INPLASY PROTOCOL

To cite: Lei et al. Efficacy and safety of bright light therapy in patients with post-stroke insomnia: A systematic review and meta-analysis. Inplasy protocol 2021100065. doi: 10.37766/inplasy2021.10.0065

Received: 18 October 2021

Published: 18 October 2021

Corresponding author:
Xusheng Xue

xuexushengssmyy@sohu.com

Author Affiliation:
Sun Simiao Hospital, Beijing University of Chinese Medicine, Tongchaun, Shaanxi 727031, China

Support: **SZY-KJCYC-2020-YJ**

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

Conflicts of interest:
None declared.

Efficacy and safety of bright light therapy in patients with post-stroke insomnia: A systematic review and meta-analysis

Lei, H[1]; Wang, W[2]; Cao, Y[3]; Ma, Y[4]; Xue, X[5].

Review question / Objective: **This review aims to systematically investigate the efficacy and safety of bright light therapy (BLT) in post-stroke insomnia (PSI) patients reported in randomized clinical trials (RCTs).**
Information sources: **The database of randomized controlled trials related to BLT of PSI will be reviewed to collect the following: Embase, MEDLINE, PubMed, Web of Science, Cochrane Library Central Register of Controlled Trials, CBM, CNKI, Wan fang database, Chongqing VIP information, Google scholar, Baidu Scholar, and SinoMed. No limitation on language or publication types restriction will be applied.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 October 2021 and was last updated on 18 October 2021 (registration number INPLASY2021100065).

INTRODUCTION

Review question / Objective: **This review aims to systematically investigate the efficacy and safety of bright light therapy (BLT) in post-stroke insomnia (PSI) patients reported in randomized clinical trials (RCTs).**

Condition being studied: **As an acute cerebrovascular disease, stroke is the main cause of death and disability in adults, and presents a high risk of recurrence. Sleep disorders are a prominent feature of stroke, of which the most common type is insomnia. Most stroke patients often suffer from insomnia after stroke. To be specific,**

post-stroke insomnia (PSI) is often manifested as difficulty in falling asleep, early awakening and declining quality of sleep. Ample evidence indicates that insomnia not only affects stroke recovery and quality of life, but also increases the risk of stroke recurrence and mental disorders such as anxiety and cognitive decline. At present, the treatment of PSI is still based on drug treatment. However, these drugs are known to have several side effects such as nausea, drowsiness, and drug dependence. In addition, long-term drug treatment poses long-term economic pressure to PSI. Because light has an important role in regulating human sleep and wakefulness, light has now been used to treat sleep disorders. Bright light therapy (BLT) is a natural, simple form of treatment that has relatively low costs, and it does not lead to residual effects and tolerance for patients. At present, some clinical studies have found that BLT exhibits therapeutic effects in PSI. Still, evidence of its efficacy and safety is inconclusive. The purpose of the protocol is to evaluate the efficacy and safety of BLT in PSI therapy.

METHODS

Search strategy: Search medical subject headings (MeSH) and key words associated with BLT in the treatment of PSI based on the following databases: Embase, MEDLINE, PubMed, Web of Science, Cochrane Library Central Register of Controlled Trials, the Chinese Biomedical Literature Database (CBM), China national knowledge infrastructure database (CNKI), Wan fang database, Chongqing VIP information, Google scholar, Baidu Scholar, and SinoMed.

Participant or population: Patients who are clinically diagnosed with PSI will be included, regardless of their gender, age, ethnicity, severity of the disease, economic status, or education. Meanwhile, some special PSI participants who were pregnant or breastfeeding mothers will be excluded. In addition, We will exclude PSI patients with other severe illnesses, including cancer, heart, liver or lung disease.

Intervention: The intervention measures of the treatment group were BLT alone or BLT as the main part of the combined therapy. Besides, there was no restriction applied to the frequency, duration, location, and color of BLT.

Comparator: The intervention measures of the control group will include no treatment, sham treatment (such as low-intensity light, dim red light, or negative ion), placebo, or other active interventions. Eligible comparisons will include BLT versus no treatment, BLT versus placebo or sham treatment, BLT versus other active therapies, BLT + active therapy versus the same active therapy.

Study designs to be included: RCTs that investigated the efficacy and safety of BLT for PSI patients will be included.

Eligibility criteria: The inclusion and exclusion criteria of this study are based on the PICOS principles (Patient, Intervention, Comparison intervention, Outcome, Study design).

Information sources: The database of randomized controlled trials related to BLT of PSI will be reviewed to collect the following: Embase, MEDLINE, PubMed, Web of Science, Cochrane Library Central Register of Controlled Trials, CBM, CNKI, Wan fang database, Chongqing VIP information, Google scholar, Baidu Scholar, and SinoMed. No limitation on language or publication types restriction will be applied.

Main outcome(s): Mainly observe the overall effectiveness.

Quality assessment / Risk of bias analysis: Two authors will independently assess the risk of bias on the basis of the Cochrane risk-of-bias tool for each study included. In addition, a third party will be invited to resolve disagreement.

Strategy of data synthesis: The software RevMan 5.3 will be used to perform the meta-analysis. If heterogeneity is minor, a fixed-effect model will be used for meta-analysis. However, if heterogeneity is

substantial, a random-effects model will be used for meta-analysis. Moreover, we will carry out subgroup analysis or other assessments to check the possible reasons.

Subgroup analysis: If necessary, we will perform subgroup analysis to study heterogeneity according to interventions, participant characteristics, and outcome measures.

Sensitivity analysis: Sensitivity analysis will be used to assess the robustness of the results.

Language: No language restrictions.

Country(ies) involved: China.

Keywords: bright light therapy, post-stroke insomnia, systematic review, protocol.

Contributions of each author:
Author 1 - Huabin Lei.
Author 2 - Wei Wang.
Author 3 - Yinan Cao.
Author 4 - Yaru Ma.
Author 5 - Xusheng Xue.