

## PROSPERO International prospective register of systematic reviews

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### A systematic review of non-pharmacological interventions for improving, and reducing disturbances of sleep, for patients with non-remissive cancer

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#### Review question(s)

To evaluate current literature on non-pharmacological interventions for promoting sleep in non-remissive cancer patients.

#### Searches

Studies were extracted from electronic databases, last searched on 11 November 2014, including: EMBASE (1996-present), MEDLINE (1996-present), PsycINFO (2002-present) via the OvidSP platform, and CINAHL (1981-present) via the EBSCO platform. Other reviews were scanned for studies that were eligible. No authors needed to be contacted for information.

Variations and expansions on terms such as: 'neoplasms', 'group interventions', and 'sleep promotion', were used to search the databases. See Appendix A for the full search strategy.

Studies with a sample size <50 were excluded. Foreign-language, conference papers or theses were excluded. No stipulations were made as to year of publication. The studies included had follow-up periods of any duration.

#### Types of study to be included

Included studies were quantitative and randomised, reducing possible confounding factors on intervention efficacy or outcome measures.

#### Condition or domain being studied

Sleep disturbance engenders physiological and psychological problems. Literature demonstrates sleep disturbance a co-symptom of concurrent cancer. There is no agreement on the best non-invasive, drug-free interventions for improving sleep quality in this population.

#### Participants/ population

Included studies had participants from any demographic background with a diagnosis of cancer of any stage/variety, but excluded if participants were in complete remission.

#### Intervention(s), exposure(s)

Included studies had non-pharmacological, and/or non-invasive sleep-related interventions of any duration.

#### Comparator(s)/ control

Included studies compared a sleep-related intervention and an alternative/control intervention, or no intervention.

#### Context

None were excluded on the basis of setting; depending on the intervention and outcome measure, different locations were necessary or practical.

#### Outcome(s)

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### Primary outcomes

Studies were included if they had outcome measures related to sleep quality, quantity and/or problems.

### Secondary outcomes

None

### Data extraction, (selection and coding)

Assessment of eligibility was performed by two non-blinded reviewers. The first stage involved abstract and title screening. Abstract/title screening removed duplicates, studies without cancer patients (or patients in remission), studies without any non-pharmacologic intervention or no sleep-related measure. Remaining studies were inspected further, using full-text screening as appropriate. This stage excluded non-randomised studies and those with a sample size <50. This was conducted by both reviewers side-by-side, ensuring agreement and open discussion.

Details extracted included information about the authors, title, year and country of publication, aims, setting and study design, and type/data (at every measurement point) for all primary and secondary outcome measures. Key demographic information was noted, including the number, age, sex and type of cancer of the participants. Any additional demographic information reported also, typically educational achievement, race, and type of previous treatments. Study participant inclusion/exclusion criteria were outlined. The intervention name, type, duration and details provided by the authors were outlined. If applicable, details of the control groups, whether they received control interventions or not, were extracted.

### Risk of bias (quality) assessment

An adapted Cochrane Collaboration risk-of-bias tool was used to assess five categories of bias.

The first related to 'selection bias' (biased allocation to interventions), including one subcategory concerning the method by which the randomisation sequence was generated - assessing whether the randomisation was truly random, and a second assessing allocation concealment - whether the sequence was concealed from investigators before and until condition assignment.

The second main category related to 'performance bias': whether the authors/researchers and participants were blind to the allocated conditions. Importantly, knowledge of the condition may alter intervention efficacy via expectancy effects. Studies were often face-to-face therapies, involving the researchers implementing their intervention, thus knowing condition assignment. This was not allowed for; the risk-of-bias was still present and adjudged appropriately.

The third was 'detection bias' - judging whether participants' data was analysed by researchers blinded to conditions, eliminating any researcher-based inflation of effects.

The fourth was 'attrition bias.' Studies had participants drop-out, or excluded, for various reasons (deaths, or found ineligible at a later date) - potentially creating non-comparable conditions. Reasoning for participant removal and statistical methods to account for missing data were assessed for transparency, and any biases detected.

Lastly, 'selective reporting' was judged, assessing whether studies published results that suited their pre-conceptions, or had missing data. Each category was judged as high, medium or low-risk. Cochrane reviews do not have 'medium' but include an 'unclear' judgment. 'Medium' was felt to be an important distinction, whereby studies made an effort to address an issue of bias, but not adequately. Because of the seriousness of the subject matter an 'unclear' bias was typically judged to be 'medium' - as a conservative and stringent way of highlighting a potential risk. If no effort was made to address an aspect of bias, it was automatically 'high-risk.'

### Strategy for data synthesis

Results of the studies were synthesised narratively describing categorical intervention type, delivery and duration efficacy.

### Analysis of subgroups or subsets

Intervention efficacy moderated by demographics and outcome measures was assessed.

### **Dissemination plans**

We aim to publish this review in a high impact journal. We will work with our university press office and patient and provider networks as advised by our RDSU and CLAHRC YH.

### **Contact details for further information**

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None

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### **Anticipated or actual start date**

31 October 2014

### **Anticipated completion date**

31 December 2015

### **Funding sources/sponsors**

None

### **Conflicts of interest**

None known

### **Language**

English

### **Country**

England

### **Subject index terms status**

Subject indexing assigned by CRD

### **Subject index terms**

Behavioral Manipulation; Humans; Neoplasms; Sleep; Sleep Disorders

### **Stage of review**

Ongoing

### **Date of registration in PROSPERO**

11 August 2015

**Date of publication of this revision**

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10.15124/CRD42015025204

<b>Stage of review at time of this submission</b>	<b>Started</b>	<b>Completed</b>
Preliminary searches	No	Yes
Piloting of the study selection process	No	Yes
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	Yes	No
Risk of bias (quality) assessment	Yes	No
Data analysis	No	No

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