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TABLE OF CONTENTS

HEADER 1
ABSTRACT 1
BACKGROUND 2
OBJECTIVES 4
METHODS 4
ACKNOWLEDGEMENTS 8
REFERENCES 9
APPENDICES 13
CONTRIBUTIONS OF AUTHORS 14
DECLARATIONS OF INTEREST 14
SOURCES OF SUPPORT 14

[Intervention Protocol]

Remote non-pharmacologic interventions for sleep problems in healthcare workers during the COVID-19 pandemic

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the effects of remote non-pharmacologic interventions, compared with other specific intervention, non-intervention or alternative intervention for sleep problems in in healthcare workers during the coronavirus disease 2019 outbreak.

BACKGROUND

Description of the condition

The coronavirus disease 2019 (COVID-19) pandemic is one of the most significant worldwide public health events in recent times, causing death and affecting quality of life. It is an unusual and challenging time. Mass home confinement has led to significant changes in people's daily lives and behaviours. For example, people tend to wake at different times, modify their diet and exercise, and are less exposed to daylight (Simpson 2020). This in turn has impacted sleep patterns, and lead to stress-related symptoms, anxiety and mood problems (Serafini 2020). Specific stressors include longer home confinement duration (Hawryluck 2004), infection fears (Jeong 2016), boredom (Braunack-Mayer 2013), inadequate or excessive information regarding the pandemic (Braunack-Mayer 2013), financial loss (Pellecchia 2015), and stigma (Bai 2004). Such trends were also observed in the severe acute respiratory syndrome (SARS) and Ebola pandemics (Bai 2004).

Within this context, increased sleep problems (both in terms of quality and quantity) and characteristic sleep changes have been observed worldwide (Gupta 2020). We use the term "sleep problems" to refer to sleep dysfunctions that do not necessarily meet all the criteria for a sleep disorder diagnosis. According to recent studies, the most common sleep problems reported include onset insomnia (Li 2020a, Lin 2021; Yee-Man 2020), terminal insomnia (Lin 2021), poor sleep quality (Casagrande 2020; Gorgoni 2021; Xiao 2020; Yee-Man 2020), increased length of time in bed and total sleep time (Li 2020a; Lin 2021), increased, delayed bedtime and wake-up time (Li 2020a; Marelli 2021), and pandemic related nightmares (Scarpelli 2021).

Healthcare workers (HCW) currently face a high risk of contracting COVID-19 and are exposed to long and distressing work shifts to meet health service requirements. Such demand may exceed their individual coping skills, which is likely to result in overload (Zhang 2020). Many recent studies from different countries have documented this problem. For example, one study investigated the early impact of COVID-19 on sleep and psychological symptoms (acute stress, anxiety, and depression) in a large group of HCWs (Lin 2021). Results showed that insomnia and psychological symptoms were more severe among participants living in the epicenter of the COVID-19 outbreak (Hubei province) and among those who experienced higher risk of contracting COVID-19 (i.e. HCW and management staff on the front lines). Investigators also compared rates of insomnia before and during COVID-19 including a retrospective evaluation prior to the pandemic (defined as the last three months of 2019). There was a 37% increase in the rates of clinical insomnia from before the peak of COVID-19. Similarly, one longitudinal study found that the sleep quality of Spanish nursing students differed between both periods analyzed, with worse sleep quality during the lockdown (Romero-Blanco 2020). Li 2020b found that 58% of HCW in Wuhan had insomnia. Further analysis showed that the symptoms of insomnia were related to gender, education, marital status, and general psychological symptoms. Similarly, Lai 2020 found that 34% of a sample of 427 Chinese HCW reported symptoms of insomnia. Nurses, women, people working in Wuhan, and frontline workers reported more severe symptoms of insomnia and other psychological measures. Zhang 2020 found that the insomnia prevalence in Wuhan was 38.4% in HCW compared to 30.5% in non-health workers at the beginning of the pandemic. Further analysis revealed that living in rural areas, being in contact with people with COVID-19, and having organic diseases were risk factors for insomnia among this population. One systematic review of 78 studies on the epidemiology of sleep disorders during the COVID-19 pandemic estimated a prevalence ranging from 2.3% to 76.6% (Tasnim 2020). Another study found that more than two-thirds of the HCW in Iraq were sleepless (68.3%) and that the majority of them were stressed (93.7%). In addition, female workers had a significantly worse sleep quality compared to male workers (Abdulah 2020). Jahrami 2020 found that in a sample of 257 Bahraini HCW, approximately 60% of both frontline and non-frontline HCW had poor sleep quality combined with moderate or severe stress.

Sleep quality as also been investigated, as well as its link with anxiety has been examined. Huang 2020 found that, compared to other occupations, 23.6% of HCW reported the highest rate of poor sleep quality (73.6%). Moreover, the prevalence of poor sleep quality was significantly higher in HCW who spent a large proportion of time (three hours/day or greater) thinking about COVID-19 than in those who spent less time (less than one hour/day and one to two hours/day). Wang 2020 found that those residents who believed COVID-19 had caused a high number of deaths or who thought that COVID-19 was not easy to cure were more likely to experience sleep disorders. Similarly, Xiao 2020b found that, in a sample of 180 mental HCW, anxiety levels significantly affected their levels of stress and significantly reduced their sleep quality. Magnavita 2020 found that, in a sample of 595 Italian HCW, sleep was a moderating factor in the relationship between occupational stress and anxiety. Korkmaz 2020 also found that, in a sample of 140 Turkish HCW, nurses had more sleep problems compared to physicians and assistant healthcare staff. In addition, the quality of life scores of nurses was also lower.

Other authors have found a relationship between poor sleep quality and post-traumatic stress disorder (PTSD). For example, Liu 2020a found that those HCW who slept better and had fewer early morning awakenings reported fewer PTSD symptoms.

Previous research on sleep problem treatments previous to the COVID-19 pandemic has shown the efficacy of some non-pharmacologic interventions: sleep hygiene, relaxation techniques for arousal reduction, time in bed restriction, cognitive interventions to modify biased cognition, and music for sleep quality (Wagley 2013). In addition, cognitive therapy, in the form of face-to-face (Buysse 2011), and remote modalities (Ritterband 2009), is as efficacious in different groups of patients. Hu and colleagues conducted a systematic review in 2015 to assess the efficacy of non-pharmacologic interventions for sleep promotion in critically ill adults in the intensive care unit (ICU) (Hu 2015). Although the certainty of the evidence was very low and results were inconsistent across studies, the authors found that there were positive effects of earplugs or eye masks, or both, on total sleep time. In addition, there was some evidence that music could improve subjective sleep quality and quantity. Moreover, relaxation techniques, foot massage, acupressure, social support (increased family visits), sleep hygiene provided by nurses, and sound masking provided small improvements in various subjective measures of sleep quality and quantity. There is emerging evidence of the effectiveness of certain interventions for the improvement of sleep quality and the reduction of anxiety in people with COVID-19, such as progressive muscle relaxation (Liu 2020b). Additionally, there is one ongoing randomized controlled trial (RCT) assessing an online

intervention (self-help leaflet with techniques for identifying and addressing sleep-dysfunctional thinking) for poor sleep during the current pandemic (Elder 2020).

The short-term consequences of sleep disruption include increased stress responsivity; somatic pain; reduced quality of life; emotional distress and mood disorders; and cognitive, memory, and performance deficits. The long-term consequences of sleep disruption include hypertension, dyslipidemia, cardiovascular disease, weight-related issues, metabolic syndrome, type 2 diabetes mellitus, and colorectal cancer (Medic 2017).

Description of the intervention

Non-pharmacologic interventions are the first approach in a stepped-care model of sleep problems, due to their minimal adverse effects and lower costs (Reynolds 2017). Previous research on treatments for sleep problems has shown the efficacy of some non-pharmacologic interventions, such as Cognitive Behavioural Therapy (CBT), both in the form of face-to-face (Buysse 2011) and remote modalities (Ritterband 2009). According to this model, sleep-incompatible behaviors and sleep-related dysfunctional cognitions play a major role in maintaining and exacerbating sleeping difficulties over time (Belanger 2006). CBT for sleep problems aims to improve sleep by two means: changing poor sleep habits and challenging negative thoughts, attitudes and beliefs about sleep (Montgomery 2003). CBT includes procedures such as sleep hygiene, stimulus control, sleep restriction, relaxation techniques for arousal reduction, and cognitive restructuring (Altena 2020).

The aim of Sleep Hygiene is to teach patients about the impact that lifestyle habits (e.g. diet, exercise and drug use) and environmental factors (e.g. light, noise and temperature) have on sleep (Hauri 1991). Studies generally recommend the avoidance of caffeine, nicotine, alcohol, heavy meals and exercise close to bed-time. while also minimising noise, light and excessive heat in the bedroom (Montgomery 2003). Stimulus control (Bootzin 1991) involves a set of instructions oriented at helping patients to re-associate the bed, bedtime and bedtime stimuli with sleep rather than with the frustration or anxiety resulting from trying to fall asleep. Patients are instructed to (1) only go to bed when sleepy; (2) only use the bed for sleeping and sex; (3) leave the bed if they have not gone to sleep within 15-20 minutes and to go back only when feeling sleepy again, (4) get up at the same time each morning regardless of the amount of sleep achieved in the previous night; and (5) avoid sleeping during the day (Montgomery 2003). Sleep Restriction (Spielman 1987a) is a method that involves restricting or limiting a patient's time in bed (TIB, sleep window) to match their average total sleep duration (Kyle 2014). The sleep window is weekly adjusted based on the individual's sleep efficiency (the proportion of TIB spent asleep). When sleep efficiency reaches 90%, the time allowed in bed increases by 15-20 minutes. These adjustments continue until the expected optimal amount of sleep time for that particular patient is reached (Montgomery 2003). Progressive muscle relaxation (Jacobsen 1938) is a deep muscle relaxation method based on the premise that muscle tension is the physiological response of the human body to irritating thinking (Cougle 2020). Some studies have also added imagery to the relaxation (Borkovec 1978). Cognitive restructuring aims at identifying and challenging anxiety-related beliefs associated with insomnia (Ziv 2008).

Moreover, music might also be an efficacious intervention (Wagley 2013). Generally, the intervention involves the use of pre-recorded music in relation to sleep initiation. Music listening can be used passively, or it can be used actively with specific instructions (e.g. relaxation instructions; Jespersen 2015).

Regarding yoga, it is an ancient form of exercise that focuses on strength, flexibility, and breathing to boost physical, mental and spiritual health (Feuerstein 2008). There are many different styles of yoga, such as Tibetan, Iyengar, and Hatha Yoga. Some styles are more vigorous than others, whereas some may have different areas of emphasis, such as posture or breathing. Yoga is also characterized as a mindful mode of physical activity. Mindfulness, as an important component of yoga, improves sleep disturbance by increasing melatonin levels, reducing hyperarousal, and addressing stress related cardiac and respiratory abnormalities (Zeichner 2017).

Finally, and considering the pandemic context, remote modalities of the aforementioned interventions may be extremely useful for reaching potential isolated people with sleep problems. Specific remote, web-based non-pharmacologic interventions (e.g. Internet-delivered CBT; ICBT) require a treatment software platform (Vlaescu 2016) through which participants can interact with their therapists in a safe way and perform a number of activities, such as reading specific treatment modules, answering self-report questionnaires on treatment progress, doing interactive homework, watching videos, listening to audio files, and more (Andersson 2014). Content can be delivered in the form of text, video or audio, and presented in the platform together with homework assignments (Andersson 2019). The layout of pages in the platform can adapt to screen size, ensuring a fully-functional user experience regardless of whether the platform is accessed using a desktop computer, a mobile phone (smartphone) or a tablet (Vlaescu 2016).

How the intervention might work

Non-pharmacologic interventions for sleep problems act through different mechanisms of action that have been previously conceptualized according to three theoretical models of insomnia (Schwartz 2012).

The behavioral model of sleep problems focuses on the disruption of homeostatic sleep mechanisms and circadian rhythms. Behaviors that disturb homeostatic regulation like daytime napping, spending excessive time in bed, going to bed early, and inactivity are examples of sleep-related behaviors that negatively impact the homeostatic system by preventing the accumulation of sleep drive throughout the day. Likewise, improper sleep scheduling, including irregular sleep times and sleeping outside one's optimal window, may alter the structure of circadian rhythms with negative outcomes. Accordingly, behavioral interventions look to rearrange the dysfunctional patterns of behavior that perpetuate sleep problems by restricting time in bed and increasing regularity in sleep schedule (Spielman 1987b).

The cognitive model proposes that people with sleep problems incur cycles of worry and rumination about the inability to sleep and about the negative consequences of sleep problems on daily functioning, together with the development of erroneous beliefs about sleep and worry (Harvey 2002). As a consequence, the increased anxiety causes hypervigilance and paradoxical arousal

before sleep, and leads to the adoption of counterproductive safety behaviors that alleviate the arousal (like napping or drinking alcohol) but ultimately maintain the dysfunctional cycle. Cognitive interventions such as psychoeducation and cognitive restructuring intend to correct dysfunctional beliefs and inadequate worry management, thereby improving sleep outcomes.

Finally, hyperarousal models based on the principles of classical conditioning, postulate that bed and sleep environment become associated with arousal after repeated associations with poor sleep and sleep-incompatible behaviors in the bedroom (e.g., reading, watching TV, eating) (Riemann 2010). Behavioral interventions such as stimulus control and techniques that favor relaxation like music therapy, muscular progressive relaxation, meditation, or yoga would be expected to reduce hyperarousal and subsequently improve sleep.

Why it is important to do this review

During the COVID-19 pandemic there has been an increase in sleep problems (i.e. insomnia, nightmares, fatigue, exhaustion; Partinen 2021). Although pharmacologic therapies are often preferred for the treatment of sleep disturbances (Abad 2015), they are frequently associated with relevant side effects, such as impaired cognitive function, risk of tolerance or dependency, depressed ventilation, and adversely affected normal sleep physiology (Mistraletti 2008). This critical aspect highlights the need to count with non-pharmacologic interventions for sleep problems within the current pandemic.

Moreover, the economic impact of the pandemic in different settings should be considered. As it reaches low-and middle-income countries (LMICs), its effects could be even more direct. It is more difficult for such countries to respond to the pandemic due to a shortage of healthcare providers, a lack of personal protection equipment, and the necessary resources to treat people will be in short supply. Furthemore, social distancing in LMICs is almost impossible due to overcrowding (Bong 2020). As a consequence, remote interventions could be extremely useful for reaching potentially isolated people who have sleep problems.

To our knowledge, no systematic review about non-pharmacologic interventions had been conducted before the emergence of the pandemic. With regard to the current pandemic, there is an ongoing randomized controlled trial (RCTs) that aims to evaluate the efficacy of an online CBT programme to specifically address immediate perceived stress in health workers, as well as the prevention of mental health problems (e.g. sleep problems, PTSD and depression) at 3- and 6-months follow-up (Weiner 2020). Moreover there is one pre-print which aims to evaluate the impact of a psychoeducational, mobile health intervention based on CBT and mindfulness-based approaches on the mental health (e.g. insomnia, stress, depression, anxiety, burnout, PTSD and self-efficacy) of healthcare workers at the frontline against COVID-19 in Spain (Serrano-Ripoli 2021).

Hwever, to date, no systematic review has evaluated the effectiveness of remote non-pharmacologic interventions for sleep problems in HCW during the COVID-19 pandemic.Thus, taking into account existing multicultural studies of sleep affection, both in the current pandemic and previous ones, and past research about the efficacy of several interventions to improve sleep, we consider it necessary to carry out a review about this issue.

OBJECTIVES

To assess the effects of remote non-pharmacologic interventions, compared with other specific intervention, non-intervention or alternative intervention for sleep problems in in healthcare workers during the coronavirus disease 2019 outbreak.

METHODS

Criteria for considering studies for this review

Types of studies

RCTs, including cluster-randomized trials and cross-over trials.

Types of participants

HCWs of 18 years of age or older, such as physicians, nurses, midwives, nursing assistants, pharmacists, physical therapists, occupational therapists, dentists, dental assistants, laboratory technicians, dispensers, medical assistants or clinical officers, and radiographers with sleep problems during the COVID-19 pandemic. Sleep problems for this review will include:

- difficulties in initiating and maintaining sleep;
- sleep efficiency;
- sleep latency;
- delayed or advanced sleep phase problems;
- parasomnias;
- impaired daytime functioning.

Types of interventions

Experimental intervention

Specific remote (such as web-based or by mobile telephone) non-pharmacologic interventions for sleep problems including:

- psychological, including cognitive or behavioral interventions, muscle relaxation, mental imagery and meditation-based interventions;
- music therapy;
- environmental interventions, such as noise reduction and lighting control.

Comparators

- attention placebo;
- pharmacologic or nutritional supplements interventions;
- waiting list;
- social support interventions (interventions that involve direct interaction with the person's social environment, such as information, tangible help, care, companionship, and emotional support).

We will compare any experimental intervention against each other or against any comparator.

Types of outcome measures

Primary outcomes

- changes in clinician's ratings of insomnia symptoms and sleeps problems (e.g. Espie 2014);

- changes in self-report ratings of insomnia symptoms and sleeps problems (e.g. Insomnia Severity Index (Morin 1993));
- changes in clinician's ratings of sleep quality (e.g. Espie 2014));
- changes in self-report ratings of sleep quality (e.g. Pittsburgh Sleep Quality Index (Buysse 1989));
- sleep duration;
- any adverse events.

Secondary outcomes

- changes in clinician's ratings of anxiety (e.g. Hamilton Anxiety Scale (Hamilton 1959));
- changes in clinician's ratings of depression (e.g. Hamilton Depression Scale (Hamilton 1960));
- changes in clinician's ratings of functional adjustment (e.g. Clinical Global Impression (CGI) scale (NIMH 1985);
- changes in self-report ratings of anxiety (e.g. Beck Anxiety Inventory (Beck 1988));
- changes in self-report ratings of depression (e.g. Beck Depression Inventory II (Beck 1996));
- changes in self-report ratings of emotional regulation (e.g. Emotional Regulation Questionnaire (Gross 2003));
- changes in self-report ratings of quality of life (e.g. 36-item Short-Form health survey (SF-36) (Ware 1992));
- occupational accidents.

Outcomes will be presented at three time points: short term (up to three months), medium term (three to six months), and long term (more than six months). These time points will be treated as different outcomes.

Hierarchy of outcome assessment

Outcomes from self-administered and clinician-administered scales will be analyzed separately. When faced with more than one scale, we will opt for the validated one. If all the scales are validated, we will select the one with the best psychometric properties or the most frequently used.

We will not exclude studies on the basis of outcomes reported.

Search methods for identification of studies

Electronic searches

Electronic searches

1. We will search the following bibliographic databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource:

- Cochrane Central Register of Controlled Trials (CENTRAL) (current issue) in the Cochrane Library;
- Cochrane COVID-19 Study Register (Covid-19.cochrane.org);
- Ovid MEDLINE databases (2019 onwards) (https://revman.cochrane.org/#/6008200811161607776/dashboard/htmlView/0.24?revertEnabled=true#APP-01);
- Ovid Embase (2019 onwards);
- Ovid PsycINFO (2019 onwards);
- LILACS (Latin American and Caribbean Health Sciences Literature (2019 onwards).

2. We will search the international trial registers (Clinicaltrials.gov and WHO ICTRP), for unpublished or ongoing trials.

3. We will also search the following databases for interventional or contextual background reviews (all available years):

- Cochrane Database of Systematic Reviews
- Epistemonikos (https://www.epistemonikos.org)
- PsyArXiv (https://psyarxiv.com)
- MedRxiv (https://www.medrxiv.org)
- COVD-19 Best Evidence Front Door (University of Michigan) (https://frontdoor.knack.com/covidbestevidence/)

Searching other resources

We will screen reference lists of included study reports (backward citations) and perform forward citation searches via the Web of Science and Google scholar. We will also contact trialists for additional or unpublished data.

Data collection and analysis

Selection of studies

Two review authors (PL, DA) will independently screen all titles and abstracts using the Covidence Systematic Review Software (Covidence 2019). If it is clear from the title and abstract that the study does not meet the eligibility criteria, it will be rejected. If it is unclear, we will obtain the full text of the study and both review authors will independently evaluate the paper using Covidence to determine if the study should be included or excluded (Covidence 2019). If there is a disagreement, the review authors will try to reach a consensus. If a consensus cannot be reached, a third review author (FT) will independently assess the study and resolve the disagreement. We will identify and exclude duplicate records and we will collate multiple reports that relate to the same study so that each study, rather than each report, is the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA flow diagram and record reasons for exclusion in the 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors (PL, DA) will independently extract data from each included study, using a data extraction form, which will be piloted on at least one trial included in the review. We will extract the following study characteristics:

- methods: study design, total duration of study, number of study centers and location, study setting, withdrawals, and date of study;
- participants: number, mean age, age range, gender, baseline symptoms, severity of condition, diagnostic criteria, inclusion criteria, exclusion criteria, and comorbid conditions;
- interventions: intervention, comparison, frequency, mode of delivery, concomitant interventions, and excluded medications;
- outcomes: primary and secondary outcomes specified and collected, and time points reported;
- notes: funding for trial, and notable conflicts of interest of trial authors.

If outcome data are not reported in a usable way (e.g. missing standard deviations (SD) or 95% confidence intervals (CIs), we will note this in the 'Characteristics of included studies' table. We will

resolve disagreements by consensus or by involving a third review author (DC). One review author (AC) will transfer data into Review Manager 5 (Review Manager 2020). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (PL) will spot-check study characteristics for accuracy against the study report.

The review authors will resolve any difference of opinion by consensus. If they are unable to do so, a third review author (FT) will be included in the decision process. All three review authors will discuss the issue and make a final decision.

Assessment of risk of bias in included studies

We will evaluate the risk of bias in each included trial using the seven criteria described in Table 8.5.d ('Criteria for judging risk of bias in the "Risk of bias" assessment tool') of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Two review author (PL, AC, or SFN) will independently assess the risk of bias in the following domains using Covidence 2019:

- random sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data;
- selective outcome reporting;
- other bias.

We will judge each potential source of bias as high, low, or unclear and will provide a supporting quotation from the study report together with a justification for our judgment in the 'Risk of bias' table. If there are discrepancies between their assessments, and the two review authors are unable to reach a consensus, a third review author (AC) will join the decision-making process. All three review authors will discuss the issue and make a final decision. We will summarize the 'Risk of bias' judgments across different studies for each of the domains listed. Where necessary, we will contact the trial authors for further information. Where information on risk of bias relates to unpublished data or correspondence with a trial author, we will note this in the 'Risk of bias' table. We will present all 'Risk of bias' data graphically and in the text.

Measures of treatment effect

Continuous data

We will calculate mean differences (MD) when studies use the same measure and standardized mean differences (SMD) when studies use different measurement scales, and we will present them with 95% CIs. We will convert SMD to relevant scales for clinical understanding. When necessary, we will calculate the SD from the P values, t statistics, CIs, or other available statistics. We will interpret the magnitude of effect for the SMD using a general rule where we consider 0.2 as a small effect, 0.5 as a moderate effect, and 0.8 as a large effect (Cohen 1988). For the studies that report only change scores, we will perform separate analyses from the studies that provide only final values. We will combine both values using the generic inverse variance method (Deeks 2019).

If we find skewed data, we will make a log transformation.

Dichotomous data

For dichotomous outcomes, we will calculate risk ratios (RR) and 95% CIs.

Unit of analysis issues

For each included study, we will determine the appropriateness of the unit of analysis for the unit of randomization and the design of each study (the number of observations have to match the number of units that were randomized). We expect to find trials with a simple parallel-group design, with participants randomly allocated as individuals, and a single measurement collected and analyzed for each outcome from each participant.

Cluster-randomized trials

In the event of cluster-randomized trials, if the reported analysis does not correctly account for the cluster design we will reanalyze the effect estimates using the intracluster correlation coefficient (ICC), the number of clusters (or groups) randomized to each intervention group and the total number of participants in the study; or the mean size of each cluster if available.

If this is not possible, we will conduct a sensitivity analysis excluding the trials that do not adjust for clustering.

Cross-over trials

In the case of cross-over trials, we will consider the first phase, if presented since there is no clear knowledge about a washout period.

Studies with more than one treatment arm

Where multiple trial arms are reported in a single trial, we will include data from only the relevant arms.

When a study presents multiple arms relevant to our question, we will analyse them in separate comparisons and we will split the control group to avoid double-counting. For dichotomous variables, we will split the comparison group evenly among the intervention groups; for continuous variables, we will divide the total number of participants and we will leave the mean and SD values unchanged (Higgins 2019).

In the case that intervention arms were pretty comparable and have similar effect we will also collapse them as a secondary analysis. If data are binary, we will add these and combine them within the two-by-two table. If data are continuous, we will combine data following the formula in Section 6.5.2.10 of *the Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

Dealing with missing data

When necessary, we will attempt to contact the corresponding authors of the included studies up to three times to collect any unreported data. We will describe missing data and dropouts for each included study in the 'Risk of bias' table, reporting the reasons for missing data and the number and characteristics of dropouts, and we will discuss in the 'Quality of the evidence' section the extent to which the missing data could threaten our results due to attrition bias.

For trials that reported MD but no standard deviation (SD) or other statistic that could be used to derive the SD, we planned to use

imputation (Furlan 2009). Specifically, we planned to impute SDs for each outcome by using the pooled SD across all other trials within the same meta-analysis by treatment group. This is an appropriate method of analysis if a majority of the trials do not have missing SDs in the meta-analysis. Where reported we will include intention-to-treat (ITT) data. If these data are not reported we will include ITT and observed case (OC) data if available in sensitivity analyses.

Assessment of heterogeneity

We will appraise the extent of clinical heterogeneity among the studies by comparing the distribution of participant characteristics (comorbidity, severity, baseline symptoms). For methodologic heterogeneity, we will assess the study factors (randomization, allocation concealment, blinding of outcome assessment, loss to follow-up, treatment type, type of control group, cointerventions, different types of outcome measurements).

In addition, we will deem a low P value for the Chi^2 test (less than 0.10) as sufficient reason to explore causes of heterogeneity.

We will describe the statistical heterogeneity of the intervention effects by calculating the I^2 statistic and using the Chi^2 test. The thresholds we will use for the interpretation of the I^2 statistic can be misleading because the importance of inconsistency depends on several factors. We will interpret it as follows:

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

We will also take the magnitude and direction of effects into account.

Assessment of reporting biases

If we include at least 10 studies in a meta-analysis, we will use funnel plots to detect bias. Funnel plot asymmetry can be due to publication bias, but it can also be due to a real relationship between trial size and effect size, such as when larger trials have a lower adherence, and adherence is positively related to effect size. In general, asymmetry may be due to selection biases (publication bias, delayed publication bias, location bias, selective outcome reporting), poor methodologic quality leading to spuriously inflated effects in smaller studies (poor methodologic design, inadequate analysis, fraud), true heterogeneity, or chance (Egger 1997). We will use the test proposed by Egger 1997 for continuous outcomes to test for funnel plot asymmetry (Page 2019).

Data synthesis

We will synthesize the results in a meta-analysis using Review Manager 5 when we consider studies to be sufficiently homogeneous in terms of population, interventions, and comparisons to avoid clinical heterogeneity, and in terms of outcome measurement methods to avoid methodologic heterogeneity (Review Manager 2020). Two review authors will assess homogeneity independently and solve discrepancies by consensus. Because we assume that clinical heterogeneity is very likely to impact our review results, given the nature of the interventions included, we will primarily report the results of the random-effects model, regardless of statistical evidence of heterogeneity. We will calculate all effects using inverse variance methods. For continuous data, the change in score from baseline to postintervention will be the main outcome of interest. Final and change scores will be combined when the same outcome measurement tool is used (MD). Otherwise, we will analyze separately continuous data reported as change scores in some studies and as final values in other studies. In order to combine final values and change scores, we will use the generic inverse variance method (Deeks 2019).

Subgroup analysis and investigation of heterogeneity

We will conduct subgroup analyses, classifying the trials by severity (mild/moderate and severe as defined by the trial authors), in order to assess if the efficacy of the intervention could be less effective in the most severe clinical presentations. We will calculate a pooled effect size for each subgroup, if there are sufficient data. In addition, we will compare subgroups using the Chi^2 test for subgroup differences.

Sensitivity analysis

We will conduct sensitivity analyses to assess the impact of risk of bias on the results for the primary outcomes. We will remove:

- studies with high risk of selection bias (associated with sequence generation or allocation concealment);
- studies with high risk of performance bias (associated with issues of blinding);
- studies with high risk of attrition bias (associated with completeness of data);
- studies with imputed data.

We will perform a sensitivity analysis by excluding cluster-RCTs.

Summary of findings and assessment of the certainty of the evidence

We will construct 'Summary of findings' tables to present the main findings of the review. We will generate these tables using GRADEpro GDT software (GRADEpro GDT), which imports data from Review Manager 5 (Review Manager 2020). We will follow standard methods as described in *the Cochrane Handbook for Systematic Reviews of Interventions* to prepare the tables (Schünemann 2019). One experienced review author (AC or PL) will assign certainty of evidence ratings and a second review author will verify the assignment. Where possible, we will present a 'Summary of findings' table for each of the two comparisons and include information on the primary outcomes of our review: changes in self-report and clinician's ratings of insomnia symptoms and sleeps problems, changes in self-report and clinician's ratings of sleep quality, sleep duration and any adverse events. We will assess the certainty of evidence using five factors:

- limitations in trial design and implementation of available trials;
- indirectness of evidence;
- unexplained heterogeneity or inconsistency of results;
- imprecision of effect estimates;
- potential publication bias.

For each outcome, we will classify the certainty of evidence according to the following categories:

- high certainty: further research is very unlikely to change our confidence in the estimate of effect;
- moderate certainty: further research is likely to have an important impact on our confidence in the estimate of effect, and may change the estimate;
- low certainty: further research is very likely to have an important impact on our confidence in the estimate of effect, and is likely to change the estimate;
- very low certainty: we are very uncertain about the estimate.

We will downgrade the evidence from high certainty by one level for serious (or by two for very serious) study limitations (risk of bias), indirectness of evidence, serious inconsistency, imprecision of effect estimates, or potential publication bias.

We will present the following outcomes in the 'Summary of findings' table:

- changes in self-report ratings of insomnia symptoms and sleeps problems;
- changes in clinician's ratings of insomnia symptoms and sleeps problems;
- changes in clinician's ratings of sleep quality;
- changes in self-report of sleep quality;
- sleep duration;
- any adverse events;

We will prioritize the longest-term outcomes available for presenting in the 'Summary of findings' table. Due to the relatively brief time elapsed since the beginning of the COVID-19 pandemic, it is highly probable that most studies included in the present review will report short-term outcomes. However, since sustained effects are of importance in assessing health interventions targeted to the general population, we will include longer-term outcomes when available.

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APPENDICES

Appendix 1. Search strategy

Draft MEDLINE Search

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 onwards>

Search Strategy:

[Outcome]

1 exp "Sleep Initiation and Maintenance Disorders"/
2 insomni*.mp.
3 Sleep Disorders/
4 exp sleep/
5 sleep*.tw,kf.
6 Wakefulness/
7 wakeful*.tw,kf.
8 or/1-7

[Exposure]

9 Coronavirus/
10 exp Coronavirus Infections/
11 Coronaviridae Infections/
12 COVID-19.rs.
13 severe acute respiratory syndrome coronavirus 2.os.
14 (2019 nCoV or 2019nCoV or 2019-novel CoV).tw,kf.
15 (corona vir* or coronavir* or neocorona vir* or neocoronavir* or betacoronavir* or beta-coronavir*).tw,kf.
16 COVID.mp.
17 COVID-19.rs.
18 (COVID19 or COVID-19 or COVID2019 or COVID-2019).tw,kf.
19 COVID*.ti.
20 nCov*.tw,kf.
21 ("SARS-CoV-2" or "SARS-CoV2" or SARSCoV2 or "SARSCoV-2").mp.
22 ("SARS coronavirus 2" or "SARS-like coronavirus" or "Severe Acute Respiratory Syndrome Coronavirus-2").mp.
23 severe acute respiratory syndrome coronavirus 2.os.
24 (lockdown or lock* down*).mp.
25 ((epidemic? or pandemic* or global* or international or worldwide or world wide) adj5 (quarantine? or isolat* or confine*)).mp.
26 or/9-25
27 (8 and 26)

[Study Design-1 (RCTs)]
28 controlled clinical trial.pt.
29 randomized controlled trial.pt.
30 clinical trials as topic/
31 (randomi#ed or randomi#ation or randomi#ing or randomly).ti,ab,kf.
32 (RCT or cRCT or "at random" or (random* adj3 (administ* or allocat* or assign* or class* or cluster or crossover or cross-over or control* or determine* or divide* or division or distribut* or expose* or fashion or number* or place* or pragmatic or quasi or recruit* or split or subsitut* or treat*))).ti,ab,kf.
33 placebo.ab,ti,kf.
34 trial.ti.
35 ((control* adj3 group*) or groups).ab.
36 (control* and (waitlist* or wait* list* or ((treatment or care) adj2 usual))).ti,ab,kf,hw.
37 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).ti,ab,kf.

38 double-blind method/ or random allocation/ or single-blind method/
39 or/28-38
40 exp animals/ not humans.sh.
41 (39 not 40)
42 (27 and 41)

[Study Design-2 (Systematic Reviews)]
43 meta-analysis/ or "systematic review"/
44 (systematic or structured or evidence or trials or studies).ti. and ((review or overview or look or examination or update* or summary).ti. or review.pt.)
45 (0266-4623 or 1469-493X or 1366-5278 or 1530-440X or 2046-4053).is.
46 meta-analysis.pt. or (meta-analys* or meta analys* or metaanalys* or meta synth* or meta-synth* or metasynth*).ti,ab,kf,hw.
47 ((systematic or meta) adj2 (analys* or review)).ti,kf. or ((systematic* or quantitativ* or methodologic*) adj5 (review* or overview*)).ti,ab,kf,sh. or (quantitativ$ adj5 synthesis$).ti,ab,kf,hw.
48 (integrative research review* or research integration).tw. or scoping review?.ti,kf. or (review.ti,kf,pt. and (trials as topic or studies as topic).hw.) or (evidence adj3 review*).ti,ab,kf.
49 review.pt. and ((medline or medlars or embase or pubmed or scisearch or psychinfo or psycinfo or psychlit or psyclit or cinahl or electronic database* or bibliographic database* or computeri#ed database* or online database* or pooling or pooled or mantel haenszel or peto or dersimonian or der simonian or fixed effect or ((hand adj2 search*) or (manual* adj2 search*))).tw,hw. or (retraction of publication or retracted publication).pt.)
50 (rapid review? or (mixed method? adj (synthes* or research or review)) or (thematic adj (review or synthes* or summary)) or ((integrative or realist) adj (synthes* or review)) or (narrative adj (review or synthes* or summary))).mp.
51 or/43-50
52 (27 and 51)
53 (42 or 52)
****

CONTRIBUTIONS OF AUTHORS

FT: overall responsibility for the protocol, protocol writing and methodologic design.
PL: protocol writing and methodologic design.
DC: search strategy design.
DA: protocol writing.
SFN: protocol writing.
LR: protocol writing and methodologic design.
AC: overall supervision of the protocol.

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FT: none.
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DC: none.
DA: none.
SFN: none.
LR: none.
AC: none.

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