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Does Improving Sleep Lead to Better Mental Health and Wellbeing? A Protocol for a Meta-Analytic Review of Randomised Controlled Trials

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Abstract

Introduction: Sleep and mental health go hand-in-hand, with many, if not all, mental health problems being associated with problems sleeping. Although sleep has been traditionally conceptualized as a secondary consequence of mental health problems, contemporary views prescribe a more influential, causal role of sleep in the formation and maintenance of mental health problems. One way to evaluate this assertion is to examine the extent to which interventions that successfully improve sleep also improve mental health and wellbeing.

Method and analysis: Randomized controlled trials describing the effects of interventions designed to improve sleep on mental health and wellbeing will be retrieved via a systematic search of bibliographic databases. Following this, meta-analysis will be used to synthesize the effects reported in eligible trials and investigate the impact of variables that could potentially moderate the effect of changes in sleep on outcomes pertaining to mental health and wellbeing.

Ethics and dissemination: This study requires no ethical approval. We will submit the findings for publication in a peer-reviewed journal and promote the review to relevant stakeholders (i.e., clinicians, policy makers, and the general public).

Word count: 180 words

Keywords: Meta-analysis; protocol; review; sleep; mental health; wellbeing; intervention

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Strengths

- The present review will significantly strengthen the evidence base on the effect of interventions designed to improve sleep on mental health and wellbeing outcomes.
- The present review will elucidate the causal relationship between sleep and mental health.
- We will use the GRADE system to report the strength of the evidence base. This will allow members of the public, researchers and clinicians to quickly access the available evidence and judge its quality.

Limitations

- The present review will include a diverse range of interventions and target problems that might lead to a heterogeneous group of studies. To mitigate this we will use moderation analysis to investigate specific factors that might influence the effect of sleep improvement on mental health and wellbeing.

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Does Improving Sleep Lead to Better Mental Health and Wellbeing? A Protocol for a Meta-Analytic Review of Randomized Controlled Trials

Difficulties sleeping and mental health problems are both public health concerns in their own right; with each having a substantive impact on both individuals and society as a whole [1-4]. However, sleep and mental health go hand-in-hand, with many, if not all, mental health problems being associated with problems sleeping [5-7]. Traditionally, sleep problems have been viewed as a consequence of mental health problems; however, evidence suggests that problems sleeping can contribute both to the formation of new mental health problems [8-10] and to the maintenance of existing ones [11-13]. In other words, sleep is now thought to be causally related to mental health, with problems sleeping likely to influence both the onset and trajectory of a variety of mental health difficulties. Having said this, although a number of empirical studies have manipulated sleep and examined the impact of so doing on outcomes related to mental health, to date there has not been a systematic review of these studies. Consequently, the magnitude of the effect of (changes in) sleep on mental health problems is difficult to estimate and has not been compared between different mental health outcomes and other factors that might influence the effect (e.g., across different groups of participants, research designs, and approaches to intervention).

The potential for a causal relationship between sleep and mental health also raises an intriguing prospect; namely, that interventions designed to improve sleep could also improve mental health. Providing a definitive answer to this question would have important implications for clinicians, researchers, and members of the public alike. From a practical perspective, if interventions designed to improve sleep can change mental health outcomes, then they may be a useful tool for tackling mental health difficulties. Indeed, interventions designed to improve sleep can often be delivered remotely, in self-help and group formats, and / or at little cost

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through the internet [14-18]. For example, a meta-analysis by Ho et al. reported that self-help interventions based on the principles of CBT for insomnia (termed CBTi) had medium-to-large effects on the symptoms of insomnia[16].

Problems with extant literature and opportunities

The relationship between sleep and mental health is well documented, with numerous reviews testifying to a robust link between the two [6-8 19-24]. However, the majority of these reviews have tended to focus on primary studies with correlational research designs. That is, they either; i) measure associations between variables at a single time point (i.e., cross-sectional designs); or ii) measure associations between variables at multiple time points (i.e., longitudinal designs). For example, many reviews simply report the typical sleep profiles of those with mental health difficulties relative to those without [25-28]. Cross-sectional designs simply tell us that variables are associated in some way. It is impossible to determine whether sleep causes mental health complaints, or mental health complaints cause difficulties sleeping, or whether the effect is bi-directional in nature.

Longitudinal studies, although still correlational in nature, are better able to elucidate causality than their cross-sectional counterparts. However, only a handful of reviews have provided evidence on the relationship between sleep (at one point in time) and mental health outcomes (measured later), and all of these have focused on depression, tending to report that poor sleep quality is associated with depression [8 29-31]. For example, Baglioni et al. [8] conducted a meta-analytic evaluation of 21 studies investigating the longitudinal associations between insomnia and depression. Baglioni et al. reported that non-depressed people with insomnia had a twofold risk of developing depression compared to people who did not experience difficulties sleeping at baseline. Longitudinal designs, although better placed to infer causation, are still

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susceptible to the 'third variable problem' [32-34]. Namely, that a third, unmeasured variable (e.g., having young children) could cause both sleep difficulties and mental health problems. In summary, correlational designs are not a valid way of disentangling the relationship between problems sleeping and mental health.

Some reviews have assessed the impact of interventions designed to improve sleep on mental health outcomes [18 35-38 24 39 40]. However, even these reviews do not permit us to draw robust conclusions as to the causal impact of sleep quality on mental health outcomes for a number of reasons. First, these reviews often include interventions that have not successfully manipulated sleep (i.e., studies in which there was no significant impact of the intervention on sleep outcomes). Such studies do not tell us anything about the relationship between sleep and mental health other than that it can be difficult to improve sleep. Second, the focus of extant reviews reporting both sleep and mental health variables has been on improving sleep, with the measurement of mental health outcomes typically limited to depression and anxiety. Consequently, the effect of improving sleep on other mental health difficulties and wellbeing more broadly is currently unclear.

Finally, to our knowledge, there has been no attempt to date to investigate variables that influence, or *moderate*, the impact of interventions that improve sleep on mental health. Interventions designed to improve sleep are likely to vary in their content and delivery, and such variables may influence how effective they are in improving sleep and / or mental health outcomes. Furthermore, variables related to the nature of the sample (e.g., age, severity of symptoms, nature of the mental health problem) and methodological features of the primary study (e.g., self-report vs. objective assessment of the outcome variables, and so on) are likely to influence the effect of the respective intervention. It is therefore crucial that the impact of such

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variables is systematically examined across the extant evidence base in order to draw reliable and valid conclusions about the impact of changes in sleep on outcomes pertaining to mental health and well-being.

The proposed review

A number of primary research studies have experimentally manipulated sleep (typically via some sort of psychological intervention) and then measured mental health outcomes. However, these individual studies have, to our knowledge, never been integrated in a manner that allows the magnitude of the effect of sleep on mental health outcomes to be estimated. Therefore, it is currently difficult to; i) draw firm conclusions about the relationship between sleep and various mental health problems; and ii) recommend with any confidence that mental health problems might be tackled using interventions that have been designed to improve sleep. Furthermore, there has been no attempt to date to understand the factors that influence, or moderate, the effect of improvements in sleep on mental health. As a consequence, clinicians, researchers, and members of the public may be unaware of whether and how the content and nature of the intervention(s), target sample and mental health problem, and methodological features of the primary study can influence the efficacy of an intervention.

Objectives

The proposed review therefore has two broad objectives; i) to synthesize and quantify the effect of interventions that *successfully* improve sleep quality on mental health outcomes; and ii) to explore variables that moderate the effect of interventions targeting sleep on both sleep and mental health outcomes.

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Method and Analysis

This protocol has been prepared in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P, see Supplementary Materials 1) checklist [41].

Eligibility Criteria

Inclusion criteria

In order to be included in the proposed review, the primary studies need to:

1. Randomly allocate participants to either an experimental group that receive an intervention that is designed to improve sleep or a comparator group.
2. Report a statistically significant improvement on a measure of sleep quality among participants in the experimental group as compared to those in the comparison group.
3. Include a measure of mental health outcomes subsequent to the measure of sleep quality.
4. Report sufficient data for us to be able to compute an effect size. Where sufficient data is not reported, we will contact the authors and request further data. However, if this is not provided then the study will not be included in the review.

Exclusion criteria

The aim of the proposed review is to be as inclusive as possible and address potential differences between the primary studies (e.g., differences in the nature of the intervention or the mental health problem under consideration) using moderation analysis. Therefore, very few exclusion criteria will be applied. For example, we will not restrict the type of intervention (e.g., psychological and pharmacological), publication status, nature of the comparison condition, or sample. However, studies with the following characteristics will be excluded in order to ensure

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that we can reliably assess the independent contribution of changes in sleep to mental health outcomes:

1. Studies where the intervention contains elements that specifically target a mental health problem alongside improving sleep (e.g., an intervention that provides CBT for anxiety alongside efforts to improve sleep).
2. Studies adopting a pre-post (or within participant) design.

Information Sources

The proposed review will use a combination of search techniques and sources in order to identify potential studies. First, we will search MEDLINE, Embase, PsycINFO, and The Cochrane Library using the Cochrane Highly Sensitive Search Strategy[42] to identify randomized controlled trials that include terms relating to sleep quality/disorders and mental health/wellbeing outcomes (see Table 1 for a list of the proposed search terms). The search strategy has been developed in collaboration with a health sciences librarian specializing in systematic search procedures and will be used to search each database (see Supplementary Materials 2 for an example search strategy). Second, the reference lists of extant reviews of the relationship between sleep and mental health (cited in the introduction) will be searched for any potential articles. Third, a search for any unpublished or ongoing studies will be conducted by searching online databases including White Rose Online, The National Research Register, WHO approved clinical trial databases, and PROSPERO. Finally, the authors of articles deemed eligible for inclusion will be contacted and asked if they are aware of any unpublished research that may be eligible for inclusion in the review.

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Data management

All records will be stored in the reference management software Endnote, and we will follow PRISMA guidelines for the selection of studies for meta-analysis [43]. Specifically, when the pool of potential studies have been identified, we will remove duplicates and initially screen each record based on the title and abstract and exclude clearly ineligible studies. Following this initial screening, the full-text versions of each article will be reviewed in detail and cross-referenced with the inclusion and exclusion criteria. The flow of articles through the review, including the reasons for excluding studies will be documented in a PRISMA flow chart.

Data Extraction

Data will be recorded on standardized data extraction forms and a manual to accompany the form will detail each variable to be extracted alongside definitions and examples (see Supplementary Materials 3 & 4). Two reviewers will pilot the data collection forms and manual on three of the included articles in order to ensure that there are no systematic problems or difficulties coding any of the variables. After this, the data will be extracted from the full set of studies by one reviewer. A second member of the review team will second code a subset of the included articles (at least 10%) and levels of agreement will be calculated. Any disagreements will be resolved through discussion, with a third member of the review team acting as arbiter for any outstanding disagreements. The review team will extract meta-data pertaining to source characteristics (e.g., publication status and year,), as well as data relating to the characteristics of the sample (e.g., age, type of sleep/mental health problem etc.), the study (e.g., nature of the comparison group, length of follow-up etc.), and characteristics of the intervention (e.g., theoretical basis, delivery modality etc.) (see Table 2 for an overview of potential moderators that we will code and examine).

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Proposed Analysis

Review Manager 5.3 Cochrane Collaboration, [44] will be used to compute Hedges *g* using the post-treatment means and standard deviations for each variable reflecting sleep quality, mental health and wellbeing reported in studies comparing outcomes between an intervention group (i.e., a group receiving an intervention that improves sleep) and a comparison group (e.g., wait-list, placebo, treatment as usual etc.). Where a study reports multiple outcome measures under one diagnostic category (e.g., several measures of depression), the effect sizes will be computed for each outcome and meta-analyzed in their own right to form one overall effect for inclusion in the main analysis. Where means and standard deviations are not reported and it is not possible to compute Hedges *g* from the data provided in the report (e.g., test statistics, confidence intervals etc.), then we will attempt to contact the author(s) for this information.

The sample-weighted average effect size (g_+) will be computed using a random effects model as studies are likely to be "different from one another in ways too complex to capture by a few simple study characteristics" [45]. Following Cohen's [46] recommendations, $g = 0.20$ will be taken to represent a 'small' effect size, $g = 0.50$ a 'medium' effect size, and $g = 0.80$ a 'large' effect size. We will use these qualitative indices to interpret the findings. Publication bias will be assessed via visual inspection of a funnel plot and Egger's test [47]. Finally, Orwin's [48] formula will be used to determine the fail-safe *n* (i.e., the number of studies producing a null effect that would be needed to reduce the overall effect of interventions that improve sleep on outcomes relating to mental health and wellbeing to a trivial effect size).

Heterogeneity, Bias and Study Quality

The I^2 statistic will be used to assess heterogeneity across all the primary studies [49]. The quality of each individual study included in the present review will be assessed using the Jadad

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scale for reporting randomized controlled trials [50]. The Jadad scale assesses three key areas of methodological quality that potentially impact the risk of bias – namely; randomization, blinding and the flow of participants through the study. In order to assess these areas, raters will be asked to answer three questions including: i) "*Was the study described as randomized (this includes the use of words such as randomly, random, and randomization*)"; ii) "*Was the study described as double blind?*"; and iii) "*Was there a description of withdrawals and dropouts*?". Scores on the Jadad scale range from 0 to 5, with higher scores indicating a lower risk of bias (and therefore higher methodological quality). The Jadad scale for reporting randomized controlled trials has been extensively used as a measure of the methodological quality of RCTs (having received over 7,500 citations to date) and has been recommended as the most reliable and valid scale for assessing the quality of RCTs, in a review of 21 measures [51]. Finally, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system[52 53] will be used to assess the quality of the body of evidence as a whole investigating the effect of interventions to improve sleep on mental health and wellbeing.

Moderation Analysis

Moderation analyses will be performed to identify the variables that influence the effect of interventions that improve sleep on both sleep outcomes, as well as those relating to mental health and wellbeing. For continuous moderators (e.g., age, publication year, study quality etc.), sample weighted meta-regression will be used to investigate the impact of the moderator on effect sizes. For categorical variables (e.g., self-report vs. objective outcome measures, the nature of the comparison condition etc.), the sample weighted mean effect size *g* and associated standard errors will be computed for each level of the moderator and the *Q* statistic will be used to assess if the difference is statistically significant.

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Ethics and Dissemination

As the proposed research is a meta-analytic review of primary studies, no ethical approval is required. We have registered the proposed review on the PROSPERO database in order to adhere to the principles of open research. Following completion of the review, we aim to publish the findings in a peer reviewed academic journal and attend conferences and dissemination events with stakeholders where possible.

Author Contributions

The first author (AJS) had the idea for the proposed review and approached TLW and GR, who contributed to the design of the research. AJS drafted the protocol and TLW and GR provided detailed comments before submission. AJS is the identified guarantor of the review.

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This research has not yet received any funding from the public, commercial or not-for-profit sectors.

Competing Interests

There are no competing interests.

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Table 1

Search Terms that will be Used to Identify Randomized Controlled Trials of Interventions Designed to Improve Sleep on Mental Health Outcomes

HSSS for RCTs[a]	Sleep quality / disorders	Mental health and wellbeing
Randomized controlled trial	Sleep*	"Psychological health"
Controlled clinical trial	"Circadian rhythm*"	Wellbeing
Randomized	Insomnia	Distress
Placebo	Hypersomnia	"Mental"
Drug therapy	Parasomnia	Psychiat*
Randomly	Narcolepsy	Affect
Trial	Apnea	Depress*
Groups	Apnoea	Mood
	Nightmare*	Stress
	"Restless legs syndrome"	Anxi*
		Phobi*
		"Obsessive compulsive disorder"
		OCD
		Psychos*s
		Psychotic
		Schiz*
		Bipolar
		Hallucination*
		Delusion*
		"Eating disturbance*"
		Anorexia
		Bulimia
		"Binge eating"

Notes: * = Indicates that variants of the word after the asterisk will be searched for (e.g., depress* will search for depressive etc.),

[a] The Highly sensitive Search Strategy (HSSS) is more than just a key word search, rather it encompasses search techniques and strategies.

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Table 2

Variables to be Extracted for Moderation Analysis (where applicable)

Source characteristics	Sample characteristics	Study characteristics	Intervention characteristics
Publication status	Age	Nature of comparison group(s)	Theoretical basis
Publication year	Gender	Attrition/drop-out rate	Delivery modality
Journal name	Type of mental health problem(s)	Methodological quality	Duration
Journal impact factor	Type of sleep problem(s)	Timing of follow-up	Self-help vs. face-to-face
	Clinical status	Method of recruitment	Adherence
	Comorbidity	Measure(s) of sleep	
	Measure of mental health	Measure(s) of mental health	
	Concurrent medication use	Study quality	
	Concurrent psychological help		

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Supplementary Materials 1

PRISMA-P Checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Page and line numbers, emboldened and in parentheses, indicate the location of the PRISMA-P item in the corresponding manuscript.

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review **(p. 1)**
Update	1b	If the protocol is for an update of a previous systematic review, identify as such **(NA)**
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number **(p. 1)**
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author **(p. 1)**
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review **(p. 13)**
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments **(NA)**
Support:		
Sources	5a	Indicate sources of financial or other support for the review **(p. 13)**
Sponsor	5b	Provide name for the review funder and/or sponsor **(NA)**
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol **(NA)**
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known **(p.4-7)**
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) **(p. 7)**
METHODS		

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Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review **(p. 8-9)**
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage **(p. 9)**
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated **(see Supplementary Materials 2)**
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review **(p. 10)**
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) **(p. 10)**
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators **(p. 10)**
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications **(see Table 2)**
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale **(p.11. See also Table 2, p. 22)**
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis **(p. 11-12)**
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised **(p.11)**
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ) **(p. 11-12)**
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) **(p. 12)**
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned **(NA)**
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) **(p. 11-12)**
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) **(p. 12)**

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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Supplementary Materials 2

Ovid Medline Example Search Strategy

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

Search Strategy:

---

1 (Sleep$ or Insomnia$ or nightmare$ or hypersomnia$ or parasomnia$ or narcolepsy or circadian rhythm$ or restless leg syndrome or apnea or apnoea).ti,ab. (180111)

2 Sleep/ or Sleep Disorders, Circadian Rhythm/ or Sleep Disorders, Intrinsic/ or Narcolepsy/ or Restless Legs Syndrome/ or Sleep Apnea Syndromes/ or "Sleep Initiation and Maintenance Disorders"/ or Parasomnias/ (70224)

3 1 or 2 (193630)

4 (psychological health or distress or mental or psychiat$ or affect or depress$ or mood or stress or anxious or anxiety or phobi$ or obsessive compulsive disorder$ or OCD or psychos#s or psychotic or schiz$ or bipolar or bi-polar or hallucination$ or delusion$ or eating disorder$ or eating disturbance$ or anorexia or bulimia or binge eating or wellbeing or well-being or QoL or quality of life).ti,ab. (2200869)

5 Stress, Psychological/ or Anxiety Disorders/ or Obsessive-Compulsive Disorder/ or Phobic Disorders/ or exp "Feeding and Eating Disorders"/ or Anorexia Nervosa/ or Binge-Eating Disorder/ or Bulimia Nervosa/ or Depressive Disorder/ or Hallucinations/ or Delusions/ or Anxiety/ or Depression/ or psychotic disorders/ (379929)

6 4 or 5 (2283788)

7 3 and 6 (57412)

8 randomized controlled trial.pt. (446587)

9 controlled clinical trial.pt. (91788)

10 randomized.ab. (389502)

11 placebo.ab. (183719)

12 drug therapy.fs. (1928261)

13 randomly.ab. (270741)

14 trial.ab. (409336)

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15 groups.ab. (1670961)

16 or/8-15 (3972831)

17 exp animals/ not humans.sh. (4311313)

18 16 not 17 (3433652)

19 7 and 18 (19379)

20 (trial$ or intervention$ or treatment$).ti,ab. (4565976)

21 7 and 20 (23924)

22 21 not 19 (11896)

****

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Data extraction form **Study ID:** | | | |

Please consult the '**data extraction coding manual**' for instructions on how to code each.

Article meta-data

1. Please state the surnames and first initials of ***all*** authors of the article (e.g., Smith, J. A., Jones, A. C.);

2. Please state the year that the article was first published: | | | | |

3. What is the publication status of the article? ☐ Published (move to Q3.1)

☐ Unpublished (move to Q4)

3.1. Please state the name of the journal that the article was published in:

Nature of the focal sample

4. State the mean age of the intervention group(s) to the nearest year at baseline:

5. State the percentage of the intervention group(s) that are female at baseline

6. Indicate the clinical status of the **mental health problems** of participants **included** in the study:

☐ Clinical ☑ Non-clinical ☐ Mixed ☐ Not known

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Data extraction form **Study ID:** | | | |

7. Indicate the clinical status of the **sleep related problems** of participants **included** in the study:

☐ Clinical ☐ Non-clinical ☐ Mixed ☐ Not known

8. What **mental-health difficulties**, symptoms or problems experienced by the participants were recorded by the study authors? Please provide details:

9. What the **sleep related difficulties**, symptoms or problems experienced by the participants were recorded by the study authors? Please provide details:

10. Did the focal sample have comorbid conditions in addition to sleep and/or mental health difficulties? An example would be alcohol dependency among those with anxiety and depression. Please record this where applicable:

11. Were the participants taking medication for a **mental health difficulty** in addition to the intervention being tested? If yes provide details; if no, please state NA.

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Data extraction form **Study ID:** | | | |

12. Were the participants taking medication for a **sleep difficulty** in addition to the intervention being tested? If yes provide details; if no, please state NA.

13. Were the participants receiving psychological help for a **mental health difficulty** in addition to the intervention being tested? If yes provide details in the box below, if no please state NA;

14. Were the participants receiving psychological help for a **sleep difficulty** in addition to the intervention being tested? If yes, provide details; if no, please state NA:

Research design

15. How were the participants recruited to the study?

16. Please state the nature of the comparison group(s) (i.e., the group(s) that the intervention group is compared to);

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Data extraction form **Study ID:** | | | |

17. State the number of participants in the intervention group(s) who have dropped out of the trial between baseline and each follow-up point recorded. Please express this as a percentage of the number of participants at baseline. If no data is reported, then please state 'not reported'.

18. Record all points where data collection has occurred after the intervention has ended in months (e.g., post-intervention, 3 months, 12 months);

19. Please record the outcome measure(s) **used to measure sleep quality** and indicate whether the measures are self-reported, clinician rated, or objective;

☐ Self-report ☐ Clinician ☐ Objective

☐ Self-report ☐ Clinician ☐ Objective

☐ Self-report ☐ Clinician ☐ Objective

☐ Self-report ☐ Clinician ☐ Objective

20. Please record the outcome measure(s) **used to record outcomes pertaining to mental health and / or wellbeing** and indicate whether the measures are self-reported or rated by a clinician rated.

☐ Self-report ☐ Clinician

☐ Self-report ☐ Clinician

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Data extraction form **Study ID:** ☐☐☐

☐ Self-report ☐ Clinician

☐ Self-report ☐ Clinician

21. Please use the Jadad quality scale to score the study in terms of randomization, blinding and the account of participants. Use the 'Score given' column, placing your score in the box provided. Examples and guidance on the interpretation of each item are provided in the coding manual;

Item	Min-max score	Description	Score given
Randomization	0 to 2	1 point if randomization is mentioned at all 1 additional point if the method of randomization is appropriate Deduct 1 point if method of randomization is inappropriate	☐
Blinding	0 to 2	1 point if blinding is mentioned 1 additional point if the method of blinding is appropriate Deduct 1 point if the method of blinding is inappropriate	☐
Account of Participants	0 to 1	The fate of all participants in the trial is known. If there are no data the reason is stated	☐

Features of the intervention

22. Please state the theoretical approach of the intervention for each group receiving an intervention designed to improve sleep (e.g., psychological, pharmacological, medical device etc.). Use the text box below to provide as much detail as possible.

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Data extraction form **Study ID:**

23. How was the intervention delivered to participants in each group receiving an intervention designed to improve sleep? Use the box below to provide details.

24. Please state the duration of the intervention(s) to the nearest week;

25. Please record levels of adherence to the intervention(s) where possible (e.g., the number of pages of the intervention materials read, the amount of time spent looking at the intervention). If no data on adherence is available, then please state "not reported";

END OF FORM

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Supplementary Materials 4

Data Extraction Manual

Data extraction manual

The following documents contains details regarding the data to be extracted from primary studies included in the present review. Characteristics of the source (green), sample (yellow), study (blue), and intervention (grey) are outlined here.

Variable	Definition for coding	Example
1. Article authors	State the surnames and first initials of all authors of the article	Smith, J. A., Jones, A. C.
2. Publication year	The year that the article was first published	For articles published in Jan 2017, the year '2017' will be recorded on the data extraction form.
3. Publication status	Refers to whether an article has been published in a peer reviewed academic journal or not. Articles reporting a study published in a peer reviewed academic journal should be coded as 'Published'. Articles reporting a study that has not been published in a peer reviewed academic journal should be coded as 'unpublished'. Unpublished studies include those taken from PhD theses, dissertations, or studies that have otherwise not been accepted following peer review, or submitted to peer review.	

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3.1. Journal name if published	State the name of the journal that the article was published in	e.g. *British Journal of Psychiatry* or *Psychiatry Research* etc.
4. Age	The mean age of participants in the experimental group(s). Record the mean age of the participants in all of the groups who received an intervention designed to improve sleep. This may be more than one group, so, in these cases record the age of participants separately for each group. If mean age is not reported for the experimental group(s) alone, then report the total sample mean age. If no age data is available, state 'not reported'	
5. Gender	The percentage of participants in the experimental group(s) who are female. Record the percentage of participants who are female in all of the groups receiving an intervention designed to improve sleep. This may be more than one group, in which case record the percentage of female participants separately for each group. If the gender of the participants is not reported for the experimental group(s) alone, then report the percentage of participants who are female in the total sample. If no data on gender is available, then state 'not reported'	
6. Clinical status of participants' (with respect to mental health)	The mental health status of the sample should be classified as either; i) clinical; ii) non-clinical or iii) mixed	A study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might recruit participants with a DSM diagnosed

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	Clinical samples are those that comprise primarily of participants that have a clinical diagnosis of a mental health problem as defined by formal criteria (e.g ICD, DSM). Studies where it is explicitly stated that participants have a formal diagnoses of a mental health problem are classed as clinical. This is often defined by formal diagnostic and research criteria such as the DSM or ICD **Non-clinical samples** are those that comprise primarily of participants that have no formal diagnosis of a mental health problem. Mental health is often studied in non-clinical samples who do not have a formal diagnosis. These participants should be classed as non-clinical. **Mixed samples** are those that include participants who have formal clinical diagnoses and those who do not. Samples that include both clinical and non-clinical participants should be classified as mixed.	psychosis spectrum disorder only. As a DSM rated diagnosis is a requirement for entry into the trial, this would be coded as a **clinical sample**. A similar study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might include participants from the general population without any formal diagnoses of a mental health problem. For example, participants might be volunteers who have responded to a media advertisement of email invitation. This would be coded as a **non-clinical sample**. A third study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might include a mix participants with a DSM rated diagnosis (clinical) and those from the general population with no diagnosis (non-clinical). This would be coded as a **mixed sample**.
7. Clinical status of participants with respect to sleep problems	The clinical status of the sleep difficulties reported by the sample are coded as either; i) clinical; ii) non-clinical or iii) mixed **Clinical samples** are those that comprise primarily of participants that have a clinical diagnosis of a sleep problem as defined by formal criteria (e.g., ICD, DSM). Studies where it is explicitly stated that participants have a formal diagnoses of a sleep problem are classed as clinical. This is often defined by formal diagnostic and research criteria such as the DSM or ICD	A study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might recruit participants with a DSM diagnosed sleep problem (e.g. insomnia). As a DSM rated diagnosis of insomnia is a requirement for entry into the trial, this would be coded as a **clinical sample**. A similar study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might include participants from the general population without any formal diagnoses of a sleep problem. For example, participants might be volunteers who have responded to a media

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	Non-clinical samples are those that comprise primarily of participants that have no formal diagnosis of a sleep problem. Sleep is often studied in non-clinical samples who do not have a formal diagnosis. These participants should be classed as non-clinical. **Mixed participants** are those that include participants who have formal clinical diagnoses and those who do not. Samples that include both clinical and non-clinical participants should be classified as mixed.	advertisement of email invitation. This would be coded as a **non-clinical sample**. A third study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might include a mix participants with a DSM rated diagnosis of a sleep problem (clinical) and those from the general population with no diagnosis of a sleep problem (non-clinical). This would be coded as a **mixed sample**.
8. Type of mental problems	Record the type of mental health problems and experiences that the authors measure. Where there are multiple mental health difficulties/problems, record all that are mentioned in the text.	A study may use the GAD-7 and the BDI to measure anxiety and depression respectively at baseline and again at post-intervention. In this case, record 'anxiety' and 'depression' in the box provided.
9. Type of sleep problem(s)	Record the type of sleep problem(s) and experiences that the authors measure. Where there are multiple sleep difficulties/problems, record all that are mentioned in the text.	A study may use the insomnia severity scale and the PSQI to measure insomnia and sleep quality respectively at baseline and again at post-intervention. In this case, record 'insomnia' and 'sleep quality' in the box provided.
10. Comorbidity	Record any problems or difficulties identified by the authors that are comorbid to the targeted sleep and/or the mental health problem.	An example would be an intervention designed to improve sleep in those with depression and alcohol dependency. For this review, sleep and depression would not be considered comorbid at these are the target problems of this review. However, alcohol dependency would be the comorbid problem to record in the box provided.

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11. Concurrent medication use for mental health	Were participants allowed to take medication for a mental health difficulty that is different to the intervention being tested while taking part in the research?	A study may investigate the effect of improving sleep using CBTi in people with depression who are also using SSRI medication. As these participants are receiving medication for depression, in addition to receiving an intervention designed to improve sleep, they would be classed as using concurrent medication for a mental health problem. Alternatively, some studies may screen those using medication for a mental health problem and remove these participants before randomisation, leaving only those with depression who are not on medication for it. In which case, state that the participants are using no concurrent medication for mental health.
12. Concurrent medication use for sleep	Were participants allowed to take medication for a sleep difficulty that is different to the intervention being tested while taking part in the research?	A study that tests the impact of a CBTi intervention for insomnia that allows participants to continue with benzodiazepine use would be classed as allowing concurrent medication for a sleep problems. Alternatively, a study might screen those taking medication for a sleep problem and remove these participants before randomization. Therefore, this study does not allow participants to take medication for a sleep problem in addition to the intervention being tested. In which case, state that the participants are using no concurrent medication for sleep.
13. Concurrent psychological treatment	Were participants receiving psychological help for a mental health difficulty that is different to the	A study where participants are able to continue receiving psychological help from outside of the

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for mental health	intervention being tested while taking part in the research?	study team for an anxiety problem while receiving the study intervention. Alternatively, some studies may screen participants who are currently receiving psychological help for a mental health problem and remove these participants before randomisation. In which case, In which case, state that the participants are receiving no concurrent psychological treatment for mental health.
14. Concurrent psychological treatment for sleep	Were participants receiving psychological help for a sleep difficulty that is different to the intervention being tested while taking part in the research?	A study where participants are able to continue receiving psychological help from outside of the study team for a sleep problem while receiving the study intervention. Alternatively, some studies may screen participants who are currently receiving psychological help for a sleep problem and remove these participants before randomization. In which case, In which case, state that the participants are receiving no concurrent psychological treatment for sleep.
15. Method of recruitment	Record how participants were recruited and from which source(s). This could include, for example, referral by GPs into the trial or from health professionals, recruitment from volunteer email lists at University's or self-referral from the participant. A study may also use a combination of multiple recruitment methods. If so, record all where possible.	Clinicians may refer participants with psychosis spectrum diagnoses from outpatient centres into the trial. In which case, record that participants were recruited by healthcare professionals from a clinical outpatient setting. Alternatively, participants may see advertisements and contact the study team directly. In which case, record that participants were recruited via media advertisement and self-referred to the study.

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16. Nature of comparison group	Describe the type of comparison group and provide a brief description.	Participants in a wait-list control group would receive no intervention for the duration of the study. In which case, record 'wait-list control group' Alternatively, an intervention might be compared to treatment as usual (TAU) where participants receive the same care they would usually receive regardless of the trial. In which case, record 'treatment as usual' alongside a brief description of what treatment as usual is.
17. Attrition/dropout	The total number of participants in the intervention group(s) who have dropped out of the trial between baseline and each follow-up point recorded should be expressed as a percentage.	If a study started with a total *n* = 100 participants in the intervention group giving baseline data, and ended with *n* = 75 at post-intervention and *n* = 50 at a six month follow-up, then this would be reported as; Post-intervention = 25% attrition 6 month follow-up = 50% attrition
18. Follow-up points	Any point in the study where data has been collected following the intervention	A study that collects data immediately after an intervention has been delivered and then again 3 and 12 months later would have the following follow-up points; 1. Post-intervention 2. 3 months 3. 12 months
19. Measure of sleep	Record the name of the measure(s) used to assess sleep. Please also record whether this measure was; i) self-reported; ii) rated by a clinician; or iii) measured objectively.	A study that uses both polysomnography (an objective measure of sleep) and the Insomnia Severity Index (ISI, a self-report measure). List the name of the measure (e.g.

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		polysomnography / Insomnia Severity Index) and then tick the appropriate box (i.e., objective in the case of polysomnography and self-report in the case of the ISI).
20. Measure of mental health	Record the name of the measure(s) used to assess mental health and/or wellbeing. Please also record if this measure was self-reported or rated by a clinician	A study that uses the Anxiety Disorder Interview Schedule (ADIS, a clinician rated measure of anxiety disorders) and the Generalised Anxiety Disorder Assessment-7(GAD-7, a self-report measure). List the name of the measure (e.g., ADIS/GAD-7) and then tick the appropriate box (i.e., clinician rated in the case of the ADIS and self-report in the case of the GAD-7).
21. Study quality	The Jadad scale assesses three key aspects of study quality that can affect the risk of bias; (i) randomization, (ii) blinding and (iii) withdrawal/drop-out. For guidance, please refer to the Jadad scale embedded within the data extraction form and the accompanying notes.	Full guidance and examples can be seen the accompanying Jaded scale document. However an example in relation to the assessment of randomization is given below; Give a max score of 2 for randomization and a minimum score of 0 Award 1 point if randomization is mentioned (e.g. "*The patients were randomly assigned into two groups*"). Award 1 additional point if the method of randomization is appropriate (e.g. *"The randomization was accomplished using a computer, generated random number list, coin toss or well-shuffled envelopes*"). Deduct 1 point if the method of randomization is

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		inappropriate (e.g. "*The group assignment was accomplished by alternate assignment, by birthday, hospital number or day of the week etc*.")
22. Theoretical basis of the intervention	Do the authors specify the theoretical basis of the intervention? If so, provide details.	The intervention group received a 6 week course of self-guided CBT for insomnia. The intervention was delivered via the internet and included multiple components. Participants were required to complete a daily sleep diary as well as complete online exercises to realign maladaptive thought processes about sleep. There was also a psychoeducation module and a section detailing several relaxation exercises based around progressive muscle relaxation and mindfulness.
23. Delivery modality	How was the intervention delivered to participants? Provide as much detail as possible in the text box provided.	A study that uses online self-help to provide an intervention to improve sleep. The delivery modality is online/computerised self-help
24. Duration of the intervention	How long did the intervention last (to the nearest week)? If this is not known or reported, please state unknown.	An intervention that comprises of 6 weekly modules would be 6 weeks long.
25. Adherence to the intervention	There are often many measures of adherence to interventions. Please state the measure reported (where possible) in the text box along with the rate of adherence.	If an intervention comprised of 6 weekly modules and the average number of modules completed was 4, then, on average, 66% of the intervention was adhered to.

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Does Improving Sleep Lead to Better Mental Health and Quality of Life? A Protocol for a Meta-Analytic Review of Randomised Controlled Trials

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Does Improving Sleep Lead to Better Mental Health and Quality of Life? A Protocol for a Meta-Analytic Review of Randomised Controlled Trials

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Abstract

Introduction: Sleep and mental health go hand-in-hand, with many, if not all, mental health problems being associated with problems sleeping. Although sleep has been traditionally conceptualized as a secondary consequence of mental health problems, contemporary views prescribe a more influential, causal role of sleep in the formation and maintenance of mental health problems. One way to evaluate this assertion is to examine the extent to which interventions that successfully improve sleep also improve mental health and quality of life. **Method and analysis:** Randomized Controlled Trials (RCTs) describing the effects of interventions designed to improve sleep on mental health and/or quality of life will be retrieved via a systematic search of four bibliographic databases (in addition to a search for unpublished literature). Hedges g and associated 95% confidence intervals will be computed from means and standard deviations where possible. Following this, meta-analysis will be used to synthesize the effects reported in eligible trials and investigate the impact of variables that could potentially moderate the effect of changes in sleep on outcomes pertaining to mental health and quality of life. The Jadad scale for reporting randomized controlled trials will be used to assess study quality and publication bias will be assessed via visual inspection of a funnel plot and Egger's test alongside Orwin's fail-safe *n*. Finally, we will use mediation analysis to investigate whether changes in outcomes relating to mental health and quality of life can be attributed to changes in sleep quality. **Ethics and dissemination:** This study requires no ethical approval. We will submit the findings for publication in a peer-reviewed journal and promote the review to relevant stakeholders. **Prospero registration:** CRD42017055450

Keywords: Meta-analysis; protocol; review; sleep; mental health; quality of life; intervention

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Strengths

- The proposed review should provide reliable evidence on the effect of interventions designed to improve sleep on outcomes reflecting mental health and quality of life.
- The proposed review will further elucidate the nature of the relationship between sleep and mental health.
- We will use the GRADE system to assess the strength of the evidence base. This will allow members of the public, researchers, and clinicians to quickly access the available evidence and judge its quality.

Limitations

- The proposed review will include a diverse range of interventions and target problems that might lead to a heterogeneous group of studies. However, to mitigate this we will use moderation analysis to investigate specific factors that might influence the effect of sleep improvement on mental health and quality of life.

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Does Improving Sleep Lead to Better Mental Health and Quality of Life? A Protocol for a Meta-Analytic Review of Randomized Controlled Trials

Difficulties sleeping and mental health problems are both public health concerns in their own right; with each having a substantive impact on both individuals and society as a whole [1-4]. However, sleep and mental health go hand-in-hand, with many, if not all, mental health problems being associated with problems sleeping [5-7]. Traditionally, sleep problems have been viewed as a consequence of mental health problems. Although the notion that mental health problems can lead to difficulties sleeping still stands, evidence suggests that problems sleeping can also contribute both to the formation of new mental health problems [8-10] and to the maintenance of existing ones [11-13]. In other words, sleep is now thought to have a bidirectional relationship to mental health, with problems sleeping likely to influence both the onset and trajectory of a variety of mental health difficulties. Having said this, although a number of empirical studies have manipulated sleep and examined the impact of so doing on outcomes related to mental health, to date there has not been a systematic review of these studies. Consequently, the magnitude of the effect of (changes in) sleep on mental health problems is difficult to estimate and has not been compared between different mental health outcomes and other factors that might influence the effect (e.g., across different groups of participants, research designs, and approaches to intervention).

The potential for a causal relationship between sleep and mental health also raises an intriguing prospect; namely, that interventions designed to improve sleep could also improve mental health. Providing a definitive answer to this question would have important implications for clinicians, researchers, and members of the public alike. From a practical perspective, if interventions designed to improve sleep can change mental health outcomes, then they may be a useful tool for tackling mental health difficulties. Indeed, interventions designed to improve sleep can often be delivered remotely, in self-help and group formats,

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and / or at little cost through the internet [14-18]. For example, a meta-analysis by Ho et al. reported that self-help interventions based on the principles of CBT for insomnia (termed CBTi) had medium-to-large effects on the symptoms of insomnia[18].

Problems with extant literature and opportunities

The relationship between sleep and mental health is well documented, with numerous reviews testifying to a robust link between the two [6-8 19-24]. However, the majority of these reviews have tended to focus on primary studies with correlational research designs. That is, they either; i) measure associations between variables at a single time point (i.e., cross-sectional designs); or ii) measure associations between variables at multiple time points (i.e., longitudinal designs). For example, many reviews simply report the typical sleep profiles of those with mental health difficulties relative to those without [6 7 25 26]. Cross-sectional designs simply tell us that variables are associated in some way. It is impossible to determine whether sleep causes mental health problems, mental health problems cause difficulties sleeping, or whether the effect is bi-directional in nature.

Longitudinal studies, although still correlational in nature, are better able to elucidate causality than their cross-sectional counterparts. However, only a handful of reviews have provided evidence on the relationship between sleep (at one point in time) and mental health outcomes (measured later). Furthermore, all of these have focused on depression [8 24 27 28]. For example, Baglioni et al. [8] conducted a meta-analytic evaluation of 21 studies investigating the longitudinal associations between insomnia and depression. Baglioni et al. reported that non-depressed people with insomnia had a twofold risk of developing depression compared to people who did not experience difficulties sleeping at baseline. Longitudinal designs, although better placed to infer causation, are still susceptible to the 'third variable problem' [29-31]. Namely, that a third, unmeasured variable (e.g., having young children) could cause

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both sleep difficulties and mental health problems. In summary, correlational designs are not a valid way of disentangling the relationship between problems sleeping and mental health.

Some reviews have assessed the impact of interventions designed to improve sleep on mental health outcomes[17 18 23 24 32-36]. However, even these reviews do not permit us to draw robust conclusions as to the causal impact of sleep quality on mental health outcomes for a number of reasons. First, these reviews often include interventions that have not successfully manipulated sleep (i.e., studies in which there was no significant impact of the intervention on sleep outcomes). Such studies do not tell us anything about the relationship between sleep and mental health other than that it can be difficult to improve sleep. Second, the focus of extant reviews reporting both sleep and mental health variables has been on improving sleep, with the measurement of mental health outcomes typically limited to depression and anxiety. Consequently, the effect of improving sleep on other mental health problems and the associated construct of quality of life[37 38] (QoL) more broadly is currently unclear.

Finally, to our knowledge, to date there has been no attempt to investigate variables that influence – or *moderate* – the impact of interventions that improve sleep on mental health. Interventions designed to improve sleep are likely to vary in their content and delivery, and such variables may influence how effective they are in improving sleep and / or mental health outcomes. Furthermore, variables related to the nature of the sample (e.g., age, severity of symptoms, nature of the mental health problem) and methodological features of the primary study (e.g., self-report vs. objective assessment of the outcome variables) are likely to influence the effect of the respective intervention. It is therefore crucial that the impact of such variables is systematically examined across the extant evidence base in order to draw reliable and valid conclusions about the impact of changes in sleep on outcomes pertaining to mental health and quality of life.

The proposed review

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A number of primary research studies have experimentally manipulated sleep (typically via some sort of psychological intervention) and then measured mental health outcomes. However, these individual studies have, to our knowledge, never been integrated in a manner that allows the magnitude of the effect of sleep quality on mental health outcomes to be estimated. Therefore, it is currently difficult to; i) draw firm conclusions about the relationship between sleep and various mental health problems; and ii) recommend with any confidence that mental health problems might be tackled using interventions that have been designed to improve sleep. Furthermore, to date there has been no attempt to understand the factors that influence, or moderate, the effect of improvements in sleep on mental health. As a consequence, clinicians, researchers, and members of the public may be unaware of whether and how the content and nature of the intervention(s), target sample and mental health problem, and methodological features of the primary study can influence the efficacy of an intervention.

Objectives

The proposed review therefore has two broad objectives; i) to synthesize and quantify the effect of interventions that improve sleep on outcomes reflecting mental health and QoL; and ii) to explore variables that moderate the effect of interventions targeting sleep on outcomes reflecting mental health and QoL.

Method and Analysis

This protocol has been prepared in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P, see Supplementary Materials 1) checklist [39].

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Outcomes and Prioritization

Measuring improvements in sleep

The concept of 'improved sleep' is multifaceted and can mean different things to different people[40-42]. Indeed, many specific sleep problems are tied to mental health in unique ways and are often measured using specific outcome measures. For example, the experience of nightmares has been found to be associated with post-traumatic stress disorder (PTSD)[43], as measured using specific outcome measures such as dream diaries[44 45] or the Clinician-Administered PTSD Scale (CAPS)[46] which includes a nightmare assessment. Consequently, one challenge for the proposed review is to ensure that all of the primary studies assess a similar notion of sleep improvement. To achieve this, the proposed review will require that the primary studies report a measure that reflects the overall quality of sleep experienced by participants. Broadly speaking, sleep quality consists of; (i) sleep continuity (e.g., sleep onset, sleep maintenance, and number of awakenings); and (ii) daytime impact (e.g., the extent to which the person feels refreshed on waking and throughout the day)[41 42].

Sleep quality can be measured using both self-report and objective indices. For example, the Pittsburgh Sleep Quality Index[47] (PSQI) is widely recognized as the 'gold standard' self-report measure of sleep quality and consists of 19 items measuring 7 components of sleep quality (subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction). The 'gold standard' for objectively measuring sleep is accepted to be polysomnography (PSG)[48]; a technique that monitors multiple biophysiological parameters and can directly record components relating to sleep quality including sleep onset and sleep maintenance (for a review, see [49]). The proposed review will include both self-report and objective indices of sleep quality, but will also seek to compare effect sizes between different measures in an

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effort to empirically examine the extent to which the nature of the measures influences the apparent effect of the interventions.

Measuring mental health and QoL

The measurement of mental health is often variable, with a range of different outcomes which differ both in their administration and interpretation. Some studies will report a general measure assessing a specific diagnostic category (e.g., a measure of the severity of depression severity). For example, the Beck Depression Inventory II is a 21 item self-report measure designed to assess multiple facets of depression including mood, pessimism, self-dislike, loss of appetite, and social withdrawal, with higher scores indicating more severe depression[50]. Other studies might assess a single symptom or problem. For example, the Green Paranoid Thoughts Scale (GPTS) measures paranoid thoughts[51], an experience that is associated with, but is not limited to, psychosis spectrum disorders[52 53]. Finally, some studies may report the effects of interventions designed to improve sleep on global measures of mental health. For example, the Clinical Global Impressions Severity scale (CGI-S)[54] asks clinicians to use their clinical experience to rate how mentally ill their client has been over the last week, on a scale ranging from 1 – *normal* to 7 – *amongst the most extremely ill patients*. Measures assessing aspects of mental health are either; (i) self-reported by the participant, or (ii) completed on behalf of the participant by a clinician or other independent rater. Both self-report and independently rated outcome measures will be included in the proposed review; however, as above, we will compare effect sizes between different measures in an effort to empirically examine the extent to which the nature of the measures influences the apparent effect of the interventions.

With regards to QoL, a consctruct closely linked with mental health[37 38], Liu[55] commented that there are as many definitions of QoL as there are people, a statement which frames QoL as a personal and varied concept meaning different things from one person to

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another. Although there is much disagreement on operational definitions of QoL[56 57], fortunately there is also considerable overlap in the dimensions that researchers assess. For example, five core dimensions of QoL that the majority of measures share are; (i) *physical wellbeing* (e.g., health and fitness); (ii) *material wellbeing* (e.g., financial security, possessions etc.); (iii) *social wellbeing* (e.g., breadth and depth of relationships); (iv) *emotional wellbeing* (e.g., affect or mood, fulfilment, self-esteem etc.); and (v) *development and activity level* (e.g., the possession and use of skills, work, education etc.)[58]. The proposed review will therefore include measures of QoL that assess at least one of the five dimensions detailed above listed by Felce and Perry[58]. For example, the Quality of Life Scale (QOLS)[59] is a 16 item instrument that measures six domains of QoL; (i) material and physical wellbeing; (ii) relationships with others; (iii) social, community and civic activities; (iv) personal development and fulfilment; (v) recreation; and (vi) independence.

Eligibility Criteria

Inclusion criteria

In order to be included in the proposed review, the primary studies need to:

1. Randomly allocate participants to either an experimental group that receive an intervention that is designed to improve sleep or a comparator group.
2. Report a statistically significant improvement at at least one follow-up point on a measure of sleep quality among participants in the experimental group as compared to those in the comparison group.
3. Include a measure of mental health and/or QoL subsequent to the measure of sleep quality.
4. Report sufficient data for us to be able to compute effect sizes reflecting the impact of the intervention on sleep quality and mental health and/or QoL. Where sufficient data is not

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reported, we will contact the authors and request further data. However, if this is not provided then the study will not be included in the review.

5. Be written in English, or be able to be translated using available translation resources.

Exclusion criteria

The aim of the proposed review is to be as inclusive as possible and address potential differences between the primary studies (e.g., differences in the nature of the intervention or the mental health problem under consideration) using moderation analysis. Therefore, very few exclusion criteria will be applied. For example, we will not restrict the type of intervention (e.g., psychological and pharmacological), publication status, nature of the comparison condition, or sample (i.e., interventions directed toward adults, children, and adolescents will all be eligible). However, studies with the following characteristics will be excluded in order to ensure that we can reliably assess the independent contribution of changes in sleep on mental health outcomes:

1. Studies where the intervention contains elements that specifically target a mental health problem alongside improving sleep (e.g., an intervention that provides CBT for anxiety alongside efforts to improve sleep).
2. Studies adopting a pre-post (or within participant) design.

Information Sources

The proposed review will use a combination of search techniques and sources in order to identify potential studies. First, we will search MEDLINE (1946 to present), Embase (1974 to present), PsycINFO (1967 to present), and The Cochrane Library(1898 to present) using the Cochrane Highly Sensitive Search Strategy[60] to identify randomized controlled trials that include terms relating to sleep quality/disorders and mental health/QoL outcomes (see Table 1 for a list of the proposed search terms). The search strategy has been developed in collaboration with a health sciences librarian specializing in systematic search procedures and

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will be used to search each database (see Supplementary Materials 2 for an example search strategy). Second, the reference lists of extant reviews of the relationship between sleep and mental health (e.g., those cited in the introduction) will be searched for any potential articles. Third, a search for any unpublished or ongoing studies will be conducted by searching online databases including White Rose Online, The National Research Register, WHO approved clinical trial databases (e.g. ISRCTN), and PROSPERO. Finally, the authors of articles deemed eligible for inclusion will be contacted and asked if they are aware of any unpublished research that may be eligible for inclusion in the review.

Data management

All records will be stored in the reference management software Endnote, and we will follow PRISMA guidelines for the selection of studies for meta-analysis [61]. Specifically, when the pool of potential studies has been identified, we will remove duplicates and initially screen each record based on the title and abstract and exclude clearly ineligible studies. Following this initial screening, the full-text versions of each article will be reviewed in detail and cross-referenced against the inclusion and exclusion criteria. The flow of articles through the review, including the reasons for excluding studies will be documented in a PRISMA flow chart.

Data Extraction

Data will be recorded on standardized data extraction forms and a manual to accompany the form will detail each variable to be extracted alongside definitions and examples (see Supplementary Materials 3 and 4). Two reviewers will pilot the data extraction forms and manual on three articles in order to ensure that there are no systematic problems or difficulties coding any of the variables. After this, the data will be extracted from the full set of studies by one reviewer. A second member of the review team will second code a subset of the included articles (at least 10%) and levels of agreement will be calculated (the subset of

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articles for second coding will be randomly selected using a computer generated algorithm). Any disagreements will be resolved through discussion, with a third member of the review team acting as arbiter for any outstanding disagreements. The review team will extract meta-data pertaining to source characteristics (e.g., publication status and year,), as well as data relating to the characteristics of the sample (e.g., age, type of mental health problem), the study (e.g., the nature of the comparison group, length of follow-up), and characteristics of the intervention (e.g., theoretical basis, delivery modality) (see Table 2 for an overview of potential moderators that we propose to code and examine).

Proposed Analysis

Review Manager 5.3[62] will be used to compute Hedges *g* (and associated 95% confidence intervals) using the means and standard deviations for each measure of sleep quality, mental health, and QoL reported in studies comparing these outcomes between an intervention group (i.e., a group receiving an intervention that improves sleep) and a comparison group (e.g., wait-list, placebo, treatment as usual)[1]. Where means and standard deviations are not available, we will compute effect sizes by converting relevant summary statistics (e.g., *F* values from an ANOVA testing the impact of an intervention on relevant outcomes) using Lyons Morris' meta-analysis calculator[63]. The effect of the interventions on sleep quality will be assessed using data from the first available follow-up point that reports a statistically significant difference in sleep quality between the intervention and comparison conditions. The effect of the intervention on outcomes pertaining to mental health and QoL will be assessed at the longest follow-up point available, whether the effect at this point is statistically significant or not (and we will investigate the effect of follow-up duration on

[1] Data that has been adjusted for baseline differences between groups will be used to compute effect sizes, where available. However, if this information is not reported then we will use the unadjusted data to compute the effect size. We will also seek to compute effect sizes using the data from Intention to Treat (ITT) analyses where they are reported. Subscripts will be added to the table reporting the effect sizes derived from the primary research studies in order to identify how each effect size was computed and also to compare outcomes between studies that report adjusted vs. unadjusted statistics and ITT analyses vs. non-ITT analyses.

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outcomes using moderation analysis). . This strategy will provide a stringent test of the effect of the interventions on outcomes pertaining to mental health and QoL (in the sense that any changes need to have been maintained over time) and also enable us to investigate whether the impact of the interventions on outcomes is mediated by changes in sleep quality that precede the impact on outcomes pertaining to mental health and QoL (this proposed analysis is discussed in detail below).

Where studies report multiple outcome measures under one diagnostic category (e.g., several measures of depression or sleep quality), the effect sizes will be computed for each outcome and meta-analyzed in their own right to form one overall effect for inclusion in the main analysis. For example, we would compute two effect sizes reflecting sleep quality for a study that reports the effects of an intervention on the Pittsburgh Sleep Quality Index[47] and the Insomnia Severity Index[64] (i.e., one effect size for each measure of sleep quality) and then average them before inclusion in the main dataset. This procedure capitalizes on the information that is available, while retaining the independence of effect sizes which is central to the validity of meta-analysis[65].

The sample-weighted average effect size (g_+) will be computed using a random effects model as studies are likely to be "different from one another in ways too complex to capture by a few simple study characteristics" [66]. Following Cohen's [67] recommendations, $g = 0.20$ will be taken to represent a 'small' effect size, $g = 0.50$ a 'medium' effect size, and $g = 0.80$ a 'large' effect size. We will use these qualitative indices to interpret the findings. Publication bias will be assessed via visual inspection of a funnel plot and Egger's test [68]. Finally, Orwin's [69] formula will be used to determine the fail-safe *n* (i.e., the number of studies producing a null effect that would be needed to reduce the overall effect of interventions that improve sleep on outcomes relating to mental health and QoL to a trivial effect size).

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Heterogeneity, Bias and Study Quality

The I^2 statistic will be used to assess the heterogeneity of effect sizes across the primary studies [70]. The quality of each individual study included in the proposed review will be assessed using the Jadad scale for reporting randomized controlled trials [71]. The Jadad scale assesses three key areas of methodological quality that potentially impact the risk of bias – namely; randomization, blinding, and the flow of participants through the study. In order to assess these areas, raters will be asked to answer three questions: i) "*Was the study described as randomized (i.e., does it include words such as randomly, random, and randomization*)?"; ii) "*Was the study described as double blind?*"; and iii) "*Was there a description of withdrawals and dropouts*?". Scores on the Jadad scale range from 0 to 5, with higher scores indicating a lower risk of bias (and therefore higher methodological quality). The Jadad scale for reporting randomized controlled trials has been extensively used as a measure of the methodological quality of RCTs (having received over 7,500 citations to date) and has been recommended as the most reliable and valid scale for assessing the quality of RCTs, in a review of 21 measures [72]. Finally, the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system[73 74] will be used to assess the quality of the body of evidence as a whole and the extent to which it can and should be used to inform clinical recommendations.

Moderation and Mediation Analysis

Moderation analyses will be used to identify variables that influence the effect of interventions that improve sleep on both mental health and QoL. For continuous moderators (e.g., age, publication year, study quality), sample weighted meta-regression will be used to investigate the impact of the moderator on effect sizes. For example, the quality of a given study, assessed using the Jadad scale[71], will be used as the independent variable in a sample-weighted meta-regression, with the effect sizes representing the effect of the interventions on

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outcomes pertaining to mental health or QoL used as the dependent variable. For categorical variables (e.g., self-report vs. objective outcome measures, the nature of the comparison condition), the sample-weighted average effect size *g* and associated standard errors will be computed for each level of the moderator and then the *Q* statistic will be used to assess if the difference is statistically significant. For example, effect sizes based on clinician completed measures of mental health (e.g., the Clinical Global Impressions Severity Scale[54]) will be compared to effect sizes based on self-report measures of mental health (e.g., the Depression, Anxiety, Stress Scale[75]).

Mediation analysis will be used to investigate whether changes in mental health and QoL can be attributed to changes in sleep. In line with Kenny, Kashy, and Bolger's [76] recommendations, we will conduct 4 multiple regressions in order to investigate mediation. These regressions will test; i) the effect of the independent variable (i.e., the intervention) on the dependent variable (i.e., outcomes reflecting mental health and QoL); ii) the effect of the independent variable on putative mediator (i.e., outcomes reflecting sleep quality); iii) the effect of the mediating variable on the dependent variable; and finally iv) the simultaneous effect of the independent variable and the mediator on the dependent variable, respectively. If the effect of the interventions on mental health and QoL can be attributed to changes in the quality of sleep, then the impact of the interventions on outcomes pertaining to mental health and QoL should be significantly reduced when the effect of the interventions on sleep quality is statistically controlled.

Ethics and Dissemination

As the proposed research is a meta-analytic review of primary studies, no ethical approval is required. We have registered the proposed review on the PROSPERO database (CRD42017055450) in order to adhere to the principles of open research. Following

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completion of the review, we aim to publish the findings in a peer reviewed academic journal and attend conferences and dissemination events with stakeholders where possible.

Discussion

The proposed review will use meta-analysis alongside moderator and mediation analyses to i) quantify the effect of interventions that improve sleep on mental health outcomes; ii) test whether any effect of the interventions on these outcomes is mediated by changes in sleep quality, and iii) explore variables that potentially moderate the effect of the interventions targeting sleep on mental health outcomes. The proposed review has a number of strengths that we believe mean that it will make a substantive contribution. For example, the proposed review will be inclusive and investigate the effect of improving sleep on a wide range of mental health problems, as well as QoL. Furthermore, the proposed review will further elucidate our understanding of the causal relationship between sleep and mental health by including only studies that successfully manipulate sleep and by conducting a mediation analysis to investigate whether any changes in mental health and QoL can be attributed to changes in sleep. We will also use the GRADE system to assess the strength of the evidence base[73 74] which should allow members of the public, researchers, and clinicians to quickly access the available evidence and judge its quality. Despite the strengths of the proposed review, the wide range of interventions, populations and target problems that are likely to be addressed by the primary research studies may lead to a relatively heterogeneous group of studies (and thus, potentially effect sizes) which may lead to concerns that we are not comparing 'like with like' (cf. the problem of mixing apples and oranges[77]) and limit the extent to which the findings can be generalized to a specific population (i.e., solely to those with depression). However, we will use moderation analysis to investigate specific factors that might influence the effect of improvements in sleep on mental health and QoL. Our hope is that these analyses prove informative, both in understanding mental health problems and

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QoL (i.e., when can changes in sleep quality be expected to influence these outcomes?).and in developing interventions designed to mitigate these problems (e.g., the review will be able to identify which interventions are most effective, and for whom)

Author Contributions

The first author (AJS) had the idea for the proposed review and approached TLW and GR, who contributed to the design of the research. AJS drafted the protocol and TLW and GR provided detailed comments before submission. AJS is the identified guarantor of the review.

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This research has not yet received any funding from the public, commercial or not-for-profit sectors.

Competing Interests

We have no competing interests to declare.

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Table 1

Search Terms that will be used to Identify Randomized Controlled Trials of Interventions Designed to Improve Sleep on Outcomes Pertaining to Mental Health and Quality of Life (QoL)

HSSS for RCTs[a]	Sleep	Mental health and QoL
Randomized controlled trial	Sleep*	"Psychological health"
Controlled clinical trial	"Circadian rhythm*"	"Mental"
Randomized	Insomnia	Wellbeing
Placebo	Hypersomnia	Distress
Drug therapy	Parasomnia	"Quality of life"
Randomly	Narcolepsy	QoL
Trial	Apnea	Psychiat*
Groups	Apnoea	Affect
	Nightmare*	Depress*
	"Restless legs syndrome"	Mood
		Stress
		Anxi*
		Phobi*
		"Obsessive compulsive disorder"
		PTSD
		"Post-traumatic stress disorder"
		Trauma
		OCD
		Psychos*s
		Psychotic
		Schiz*
		Bipolar
		Hallucination*
		Delusion*
		"Eating dis*"
		Anorexia
		Bulimia
		"Binge eating"
		"Attention deficit"
		"Hyperactivity disorder"
		ADHD

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	Autis*
	Asperger*

Notes: Studies will need to include at least one search term from each of the filter above in the title, abstract, or keywords, for consideration for inclusion in the review.

* = Indicates that variants of the word after the asterisk will be searched for (e.g., depress* will search for depressive etc.),

[a] The Highly Sensitive Search Strategy (HSSS) is more than just a key word search, rather it encompasses search techniques and strategies[60].

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Table 2

Variables to be Extracted for Moderation Analysis (where available)

Source characteristics	Sample characteristics	Study characteristics	Intervention characteristics
Publication status	Age	Nature of comparison group(s)	Theoretical basis
Publication year	Gender	Attrition/drop-out rate	Delivery modality
Journal impact factor	Type of mental health problem(s)	Methodological quality	Duration
	Type of sleep problem(s)	Timing of follow-up	Self-help vs. face-to-face
	Clinical status	Method of recruitment	Adherence
	Comorbidity	Measure(s) of sleep	
	Measure of mental health	Measure(s) of mental health	
	Concurrent medication use	Study quality	
	Concurrent psychological help	Type of analysis	
		Adjusted vs. unadjusted data	

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Summary of the Main Revisions

Requesting reviewer	Revision description	Location in protocol
Editor	The abstract has been updated in line with the Editors request for more detail.	p. 2
Editor & Reviewer 2	Dates of coverage added to each database searched	p. 11, line 240 - 241
Reviewer 1	Mediation analysis added in line with Reviewer 1s feedback	p. 16, line 350
Reviewer 1	More detail added to explain our proposed moderation analysis including examples	p. 15, line 335
Reviewer 1 & 2	New section, 'Outcomes and Prioritization', added to the method and analysis section. Here we detail how we will assess sleep improvement, mental health and quality of life.	p. 8, line 148
Reviewer 1	More detail added to explain our procedure for computing effect sizes from multiple outcome measures assessing the same, or similar, constructs	p. 14, line 299
Reviewer 1	More detail added to inclusion criteria 2 to indicate requirements for an intervention to demonstrate a *significant* impact (i.e. statistical significance at at least 1 follow-up point)	p. 10, line 214
Reviewer 1	Procedure for handing adjusted data, and data from ITT analyses added	p. 13 and p. 29, line 654/655
Reviewer 1 & 2	Detail added to state how we will convert effect sizes where needed (including from dichotomous outcomes)	p. 13, line 284
Reviewer 1	Rephrased a sentence which could be read as suggesting the traditional view that mental health problems cause sleep disturbance has been replaced by a view that the causal relationship is in the other direction to be more accurate (i.e. that the relationship is bidirectional).	p. 4, line 61
Reviewer 1	Discussion added reflecting on review strengths and weaknesses	p. 17, line 368
Reviewer 1	Reference list amended in line with *BMJ Open* policies	p. 19
Reviewer 2	Inclusion criteria revised to be explicit that children and adolescents are eligible for inclusion	p. 11, line 230
Reviewer 2	Search terms relating to ADHD and autism have been added	Table 1, p. 27
Reviewer 2	Inclusion criteria revised to state that we will include studies not written in English providing we can translate them using available translation resources	p. 11, line 223
Reviewer 2	Detail added to state that 2nd coding will involve a random subset of studies	p. 13, line 271

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Supplementary Materials 2

Ovid Medline Example Search Strategy

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

Search Strategy:

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1 (Sleep$ or Insomnia$ or nightmare$ or hypersomnia$ or parasomnia$ or narcolepsy or circadian rhythm$ or restless leg syndrome or apnea or apnoea).ti,ab. (180111)

2 Sleep/ or Sleep Disorders, Circadian Rhythm/ or Sleep Disorders, Intrinsic/ or Narcolepsy/ or Restless Legs Syndrome/ or Sleep Apnea Syndromes/ or "Sleep Initiation and Maintenance Disorders"/ or Parasomnias/ (70224)

3 1 or 2 (193630)

4 (psychological health or distress pr “quality of life” or QoL or mental or psychiat$ or affect or depress$ or mood or stress or anxious or anxiety or phobi$ or obsessive compulsive disorder$ or OCD or psychos#s or psychotic or schiz$ or bipolar or bi-polar or hallucination$ or delusion$ or eating disorder$ or eating disturbance$ or anorexia or bulimia or binge eating or wellbeing or well-being or QoL or quality of life).ti,ab. (2200869)

5 Stress, Psychological/ or Anxiety Disorders/ or Obsessive-Compulsive Disorder/ or Phobic Disorders/ or exp "Feeding and Eating Disorders"/ or Anorexia Nervosa/ or Binge-Eating Disorder/ or Bulimia Nervosa/ or Depressive Disorder/ or Hallucinations/ or Delusions/ or Anxiety/ or Depression/ or psychotic disorders/ (379929)

6 4 or 5 (2283788)

7 3 and 6 (57412)

8 randomized controlled trial.pt. (446587)

9 controlled clinical trial.pt. (91788)

10 randomized.ab. (389502)

11 placebo.ab. (183719)

12 drug therapy.fs. (1928261)

13 randomly.ab. (270741)

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14 trial.ab. (409336)

15 groups.ab. (1670961)

16 or/8-15 (3972831)

17 exp animals/ not humans.sh. (4311313)

18 16 not 17 (3433652)

19 7 and 18 (19379)

20 (trial$ or intervention$ or treatment$).ti,ab. (4565976)

21 7 and 20 (23924)

22 21 not 19 (11896)

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Data extraction form **Study ID:** | | | |

Please consult the '**data extraction coding manual**' for instructions on how to code each.

Article meta-data

1. Please state the surnames and first initials of ***all*** authors of the article (e.g., Smith, J. A., Jones, A. C.);

2. Please state the year that the article was first published: | | | | |

3. What is the publication status of the article? ☐ Published (move to Q3.1)

☐ Unpublished (move to Q4)

3.1. Please state the name of the journal that the article was published in:

Nature of the focal sample

4. State the mean age of the intervention group(s) to the nearest year at baseline:

5. State the percentage of the intervention group(s) that are female at baseline

6. Indicate the clinical status of the **mental health problems** of participants **included** in the study:

☐ Clinical ☑ Non-clinical ☐ Mixed ☐ Not known

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Data extraction form **Study ID:** | | | |

7. Indicate the clinical status of the **sleep related problems** of participants **included** in the study:

☐ Clinical ☐ Non-clinical ☐ Mixed ☐ Not known

8. What **mental-health difficulties**, symptoms or problems experienced by the participants were recorded by the study authors? Please provide details:

9. What the **sleep related difficulties**, symptoms or problems experienced by the participants were recorded by the study authors? Please provide details:

10. Did the focal sample have comorbid conditions in addition to sleep and/or mental health difficulties? An example would be alcohol dependency among those with anxiety and depression. Please record this where applicable:

11. Were the participants taking medication for a **mental health difficulty** in addition to the intervention being tested? If yes provide details; if no, please state NA.

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Data extraction form **Study ID:** | | | |

12. Were the participants taking medication for a **sleep difficulty** in addition to the intervention being tested? If yes provide details; if no, please state NA.

13. Were the participants receiving psychological help for a **mental health difficulty** in addition to the intervention being tested? If yes provide details in the box below, if no please state NA;

14. Were the participants receiving psychological help for a **sleep difficulty** in addition to the intervention being tested? If yes, provide details; if no, please state NA:

Research design

15. How were the participants recruited to the study?

16. Please state the nature of the comparison group(s) (i.e., the group(s) that the intervention group is compared to);

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Data extraction form **Study ID:** | | | |

17. State the number of participants in the intervention group(s) who have dropped out of the trial between baseline and each follow-up point recorded. Please express this as a percentage of the number of participants at baseline. If no data is reported, then please state 'not reported'.

18. Record all points where data collection has occurred after the intervention has ended in months (e.g., post-intervention, 3 months, 12 months);

19. Please record the outcome measure(s) **used to measure sleep quality** and indicate whether the measures are self-reported, clinician rated, or objective;

☐ Self-report ☐ Clinician ☐ Objective

☐ Self-report ☐ Clinician ☐ Objective

☐ Self-report ☐ Clinician ☐ Objective

☐ Self-report ☐ Clinician ☐ Objective

20. Please record the outcome measure(s) **used to record outcomes pertaining to mental health and / or wellbeing** and indicate whether the measures are self-reported or rated by a clinician rated.

☐ Self-report ☐ Clinician

☐ Self-report ☐ Clinician

☐ Self-report ☐ Clinician

☐ Self-report ☐ Clinician

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Data extraction form **Study ID:** | | | |

21. Please use the Jadad quality scale to score the study in terms of randomization, blinding and the account of participants. Use the 'Score given' column, placing your score in the box provided. Examples and guidance on the interpretation of each item are provided in the coding manual;

Item	Min-max score	Description	Score given
Randomization	0 to 2	1 point if randomization is mentioned at all 1 additional point if the method of randomization is appropriate Deduct 1 point if method of randomization is inappropriate	
Blinding	0 to 2	1 point if blinding is mentioned 1 additional point if the method of blinding is appropriate Deduct 1 point if the method of blinding is inappropriate	
Account of Participants	0 to 1	The fate of all participants in the trial is known. If there are no data the reason is stated	

Features of the intervention

22. Please state the theoretical approach of the intervention for each group receiving an intervention designed to improve sleep (e.g., psychological, pharmacological, medical device etc.). Use the text box below to provide as much detail as possible.

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Data extraction form **Study ID:** | | | |

23. How was the intervention delivered to participants in each group receiving an intervention designed to improve sleep? Use the box below to provide details.

24. Please state the duration of the intervention(s) to the nearest week;

25. Please record levels of adherence to the intervention(s) where possible (e.g., the number of pages of the intervention materials read, the amount of time spent looking at the intervention). If no data on adherence is available, then please state "not reported";

END OF FORM

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Supplementary Materials 4

Data Extraction Manual

Data extraction manual

The following documents contains details regarding the data to be extracted from primary studies included in the present review. Characteristics of the source (green), sample (yellow), study (blue), and intervention (grey) are outlined here.

Variable	Definition for coding	Example
1. Article authors	State the surnames and first initials of all authors of the article	Smith, J. A., & Jones, A. C.
2. Publication year	The year that the article was first published	For articles published in Jan 2017, the year '2017' will be recorded on the data extraction form.
3. Publication status	Refers to whether an article has been published in a peer reviewed academic journal or not. Articles reporting a study published in a peer reviewed academic journal should be coded as 'Published'. Articles reporting a study that has not been published in a peer reviewed academic journal should be coded as 'unpublished'. Unpublished studies include those taken from PhD theses, dissertations, or studies that have otherwise not been accepted following peer review, or submitted to peer review.	

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3.1. Journal name if published	State the name of the journal that the article was published in	e.g. *British Journal of Psychiatry* or *Psychiatry Research* etc.
4. Age	The mean age of participants in the experimental group(s). Record the mean age of the participants in all of the groups who received an intervention designed to improve sleep. This may be more than one group, so, in these cases record the age of participants separately for each group. If mean age is not reported for the experimental group(s) alone, then report the total sample mean age. If no age data is available, state 'not reported'	
5. Gender	The percentage of participants in the experimental group(s) who are female. Record the percentage of participants who are female in all of the groups receiving an intervention designed to improve sleep. This may be more than one group, in which case record the percentage of female participants separately for each group. If the gender of the participants is not reported for the experimental group(s) alone, then report the percentage of participants who are female in the total sample. If no data on gender is available, then state 'not reported'	
6. Clinical status of participants' (with respect to mental health)	The mental health status of the sample should be classified as either; i) clinical; ii) non-clinical or iii) mixed	A study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might recruit participants with a DSM diagnosed

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	Clinical samples are those that comprise primarily of participants that have a clinical diagnosis of a mental health problem as defined by formal criteria (e.g ICD, DSM). Studies where it is explicitly stated that participants have a formal diagnoses of a mental health problem are classed as clinical. This is often defined by formal diagnostic and research criteria such as the DSM or ICD **Non-clinical samples** are those that comprise primarily of participants that have no formal diagnosis of a mental health problem. Mental health is often studied in non-clinical samples who do not have a formal diagnosis. These participants should be classed as non-clinical. **Mixed samples** are those that include participants who have formal clinical diagnoses and those who do not. Samples that include both clinical and non-clinical participants should be classified as mixed.	psychosis spectrum disorder only. As a DSM rated diagnosis is a requirement for entry into the trial, this would be coded as a **clinical sample**. A similar study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might include participants from the general population without any formal diagnoses of a mental health problem. For example, participants might be volunteers who have responded to a media advertisement or email invitation. This would be coded as a **non-clinical sample**. A third study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might include a mix participants with a DSM rated diagnosis (clinical) and those from the general population with no diagnosis (non-clinical). This would be coded as a **mixed sample**.
7. Clinical status of participants with respect to sleep problems	The clinical status of the sleep difficulties reported by the sample are coded as either; i) clinical; ii) non-clinical or iii) mixed **Clinical samples** are those that comprise primarily of participants that have a clinical diagnosis of a sleep problem as defined by formal criteria (e.g., ICD, DSM). Studies where it is explicitly stated that participants have a formal diagnoses of a sleep problem are classed as clinical. This is often defined by formal diagnostic and research criteria such as the DSM or ICD	A study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might recruit participants with a DSM diagnosed sleep problem (e.g. insomnia). As a DSM rated diagnosis of insomnia is a requirement for entry into the trial, this would be coded as a **clinical sample**. A similar study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might include participants from the general population without any formal diagnoses of a sleep problem. For example, participants might be volunteers who have responded to a media

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	Non-clinical samples are those that comprise primarily of participants that have no formal diagnosis of a sleep problem. Sleep is often studied in non-clinical samples who do not have a formal diagnosis. These participants should be classed as non-clinical. **Mixed participants** are those that include participants who have formal clinical diagnoses and those who do not. Samples that include both clinical and non-clinical participants should be classified as mixed.	advertisement of email invitation. This would be coded as a **non-clinical sample**. A third study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might include a mix participants with a DSM rated diagnosis of a sleep problem (clinical) and those from the general population with no diagnosis of a sleep problem (non-clinical). This would be coded as a **mixed sample**.
8. Type of mental problems	Record the type of mental health problems and experiences that the authors measure. Where there are multiple mental health difficulties/problems, record all that are mentioned in the text.	A study may use the GAD-7 and the BDI to measure anxiety and depression respectively at baseline and again at post-intervention. In this case, record 'anxiety' and 'depression' in the box provided.
9. Type of sleep problem(s)	Record the type of sleep problem(s) and experiences that the authors measure. Where there are multiple sleep difficulties/problems, record all that are mentioned in the text.	A study may use the insomnia severity scale and the PSQI to measure insomnia and sleep quality respectively at baseline and again at post-intervention. In this case, record 'insomnia' and 'sleep quality' in the box provided.
10. Comorbidity	Record any problems or difficulties identified by the authors that are comorbid to the targeted sleep and/or the mental health problem.	An example would be an intervention designed to improve sleep in those with depression and alcohol dependency. For this review, sleep and depression would not be considered comorbid at these are the target problems of this review. However, alcohol dependency would be the comorbid problem to record in the box provided.

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11. Concurrent medication use for mental health	Were participants allowed to take medication for a mental health difficulty that is different to the intervention being tested while taking part in the research?	A study may investigate the effect of improving sleep using CBTi in people with depression who are also using SSRI medication. As these participants are receiving medication for depression, in addition to receiving an intervention designed to improve sleep, they would be classed as using concurrent medication for a mental health problem. Alternatively, some studies may screen those using medication for a mental health problem and remove these participants before randomisation, leaving only those with depression who are not on medication for it. In which case, state that the participants are using no concurrent medication for mental health.
12. Concurrent medication use for sleep	Were participants allowed to take medication for a sleep difficulty that is different to the intervention being tested while taking part in the research?	A study that tests the impact of a CBTi intervention for insomnia that allows participants to continue with benzodiazepine use would be classed as allowing concurrent medication for a sleep problems. Alternatively, a study might screen those taking medication for a sleep problem and remove these participants before randomization. Therefore, this study does not allow participants to take medication for a sleep problem in addition to the intervention being tested. In which case, state that the participants are using no concurrent medication for sleep.

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13. Concurrent psychological treatment for mental health	Were participants receiving psychological help for a mental health difficulty that is different to the intervention being tested while taking part in the research?	A study where participants are able to continue receiving psychological help from outside of the study team for an anxiety problem while receiving the study intervention. Alternatively, some studies may screen participants who are currently receiving psychological help for a mental health problem and remove these participants before randomisation. In which case, In which case, state that the participants are receiving no concurrent psychological treatment for mental health.
14. Concurrent psychological treatment for sleep	Were participants receiving psychological help for a sleep difficulty that is different to the intervention being tested while taking part in the research?	A study where participants are able to continue receiving psychological help from outside of the study team for a sleep problem while receiving the study intervention. Alternatively, some studies may screen participants who are currently receiving psychological help for a sleep problem and remove these participants before randomization. In which case, In which case, state that the participants are receiving no concurrent psychological treatment for sleep.
15. Method of recruitment	Record how participants were recruited and from which source(s). This could include, for example, referral by GPs into the trial or from health professionals, recruitment from volunteer email lists at University's or self-referral from the participant. A study may also use a combination of multiple recruitment methods. If so, record all where possible.	Clinicians may refer participants with psychosis spectrum diagnoses from outpatient centres into the trial. In which case, record that participants were recruited by healthcare professionals from a clinical outpatient setting. Alternatively, participants may see advertisements and contact the study team directly. In which case,

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		record that participants were recruited via media advertisement and self-referred to the study.
16. Nature of comparison group	Describe the type of comparison group and provide a brief description.	Participants in a wait-list control group would receive no intervention for the duration of the study. In which case, record 'wait-list control group' Alternatively, an intervention might be compared to treatment as usual (TAU) where participants receive the same care they would usually receive regardless of the trial. In which case, record 'treatment as usual' alongside a brief description of what treatment as usual is.
17. Attrition/dropout	The total number of participants in the intervention group(s) who have dropped out of the trial between baseline and each follow-up point recorded should be expressed as a percentage.	If a study started with a total $n = 100$ participants in the intervention group giving baseline data, and ended with $n = 70$ at post-intervention and $n = 50$ at a six month follow-up, then this would be reported as; Post-intervention = 25% attrition 6 month follow-up = 50% attrition
18. Follow-up points	Any point in the study where data has been collected following the intervention	A study that collects data immediately after an intervention has been delivered and then again 3 and 12 months later would have the following follow-up points; 1. Post-intervention 2. 3 months 3. 12 months

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19. Measure of sleep	Record the name of the measure(s) used to assess sleep. Please also record whether this measure was; i) self-reported; ii) rated by a clinician; or iii) measured objectively.	A study that used both polysomnography (an objective measure of sleep) and the Insomnia Severity Index (ISI, a self-report measure). List the name of the measure (e.g. polysomnography / Insomnia Severity Index) and then tick the appropriate box (i.e., objective in the case of polysomnography and self-report in the case of the ISI).
20. Measure of mental health	Record the name of the measure(s) used to assess mental health and/or wellbeing. Please also record if this measure was self-reported or rated by a clinician	A study that used the Anxiety Disorder Interview Schedule (ADIS, a clinician rated measure of anxiety disorders) and the Generalised Anxiety Disorder Assessment-7(GAD-7, a self-report measure). List the name of the measure (e.g., ADIS/GAD-7) and then tick the appropriate box (i.e., clinician rated in the case of the ADIS and self-report in the case of the GAD-7).
21. Study quality	The Jadad scale assesses three key aspects of study quality that can affect the risk of bias; (i) randomization, (ii) blinding and (iii) withdrawal/drop-out. For guidance, please refer to the Jadad scale embedded within the data extraction form and the accompanying notes.	Full guidance and examples can be seen the accompanying Jadad scale document. However an example in relation to the assessment of randomization is given below; Give a max score of 2 for randomization and a minimum score of 0 Award 1 point if randomization is mentioned (e.g. "*The patients were randomly assigned into two groups*"). Award 1 additional point if the method of randomization is appropriate (e.g. *"The*

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		randomization was accomplished using a computer, generated random number list, coin toss or well-shuffled envelopes"). Deduct 1 point if the method of randomization is inappropriate (e.g. "*The group assignment was accomplished by alternate assignment, by birthday, hospital number or day of the week etc.*")
22. Theoretical basis of the intervention	Do the authors specify the theoretical basis of the intervention? If so, provide details.	The intervention group received a 6 week course of self-guided CBT for insomnia. The intervention was delivered via the internet and included multiple components. Participants were required to complete a daily sleep diary as well as complete online exercises to reform maladaptive thought processes about sleep. There was also a psychoeducation module and a section detailing several relaxation exercises based around progressive muscle relaxation and mindfulness.
23. Delivery modality	How was the intervention delivered to participants? Provide as much detail as possible in the text box provided.	A study that uses online self-help to provide an intervention to improve sleep. The delivery modality is online/computerised self-help
24. Duration of the intervention	How long did the intervention last (to the nearest week)? If this is not known or reported, please state unknown.	An intervention that comprises of 6 weekly modules would be 6 weeks long.
25. Adherence to the intervention	There are often many measures of adherence to interventions. Please state the measure reported (where possible) in the text box along with the rate of adherence.	If an intervention comprised of 6 weekly modules and the average number of modules completed was 4, then, on average, 66% of the intervention was adhered to.

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Supplementary Materials 1

PRISMA-P Checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Page and line numbers, emboldened and in parentheses, indicate the location of the PRISMA-P item in the corresponding manuscript.

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review **(p. 1)**
Update	1b	If the protocol is for an update of a previous systematic review, identify as such **(NA)**
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number **(p. 2)**
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author **(p. 1)**
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review **(p. 18)**
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments **(NA)**
Support:		
Sources	5a	Indicate sources of financial or other support for the review **(p. 18)**
Sponsor	5b	Provide name for the review funder and/or sponsor **(NA)**
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol **(NA)**
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known **(p. 4-7)**
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) **(p. 7 and p. 10-11)**
METHODS		

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Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review **(p. 10-11)**
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage **(p. 11)**
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated **(see Supplementary Materials 2)**
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review **(p. 12)**
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) **(p. 13)**
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators **(p. 13)**
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications **(see Table 2)**
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale **(p.8. See also Table 2, p. 31)**
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis **(p. 15)**
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised **(p.15)**
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ) **(p. 13-15)**
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) **(p. 15)**
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned **(NA)**
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) **(p. 15)**
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) **(p. 15)**

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

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Does Improving Sleep Lead to Better Mental Health? A Protocol for a Meta-Analytic Review of Randomised Controlled Trials

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Does Improving Sleep Lead to Better Mental Health? A Protocol for a Meta-Analytic Review of Randomised Controlled Trials

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For submission to: *BMJ Open*

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Abstract

Introduction: Sleep and mental health go hand-in-hand, with many, if not all, mental health problems being associated with problems sleeping. Although sleep has been traditionally conceptualized as a secondary consequence of mental health problems, contemporary views prescribe a more influential, causal role of sleep in the formation and maintenance of mental health problems. One way to evaluate this assertion is to examine the extent to which interventions that improve sleep also improve mental health. **Method and analysis:** Randomized Controlled Trials (RCTs) describing the effects of interventions designed to improve sleep on mental health will be identified via a systematic search of four bibliographic databases (in addition to a search for unpublished literature). Hedges *g* and associated 95% confidence intervals will be computed from means and standard deviations where possible. Following this, meta-analysis will be used to synthesize the effect sizes from the primary studies and investigate the impact of variables that could potentially moderate the effects. The Jadad scale for reporting RCTs will be used to assess study quality and publication bias will be assessed via visual inspection of a funnel plot and Egger's test alongside Orwin's fail-safe *n*. Finally, mediation analysis will be used to investigate the extent to which changes in outcomes relating to mental health can be attributed to changes in sleep quality. **Ethics and dissemination:** This study requires no ethical approval. The findings will be submitted for publication in a peer-reviewed journal and promoted to relevant stakeholders. **Prospero registration:** CRD42017055450

Keywords: Meta-analysis; protocol; review; sleep; mental health; intervention

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Strengths

- The proposed review should provide reliable evidence on the effect of interventions designed to improve sleep on outcomes reflecting mental health.
- The findings of the proposed review will further elucidate the nature of the relationship between sleep and mental health.
- The GRADE system will be used to assess the strength of the evidence base and allow members of the public, researchers, and clinicians to judge the quality of the available evidence.

Limitations

- The proposed review will include a diverse range of interventions and target problems and so might lead to a heterogeneous group of studies. However, to mitigate this, moderation analysis will be used to investigate specific factors that might influence the effect of sleep improvement on mental health.

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Does Improving Sleep Lead to Better Mental Health? A Protocol for a Meta-Analytic Review of Randomized Controlled Trials

Difficulties sleeping and mental health problems are both public health concerns in their own right; with each having a substantive impact on both individuals and society as a whole [1-4]. However, sleep and mental health go hand-in-hand, with many, if not all, mental health problems being associated with problems sleeping [5-7]. Traditionally, sleep problems have been viewed as a consequence of mental health problems. Although this is not contested, evidence also suggests that problems sleeping can contribute to the formation of new mental health problems [8-10] and to the maintenance of existing ones [11-13]. In other words, sleep is now thought to have a *bidirectional* relationship with mental health, with problems sleeping likely to influence both the onset and trajectory of a variety of mental health difficulties. Having said this, although a number of empirical studies have manipulated sleep and examined the impact of so doing on outcomes related to mental health, to date there has not been a systematic review of these studies. Consequently, the magnitude of the effect of (changes in) sleep on mental health problems is difficult to estimate and has not been compared between different mental health outcomes and other factors that might influence the effect (e.g., across different groups of participants, research designs, and approaches to intervention).

The potential for a causal relationship between sleep and mental health also raises an exciting prospect; namely, that interventions designed to improve sleep could also improve mental health. Providing a definitive answer to this question would have important implications for clinicians, researchers, and members of the public alike. From a practical perspective, if interventions designed to improve sleep can change mental health outcomes, then they may be a useful tool for tackling mental health difficulties. Indeed, interventions designed to improve

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sleep can often be delivered remotely, in self-help and group formats, and / or at little cost through the internet [14-18]. For example, a meta-analysis by Ho et al. reported that self-help interventions based on the principles of CBT for insomnia (termed CBTi) had medium-to-large effects on the symptoms of insomnia[18].

Current evidence on the relationship between sleep and mental health

The relationship between sleep and mental health is well documented, with numerous reviews testifying to a robust link between the two [6-8 19-24]. However, the majority of these reviews have focused on primary studies with correlational research designs. That is, they; i) measure associations between variables at a single time point (i.e., cross-sectional designs); ii) measure associations between variables at multiple time points (i.e., longitudinal designs); or iii) compare the typical sleep profiles of those with mental health difficulties to those without [6 7 25 26]. Unfortunately, cross-sectional designs simply tell us that variables are associated in some way. It is impossible to determine whether sleep causes mental health problems, mental health problems cause difficulties sleeping, or whether the effect is bidirectional in nature.

Longitudinal studies, although still correlational in nature, are better able to elucidate causality than their cross-sectional counterparts. However, only a handful of reviews have provided evidence on the relationship between sleep (at one point in time) and mental health outcomes (measured later). Furthermore, all of these have focused on depression [8 24 27 28]. For example, Baglioni et al. [8] meta-analysed 21 studies that investigated the longitudinal associations between insomnia and depression. Baglioni et al. reported that people with insomnia had a twofold risk of developing depression compared to people who did not experience difficulties sleeping. Longitudinal designs are also still susceptible to the 'third variable problem' [29-31]. Namely, that a third, unmeasured variable (e.g., having young children) could cause both sleep

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difficulties and mental health problems. In summary, correlational designs are not a valid way of disentangling the relationship between problems sleeping and mental health.

Some reviews have assessed the impact of interventions designed to improve sleep on mental health outcomes[17 18 23 24 32-36]. However, for a number of reasons, even these reviews do not permit us to draw robust conclusions as to the causal impact of sleep quality on mental health outcomes. First, these reviews often include interventions that have not successfully manipulated sleep (i.e., studies in which there was no significant impact of the intervention on sleep outcomes). Such studies do not tell us anything about the relationship between sleep and mental health other than that it can be difficult to improve sleep. Second, the focus of extant reviews has been on improving sleep, with the measurement of mental health outcomes being secondary and typically limited to depression and anxiety. Consequently, the effect of improving sleep on other mental health problems is currently unclear.

Finally, to our knowledge, to date there has been no attempt to investigate variables that influence – or *moderate* – the impact of interventions that improve sleep on mental health. However, interventions designed to improve sleep are likely to vary in their content and delivery, and such variables may influence how effective they are (or appear to be) in improving sleep and / or mental health outcomes. Furthermore, variables related to the nature of the sample (e.g., age, severity of symptoms, nature of the mental health problem) and methodological features of the study (e.g., self-report vs. objective assessment of the outcome variables) are likely to influence the apparent effect of the intervention. It is therefore crucial that the impact of such variables is systematically examined across the extant evidence base in order to draw reliable and valid conclusions about the impact of changes in sleep on outcomes pertaining to mental health.

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The proposed review

A number of primary research studies have experimentally manipulated sleep (typically via some sort of psychological intervention) and then measured mental health outcomes. However, as described above, these individual studies have, to our knowledge, never been integrated in a manner that allows the magnitude of the effect of sleep quality on mental health outcomes to be estimated. Therefore, it is currently difficult to; i) draw firm conclusions about the relationship between sleep and various mental health problems; and ii) recommend with any confidence that mental health problems might be tackled using interventions that have been designed to improve sleep. Furthermore, to date there has been no attempt to understand the factors that influence, or moderate, the effect of improvements in sleep on mental health. As a consequence it is currently unclear whether and how the content and nature of the intervention(s), target sample and mental health problem, and methodological features of the primary study influence the effects of interventions designed to improve sleep on mental health outcomes.

Objectives

The proposed review therefore has two broad objectives; i) to synthesize and quantify the effect of interventions that improve sleep on outcomes reflecting mental health; and ii) to explore variables that moderate the effect of interventions targeting sleep on outcomes reflecting mental health.

Method and Analysis

This protocol has been prepared in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P, see Supplementary Materials 1) checklist [37].

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Outcomes and Prioritization

Measuring improvements in sleep

The concept of 'improved sleep' is multifaceted and can mean different things to different people[38-40]. Indeed, many specific sleep problems are tied to mental health in unique ways and often have their own unique measures. For example, the experience of nightmares has been found to be associated with post-traumatic stress disorder (PTSD)[41], as measured using specific outcome measures such as dream diaries[42 43] or the Clinician-Administered PTSD Scale (CAPS)[44]. Consequently, one challenge for the proposed review is to ensure that all of the primary studies assess a similar notion of sleep improvement. To achieve this, the proposed review will require that the primary studies report a measure that reflects the overall quality of sleep experienced by participants. Broadly speaking, sleep quality consists of; (i) sleep continuity (e.g., sleep onset, sleep maintenance, and number of awakenings); and (ii) daytime impact (e.g., the extent to which the person feels refreshed on waking and throughout the day)[39 40].

Sleep quality can be measured using both self-report and objective indices. For example, the Pittsburgh Sleep Quality Index[45] (PSQI) is widely recognized as the 'gold standard' self-report measure of sleep quality and consists of 19 items measuring 7 aspects of sleep quality (namely, subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction). The 'gold standard' for objectively measuring sleep is accepted to be polysomnography (PSG)[46]; a technique that monitors multiple biophysiological parameters and directly records aspects of sleep quality including sleep onset and sleep maintenance (for a review, see [47]). As such, the proposed review will include both self-report and objective indices of sleep quality, but will also seek to compare

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effect sizes between different measures in an effort to empirically examine the extent to which the nature of the measures influences the apparent effect of the interventions.

Measuring mental health

Measuring mental health is also complex and multifaceted, with a range of different outcomes which differ both in their administration and interpretation. Some studies will report a general measure assessing a specific diagnostic category (e.g., a measure of the severity of depression). For example, the Beck Depression Inventory II is a 21 item self-report measure designed to assess multiple facets of depression including mood, pessimism, self-dislike, loss of appetite, and social withdrawal, with higher scores indicating more severe depression[48]. Other studies might assess a single symptom or problem. For example, the Green Paranoid Thoughts Scale (GPTS) measures paranoid thoughts[49]; an experience that is associated with, but is not limited to, psychosis spectrum disorders[50 51]. Finally, some studies may report the effects of interventions designed to improve sleep on global measures of mental health. For example, the Clinical Global Impressions Severity scale (CGI-S)[52] asks clinicians to use their clinical experience to rate how mentally ill their client has been over the last week, on a scale ranging from 1 – *normal* to 7 – *amongst the most extremely ill patients*.

Measures assessing aspects of mental health can either be; (i) self-reported by the participant, or (ii) completed on behalf of the participant by a clinician or other independent rater. Both self-report and independently rated outcome measures will be included in the proposed review; however, as above, we will compare effect sizes between different measures in an effort to empirically examine the extent to which the nature of the measure(s) influences the apparent effect of the interventions.

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Eligibility Criteria

Inclusion criteria

In order to be included in the proposed review, the primary studies need to:

1. Randomly allocate participants to either an experimental group that receives an intervention that is designed to improve sleep or a comparison group.
2. Report a statistically significant improvement at on a measure of sleep quality at least one follow-up point among participants in the experimental group as compared to those in the comparison group.
3. Include a measure of mental health subsequent to the measure of sleep quality.
4. Report sufficient data for us to be able to compute effect sizes reflecting the impact of the intervention on i) sleep quality and ii) mental health. Where sufficient data is not reported, we will contact the authors and request further data. However, if this is not provided, then the study will not be included in the review.
5. Be written in English, or be able to be translated using available translation resources.

Exclusion criteria

The aim of the proposed review is to be as inclusive as possible and address potential differences between the primary studies (e.g., differences in the nature of the intervention or the mental health problem under consideration) using moderation analysis. Therefore, we will not restrict the type of intervention (e.g., psychological and pharmacological), publication status, nature of the comparison condition, or sample (i.e., interventions directed toward adults, children, and adolescents will all be eligible). However, in order to ensure that we can reliably and validly assess the independent contribution of changes in sleep on mental health outcomes among adult populations, studies with the following characteristics will be excluded:

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1. Studies where the intervention contains elements that specifically target a mental health problem alongside improving sleep (e.g., an intervention that provides CBT for anxiety alongside efforts to improve sleep).
2. Studies that recruit children and young people (i.e. under the age of 18 years old).
3. Studies adopting a pre-post (or within participant) design.

Information Sources

The proposed review will use a combination of search techniques and sources in order to identify potential studies. First, we will search MEDLINE (1946 to present), Embase (1974 to present), PsycINFO (1967 to present), and The Cochrane Library(1898 to present) using the Cochrane Highly Sensitive Search Strategy[53] to identify RCTs that include terms relating to sleep quality and/or sleep disorders and mental health (see Table 1 for a list of the proposed search terms). The search strategy has been developed in collaboration with a health sciences librarian specializing in systematic search procedures and will be used to search each database (see Supplementary Materials 2 for an example search strategy). Second, the reference lists of extant reviews of the relationship between sleep and mental health (e.g., those cited in the introduction) will be searched for any potential articles. Third, a search for any unpublished or ongoing studies will be conducted by searching online databases including White Rose Online, The National Research Register, WHO approved clinical trial databases (e.g. ISRCTN), and PROSPERO. Finally, the authors of articles deemed eligible for inclusion will be contacted and asked if they are aware of any unpublished research that may be eligible for inclusion in the review.

Data management

All records will be stored in the reference management software Endnote, and we will follow PRISMA guidelines for the selection of studies for meta-analysis [54]. Specifically, when

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the pool of potential studies has been identified, we will remove duplicates and initially screen each record based on the title and abstract and exclude clearly ineligible studies. Following this initial screening, the full-text versions of each article will be reviewed in detail and cross-referenced against the inclusion and exclusion criteria. The flow of articles through the review, including the reasons for excluding studies, will be documented in a PRISMA flow chart.

Data Extraction

Data will be recorded on a standardized data extraction form and a manual will accompany this form and detail each variable to be extracted alongside definitions and examples (see Supplementary Materials 3 and 4). Two reviewers will pilot the data extraction forms and manual on three articles in order to ensure that there are no systematic problems or difficulties coding any of the variables. After this, the data will be extracted from the full set of studies by one reviewer. A second member of the review team will second code a subset of the included articles (at least 10%) and levels of agreement will be calculated (the subset of articles for second coding will be randomly selected using a computer generated algorithm). Any disagreements will be resolved through discussion, with a third member of the review team acting as arbiter for any outstanding disagreements. The review team will extract meta-data pertaining to source characteristics (e.g., publication status and year), as well as data relating to the characteristics of the sample (e.g., age, type of mental health problem), the study (e.g., the nature of the comparison group, length of follow-up), and characteristics of the intervention (e.g., theoretical basis, mode of delivery). Table 2 provides an overview of the potential moderators that we propose to code and examine and Supplementary Materials 3 provides detail on specific moderator levels and categories.

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Proposed Analysis

Review Manager 5.3 (Cochrane Collaboration, [55] will be used to compute Hedges *g* (and associated 95% confidence intervals) using the means and standard deviations for each measure of sleep quality and mental health reported in studies comparing these outcomes between an intervention group (i.e., a group receiving an intervention that improves sleep) and a comparison group (e.g., wait-list, placebo, treatment as usual)[1]. Where means and standard deviations are not available, we will compute effect sizes by converting relevant summary statistics (e.g., *F* values from an ANOVA testing the impact of an intervention on relevant outcomes) using Lyons Morris' meta-analysis calculator [56]. The effect of the interventions on sleep quality will be assessed using data from the first available follow-up point that reports a statistically significant difference in sleep quality between the intervention and comparison conditions. The effect of the interventions on outcomes pertaining to mental health will be assessed at the longest follow-up point available, whether the effect at this point is statistically significant or not (and we will investigate the effect of follow-up duration on outcomes using moderation analysis). This strategy will provide a stringent test of the effect of the interventions on outcomes pertaining to mental health (in the sense that any changes need to have been maintained over time) and also enable us to investigate whether the impact of the interventions on outcomes is mediated by changes in sleep quality that precede the impact on outcomes pertaining to mental health (this proposed analysis is discussed in detail below).

[1] Where available, data that has been adjusted for baseline differences between groups will be used to compute effect sizes. However, if this information is not reported then we will use the unadjusted data to compute the effect sizes. We will also seek to compute effect sizes using the data from Intention to Treat (ITT) analyses where they are reported. Subscripts will be added to the table reporting the effect sizes derived from the primary research studies in order to identify how each effect size was computed and also to compare outcomes between studies that report adjusted vs. unadjusted statistics and ITT analyses vs. non-ITT analyses.

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Where studies report multiple outcome measures under one diagnostic category (e.g., several measures of depression or sleep quality), the effect sizes will be computed for each outcome and meta-analyzed in their own right to form one overall effect for inclusion in the main analysis. For example, we would compute two effect sizes reflecting sleep quality if a study reported the effects of an intervention on the Pittsburgh Sleep Quality Index[45] and the Insomnia Severity Index[57] (i.e., one effect size for each measure of sleep quality) and then average them before inclusion in the main dataset. This procedure capitalizes on the information that is available, while retaining the independence of effect sizes which is central to the validity of meta-analysis[58].

The sample-weighted average effect size (g_+) will be computed using a random effects model as studies are likely to be "different from one another in ways too complex to capture by a few simple study characteristics" [59]. Following Cohen's [60] recommendations, $g = 0.20$ will be taken to represent a 'small' effect size, $g = 0.50$ a 'medium' effect size, and $g = 0.80$ a 'large' effect size. We will use these qualitative indices to interpret the findings. Publication bias will be assessed via visual inspection of a funnel plot and Egger's test [61]. Finally, Orwin's [62] formula will be used to determine the fail-safe *n* (i.e., the number of studies producing a null effect that would be needed to reduce the overall effect of interventions that improve sleep on outcomes relating to mental health to a trivial effect size).

Heterogeneity, Bias and Study Quality

The I^2 statistic will be used to assess the heterogeneity of effect sizes across the primary studies [63]. The quality of each individual study included in the proposed review will be assessed using the Jadad scale for reporting RCTs [64]. The Jadad scale assesses three key areas of methodological quality that potentially lead to bias – namely; randomization, blinding, and the

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flow of participants through the study. In order to assess these areas, raters will be asked to answer three questions: i) "*Was the study described as randomized (i.e., does it include words such as randomly, random, and randomization*)?"; ii) "*Was the study described as double blind?*"; and iii) "*Was there a description of withdrawals and dropouts*?". Scores on the Jadad scale range from 0 to 5, with higher scores indicating a lower risk of bias (and therefore higher methodological quality). The Jadad scale for reporting RCTs has been extensively used as a measure of the methodological quality of RCTs (having received over 7,500 citations to date) and has been recommended as the most reliable and valid scale for assessing the quality of RCTs, in a review of 21 measures [65]. Finally, the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system[66 67] will be used to assess the quality of the body of evidence as a whole and the extent to which it can and should be used to inform clinical recommendations.

Moderation Analysis

Moderation analyses will be used to identify variables that influence the effect of interventions that improve sleep on both mental health. Many of these variables and their sub-categories are outlined in Table 2 (for more detail see Supplementary Materials 3); however, we are keen to be flexible and responsive to the literature as the search develops. Imposing an exhaustive coding structure *a priori* without knowledge of the primary studies included in the review may result in an unsuitable structure that does not accurately reflect the nature of the included studies. Consequently, Table 2/Supplementary Materials 3 is not intended to provide an exhaustive list of moderators and we are open to considering additional moderators and categories as the search and data-extraction develops. However, in order to ensure that the reader is clear on what analyses were pre-planned, we will label any analyses that are *not* pre-specified

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in this protocol as exploratory in the final report. Moderation analysis will be undertaken to explore the effect of variables relating to the nature of the focal sample, the methodological design and intervention characteristics across all studies within the main meta-analyses.

We will require a minimum of $k = 3$ studies representing each moderator level category in order to conduct moderation analysis (e.g., to investigate the effect of outcome type on effect sizes we will require data from at least 3 studies using self-report outcomes and at least 3 studies using clinician completed outcomes). For continuous moderators (e.g., age, publication year, study quality), sample weighted meta-regression will be used to investigate the impact of the moderator on effect sizes. For example, the quality of a given study, assessed using the Jadad scale[64], will be used as the independent variable in a sample-weighted meta-regression, with the effect sizes representing the effect of the interventions on outcomes pertaining to mental health used as the dependent variable. For categorical variables (e.g., self-report vs. clinician rated outcomes, the nature of the comparison condition), the sample-weighted average effect size (g_+) and associated standard errors will be computed for each level of the moderator and then the Q statistic will be used to assess if the effect sizes are significantly different. For example, effect sizes based on clinician rated measures of mental health (e.g., the Clinical Global Impressions Severity Scale[52]) will be compared to effect sizes based on self-report measures of mental health (e.g., the Depression, Anxiety, and Stress Scale[68]).

Mediation Analysis

Mediation analysis will be used to investigate the extent to which changes in mental health can be attributed to changes in sleep. These analyses will include all studies that report the correlation between (changes in) sleep quality and (changes in) mental health outcomes (the correlation between the intervention and sleep quality and mental health outcomes, respectively,

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will be computed by converting the sample-weighted average effect of the interventions on these outcomes into effect size *r*). These (sample-weighted, average) correlations will be entered using the matrix function into SPSS to permit analysis as if they resulted from a primary dataset. In line with Kenny, Kashy, and Bolger's [69] recommendations, we will then conduct 4 multiple regressions in order to investigate mediation. These regressions will test; i) the effect of the independent variable (i.e., the intervention) on the dependent variable (i.e., outcomes reflecting mental health); ii) the effect of the independent variable on the putative mediator (i.e., outcomes reflecting sleep quality); iii) the effect of the mediating variable on the dependent variable; and iv) the simultaneous effect of the independent variable and the mediator on the dependent variable, respectively. If the effect of the interventions on mental health can be attributed to changes in the quality of sleep, then the impact of the interventions on outcomes pertaining to mental health should be significantly reduced when the effect of the interventions on sleep quality is statistically controlled.

Ethics and Dissemination

As the proposed research is a meta-analytic review of primary studies, no ethical approval is required. We have registered the proposed review on the PROSPERO database (CRD42017055450) in order to adhere to the principles of open research. Following completion of the review, we will submit the findings for publication in a peer reviewed academic journal and attend conferences and dissemination events with stakeholders where possible.

Discussion

The proposed review will use meta-analysis alongside moderator and (meta)mediation analyses to i) quantify the effect of interventions that improve sleep on mental health outcomes; ii) test whether any effect of the interventions on these outcomes is mediated by changes in sleep

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quality, and iii) explore variables that potentially moderate the effect of the interventions targeting sleep on mental health outcomes. The proposed review has a number of strengths that we believe mean that it will make a substantive contribution. First, the review will be inclusive and investigate the effect of improving sleep on a wide range of mental health problems. Second, the review will further elucidate our understanding of the causal relationship between sleep and mental health by including only studies that successfully manipulate sleep and by conducting a mediation analysis to investigate whether any changes in mental health can be attributed to changes in sleep. Finally, the GRADE system will be used to assess the strength of the evidence base[66 67] which should allow members of the public, researchers, and clinicians to quickly access the available evidence and judge its quality.

Despite the strengths of the proposed review, however, the wide range of interventions and target problems that are likely to be addressed by the primary research studies may lead to a relatively heterogeneous group of studies (and thus, potentially effect sizes) which may lead to concerns that we are not comparing 'like with like' (cf. the problem of mixing apples and oranges[70]) and limit the extent to which the findings can be generalized to a specific population (e.g., to those with depression). However, to mitigate these concerns we will use moderation analysis to investigate specific factors that might influence the effect of improvements in sleep on mental health and to estimate the sample-weighted average effect sizes for different types of interventions and on different mental health outcomes. Our hope is that these analyses prove informative, both in understanding mental health problems (i.e., for which mental health problems can changes in sleep quality be expected to influence outcomes?) and in developing interventions designed to mitigate these problems (e.g., the review will be able to identify which interventions are most effective).

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Author Contributions

The first author (AJS) had the idea for the proposed review and approached TLW and GR, who contributed to the design of the research. AJS drafted the protocol and TLW and GR provided detailed comments before submission. AJS is the identified guarantor of the review.

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This research has not yet received any funding from the public, commercial or not-for-profit sectors.

Competing Interests

We have no competing interests to declare.

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Table 1

Search Terms that will be used to Identify Randomized Controlled Trials of Interventions Designed to Improve Sleep on Outcomes Pertaining to Mental Health

HSSS for RCTs[a]	Sleep	Mental health
Randomized controlled trial	Sleep*	"Psychological health"
Controlled clinical trial	"Circadian rhythm*"	"Mental"
Randomized	Insomnia	Psychiat*
Placebo	Hypersomnia	Affect*
Drug therapy	Parasomnia	Depress*
Randomly	Narcolepsy	Mood
Trial	Apnea	Stress
Groups	Apnoea	Anxi*
	Nightmare*	Phobi*
	"Restless legs syndrome"	"Obsessive compulsive disorder"
		OCD
		PTSD
		"Post-traumatic stress disorder"
		Psychos*s
		Psychotic
		Schiz*
		Bipolar
		Hallucination*
		Delusion*
		"Eating disturbance*"
		Anorexia
		Bulimia
		"Binge eating"

Notes: Studies will need to include at least one search term from each of the filter above in the title, abstract, or keywords, for consideration for inclusion in the review.

* = Indicates that variants of the word after the asterisk will be searched for (e.g., depress* will search for depressive etc.)

[a] The Highly Sensitive Search Strategy (HSSS) is more than just a key word search, rather it encompasses search techniques and strategies[53].

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Table 2

Variables to be Extracted for Moderation Analysis (where available, see Supplemenatry Materials 3 for detailed variable categories and levels)

Source characteristics	Sample characteristics	Design characteristics	Intervention characteristics
Publication status	Age	Method of recruitment	Size of the effect on sleep
Publication year	Gender	Nature of comparison group(s)	Duration
Journal impact factor	Type of mental health problem(s)	Attrition/drop-out rate	Theoretical basis
	Type of sleep problem(s)	Timing of follow-up	Mode of delivery
	Clinical status of mental health	Nature of outcome measure(s)	Adherence
	Clinical status of sleep problem	Type of analysis	
	Comorbidity	Adjusted vs. unadjusted data	
	Concurrent medication use	Study quality	
	Concurrent psychological help		

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Supplementary Materials 2

Ovid Medline Example Search Strategy

Database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

Search Strategy:

---

1 (Sleep$ or Insomnia$ or nightmare$ or hypersomnia$ or parasomnia$ or narcolepsy or circadian rhythm$ or restless leg syndrome or apnea or apnoea).ti,ab. (180111)

2 Sleep/ or Sleep Disorders, Circadian Rhythm/ or Sleep Disorders, Intrinsic/ or Narcolepsy/ or Restless Legs Syndrome/ or Sleep Apnea Syndromes/ or "Sleep Initiation and Maintenance Disorders"/ or Parasomnias/ (70224)

3 1 or 2 (193630)

4 (psychological health or distress or mental or psychiat$ or affect or depress$ or mood or stress or anxious or anxiety or phobi$ or obsessive compulsive disorder$ or OCD or psychos#s or psychotic or schiz$ or bipolar or bi-polar or hallucination$ or delusion$ or eating disorder$ or eating disturbance$ or anorexia or bulimia or binge eating or wellbeing or well-being or).ti,ab. (2200869)

5 Stress, Psychological/ or Anxiety Disorders/ or Obsessive-Compulsive Disorder/ or Phobic Disorders/ or exp "Feeding and Eating Disorders"/ or Anorexia Nervosa/ or Binge-Eating Disorder/ or Bulimia Nervosa/ or Depressive Disorder/ or Hallucinations/ or Delusions/ or Anxiety/ or Depression/ or psychotic disorders/ (379929)

6 4 or 5 (2283788)

7 3 and 6 (57412)

8 randomized controlled trial.pt. (446587)

9 controlled clinical trial.pt. (91788)

10 randomized.ab. (389502)

11 placebo.ab. (183719)

12 drug therapy.fs. (1928261)

13 randomly.ab. (270741)

14 trial.ab. (409336)

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15 groups.ab. (1670961)

16 or/8-15 (3972831)

17 exp animals/ not humans.sh. (4311313)

18 16 not 17 (3433652)

19 7 and 18 (19379)

20 (trial$ or intervention$ or treatment$).ti,ab. (4565976)

21 7 and 20 (23924)

22 21 not 19 (11896)

****

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Article meta-data

1. Please state the surnames and first initials of ***all*** authors of the article in the box below (e.g. Smith, J. A., Jones, A. C.);

2. Please state the year the article was first available or published; ☐☐☐☐

3. What is the publication status of the article: ☐ Published
   ☐ Unpublished (move to Q4)

   3.1. Please state the name of the journal the article was published in below;

   3.2. Please state the journals most recent impact factor; ☐☐.☐☐

Nature of the focal sample

4. Stage the mean age of the intervention group to the nearest whole year; ☐☐

5. State the rounded percentage of the total sample who are female; ☐☐

6. What is the clinical status of the mental health related problems of participants included in the study;
   ☐ Clinical status ☐ Non-clinical status ☐ Mixed status

7. What is the clinical status of the sleep related problems of participants included in the study;
   ☐ Clinical status ☐ Non-clinical status ☐ Mixed status

Nature of the focal sample

8. Record the type of mental health problems and experiences that the authors measure. Where there are multiple mental health difficulties/problems, record all that are mentioned in the text;

☐ Depression ☐ Anxiety ☐ Stress ☐ Psychosis ☐ Eating disorder ☐ OCD

☐ Phobias ☐ Wellbeing/distress ☐ PTSD

☐ Other (provide details in 8.1)

8.1. Please use the box below to provide further details regarding mental health problems/symptoms if necessary;

9. Record the type of sleep problems and experiences that the authors measure. Where there are multiple sleep problems, record all that are mentioned in the text;

☐ Insomnia ☐ Parasomnia ☐ Hypersomnia ☐ Circadian rhythm

☐ Narcolepsy ☐ Sleep apnoea ☐ Nightmares ☐ Restless-legs

☐ Other (if other, provide details in 9.1)

9.1. Please use the box below to provide further details regarding sleep problems/symptoms if necessary;

10. Do participants have any additional problems/difficulties that are comorbid to the target problem (e.g. alcohol dependency, physical disability etc.)

☐ Yes (move to Q10.1) ☐ No (move to Q12)

10.1. Please list any comorbidities stated by the authors;

Nature of the focal sample

11. Were participants allowed to take medication for a mental health difficulty/problem that is different to the intervention being tested whilst taking part in the research?

☐ Yes ☐ No

12. Were participants allowed to take medication for a sleep difficulty that is different to the intervention being tested whilst taking part in the research?

☐ Yes ☐ No

13. Were participants receiving psychological help for a mental health difficulty/problem that is different to the intervention being tested whilst taking part in the research?

☐ Yes ☐ No

14. Were participants receiving psychological help for a sleep difficulty that is different to the intervention being tested whilst taking part in the research?

☐ Yes ☐ No

Research design

15. Select the method of recruitment used in the study;

☐ Health professional referral ☐ Self-referral/voluntary ☐ Mixed ☐ Other

16. Please state the nature of the comparison group;

16.1. **Comparator 1**

☐ Wait-list ☐ TAU ☐ Placebo ☐ Active control

16.2. **Comparator 2**

☐ Wait-list ☐ TAU ☐ Placebo ☐ Active control ☐ NA

16.3. **Comparator 3**

☐ Wait-list ☐ TAU ☐ Placebo ☐ Active control ☐ NA

16.4. **Comparator 4**

☐ Wait-list ☐ TAU ☐ Placebo ☐ Active control ☐ NA

Research design

17. State the level of attrition from the intervention group as well as the total attrition rate of all groups as a percentage (see coding manual for more details);

17.1. The attrition rate of the intervention group only is: ☐☐

17.2. The attrition rate across all groups is: ☐☐

18. Record all points where data collection has occurred after the intervention has ended in months (e.g., post-intervention, 3 months, 12 months);

19. Please record the outcome measure(s) used to measure sleep quality and indicate whether the measures are self-reported, clinician rated, or objective;

☐ Self-report ☐ Clinician rated ☐ Objective

☐ Self-report ☐ Clinician rated ☐ Objective

☐ Self-report ☐ Clinician rated ☐ Objective

☐ Self-report ☐ Clinician rated ☐ Objective

20. Please record the outcome measure(s) used to record outcomes pertaining to mental health and indicate whether the measures are self-reported or rated by a clinician rated;

☐ Self-report ☐ Clinician rated

☐ Self-report ☐ Clinician rated

☐ Self-report ☐ Clinician rated

☐ Self-report ☐ Clinician rated

Research design

21. Please sate the type of analysis conducted;

☐ Intention to treat (ITT) ☐ Per protocol ☐ Not stated ☐ Other →

22. State whether adjusted or unadjusted data has been used to compute an effect size;

☐ Adjusted ☐ Unadjusted

23. Please use the Jadad quality scale to score the study in terms of randomization, blinding and the account of participants. Use the 'Score given' column, placing your score in the box provided. Examples and guidance on the interpretation of each item are provided in the coding manual;

Item	Min/max score	Description	Score
Randomization	0 to 2	1 point if randomization is mentioned at all 1 additional point if the method of randomization is appropriate Deduct 1 point if method of randomization is inappropriate	☐
Blinding	0 to 2	1 point if blinding is mentioned 1 additional point if the method of blinding is appropriate Deduct 1 point if the method of blinding is inappropriate	☐
Account of participants	0 to 1	The fate of all participants in the trial is known. If there are no data the reason is stated	☐
Total score	0 to 5	Sum total of all domains	☐

Intervention characteristics

24. Please indicate the size of the effect on sleep quality (Hedges *g*) of the intervention at the first statistically significant follow-up;

☐ Small (≤ 0.33) ☐ Medium (> 0.33, ≤ 0.66) ☐ Large (> 0.66)

25. Please state the duration of the intervention(s) to the nearest week;

26. Do the authors specify the theoretical basis of the intervention? If so, provide the broad theoretical category;

☐ Psychological ☐ Pharmacological ☐ Medical device

27. State the approach to intervention that the study describes (tick all that apply);

☐ CBTi ☐ Psychoeducation ☐ Sleep hygiene
☐ Mindfulness ☐ Relaxation ☐ Exercise/activity increase
☐ Exposure ☐ Image rehearsal ☐ Alternative medicine
☐ Medication ☐ Paradoxical intention ☐ Sleep restriction
☐ Behavioural ☐ Other (if other, provide more detail in 22.1)

27.1. Please use the box below to provide more details if required;

28. Please state the mode of delivery of the intervention (tick all that apply;

☐ Face-to-face ☐ Self-help/self-administration

28.1. If self-help/self-administration, please state how the intervention was delivered (tick all that apply);

☐ Internet ☐ Video ☐ Pen/paper ☐ Bibliotherapy

☐ Other (other, provide more detail in 28.2)

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Intervention characteristics

28.2. Please provide more detail if necessary below;

29. Please record adherence to the intervention where possible. If no adherence data is available, please state “not reported”;

Notes and comments

END OF FORM

Supplementary Materials 4

Data Extraction Manual

Data extraction manual

The following document contains details regarding the data to be extracted from primary studies included in the present review. Characteristics of the source (green), sample (yellow), study (blue), and intervention (grey) are outlined here.

Variable	Definition for coding	Example
1. Authors	The surnames and first initials of all authors.	Smith, J. A., Jones, A. C.
2. Publication year	The year that the article was first published.	2017
3. Publication status	Refers to whether the article has been published in a peer reviewed academic journal or not. Articles published in a peer reviewed academic journal should be coded as 'Published'. Articles that have not been published in a peer reviewed academic journal should be coded as 'unpublished'. Unpublished studies include those taken from PhD theses, dissertations, or studies that have otherwise not been accepted following peer review, or submitted to peer review.	Published
3.1. Journal name (if published)	The name of the journal that the article was published in.	e.g. *British Journal of Psychiatry* or *Psychiatry Research* etc.
3.2. Impact factor	Impact factor of the journal in which the article was published. This should be computed using the most recent available data from Thomson Reuters InCites	4.72 (2016)

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	Journal Citation Reports (please note the year in parentheses)	
4. Age	The mean age of the participants in the group who received an intervention designed to improve sleep. If mean age is not reported for the experimental group alone, then report the mean age of the sample as a whole. If no data on the age of the sample is available, then state 'not reported'	27 years
5. Gender	The percentage of participants who are female in the group receiving an intervention designed to improve sleep. If the gender of the participants is not reported for the experimental group alone, then report the percentage of participants who are female in the total sample. If no data on gender is available, then state 'not reported'	67%
6. Clinical status of participants' (with respect to mental health)	The mental health status of the sample should be coded as either; i) clinical; ii) non-clinical, or iii) mixed **Clinical samples** are those that comprise primarily of participants that have a clinical diagnosis of a mental health problem as defined by formal criteria (e.g., ICD, DSM). **Non-clinical samples** are those that comprise primarily of participants that have no formal diagnosis of a mental health problem.	A study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might recruit participants with a DSM diagnosed psychosis spectrum disorder only. As a DSM rated diagnosis is a requirement for entry into the trial, this would be coded as a **clinical sample**. A similar study investigating the impact of an intervention aimed at improving sleep on paranoid thinking might include participants from the general population who do not have a formal diagnoses of a mental health problem. For example, participants might volunteer in response to a media advertisement

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	Mixed samples are those that include a mix of participants who have formal clinical diagnoses and those who do not.	of email invitation. This would be coded as a **non-clinical sample**.
7. Clinical status of participants with respect to sleep problems	The clinical status of the sleep difficulties reported by the sample should be coded as either; i) clinical; ii) non-clinical, or iii) mixed **Clinical samples** are those that comprise primarily of participants that have a clinical diagnosis of a sleep problem as defined by formal criteria (e.g., ICD, DSM). **Non-clinical samples** are those that comprise primarily of participants that have no formal diagnosis of a sleep problem. **Mixed participants** are those that include a mix of participants who have formal clinical diagnoses and those who do not.	A study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might recruit participants with a DSM diagnosed sleep problem (e.g. insomnia). As a DSM rated diagnosis of insomnia is a requirement for entry into the trial, this would be coded as a **clinical sample**. A similar study investigating the impact of an intervention aimed at improving sleep on depressive symptoms might include participants from the general population who do not have a formal diagnoses of a sleep problem. For example, participants might volunteer in response to a media advertisement or email invitation. This would be coded as a **non-clinical sample**.
8. Type of mental problems	The type of mental health problem(s) and experiences that the authors measure. Where there are multiple mental health problems, record all that are mentioned in the text.	A study may use the GAD-7 and the BDI to measure anxiety and depression at baseline and again at post-intervention. In this case, record 'anxiety' and 'depression'.
9. Type of sleep problem(s)	The type of sleep problem(s) and experiences that the authors measure. Where there are multiple sleep problems, record all that are mentioned in the text.	A study may use the insomnia severity scale and the PSQI to measure insomnia and sleep quality at baseline and again at post-intervention. In this case, record 'insomnia' and 'sleep quality'.
10. Comorbidity	Any problems or difficulties identified by the authors that are comorbid to the targeted sleep and/or mental health problem.	An example would be an intervention designed to improve sleep in those with depression and alcohol dependency. For this review, sleep and depression would not be considered comorbid at these are the

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		target problems of this review. However, alcohol dependency would be considered a comorbid problem.
11. Concurrent medication use for mental health	Did participants take medication for a mental health difficulty in addition to the intervention being tested while taking part in the research?	A study may investigate the effect of improving sleep using CBTi in people with depression who are also using SSRI medication. As these participants are receiving medication for depression in addition to receiving an intervention designed to improve sleep, they would be classed as using concurrent medication for a mental health problem. Alternatively, a study may screen those using medication for a mental health problem and remove these participants before randomisation. In which case, state that the participants are not using concurrent medication for mental health.
12. Concurrent medication use for sleep	Did participants take medication for a sleep difficulty that is different to the intervention being tested while taking part in the research?	A study that tests the impact of an intervention for insomnia that allows participants to continue with benzodiazepine use would be classed as allowing concurrent medication for a sleep problems. Alternatively, a study might screen those taking medication for sleep problem and remove these participants before randomization. In which case, state that the participants are not using concurrent medication for sleep.
13. Concurrent psychological treatment for mental health	Did participants receive psychological help for a mental health difficulty in addition to the intervention being tested while taking part in the research?	A study where participants continued receiving psychological help from outside of the study team for an anxiety problem while receiving the study intervention would be classed as involving concurrent psychological treatment for mental health.

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		Alternatively, a study may screen participants who are currently receiving psychological help for a mental health problem and remove these participants before randomisation. In which case, state that the participants are not receiving concurrent psychological treatment for mental health.
14. Concurrent psychological treatment for sleep	Did participants receive psychological help for a sleep difficulty in addition to the intervention being tested while taking part in the research?	A study where participants are able to continue receiving psychological help from outside of the study team for a sleep problem while receiving the study intervention. Alternatively, a study may screen participants who are currently receiving psychological help for a sleep problem and remove these participants before randomization. In which case, state that the participants are not receiving concurrent psychological treatment for sleep.
15. Method of recruitment	How participants were recruited and from which source(s). The method of recruitment should be coded as; 1. Referral by a health professional (e.g., GP) 2. Self-referral/voluntary 3. Mixed 4. Other	Clinicians may refer participants with psychosis spectrum diagnoses from outpatient centres into the trial. In which case, record that participants were referred by a healthcare professionals. Alternatively, participants may see advertisements and contact the study team directly. In which case, record that participants were self-referred to the study. Some studies could recruit participants who are referred by a health professional and those who self-refer, in which case code this as mixed recruitment. Code any studies that use a method of recruitment not specified here as 'other'

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16. Nature of comparison group	Identify the nature of the comparison group. **Wait-list** groups are defined as those who receive no intervention (including usual care) for the duration of the study **Treatment as Usual (TaU)** groups are those that receive only their usual care throughout the study **Placebo** groups are those that unknowingly receive a 'sham' treatment that is specifically designed to have no real effect. **Active control** groups are those that receive an intervention that can theoretically have an effect on outcomes, but it is not the primary intervention being tested in the study.	An example of an active control group would be a trial comparing a group receiving full CBTi intervention with a group who simply complete a daily sleep diary. Although the sleep diary group have not received a CBTi intervention, the act of keeping a diary could improve sleep quality and is therefore considered an 'active' intervention. Other examples of active control groups include trials that compare CBT for depression against a befriending group or comparing two drugs that can affect outcomes (e.g. melatonin vs. benzodiazepines on sleep related outcomes)
17. Attrition/dropout	The total number of participants in the intervention group(s) who have dropped out of the trial between baseline and each follow-up point should be expressed as a percentage.	If a study states that *n* = 100 participants in the intervention group provided baseline data, *n* = 75 provided data immediately post-intervention and *n* = 50 provided data at 6 month follow-up, then this would be reported as; Post-intervention = 25% attrition 6 month follow-up = 50% attrition
18. Follow-up point	The number of weeks following the intervention where outcome data is reported. Where there are multiple follow-up periods, state the number of weeks following the intervention for each.	A study that collects data immediately after an intervention has been delivered and then again 3 and 12 months later would have the following follow-up points; 1. 0 weeks (post-intervention) 2. 13 weeks (3 months) 3. 52 weeks (12 months)

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19. Measure of sleep	The name of the measure(s) used to assess sleep. Identify whether each measure was; i) self-reported; ii) rated by a clinician; or iii) measured objectively.	A study that uses both polysomnography and the Insomnia Severity Index (ISI) would be coded as having both an objective and a self-report measure of sleep.
20. Measure of mental health	The name of the measure(s) used to assess mental health and/or wellbeing. Identify whether each measure was self-reported or rated by a clinician	A study that uses the Anxiety Disorder Interview Schedule (ADIS) and the Generalised Anxiety Disorder Assessment-7 (GAD-7) would be coded as having both a clinician-rated measure of anxiety disorders and a self-report measure.
21. Study quality	The Jadad scale assesses three key aspects of study quality that can affect the risk of bias; (i) randomization, (ii) blinding, and (iii) rates of withdrawal / drop-out. For guidance, please refer to the Jadad scale embedded within the data extraction form and the accompanying notes.	Full guidance & examples are provided in the data extraction form. However, an example in relation to the assessment of randomization is given below; Give a max score of 2 for randomization and a minimum score of 0 Award 1 point if randomization is mentioned (e.g. "*The patients were randomly assigned to one of two groups*"). Award 1 additional point if the method of randomization is appropriate (e.g. *"The randomization was accomplished using a computer, generated random number list, coin toss, or well-shuffled envelopes*"). Deduct 1 point if the method of randomization is inappropriate (e.g. "*The group assignment was accomplished by alternate assignment, by birthday, hospital number or day of the week etc*.")

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22. Size of the effect of the intervention on sleep quality.	Please indicate the size of the effect that the intervention has on sleep quality at the first follow-up point at which this effect is statistically significant. Use the method for computing effect sizes outlined in the protocol and then interpret the effect size with respect to Cohen's (1992) criteria, which for Hedges *g* corresponds to: **Small** effect ($g \leq 0.33$) **Medium** effect ($g > 0.33, \leq 0.66$) **Large** effect ($g > 0.66$)	Medium effect.
23. Duration of the intervention	How long did the intervention last (to the nearest week)? If this is not known or reported, then please state unknown. Note that this should be coded as the *intended* duration of the intervention, regardless of how long participants actually engaged with the intervention.	An intervention that comprises of 6 weekly modules would be coded as 6 weeks long, even if 80% of the participants only attended the first 4 weeks of the intervention.
24. Theoretical basis of the intervention	Do the authors specify the theoretical basis of the intervention? If so, state which theory (or theories) were used.	CBTi
25. Delivery modality	Identify the primary mode by which the intervention was delivered. **Face-to-face delivery** includes interventions which are administered in person by a clinician, researcher, therapist or peer **Self-help / self-administered interventions** are defined as those that are "designed to be conducted predominantly independently of professional contact" (Bower, Richards, & Lovell, 2001, p. 839)	Face-to-face delivery

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26. Adherence to the intervention	If the study assessed rate of adherence to intervention, then describe the nature of the measure along with the rate of adherence. If adherence was not assessed, then state "Not assessed".	If an intervention comprised of 6 weekly modules and the average number of modules completed was 4, then state "Average proportion of modules completed - 66%".

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Supplementary Materials 1

PRISMA-P Checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Page and line numbers, emboldened and in parentheses, indicate the location of the PRISMA-P item in the corresponding manuscript.

Section and topic	Item No	Checklist item
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review **(p. 1)**
Update	1b	If the protocol is for an update of a previous systematic review, identify as such **(NA)**
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number **(p. 2)**
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author **(p. 1)**
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review **(p. 19)**
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments **(NA)**
Support:		
Sources	5a	Indicate sources of financial or other support for the review **(p. 19)**
Sponsor	5b	Provide name for the review funder and/or sponsor **(NA)**
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol **(NA)**
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known **(p. 4-7)**
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO) **(p. 7 and p. 10-11)**
METHODS		

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Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review **(p. 10-11)**
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage **(p. 11)**
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated **(see Supplementary Materials 2)**
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review **(p. 11)**
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis) **(p. 12)**
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators **(p. 12)**
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications **(see Table 2 and Supplementary Materials 3 & 4)**
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale **(p.8. See also Table 2, p. 30)**
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis **(p. 14)**
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised **(p.13)**
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ) **(p. 13-15)**
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression) **(p. 15-17)**
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned **(NA)**
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies) **(p. 14)**
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE) **(p. 15)**

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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