

INPLASY PROTOCOL

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**Review Stage at time of this
submission:** Data analysis.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: This study
aimed to evaluate the effectiveness of
footbaths on the sleep quality of older
adults: A systematic review and meta-
analysis.

Effectiveness of footbaths on the sleep quality of older adults: A systematic review and meta-analysis

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Review question / Objective: This study aimed to evaluate
the effectiveness of footbaths on the sleep quality of older
adults: A systematic review and meta-analysis.

Condition being studied: A systematic review was performed
in Medline OVID, Embase, Cochrane Library, Airtiti Library,
and Google Scholar up to May 2023. Original studies
investigating the effects of footbaths on sleep quality were
included.

INPLASY registration number: This protocol was registered
with the International Platform of Registered Systematic Review
and Meta-Analysis Protocols (INPLASY) on 06 September 2022
and was last updated on 25 August 2023 (registration number
INPLASY202290025).

Rationale: Although multiple experimental
studies have explored how footbaths
influence sleep among older adults, the
ideal procedure remains poorly
understood. To bridge this gap in
knowledge, a systematic review and meta-
analysis were performed. The aim was to
assess existing literature regarding the

impact of footbaths on the sleep quality of older adults and to offer comprehensive insights for establishing evidence-based guidelines pertaining to the optimal utilization of footbaths.

Condition being studied: A systematic review was performed in Medline OVID, Embase, Cochrane Library, Airiti Library, and Google Scholar up to May 2023. Original studies investigating the effects of footbaths on sleep quality were included.

METHODS

Search strategy: Our SR/MA was the first article to examine the optimal use of footbaths on the sleep quality of older adults.

Participant or population: Over 60 years old.

Intervention: Footbath.

Comparator: No footbaths or no-footbaths (i.e., reflexology and hand-bath).

Study designs to be included: Study design was randomized controlled trials (RCTs), randomized crossover trials or quasi-experimental studies without language limitations. The exclusion criteria were studies (1) without full text available and (2) with insufficient data.

Eligibility criteria: The research's inclusion criteria aligned with our PICO question: (1) participants were individuals aged 60 and above; (2) the intervention involved footbaths; (3) outcomes encompassed sleep quality evaluated through either objective or subjective measures; and (4) the study designs encompassed randomized controlled trials (RCTs), randomized crossover trials, or quasi-experimental studies, with no language limitations. Exclusion criteria encompassed studies (1) lacking full-text availability and (2) possessing inadequate data.

Information sources: We conducted a systematic review by searching Medline OVID, Embase, Cochrane Library, Airiti

Library, and Google Scholar databases up until May 2023. Our review included original studies that examined the impact of footbaths on sleep quality.

Main outcome(s): Warm footbaths enhance the sleep quality of elderly individuals.

Additional outcome(s): For enhancing sleep quality in older adults while prioritizing safety and feasibility in clinical or home settings, the optimal procedure involves immersing their feet in warm water at 41°C for 20 minutes before bedtime, for 1-1.5 hours daily over the span of a week.

Data management: Following the PRISMA guidelines, two independent reviewers screened and extracted data.

Quality assessment / Risk of bias analysis: The quality assessment of the included studies was conducted using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for randomized controlled trials and quasi-experimental studies (19,20). For randomized controlled trials (RCTs), the JBI Critical Appraisal Checklist was employed to evaluate internal validity. This assessment covered factors such as bias related to selection and allocation (3 items), bias associated with intervention/exposure administration (3 items), bias related to outcome assessment, detection, and measurement (3 items), bias pertaining to participant retention (1 item), and statistical conclusion validity (3 items). The same checklist with 9 items was employed for evaluating the quality of quasi-experimental studies. The quality assessment was carried out independently by two reviewers (SYC, YCL), followed by the involvement of the third and fourth authors (YCC, HYH) to address any disparities in assessments between SYC and YCL and to reach a consensus.

Strategy of data synthesis: The data synthesis strategy involved combining the findings from the included studies to derive comprehensive insights. Meta-analysis was conducted using Cochrane Review Manager (RevMan) version 5.4, following the guidelines set by the Cochrane

Collaboration (2020). To assess the heterogeneity among the studies, the chi-squared (Cochran's Q test) and the I² test were applied, where $p < 0.01$ indicated significant heterogeneity. Due to the observed heterogeneity and the continuous nature of the outcome measures, a random-effects model was adopted. Standard mean difference (SMD) with corresponding 95% confidence intervals (CIs) were used to evaluate the effect of footbaths on older adults' sleep quality. Subgroup analysis was carried out to explore variations based on different control interventions, water temperature, immersion duration, and total footbath time. The outcomes were presented through forest plots, providing a visual representation of the meta-analysis results.

Subgroup analysis: Subgroup analyses were performed, considering distinct control interventions, water temperatures, immersion durations, and total footbath duration.

Sensitivity analysis: Due to the substantial heterogeneity observed among the included studies ($I^2 = 82\%$), we recognized the importance of assessing the robustness of our findings. As a result, in addition to subgroup analyses based on different control interventions, water temperature, immersion duration, and total footbath time, we conducted a sensitivity analysis. This analysis involved exploring the impact of excluding studies with potential outliers and recalculating the results using alternative statistical methods. The consistency of the sensitivity analysis outcomes with the main analysis provided further confidence in the reliability of our conclusions.

Language: No language restrictions.

Country(ies) involved: Taiwan/National Cheng Kung University Hospital.

Keywords: Footbaths, Sleep quality, Older adults, A systematic review and Meta-analysis.

Dissemination plans: Submission journal.

Contributions of each author:

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