INPLASY

Effect of non-pharmacological interventions aimed at sleep self-management on glycemic control in adults with type 2 diabetes mellitus

INPLASY202650051
doi: 10.37766/inplasy2026.5.0051
Received: 8 May 2026
Published: 8 May 2026

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ADMINISTRATIVE INFORMATION

Support - Doctoral Program, National Autonomous University of Mexico. SECIHTI, Secretariat of Science, Humanities, Technology and Innovation.

Review Stage at time of this submission - Risk of bias assessment.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202650051

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 May 2026 and was last updated on 8 May 2026.

INTRODUCTION

Review question / Objective This systematic review seeks to synthesize the existing evidence on how non-pharmacological interventions aimed at improving sleep affect adults with type 2 diabetes mellitus. In these cases, strategies such as cognitive-behavioral therapy for insomnia (CBT-I), combined with the assessment of variables related to sleep and blood glucose control, have been tested[1].

The research question was structured according to the PICO framework. The study population consists of adults with type 2 diabetes mellitus, sleep disturbances, or sleep practices amenable to intervention[2]. The intervention includes non-pharmacological approaches aimed at improving sleep, such as cognitive behavioral therapy, sleep education, sleep hygiene[3]. The comparator will be usual care, a control group, health education, or an equivalent condition defined in each trial[4]. The primary outcome will be glycemic control, preferably measured by glycosylated hemoglobin, although fasting glucose or other metabolic markers will also be considered when reported by the study[5].

Rationale Interest in studying sleep in people with type 2 diabetes has grown because poor sleep quality is associated with a higher risk of glycemic dysregulation[6]. Furthermore, not only does the amount of sleep matter, but also the regularity and variability of sleep, as these factors may be related to less favorable HbA1c levels[7].

From a clinical perspective, this relationship has driven the development of non-pharmacological interventions. A randomized clinical trial demonstrated that a cognitive-behavioral intervention improved sleep quality and reduced HbA1c levels during follow-up[1]. In another pilot study, cognitive-behavioral therapy for insomnia led to improvements in diabetes-related outcomes, including indicators of glycemic control and self-care[2].

Education on sleep habits has also yielded promising results. In a pilot study in China, an

educational intervention targeting people with type 2 diabetes who slept past midnight was associated with improved sleep quality and a reduction in HbA1c[5]. Similarly, a clinical trial using educational strategies showed improvements in sleep quality in people with diabetes[8].
However, the evidence is not entirely consistent. A more recent trial of online CBT-I showed more consistent effects on insomnia and depressive symptoms than on HbA1c in the primary analysis[4].
Therefore, a review is warranted to critically integrate the available primary studies and, where sufficient homogeneity exists, estimate the effect of these interventions on glycemic control[9].

Condition being studied This review analyzes glycemic control in adults with type 2 diabetes, highlighting sleep as a modifiable clinical factor in the comprehensive management of the disease. The importance of this aspect lies in the fact that sleep disturbances are frequent in people with type 2 diabetes and have been associated with poorer glycemic control[6].
In this context, non-pharmacological sleep interventions are relevant because they can influence behavioral and physiological aspects that affect metabolic regulation. Of these, cognitive behavioral therapy, education, and sleep hygiene are the most commonly used interventions, although the results do not appear to be entirely consistent. Cognitive behavioral therapy for insomnia is one of the most researched strategies in this population[2]. Education and sleep hygiene have also been used as viable options to improve nighttime practices and promote better rest[5]. Hence the interest in carrying out this review.

METHODS

Search strategy A search will be conducted following the PRISMA-2020 guidelines. The literature search will be performed in PubMed, Scopus, Web of Science, LILACS, SciELO, and TESIUNAM as gray literature.
The strategy combined terms related to type 2 diabetes mellitus, sleep, and non-pharmacological interventions. The use of terms related to cognitive behavioral therapy for insomnia is relevant, as this has been one of the most studied approaches in people with type 2 diabetes[1]. Terms related to sleep education and hygiene will also be included, as these strategies have been used as specific interventions in this population[5].
As a search strategy, the following equation will be used: ("cognitive behavioral therapy for insomnia") AND ("glycemic control" OR "diabetes mellitus") AND ("adults"), which will be adapted to the characteristics of each source. When relevant, synonyms and variants such as type 2 diabetes mellitus, T2DM, older adults, elderly, insomnia, and sleep quality will be incorporated. In addition to the electronic search, the reference lists of the included studies will be manually reviewed to locate additional literature.

Participant or population Adults aged 18 years or older with a diagnosis of type 2 diabetes mellitus will be included[2].
Studies conducted in older adults with type 2 diabetes will also be eligible, given that this population has been included in research on sleep and circadian rhythm in institutional settings[3].
When a study includes a mixed population, such as prediabetes and type 2 diabetes, it will only be considered if the data from the subsample with type 2 diabetes can be clearly identified or if its inclusion does not compromise the clinical and methodological consistency of the review.

Intervention Non-pharmacological interventions explicitly aimed at the management, regulation, or improvement of sleep will be included[1].
Likewise, educational interventions focused on sleep will be eligible[5].

Comparator The accepted comparators will be the usual care of the control group (without intervention), usual care, health education, or an equivalent condition defined in each trial.

Study designs to be included Randomized controlled trials, randomized pilot trials, and comparative intervention studies with quantitative outcome assessment will be included.

Eligibility criteria Studies that meet the following criteria will be included: adult population with type 2 diabetes mellitus; non-pharmacological sleep-related intervention; presence of a comparator group; and measurement of at least one glycemic outcome, such as HbA1c or fasting glucose. This last criterion is essential because the review seeks to assess not only the effect on sleep, but also on metabolic control[5].
Observational studies, narrative reviews, systematic reviews, and meta-analyses will be excluded, as well as studies whose main focus is not a sleep intervention in people with type 2 diabetes, even if they address other psychological or self-care dimensions[7].

Information sources The information sources will be PubMed, Scopus, Web of Science, LILACS, SciELO, and TESIUNAM.

Main outcome(s) The primary outcome will be glycemic control measured by glycosylated hemoglobin and/or fasting blood glucose.

Additional outcome(s) Secondary outcomes will include sleep quality, insomnia severity, sleep efficiency, sleep latency, and sleep regularity.

Data management The full texts of potentially eligible studies will be reviewed to determine their final inclusion.
Data extraction will include author, year, country, study design, sample characteristics, type of intervention, comparator, follow-up duration, sleep assessment instruments, glycemic outcomes, and primary results.
When studies do not clearly report the data necessary for quantitative synthesis, attempts will be made to contact the corresponding authors.

Quality assessment / Risk of bias analysis The assessment of methodological quality will depend on the design of the included studies. For randomized clinical trials, RoB 2 will be used, while for non-randomized or quasi-experimental studies, ROBINS-I will be used.
The main synthesis will be systematic, organized by study type, population characteristics, nature of the intervention, comparator, and outcomes. However, if the studies ultimately prove sufficiently homogeneous, a meta-analysis will be considered using models appropriate for continuous data and for heterogeneity between studies.

Strategy of data synthesis A systematic review chart will be elaborated, considering the elements of the achromic PICO. Software Revman version 5.4.1 will be used to create the possibility to carry out a meta-analysis and a model of random effects to estimate the effect size.

Subgroup analysis If the quantity and quality of the studies are allowed, subgroup analyses will be performed according to: age group, intervention format (individual, group, face-to-face, online), treatment duration, comparator type, and glycemic outcome type. The difference between samples exclusively of older adults and mixed samples with older age subgroups could also be explored.

Sensitivity analysis If a meta-analysis is conducted, sensitivity analyses will be performed to exclude studies with a high risk of bias, very small pilot studies, theses, grey literature, and studies with poorly detailed interventions.

Language restriction Provisionally, it is suggested to include studies in English, Portuguese, and Spanish.

Country(ies) involved Mexico.

Keywords Type 2 diabetes mellitus; sleep; insomnia; cognitive-behavioral therapy for insomnia; sleep hygiene; sleep education; glycemic control; HbA1c.

Dissemination plans The results of this review will be integrated into the development of the doctoral thesis, presented at academic forums or nursing and health congresses, and submitted to a scientific journal related to nursing, sleep, aging, or diabetes.

Contributions of each author

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