PROTOCOL BRIEF

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Comparative effectiveness and safety of pharmacological and non-pharmacological interventions for insomnia: an overview of reviews

Rationale

Insomnia is a common health complaint and a symptom of a number of other psychiatric and medical conditions. Treatment for insomnia includes both drug interventions and non-pharmacological treatment. The use of prescription drugs to treat insomnia, particularly benzodiazepines, is widespread and often long-term, which may be associated with serious harms. The goal of this review is to identify drug and non-drug therapies for insomnia that have been evaluated in systematic reviews or meta-analyses and compare their effectiveness and safety.

Implications

Insomnia has many direct costs related to increased healthcare utilization and indirect social costs related to loss of productivity. Additionally, drug therapies for insomnia may carry serious risks, further increasing costs to the healthcare system. Non-drug interventions for insomnia are potentially safer and more effective in the long-term but their availability is limited and evidence is needed to determine how to encourage use of more appropriate interventions for insomnia.

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Background

- Insomnia is a common complaint in the primary care setting and can result in serious impacts to quality of life and ability to carry out day-to-day activities
- In Canada, the prevalence of insomnia in the general population was reported to be 13.4% in 2005.
- Pharmacological and non-pharmacological interventions for insomnia are vast and many. The comparative effectiveness and safety of these interventions is unclear

Objective

- To compare the effectiveness and long-term safety of pharmacological and non-pharmacological interventions for insomnia through the conduct of an overview of reviews

Methodology

- Our Eligibility criteria are outlined using the PICOST framework as follows:
  - **Population:** 18 and older with insomnia disorder (chronic or acute)
  - **Interventions:** Pharmacologic interventions, non-pharmacological interventions, combination pharmacologic and non-pharmacologic interventions
  - **Comparators:** Placebo, sham intervention, wait-list control, other interventions in scope
  - **Outcomes:** Effectiveness (e.g. sleep onset latency, Insomnia severity index), and safety (e.g. accidental injuries, delirium, all-cause mortality)
  - **Study Designs:** We will limit to systematic reviews and meta-analyses. For safety, we will conduct targeted searches for randomized controlled trials and observational studies whenever systematic reviews and meta-analyses are missing
  - **Time:** All periods of time for publication and duration of follow-up will be included for effectiveness.
- The literature search will be executed by an experienced librarian in MEDLINE, EMBASE, CINAHL, and The Cochrane Library databases. Unpublished literature will be retrieved through grey literature searches
- Title and abstract screening, full-text screening, data abstraction, and quality appraisal will be conducted in duplicate. All discrepancies will be resolved by discussion or involvement of a third reviewer.
- Study, participant, and intervention characteristics and relevant outcome data will be abstracted and summarized in tables to facilitate a descriptive synthesis and comparison

Knowledge Translation Strategy

- Results will be disseminated through publication in an open-access, peer-reviewed journal, a 1-page policy brief and presentations to relevant stakeholders and knowledge users

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