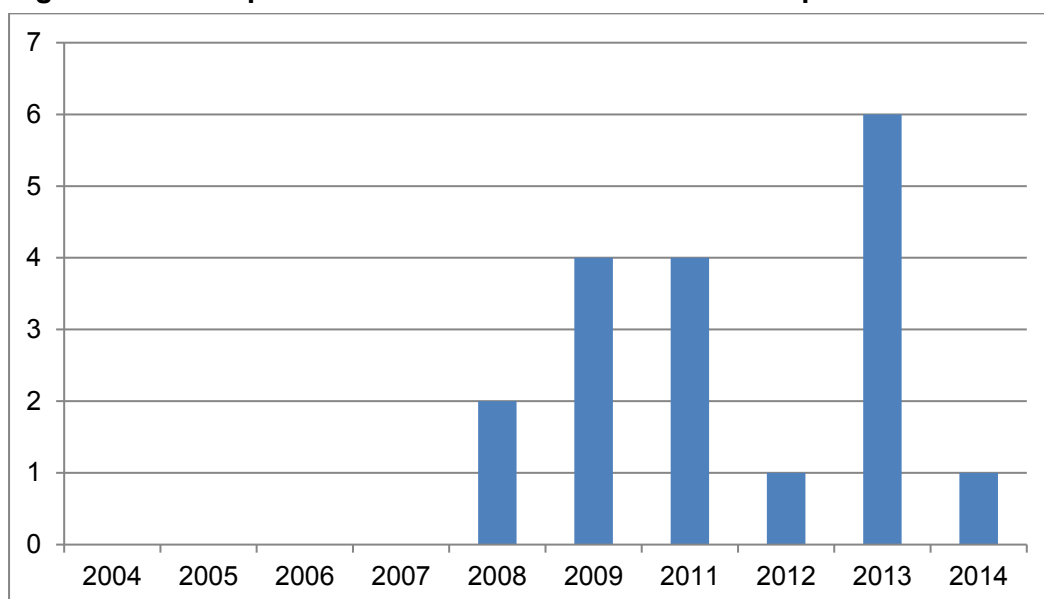


Figure 4. Year of publication of studies included in the rapid evidence assessment



Summary of the evidence

A total of 18 articles were included in this review that examined effective interventions in the treatment of veterans with sleep disturbances. Ten studies investigated the effectiveness of cognitive behavioural therapy for insomnia (CBTi), five studies investigated CBTi with an adjunctive psychotherapy for PTSD-specific sleep disturbances and one further study investigated sleep hygiene education with adjunctive pharmacotherapy for PTSD-related nightmares. Two final studies investigated hypnotherapy and mind-body bridging, respectively. A summary of the studies is found in the evidence profile presented in Appendix 4 in detail and in Appendix 5 as a brief overview.

Cognitive behavioural therapy for insomnia (CBTi)

Ten studies investigated the effectiveness of CBTi. One of these was an RCT that investigated effectiveness of CBTi in veterans who had primary insomnia or insomnia associated with various psychiatric disorders, and who were also followed up six months post-treatment⁴⁸. Four sessions were administered to 41 veterans in the intervention group compared to 40 veterans in the control group who received sleep hygiene alone. Overall, both groups showed significant improvements to wake after sleep onset and total sleep time, and the latter showed an additional significant improvement between post-treatment and 6 month follow-up. However, the CBTi group showed significantly greater improvements at post-treatment on several measures of sleep quality and insomnia severity. There were no differences between veterans with primary insomnia or insomnia co-morbid with other psychiatric disorders. A second study was a large ($N=183$) nonrandomised case control study of US veterans partially hospitalised in a psychiatric program⁴⁹. CBTi was offered to participants as part of the psychiatric program, of which 106 veterans attended between one to four group sessions. The remaining 77 did not attend any group CBTi sessions, serving as controls. It is unknown why certain veterans participated and others did not. Both groups improved significantly in terms of sleep quality, and there was no statistically significant difference in the level of improvement between the control and intervention group.

The remaining eight studies were all single group studies. One study involved US OEF/OIF veterans ($N=41$) who were administered one initial session of CBTi, and given iPods containing audio files on relaxation and websites with sleep information for use outside of the sessions⁵⁰. Three follow-up telephone calls were also conducted to reinforce skills, totalling four sessions of CBTi. The study also had a three month follow-up. There were significant improvements in sleep quality and insomnia severity on most measures from pre to post-treatment and these improvements were maintained at three months follow-up. Four

further studies involved a range of sample sizes (N ranging from 8-432) of US veterans and administered group or individual CBTi^{30,51-53}. Post-treatment there were significant improvements in sleep quality and insomnia severity in all studies; however, three of the studies reported that some participants continued to have clinically significant symptoms of insomnia. Another study reviewed medical charts for US veterans who were psychiatric inpatients at hospitals and found that of the 19 veterans who were administered one session of group CBTi there was a significant reduction in insomnia severity after treatment⁵⁴. However, 32% of participants reported a slight worsening of sleep after treatment although it is not known if this decline was statistically significant. The final two studies were single case studies of US veterans, who reported reductions in insomnia severity and improvements in sleep quality following CBTi treatment, but the absence of significance testing in each of these studies means it is not known if these improvements were statistically significant^{55,56}.

Despite the quantity of studies comprising the evidence base (N=10) for CBTi, there was significant diversity in their quality and risk of bias. Overall, the strength of the evidence base for CBTi to treat veterans with sleep disturbances was found to be low to moderate, as there was only a single RCT and the majority of studies lacked a control group. The consistency of the findings was deemed to be high, as all studies showed significant improvements on several measures of sleep quality and insomnia severity. Generalisability of the findings to the target population of this REA (Australian veterans), and applicability in the Australian context was considered high. Taken together, these ratings meant that the evidence base for the use of CBTi for the treatment of veterans with sleep disturbances was ranked as 'Promising'.

CBTi and adjunctive psychotherapies for PTSD-related sleep disturbances

Five studies investigated the effectiveness of CBTi combined with another psychotherapy targeting PTSD-related sleep disturbances^{36,57-60}. Of these, three were RCTs^{36,59,60} and two were single-group studies^{57,58}. In a small RCT of US veterans with PTSD (N=22), 12 veterans received individual therapy sessions which included three sessions of CBTi and three sessions of IRT in that order³⁶. The remaining veterans received usual care by their primary care provider. At post-intervention, those in the intervention group had significant improvements in total sleep time, sleep onset latency and nightmare frequency compared to those who received usual care. In terms of quantifying these improvements to indicate clinical significance, all of the veterans who received the intervention had achieved normal sleep onset latency (less than 30 minutes to fall asleep) at post-treatment whereas only 14% of veterans who received usual care had achieved normal sleep onset latency. Insomnia

severity and sleep quality improved significantly in the veterans who received the intervention compared to those who did not.

In a larger RCT of US OEF/OIF veterans with PTSD ($N= 40$), half of the veterans received four individual CBTi sessions which included IRT for those veterans who reported problem nightmares in addition to insomnia⁶⁰. The other veterans remained on the waitlist during the intervention period. After treatment, the intervention group showed significant improvements in all sleep diary measures (sleep efficiency, sleep onset latency and sleep after wake onset) and in sleep quality compared to those who remained on the waitlist. Overall however, there were no significant changes in total sleep time between groups. In terms of clinical significance, at post-treatment the intervention group decreased from moderately severe insomnia to subthreshold insomnia whereas the controls remained moderately severe.

The third RCT of 50 US veterans investigated the effectiveness of individual therapy combining CBTi and IRT over five weeks ($n=17$), with three weeks of follow-up telephone contact compared to pharmacotherapy alone ($n=18$) and placebo ($n= 15$)⁵⁹. Approximately half the sample had diagnosed PTSD and the remainder had sub threshold symptoms. The pharmacotherapy treatment (*Prazosin*) targeted both nightmares and insomnia. Groups were followed-up at four months post-treatment. All groups had significant improvements in sleep quality and nightmare improvement between pre and post-treatment. However, both interventions were found to be more effective in reducing insomnia severity than the placebo, and there were no differences in insomnia severity reduction between the two treatment conditions. At four month follow-up, the psychotherapy intervention group had significantly greater improvements for insomnia severity compared to the pharmacotherapy intervention group.

Two small uncontrolled studies delivered CBTi with IRT⁵⁷ or CBTi with ERRT⁵⁸ to US veterans with PTSD. The CBTi/IRT study delivered six individual sessions to 11 veterans and found sleep quality improved significantly, but there was no change in frequency of nightmares. Additionally, while four participants (36%) responded very well to treatment, three participants (27%) did not show improvement or worsened. The CBTi/ERRT study delivered ten group sessions to 10 veterans and found that sleep quality and insomnia severity improved significantly from pre to post-treatment and weekly nightmares reduced by 50% and nightmare distress reduced by 46%.

Overall, the strength of the evidence base for CBTi with adjunctive psychotherapies for PTSD-related sleep disturbances was found to be high. This ranking was drawn primarily from the findings of the three RCTs judged to be of good quality and low risk of bias, with small to moderate sample sizes. The consistency of the findings was deemed to be high, as

all studies showed significant improvements to several measures of sleep quality and insomnia severity. Generalisability of the findings to the target population of this REA, and applicability in the Australian context was considered high. Taken together, these findings led the evidence base for the use of CBTi with adjunctive psychotherapies for PTSD-related sleep disturbances for the treatment of veterans with sleep disturbances to be ranked as 'Supported'.

Sleep hygiene education with adjunctive pharmacotherapy

A single study investigated the effectiveness of sleep hygiene education (a component of CBTi) with adjunctive pharmacotherapy (*Prazosin*)⁶¹. The observational cohort study had no control group, and followed a sample of US veterans with combat-related mild TBI with neuropsychological abnormalities and ongoing severe headaches over six months. The veterans first received sleep hygiene followed by nine weeks of pharmacotherapy. Insomnia was measured by subjective reports to non-standardised questions and levels of daytime sleepiness. After taking the pharmacotherapy for nine weeks, both the veterans who completed the entire course of pharmacotherapy (n=62) and those who did not (n=12) showed significant reductions in levels of daytime sleepiness. Of those who completed pharmacotherapy, 97% reported restful sleep and reduced or eliminated nightmare frequency whereas of those who did not finish the pharmacotherapy course 75% reported non-restful sleep at post-treatment. At follow-up, the veterans who were not taking pharmacotherapy at follow-up reported significantly higher levels of daytime sleepiness.

The strength of the evidence base for sleep hygiene education with adjunctive pharmacotherapy was limited by the single study, which had a low representative sample and subsequent risk of bias. Given the strength of the evidence base was low, generalisability, consistency, and applicability were not rated, and the use of sleep hygiene education with pharmacotherapy for the treatment of veterans with sleep disturbances was ranked as 'Unknown'.

Hypnotherapy with adjunctive sleep hygiene education

One study investigated the effect of two sessions of hypnotherapy for the treatment of sleep disturbances in veterans⁶². The study used an RCT in Israeli veterans with PTSD (n= 17) and chronic sleep difficulties compared to pharmacotherapy treatment for two weeks (*Zolpidem*; n=16). Both groups also received sleep hygiene instruction. The participants were also followed-up at one month post-treatment⁶². Participants were pre-screened to assess their level of hypnotisability, which is known to affect hypnotherapy outcomes, and only those with mid-range scores were selected for randomisation. Both groups improved

significantly from pre to post-treatment in total sleep time, while sleep quality improved significantly more in the hypnotherapy group compared to the pharmacotherapy group. While number of awakenings decreased in both groups from pre to post-treatment, they decreased more in the hypnotherapy group. Because the intervention group combined a component of CBTi (sleep hygiene) with another psychological intervention, it is impossible to determine how each of these elements of the intervention contributed meaningfully to sleep improvements.

The strength of the evidence base for hypnotherapy with adjunctive sleep hygiene education to treat veterans with sleep disturbances was found to be moderate. This rating was given as a result of one RCT, judged to be of good quality and low risk of bias. The consistency of the findings was not rated, as there was only a single study. Generalisability of the findings to the target population of this REA was considered low, as the study investigated Israeli veterans with PTSD who had moderate levels of hypnotisability. The applicability in the Australian context was considered high. Taken together, the overall ratings for the evidence base led to the use of hypnotherapy with adjunctive sleep hygiene education to treat veterans with sleep disturbances being ranked as 'Unknown'.

Mind-body bridging

A final study investigated mind-body bridging in US veterans ($N=63$) with PTSD sleep disturbances⁶¹. The focus of mind-body bridging is largely mindfulness, with emphasis on awareness of somatic (physical) sensations⁴⁵. An RCT design was used in which 35 veterans received two sessions of mind-body bridging and the control group completed sleep hygiene alone (a component of CBTi). There was a significant reduction in sleep problems in both groups, however, the magnitude of improvement in sleep for the intervention group was significantly greater than for the control group. Post-intervention, 3% of participants in the intervention group reported no improvement or a deterioration in sleep compared to 25% of the controls.

The strength of the evidence base for mind-body bridging to treat veterans with sleep disturbances was found to be moderate. This rating was given as a result of one RCT, judged to be of good quality and low risk of bias. The consistency of the findings was not rated, as there was only a single study. Generalisability of the findings to the target population of this REA was considered high, as the study investigated US veterans but the findings were not applicable in the Australian context because the intervention requires certified instructors and certification is currently not available in Australia. Taken together, the overall ratings for the evidence base led to the use of mind-body bridging to treat veterans with sleep disturbances being ranked as 'Unknown'.

Discussion

The aim of this review was to assess the evidence related to effective psychological interventions for veterans with sleep disturbances. The results indicate that the vast majority (95%) of current literature (2004 - 2014) investigated the efficacy of CBTi in isolation or in combination with another intervention, with only a single study⁶³ investigating an alternative psychological intervention to treat sleep disturbances in veterans without any CBTi components included. This pattern is consistent with the broader literature on treatment of sleep disturbances in non-veterans, with the vast majority of psychological treatments being some variant of, or combination of CBTi components^{25,26}.

While CBTi-based interventions were found to be the most common, in order to make meaningful judgements on the effectiveness of the studies identified in this review, the studies were divided into categories based on the intervention combinations used in the study. Overall, the results of the REA showed that evidence for the use of CBTi, either alone or in combination with an additional psychotherapy for PTSD-related sleep disturbances is 'Promising' and 'Supported', respectively. While the strength of the evidence base for CBTi alone was limited to a single good quality RCT, the ranking of 'Promising' is further supported by the extensive evidence base indicating the efficacy of the use of CBTi in treating insomnia in civilian adults^{27,29}. As such, the 'Promising' ranking given to CBTi in treating veterans with sleep disturbances is likely to increase to 'Supported' if further high-quality studies are published.

The evidence for the use of sleep hygiene education (a single CBTi component) in combination with pharmacotherapy was insufficient and ranked as 'Unknown'. The 'Unknown' ranking arose due to there being only one study with a limited study design investigating the effectiveness of this combination of interventions. However, it is important to note that guidelines for the treatment of insomnia in adults recommend the short-term use of pharmacotherapy and the conjunctive use of psychological interventions^{27,33}. Therefore, the 'Unknown' ranking given in this REA may need to be revised in the future if further, higher quality studies investigating pharmacotherapy in conjunction with CBTi in veterans indicate effectiveness.

The strongest evidence base was for the use of CBTi in combination with additional psychotherapy for PTSD-related sleep disturbances. It is important to note that because the interventions were conducted concurrently, the impact that CBTi had uniquely on sleep disturbances, such as sleep quality and insomnia severity, is unknown. It is possible that the adjunctive psychotherapies were the main contributor to sleep improvements in veterans

post-treatment. Additionally, this finding should be considered in light of the studies' sample characteristics. All of the studies had veterans with diagnosed PTSD or sub-threshold symptoms, but not all veterans with sleep disturbances have PTSD, limiting the generalisability of these findings to the broader Australian veteran population. Therefore, the 'Supported' ranking of this intervention is only applicable to veterans with PTSD and sleep disturbances.

Few studies focused on psychological interventions that were not CBTi-based. The current REA did not find sufficient evidence to support alternative psychological interventions in the treatment of sleep disturbances in veterans. However, it is important to note that the two highly rated RCTs investigating hypnotherapy and mind-body bridging respectively, represent the beginnings of an evidence base upon which future research can build.

In addition to the overall evidence of the REA indicating that psychological interventions are effective in improving sleep outcomes in veterans, many of the studies reviewed reported that post-treatment, participants had improvements to a variety of other non-sleep specific clinical outcomes, such as PTSD symptoms^{36,57,60,62,63}, depression symptoms^{51,52,60,62}, anxiety symptoms⁵², and quality of life⁵¹. However, other studies reported no differences to these variables post-treatment, or no significant differences compared to controls^{30,36,59,63}. While the exact reasons for improvements to these clinical variables are unknown, it is important to note that treating veterans with sleep disturbances with psychological interventions can potentially impact on a range of psychiatric issues.

Lastly, it is important to consider that our methodology allowed for a wide range of trial methodologies. We included studies that used methodologies such as single case studies or case series designs, which are often excluded from systematic reviews. Our inclusion of a wide range of study designs was in recognition of the emerging nature of this body of literature, and was reflected in the findings that no studies were published between 2004 and 2008. As such, we anticipate that more research will be published in this area in the coming years, which will be of higher quality, particularly for non-CBTi based psychological interventions.

Implications

There is good evidence for the use of CBTi or CBTi combined with psychotherapies to treat PTSD-related sleep disturbances to treat veterans. However, the exact component(s) of CBTi or the specific combinations that are most effective remain unknown. CBTi is a multimodal intervention, in that one or all of the several components can be used in treatment. Further dismantling studies are needed to determine which components are most

effective in treating veterans with sleep disturbances. If brief interventions, or those that require minimal training are found to be effective, there is potential for widespread dissemination of treatment for sleep disturbance, a highly prevalent problem amongst veterans. The additional advantage of a brief intervention is its potential to engage veterans who are not able or willing to undertake a longer course of therapy.

Despite uncertainty around the efficacy of individual CBTi components, the consistency in improvements to sleep across modalities for CBTi studies (e.g., group; individual; brief; use of electronic aids) indicate that the treatment itself is fairly adaptable and effective in several modes. Given the target population of veterans, who may be remotely located from service providers, limited in mobility, and have a varying range of treatment preferences, the findings indicating high adaptability of CBTi in treating veterans are promising. However, this was not systematically explored, and simply a pattern observed across studies, so these findings should be taken cautiously and re-assessed in light of future studies.

Additionally, while there was significant evidence supporting the use of CBTi for veterans, it is important to note that this intervention is typically undertaken in those with diagnosed insomnia. Not all veterans with sleep disturbances will meet the criteria for diagnosed insomnia, and the majority may have sub-clinical levels of sleep disturbances. Research into viable treatment options to help veterans manage ongoing, sub-clinical sleep disturbances is needed. This could be extended to include prevention strategies for veterans that promote healthy sleep behaviours and strategies to manage training or deployment related sleep disturbances. Given the evidence of this REA indicating that improving sleep disturbances in veterans also improved related psychological problems, by informing practitioners about best-practice treatment options for sleep disturbances in veterans, improved mental health outcomes are likely to result.

It is important to note that although CBTi has been shown to be highly effective in veterans, including in veterans with complex psychiatric problems such as PTSD and traumatic brain injury (TBI), it may not be the treatment of preference in this population. In an investigation of OEF/OIF US veterans' preferences for different treatments for sleep disturbances, relaxation, pharmacotherapy and mindfulness treatments were rated as significantly more preferable to the CBTi components of sleep hygiene education, sleep restriction and stimulus control⁶⁴. It is not entirely clear as to why veterans prefer these modes, although the authors suggest that the 'quick-fix' appeal of pharmacotherapy and the anxiety-arousal reducing aspect of relaxation therapies could be reasons for their higher preference ratings. In addition, veterans preferred treatments that lasted fewer than five weeks, whereas CBTi typically involves six sessions run over the course of six weeks. Both of the alternative

interventions reviewed in this REA provided an intervention that ran for two weeks or less. Further, alternative interventions to traditional psychological interventions could potentially overcome stigma-related issues. Self-stigma (an individual's view towards their own mental health) and public stigma (beliefs an individual has about others with mental health) towards traditional psychological interventions are potential barriers for individuals seeking care, including for veterans^{65,66}. Stigma is particularly important to address in veterans, as studies have shown that US OEF/OIF veterans with psychiatric disorders are significantly more likely to report concerns about stigma than veterans without psychiatric disorders, and stigma concerns contribute to low levels of help-seeking behaviours in this group^{67,68}. Non-traditional therapies, such as mindfulness-based therapies, may be less stigmatising for veterans than traditional psychotherapies as the negative attitudes held by veterans towards psychotherapy may be based on archaic stereotypes around what psychotherapeutic treatment entails and its efficacy⁶⁷. In contrast, non-traditional therapies that do not suffer from the psychotherapy stereotype of “talking” therapy may not suffer similar levels of stigma. This may account for previous findings indicating that relaxation therapy is more preferred than traditional CBT interventions⁶⁴. It is important to note that in addition to the two non-traditional interventions of hypnotherapy and mind-body bridging, the initial literature yield for this REA also found studies investigating alternative, non-pharmacological interventions such as acupuncture in veterans with sleep disturbances^{69,70}. Acupuncture, which is also a treatment for physical health disorders, may not suffer from the same stigma that psychotherapies do, as the reasons for receiving the treatment are not as identifiable to a third-party as they are when an individual is undergoing psychotherapeutic treatment⁶⁹.

There are two important implications of these findings. First, efforts to increase the uptake of effective interventions for sleep may benefit from de-emphasizing CBTi as psychotherapy and promoting it as brief self-help sleep strategies. Secondly, although alternative psychological interventions were not supported, it is important to continue to investigate their effectiveness for treatment of sleep disturbances in veterans as it may be a more preferable treatment option to veterans. Despite veterans' preference for pharmacotherapy in treating sleep disturbances⁶⁴, the significant side effects mean that pharmacotherapy alone is not a long-term solution.

Limitations of the rapid evidence assessment

The findings from this REA should be considered alongside its limitations. In order to make this review ‘rapid’, some restrictions on our methodology were necessary. These limitations included: the omission of potentially relevant papers that were published prior to or after the defined search period; the omission of non-English language papers; and reference lists of

included papers not being hand-searched to find other relevant studies. Similarly, although we did evaluate the evidence in terms of its strength, consistency, and generalisability, these evaluations were not as exhaustive as in a systematic review methodology. Finally, we made a qualitative judgement based on the level of evidence about the certainty of our estimates of prevalence. We did not use a meta-analysis methodology to combine or synthesise the results in a statistical way.

The information presented in this REA is a summary of information presented in available papers. We recommend readers source the original papers if they would like to know more about a particular intervention or study.

Conclusion

This REA found that the effective interventions for the treatment of sleep related disturbances in veterans are largely CBTi-based, either used alone, or in combination with other psychotherapies targeting PTSD-related sleep disturbances. CBTi with adjunctive psychotherapy to treat PTSD-related sleep disturbances was ranked as supported for veterans with PTSD. CBTi alone was ranked as a promising intervention. While the promising ranking indicates a beneficial effect, more research is needed to confidently establish efficacy in a veteran population. There is currently insufficient evidence to support the use of sleep hygiene education and pharmacotherapy, hypnotherapy, or mind-body bridging.

Sleep disturbance is highly prevalent in veterans, with and without mental health problems and should be a priority for treatment, given the positive effects on overall mental health of improved sleep. This review found that effective treatments for veterans with PTSD-related sleep disturbance are available and there are promising treatments for all veterans with insomnia. However further research dismantling the components of CBT-i is needed to identify which are the critical components. Such research has the potential to lead to brief, targeted and accessible treatments that overcome the time and stigma related barriers to care that have been identified in previous research.

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Appendix 1

Population Intervention Comparison Outcome (PICO) framework

This question was formulated within a Population Intervention Comparison Outcome (PICO) framework. Application of a PICO framework helps to structure, contain and set the scope for the research question. Inclusion of intervention and comparison components is dependent on the question asked, and may not be appropriate for all question types.

- **What are effective interventions for veterans with sleep problems?**
 - **PICO format:** In veterans diagnosed with insomnia or sleep disturbances, which psychological interventions are effective for reducing the symptoms of insomnia or sleep disturbances?

P Patient, Problem, Population	I Intervention	C Comparison (<i>optional</i>)	O Outcome <i>when defining "more effective" is not acceptable unless it describes how the intervention is more effective</i>
Patient: Veterans Problem: Sleep disturbances	Psychological intervention which targets sleep disturbances	<ul style="list-style-type: none"> • None • Psychological intervention which does not target sleep disturbances • Waitlist control • Treatment as usual • Pharmacotherapy • Attention/placebo control 	Sleep-related outcomes

Appendix 2

Example search strategy

The following is an example of the search strategy conducted in the Embase database:

Step	Search Terms	No of records
S1	(insomnia or sleep disturbance or sleep problem or sleep disorder).mp.	97249
S2	limit 1 to yr="2004-Current"	64714
S3	insomnia/ or primary insomnia/	43489
S4	limit 3 to yr="2004-Current"	28172
S5	2 or 4	64714
S6	(psychological intervention or nonpharmacologic or behavi* therapy or cognitive therapy or psychotherapy or psychological therapy or clinical trial or control trial or treatment or effectiveness or therapy or treatment study or clinical study or control study).mp.	8483826
S7	limit 1 to yr="2004-Current"	3833987
S8	cognitive therapy/ or psychotherapy/ or mental health service/ or therapy/ or behaviour therapy/	1354265
S9	limit 8 to yr="2004-Current"	291077
S10	clinical trial/	838489
S11	limit 10 to yr="2004-Current"	408582
S12	7 or 9 or 11	3844459
S13	(military or veteran* or defence or defense).mp.	197448
S14	Limit 1 to yr="2004-current"	95246
S15	army/	14249
S16	limit 15 to yr="2004-Current"	5765
S17	veteran/	10714
S18	limit 17 to yr="2004-Current"	8890
S19	5 and 12 and 18	518

Appendix 3

Quality and bias checklist

Chalmers Checklist for appraising the quality of studies of interventions⁷¹

Completed		
Yes	No	
		1. Method of treatment assignment
		<ul style="list-style-type: none"> • Correct, blinded randomisation method described OR randomised, double-blind method stated AND group similarity documented
		<ul style="list-style-type: none"> • Blinding and randomisation stated but method not described OR suspect technique (eg allocation by drawing from an envelope)
		<ul style="list-style-type: none"> • Randomisation claimed but not described and investigator not blinded
		<ul style="list-style-type: none"> • Randomisation not mentioned
		2. Control of selection bias after treatment assignment
		<ul style="list-style-type: none"> • Intention to treat analysis AND full follow-up
		<ul style="list-style-type: none"> • Intention to treat analysis AND <25% loss to follow-up
		<ul style="list-style-type: none"> • Analysis by treatment received only OR no mention of withdrawals
		<ul style="list-style-type: none"> • Analysis by treatment received AND no mention of withdrawals OR more than 25% withdrawals/loss-to-follow-up/post-randomisation exclusions
		3. Blinding
		<ul style="list-style-type: none"> • Blinding of outcome assessor AND patient and care giver (where relevant)
		<ul style="list-style-type: none"> • Blinding of outcome assessor OR patient and care giver (where relevant)
		<ul style="list-style-type: none"> • Blinding not done
		<ul style="list-style-type: none"> • Blinding not applicable
		4. Outcome assessment (if blinding was not possible)
		<ul style="list-style-type: none"> • All patients had standardised assessment
		<ul style="list-style-type: none"> • No standardised assessment OR not mentioned

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		5. Additional Notes
		<ul style="list-style-type: none">• Any factors that may impact upon study quality or generalisability

Appendix 4

Evidence Profile

Authors & year	Design	Intervention (I) and Comparison (C)	Population Mean age (SD) ¹ Gender (%)	Delivered to	Dosage (total number of sessions)	Primary Outcome domain (Measure(s))	Secondary Outcome domain (Measure(s))	Total sample size	Participants	
									I	C
Cognitive behavioural therapy for insomnia										
Baddeley et al., 2013	Case study with 90 day follow-up	I: Cognitive behavioural therapy for insomnia	US Navy veteran with PTSD and insomnia Mean age: 70 Gender: Male	Individual	Six sessions	- Insomnia (Sleep diary: sleep efficiency; total sleep time; sleep quality; ISI)	- PTSD (PCL) - Depression, Anxiety & stress (DASS) - Sleep-related beliefs (DBAS-16)	N= 1	n= 1	N/A
The results of the case study showed that the participant's total sleep time increased from 4.5 hours per night to 5 hours per night, and sleep efficiency was increased from 56.3% to 83%, after CBTi. It was not reported whether these differences are clinically significant. Sleep quality increased from 2 to 3, where 1= very poor and 5= very good. The ISI score dropped a clinically significant degree, moving from the severe insomnia range to the minimal range at follow-up. It should be noted, however, that this was after the individual also received therapy for PTSD. It remains unclear how significantly insomnia severity was affected by the CBTi intervention due to the confounding effect of the PTSD therapy. There was also a reduction in PTSD, depression and stress scores post-intervention, but the unique effect of CBTi on this change is unknown.										
Edinger et al., 2009	RCT with six month follow up	I: Cognitive behavioural therapy for insomnia C: Sleep hygiene	US adults with mixed psychiatric disorders and insomnia (veteran status not described) Mean age: 54.2 (13.7) Gender: Male (86%)	Individual	Four bi-weekly sessions 30-60 minutes each	- Insomnia (ISQ; PSQI; Sleep diary: time in bed; total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; actigraphy ²)	- Sleep-related beliefs (DBAS-14)	N= 81	n= 41	n= 40
CBTi produced significantly greater sleep improvements compared to sleep hygiene at post-treatment for sleep onset latency and sleep efficiency, with moderate effect sizes. In actigraphy										

¹ Mean age and SD is given when provided, alternatively age range is provided

² Objective measure of sleep/wake cycles

What are effective interventions for veterans with sleep disturbances?

measures, the CBTi group also showed significant improvements in sleep after wake onset at six months follow-up. As a whole, there was a significant reduction in wake after sleep onset and increase in total sleep time for both groups at post-treatment, with an additional significant increase in total sleep time between post-treatment and six month follow-up. The CBTi group also showed greater short and long-term improvements to sleep-interfering beliefs and insomnia symptoms.										
Epstein et al., 2013	Single group pre-post with three month follow-up	I: Brief insomnia treatment with electronic components	US OEF/OIF veterans exposed to a potential TBI with insomnia Mean age: 30.3 (7.7) Gender: Male (95%)	Individual	Four sessions	- Insomnia (Sleep diary: total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; time in bed; PSQI; PSQI-A; ISI) - Sleep self-efficacy	None	N= 41	n= 41	N/A
There were significant improvements to insomnia severity (ISI), sleep quality (PSQI) and sleep self-efficacy from pre-treatment to post-treatment and these improvements were maintained at three month follow-up. There was no significant change to disruptive nocturnal behaviours (PSQI-A). While there were no significant differences in sleep diary measures of sleep onset latency and wake after sleep onset between pre and post-treatment, there were significant increases in total sleep time, time in bed, and sleep efficiency between pre and post-treatment.										
Gellis & Gehrman, 2011	Single group pre-post	I: Cognitive behavioural therapy for insomnia	US veterans (88% Vietnam) with PTSD and insomnia Mean age: 58.6 (3.0) Gender: Male (100%)	Individual	Five sessions	- Insomnia (ISQ; actigraphy)	- PTSD (CAPS; PCL-M) - Other psychiatric disorders (MINI; STAXI; PHQ-9) - Daytime sleepiness (ESS) - Fatigue (FSS) - Nightmares (NFQ; NES)	N= 8	n= 8	N/A
In this small, single group pre-post study (n=9), it was found that post-treatment, there were significant improvements to all subjective measures of sleep diary (sleep onset latency; wake time after sleep onset; total sleep time; sleep efficiency) and severity of insomnia, with moderate to large effect sizes ($d= 0.6-3.2$). There were no differences in objective measures of sleep (actigraphy). Five of the eight participants continued to have sleep patterns consistent with clinically significant insomnia post-treatment. There were no significant differences in nightmares, PTSD severity or other psychiatric or sleep related outcomes post-treatment.										
Haynes et al., 2011	Retrospective single group pre-post	I: Brief group therapy based on cognitive behavioural therapy for insomnia	US veterans with severe mental illness and insomnia in psychiatric hospitals Mean age: 51.6 (12.2) Gender: Male (95%)	Group	One session, 60 minutes	- Insomnia (ISI)	None	N= 19	n= 19	N/A
There was a significant reduction in insomnia severity scores after treatment, with scores moving from the moderate severity range to the sub-threshold range. These reductions were almost clinically significant for seven participants, while six participants reported a slight worsening of their sleep.										
Karlin et al.,	Single group	I: Cognitive	US veterans	Individual	Six sessions	- Insomnia (ISI)	- Depression (BDI-II)	N= 182	N=	N/A

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2013	pre-post	behavioural therapy	presenting for treatment at mental health and primary care settings with insomnia Mean age: 50 (15) Gender: Male (78%)				- Quality of life (WHOQOL-BREF)		182	
On average, participants experienced a moderate clinical improvement to insomnia severity scores post-treatment. Sixty-one participants of the 115 who completed treatment (53%) no longer had clinically recognised insomnia. There were also statistically significant improvements to depression symptoms and quality of life post-treatment.										
Khawaja et al.,	Retrospective case-control	I: Cognitive behavioural therapy informed sleep skills education C: Non-attenders to the intervention	US veterans partially hospitalised in a psychiatric program Mean age: 48-48.5 (11.6-13.1) Gender: Male (91%)	Group	One to four sessions, 60 minutes each	- Insomnia (PSQI; sleep latency; sleep time)	None	N= 183	n= 106	n=77
Both groups improved significantly in terms of sleep quality as indicated by the PSQI, and there was no statistically significant difference in the level of improvement between the control and intervention group. There were significant reductions in sleep latency (18 minutes) and increases in sleep time, from 6.1 - 6.7 hours in the intervention group.										
Perlman et al., 2008	Single group pre-post	I: Cognitive behavioural therapy for insomnia	US veterans with insomnia and co-morbid psychiatric disorders Mean age: 52.4 (13.5) Gender: Male (75%)	Group	Eight to ten sessions, 75 minutes each	- Insomnia (Sleep diary: total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; PSQI; ISI) - Sleep-related beliefs (DBAS-16)	- Daytime impairment (MFI-20; QIDS-SR; STAI) - Hypnotic use	N= 20	N= 20	N/A
After treatment, wake after sleep onset time decreased on average by 99 minutes, total sleep time increased by 45 minutes, and sleep efficiency increased from 63% to 84%. In addition, sleep onset latency, frequency of awakenings and sleep diary subjective reports of sleep quality and restedness all improved significantly. All other subjective measures (PSQI; ISI; DBAS-16; MFI-20; QIDS-SR; STAI) of sleep quality, daytime impairment and depression and anxiety symptoms improved significantly post-treatment. However, the PSQI and ISI showed that on average, the group continued to have residual insomnia after treatment. Hypnotic use also improved, with 88% of participants taking hypnotics reducing use or stopping entirely.										
Pigeon et al., 2013	Case study with three month follow-up	I: Brief cognitive behavioural therapy for insomnia (two sessions delivered via telephone)	US veteran with insomnia and depression Mean age: Not reported	Individual	Four sessions, S1: 45 minutes, S2-4: 15-30 minutes	- Insomnia (Sleep diary: total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; number of	- Depression (PHQ-9)	N= 1	n= 1	N/A

What are effective interventions for veterans with sleep disturbances?

			Gender: Male			awakenings; ISI)				
<p>For the single participant in this case study, the ISI score decreased from 21 at pre-treatment to 8 at post-treatment and 6 at follow-up, meaning the person no longer had clinically meaningful insomnia. Depression scores also dropped from 11 to 2 by follow-up. Sleep latency was reduced from 52 minutes to 11 minutes at follow-up, wake after sleep onset reduced from 57 minutes to 8 minutes at follow-up and sleep efficiency improved from 76% to 95% at follow-up. However, as no significance testing was done, it is not known if these sleep diary indicated improvements are significant.</p>										
Trockel et al., 2014	Single group pre-post	I: Cognitive behavioural therapy for insomnia delivered by therapists in training	US veterans with insomnia Mean age: 52 (14.0) Gender: Male (85%)	Individual	Six sessions	- Insomnia (ISI)	None	N= 696	N= 696	N/A
<p>Of the 696 participants who started treatment in this single group, pre-post study, 62% completed all sessions (n= 432). For those that completed treatment, it was found that overall, ISI score decreased from 20.7 at pre-treatment to 10.9 at post-treatment (d= 2.3). At post-treatment, 35% had no clinically significant insomnia, 38% had sub threshold insomnia, 20% had moderate insomnia and 7% had severe insomnia.</p>										
<p>Cognitive behavioural therapy for insomnia with an adjunctive psychological intervention</p>										
Germain et al., 2012	RCT with four month follow-up	I1: Behavioural sleep intervention incorporating cognitive behavioural therapy for insomnia and imagery rehearsal therapy I2: Pharmacotherapy C2: Placebo	US veterans with sleep complaints Mean age: 40.9 (13.2) Gender: Male (90%)	Individual	Five to eight sessions, 45 minutes each	- Insomnia (Sleep diary: total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; number of awakenings; ISI; PSQI; polysomnogram) - Nightmares (Sleep diary: frequency) - Improvement or worsening of symptoms (CGI)	- Mental health symptom severity (PCL; BDI; BAI)	N= 50	n:I1= 17 n:I2= 18	n:I1= 15
<p>Insomnia severity was significantly lower in both intervention groups post-treatment, in comparison to the placebo group. All groups showed improvements to sleep quality using the PSQI across time. All groups showed improvements in sleep diary indicators. Overall, sleep improvements were found in 62% of those in the intervention groups and 25% of those in the placebo group. At follow-up, the behavioural intervention group had significantly greater insomnia improvements compared to the pharmacotherapy group. There were no other significant differences in sleep measures at follow-up between groups, and significantly greater improvements to insomnia severity were maintained for the psychological intervention group at follow-up. There were no significant differences in objective sleep measures (polysomnogram) or daytime mental health symptom measures.</p>										
Harb et al., 2009	Single group pre-post	I: Cognitive behavioural therapy for insomnia combined with imagery rehearsal	US OIF veterans recently post deployment with PTSD and recurrent nightmares	Individual	Six sessions (three CBT; three IRT)	- Insomnia (PSQI; sleep diary) - Nightmares (NFQ; sleep diary)	- PTSD (PCL-M)	N= 11	n= 11	N/A

What are effective interventions for veterans with sleep disturbances?

			Mean age: 37.3 (9.2) Gender: Male (100%)							
<p>Sleep quality improved significantly after treatment as indicated by the PSQI. Sleep diaries indicated an average nightly increase in sleep of 37 minutes and a decrease in sleep onset latency by 10 minutes. There were no changes in frequency of overall nightmares from the sleep diaries however, there was a trend for less intense dreams, and lower frequency of the primary nightmare (the target of the imagery rehearsal therapy). While four participants responded very well to treatment, three participants (from the group of 11) did not show improvement or worsened. There was a moderate change in PTSD symptom severity post-treatment.</p>										
Margolies et al.,	RCT	I: Cognitive behavioural therapy for insomnia with adjunctive imagery rehearsal therapy (when participants reported problem nightmares) C: Waitlist	US OEF/OIF veterans with PTSD and insomnia Mean age: 37.7 (9.1) Gender: Male (90%)	Individual	Four sessions, 60 minutes each	- Insomnia (Sleep diary: total wake time; total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; actigraphy, PSQI; ISI) - Sleep-related beliefs (DBAS-16)	- PTSD (PSS-SR) - Mood (PHQ-9; POMS)	N= 40	n= 20	n= 20
<p>After CBTi and IRT the intervention group showed significant improvements to sleep diary outcomes, in terms of sleep efficiency, sleep onset latency and wake after sleep onset ($d = .13 - .40$) and for sleep quality (PSQI), in comparison to the control group. There was no difference in changes in total sleep time between groups, although the intervention group trended towards increases in total sleep time. On the ISI, the intervention group decreased from moderately severe insomnia to sub threshold insomnia after treatment, whereas the controls remained as moderately severe. There were significant improvements in the treatment group on objective sleep measures (actigraphy) for sleep efficiency and wake after sleep onset but not for sleep latency and total sleep time. In terms of within-group effects, the treatment group had significant decreases in PTSD symptoms and improvements to mood post-treatment, whereas the controls showed significant increases in PTSD symptoms and no change in mood post-treatment.</p>										
Swanson et al., 2009	Single group pre-post	I: Cognitive behavioural therapy with adjunctive exposure, relaxation and rescripting therapy	US veterans (90% Vietnam) with PTSD and insomnia Mean age: 59 (4.0) Gender: Male (100%)	Group	Ten sessions, 90 minutes each	- Insomnia (Sleep diary: total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; time in bed; PSQI; ISI) - Nightmares (Sleep diary: distress level; frequency)	- PTSD (PDS)	N= 10	n= 10	N/A
<p>All sleep diary measures and PSQI and ISI scores improved significantly from pre to post-treatment ($d = 0.46- 1.70$). Post-treatment, 80% of participants reported an ISI score in the subthreshold range, whereas pre-treatment, the average ISI score for participants was in the moderate severity insomnia range. Weekly nightmares reduced by 50% and nightmare distress reduced by 46% from pre- to post-treatment.</p>										
Ulmer et al., 2011	RCT	I: Cognitive behavioural therapy for insomnia and imagery rehearsal therapy C: Usual care	US veterans with insomnia and PTSD Mean age: 46 (11.1) Gender: Male	Individual	Six sessions, 60 minutes each	- Insomnia (Sleep diary: total sleep time; sleep onset latency; wake after sleep onset; sleep efficiency; PSQI; ISI)	- PTSD (PCL-M) - Depression (PHQ-9)	N= 22	n= 13	n= 9

What are effective interventions for veterans with sleep disturbances?

			(68%)			- Nightmares (Sleep diary: frequency)				
<p>The intervention produced significantly greater improvements in the sleep diary measures of total sleep time, sleep onset latency and nightmare frequency compared to the control condition. Post-intervention, all the intervention participants had achieved normal sleep onset latency compared to just 14% of controls. However, the two groups did not differ at post-intervention on the percentage of those who had achieved normal wake after sleep onset levels. For insomnia (ISI), sleep quality (PSQI) and PTSD symptoms (PCL-M), significantly greater improvements were found in the intervention group compared to the control group. The two groups did not differ in terms of depression from pre to post-treatment. Remission rates in the intervention group for insomnia were 11%, for sleep quality they were 33% and for PTSD they were 50%.</p>										
Cognitive behavioural therapy for insomnia with pharmacotherapy										
Ruff et al., 2009	Prospective cohort with six month follow-up	I: Sleep hygiene and pharmacotherapy for nightmares	US OEF/OIF veterans with mTBI and headaches, the majority with PTSD Mean age: 29.4 (2.9) Gender: Male (93%)	Individual	Five sessions	- Insomnia (Subjective reports; ESS)	None	N= 74	n= 74	N/A
<p>After taking the pharmacotherapy for nine weeks, both the veterans who completed the entire course of pharmacotherapy (n= 62) and those veterans who did not (n= 12) showed significant reductions in levels of daytime sleepiness. Of those who completed pharmacotherapy, 97% reported restful sleep and reduced or eliminated nightmare frequency. Of those who did not complete the pharmacotherapy course, 75% reported non-restful sleep at post-treatment. Comparisons were made between veterans who were taking pharmacotherapy at follow-up (n= 64) and those who weren't (n= 10). The non-pharmacotherapy group reported significantly higher levels of daytime sleepiness (ESS) at follow-up, and those who were taking pharmacotherapy had ESS scores in normal range.</p>										
Alternative interventions										
Mind-body bridging										
Nakamura et al., 2011	RCT	I: Brief mind-body bridging program C: Sleep hygiene	US veterans with sleep disturbances Mean age: 49.9-53.8 (10.4) Gender: Male (95%)	Group	Two sessions, 90 minutes each	- Sleep (MOSS-SS)	- Quality of life (MOS-SF-36) - Depression (CES-D) - PTSD (PCL-m)	N= 63	n= 35	n= 28
<p>There was a significant reduction in sleep problems in both groups however, the magnitude of improvement in sleep for the intervention group was significantly greater than that for the control group. Post intervention, 3% of participants in the intervention group reported no improvement or a deterioration in sleep compared to 25% of the controls. There were no significant differences in quality of life. There were significant reductions in severity of PTSD symptoms for those in the intervention group with moderate to severe PTSD symptoms in comparison to the control group. Depression scores decreased significantly in both groups post-treatment.</p>										
Hypnotherapy										
Abramowitz	RCT with one month	I: Hypnotherapy and	Israeli veterans	Individual	Four sessions,	- Insomnia (Sleep diary: total sleep time;	- PTSD (IES; PDS)	N= 42	n= 17	n= 16

What are effective interventions for veterans with sleep disturbances?

et al., 2008	follow-up	sleep hygiene C: Pharmacotherapy and sleep hygiene	with PTSD Mean age: 31.7 (not reported) Gender: Male (100%)		90 minutes each	quality of sleep; number of awakenings - Daytime (ability to concentrate; morning sleepiness)	- Depression (BDI)			
<p>Total sleep time improved significantly in both groups from pre to post-treatment. Sleep quality improved significantly in the hypnotherapy group compared to the pharmacotherapy group. While number of awakenings decreased in both groups from pre to post-treatment, they decreased more pronouncedly in the hypnotherapy group. Ability to concentrate and levels of morning sleepiness stayed relatively unchanged in the pharmacotherapy group from pre to post-treatment while the hypnotherapy group improved significantly. PTSD symptoms and depression reduced in both groups following intervention, with the greatest reductions observed in the intervention group.</p>										

Appendix 5

Evaluation of the evidence

Type of Intervention	Included Studies
Supported	
CBTi with adjunctive psychotherapies for PTSD-related sleep disturbances	<ul style="list-style-type: none"> • Germain et al. (2012) • Harb, Cook, Gehrman, Gamble & Ross (2009) • Margolies, Rybarczyk, Vrana, Leszczyszyn & Lynch (2013) • Swanson, Favorite, Horin & Arnedt (2009) • Ulmer, Edinger & Calhoun (2011)
Promising	
CBTi	<ul style="list-style-type: none"> • Baddeley & Gros (2013) • Edinger et al. (2009) • Epstein, Babcock-Parziale, Herb, Goren & Bushnell (2013) • Gellis & Gehrman (2011) • Haynes, Parthasarathy, Kersh & Bootzin (2011) • Karlin, Trockel, Taylor, Gimeno & Manber (2013) • Khawaja et al (2013) • Perlman, Arnedt, Earnheart, Gorman & Shirley (2008) • Pigeon & Funderburk (2013) • Trockel, Karlin, Taylor & Manber (2014)
Unknown	
Sleep hygiene with adjunctive pharmacotherapy	<ul style="list-style-type: none"> • Ruff, Ruff & Wang (2009)
Hypnotherapy	<ul style="list-style-type: none"> • Abramowitz , Barak, Ben-Avi & Knobler (2008)
Mind-body bridging	<ul style="list-style-type: none"> • Nakamura, Lipschitz, Landward, Kuhn & West (2011)