INPLASY

Effect of extended-release melatonin on insomnia in older adults, a systematic review

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ADMINISTRATIVE INFORMATION

Support - Programa de Apoyos para la Superación del Personal Académico de la UNAM (PASPA) y Proyecto DGAPA PAPIME PE210523.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202540091

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2025 and was last updated on 26 April 2025.

INTRODUCTION

Review question / Objective This systematic review aims to present an updated synthesis of the effect of extended-release melatonin on insomnia in older adults, considering the evaluation of the instrument called the Pittsburgh Sleep Quality Index (PSQI). This instrument is composed of 24 items divided to evaluate subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, medication use and daytime dysfunction. Therefore, the following question is proposed: What is the effect of extended-release melatonin on insomnia in older adults?
P: Older adults; I: Extended-release melatonin; C: alternative treatments or placebo; O: Insomnia.
This systematic review aims to present an updated synthesis of the effect of extended-release melatonin on insomnia in older adults, considering the evaluation of the instrument called the Pittsburgh Sleep Quality Index (PSQI). This instrument is composed of 24 items divided to evaluate subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, medication use and daytime dysfunction. Therefore, the following question is proposed: What is the effect of extended-release melatonin on insomnia in older adults?
P: Older adults; I: Extended-release melatonin; C: alternative treatments or placebo; O: Insomnia.

Rationale Insomnia is defined by the WHO Classification of Diseases, in the 10th Revision (ICD-10) it is referred to as “difficulty initiating or maintaining sleep, or not having restful sleep for at least one month and that is also accompanied by daytime fatigue, a feeling of significant personal discomfort and deterioration in social, work or other important areas of personal activity.”

On the other hand, melatonin is the hormone involved in regulating the sleep cycle; it can be easily synthesized and consumed orally, which

makes it of pharmaceutical interest for the treatment of insomnia. Furthermore, the natural production of this substance decreases with age, being inversely proportional to the frequency of bad sleep, this reinforces the idea that its deficiency is at least partially responsible for these disorders. Based on this reasoning, overcoming deficits that occur later in life would be a natural way to restore the sleep integrity that is lost as we age.

Therefore, it is essential to have a synthesis of knowledge on the effects of prolonged-release melatonin on insmonium in older adults. In this sense, we consider the results of the evaluation of the Pittsburgh Sleep Quality Index instrument as initiators of sleep disturbances.

However, although there are systematic reviews related to the topic, they mostly address alternative methods against insomnia, so our focus is to identify the effect of melatonin to improve sleep quality in older adults, mediated through the Pittsburgh instrument.
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Condition being studied In the current concept of insomnia (ICD-10), the relevance of adopting lifestyles to achieve sleep hygiene and, in addition, quality of sleep, is specified. In this sense, this systematic review aims to prepare a synthesis of knowledge of the effect of extended-release melatonin on insomnia through a systematic search of randomized clinical trials (RCTs) and the application that impacts the domains of the Pittsburgh Sleep Quality Index (PSQI) instrument.In the current concept of healthy aging (WHO, 2015), the relevance of the adoption of healthy lifestyles is specified for the optimization of intrinsic and functional capacity during aging and old age. In this regard, community programs or models constitute an accessible strategy to maintain and prolong functional capacity, for which the WHO (2017) proposed the ICOPE model, establishing as indicators or domains: (i) cognitive functions; (ii) mobility,
(iii) nutrition and strength; (iv) sensory capacity, (v) depressive symptoms; (vi) social participation, self-care and (vii) well-being). This systematic review aims to prepare a

synthesis of knowledge regarding the effect of community intervention programs on functional capacity through a systematic search of randomized clinical trials (RCTs) and community interventions that impact one or more of the following domains of the ICOPE.
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METHODS

Search strategy The search terms for the PubMed platforms were: (melatonin)) AND (insomnia)) AND (“older adults” OR elderly OR senior OR aging).
For the Scopus platform it was: (TITLE-ABS-KEY (melatonin) AND TITLE-ABS-KEY (insomnia) AND TITLE-ABS-KEY ("older adults") OR TITLE-ABS-KEY (elderly) OR TITLE-ABS-KEY (senior) OR TITLE-ABS-KEY (aging)) AND (LIMIT-TO (DOCTYPE , "ar")) AND (LIMIT-TO (EXACTKEYWORD, "Human")).
For the Web of Science platform, the search strategy was: Melatonin (All fields) and insomnia (All fields) and “older adults” (All fields).
Meanwhile the search terms for the Lilacs platform were: (melatonin) AND (insomnia) AND ("older adults").
The search terms for the PubMed and Scopus platforms were: ("Community model" OR "Community program" OR "Community intervention" OR “Community Exercise” OR “Community alimentation” OR “community peer support” OR “community leisure” OR “Generativity” OR “community volunteering”) AND “healthy aging” OR ((ICOPE) OR (Mobility, Cognition, Depression, Vitality, Sensory, Social participation))
For the Web of Science platform, the search strategy was: ("Community model" OR "Community program" OR "Community intervention" OR “Community Exercise” OR “Community alimentation” OR “community peer support” OR “community leisure” OR “Generativity” OR “community volunteering”)) AND ALL=(“healthy aging” OR (ICOPE) OR "Mobility" OR "Cognition" OR "Depression" OR "Vitality" OR "Sensory" OR "Social participation")
For the Lilacs platform, the search strategy was: ("Community model" OR "Community program" OR "Community intervention")) AND (“healthy aging” OR (ICOPE)) utilizando los filtros: ingles, español (se eliminaron artículos en inglés, portugués y japonés)
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Participant or population Older adults aged 60 years or older with insomnia taking extended-release melatonin who have their sleep quality assessed with the Pittsburgh instrument are eligible for this review.

Intervention Extended release melatonin.

Comparator Alternative treatments or placebo.

Study designs to be included Randomized, pre-experimental and quasi-experimental clinical trials (according to the PICO question).Randomized, pre-experimental and quasi-experimental clinical trials (according to the PIO question).

Eligibility criteria Age (≥60 years), intervention study design; community programs, community-dwelling; healthy lifestyles; ICOPE domains; English, Spanish, and Portuguese language.

Information sources An exhaustive search of scientific information will be carried out in 4 databases: PubMed, Web of Science, Scopus, LILACS. In addition, the gray literature from TESIUNAM and Google school, in accordance with the PRISMA-2020 guidelines.

Main outcome(s) Improvement and/or maintenance of the Pittsburgh scale indicators. A synthesis will be presented on the effect of melatonin (changes before and after) related to sleep hygiene.

Additional outcome(s) None.

Data management For this review, studies will be classified according to: (i) year of author, (ii) country, (iii) study design, (iv) population, age, (v) measurement instruments, (vi) Pittsburgh scale indicators. Two reviewers will participate in the selection of studies for inclusion and eligibility and in case of discrepancy a third researcher will intervene.

Quality assessment / Risk of bias analysis The RoB2 and ROBINS-I tool will be used.

Strategy of data synthesis A systematic review table will be prepared considering the elements of the PICO acronym. Revman software version 5.4.1 will be used, in the case of carrying out a meta-analysis with a random effects model to estimate the effect size.

Subgroup analysis None.

Sensitivity analysis None.

Language restriction Only studies published in English, Spanish and Portuguese will be considered.

Country(ies) involved México.

Other relevant information None

Keywords Older adults; extended release melatonin; Insomnia, Pittsburgh; sleep quality; sleep hygiene.Older adults; Community intervention; intrinsic capacity, functional capacity; healthy aging.

Dissemination plans At the end of the review it will be published in a peer-reviewed journal.

Contributions of each author

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