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 Articles that have not been published in a peer reviewed academic journal should be coded as 'unpublished'. Unpublished studies include those taken from PhD theses, dissertations, or studies that have otherwise not been accepted following peer review, or submitted to peer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)

	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

	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

		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 a 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.

		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'

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 stated 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)

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 and 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*.")

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

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%”.