INPLASY PROTOCOL

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Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None declared.

Moxibustion for the treatment of fatigue in dialysis patients: a systematic review and meta-analysis

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Review question / Objective: **The objective of the proposed work is to evaluate the efficacy and safety of moxibustion as a treatment in improving fatigue in dialysis patients.**
Condition being studied: **Fatigue is a highly prevalent and debilitating symptom in patients undergoing dialysis and is associated with impaired quality of life, cardiovascular disease, and mortality. The causes of fatigue in patients receiving dialysis are complex and multifactorial. Uremia, anemia, depression, quality of sleep and physical deconditioning can lead to fatigue in dialysis patients. There is evidence suggested that specific non-pharmaceutical interventions were potentially effective in improving dialysis related-fatigue, such as cognitive behavioral therapy, exercise, reflexology, aromatherapy, acupressure and moxibustion. By far, how to relieve fatigue in dialysis patients remained controversial.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 May 2022 and was last updated on 15 May 2022 (registration number INPLASY202250094).

INTRODUCTION

Review question / Objective: **The objective of the proposed work is to evaluate the efficacy and safety of moxibustion as a treatment in improving fatigue in dialysis patients.**

Rationale: **Fatigue was a highly prevalent and debilitating symptom in patients maintaining dialysis. It substantially impaired patients' quality of life, with limited treatments. Moxibustion, an external therapy of traditional Chinese**

medicine, has been widely used for alleviating fatigue in cancer and subhealth population. Attempts have been made to apply moxibustion for treating dialysis related-fatigue. The efficacy and safety of moxibustion in the treatment of fatigue in dialysis patients remained unclear.

Condition being studied: Fatigue is a highly prevalent and debilitating symptom in patients undergoing dialysis and is associated with impaired quality of life, cardiovascular disease, and mortality. The causes of fatigue in patients receiving dialysis are complex and multifactorial. Uremia, anemia, depression, quality of sleep and physical deconditioning can lead to fatigue in dialysis patients. There is evidence suggested that specific non-pharmaceutical interventions were potentially effective in improving dialysis related-fatigue, such as cognitive behavioral therapy, exercise, reflexology, aromatherapy, acupressure and moxibustion. By far, how to relieve fatigue in dialysis patients remained controversial.

METHODS

Search strategy: The search terms will be collected from subject terms in the databases and published systematic reviews. Both Chinese and English synonyms representing the concept of dialysis, fatigue and moxibustion will be recorded. Subject terms and text word will be combined in the searching.

Participant or population: Maintaining dialysis patients with symptom of fatigue. Patients receiving kidney transplant are not eligible. Fatigue can be measured in patient reported outcomes or be measured by valid scales. Fatigue caused by any known comorbidities, such as cancer, should be excluded.

Intervention: Any form of moxibustion therapy, including traditional moxibustion ignited with fire or modern infrared devices.

Comparator: Sham moxibustion and/or blank control.

Study designs to be included: Data for the proposed study will be obtained from randomized controlled studies.

Eligibility criteria: Inclusion criteria: (1) Randomized controlled trials include parallel controlled and crossover controlled. (2) All participants were adults who were maintaining dialysis. (3) Intervention can be any types of moxibustion therapy, either alone or in combination with other therapies. (4) Outcome measures reported at least one fatigue-related outcome.Exclusion criteria: (1) Basic research, such as cell and/or animal experiments. (2) Included renal transplantation participants, or patients receiving temporarily dialysis treatment. (3) Studies that do not report outcome measures related to fatigue, or studies with incorrect data.

Information sources: We will search the following Chinese and English databases from their inception to 24 March 2022. Chinese databases include China National Knowledge Infrastructure (CNKI), Wan Fang, Chinese Science and Technology Journal Database (VIP), and SinoMed Database. English databases include PubMed, EMbase, CINAHL and Cochrane Library. Clinical trial registers will be searched for related studies, including Chinese Clinical Trial Registry, Clinical Trials.gov, Japan Primary Registries Network and Clinical Research Information Service (CRiS), Republic of Korea. Additionally, references of published systematic review will be examined for relevant studies. No language or publication type is imposed.

Main outcome(s): The change of degree of fatigue, which are measured by valid scales.

Additional outcome(s): Risks of adverse events.

Data management: RevMan 5.4.

Quality assessment / Risk of bias analysis: Studies that are eligible for quantitative analyses will be assessed for the

methodology quality individually. Within-study risk of bias (RoB) will be assessed by using Cochrane's RoB tool.

Strategy of data synthesis: RevMan 5.4 software is used for data integration and meta-analysis. The relative risk (RR) is selected as the effect size for dichotomous variables, and the mean difference (MD) is selected as the effect size for continuous variable data. The 95% confidence interval (CI) is used to express the interval estimation between the two groups. Considering the clinical and methodological heterogeneity, random-effect model will be used.

Subgroup analysis: Subgroup analysis will be performed according to the mode of dialysis, the severity of fatigue, the form of moxibustion and the duration of treatments, if applicable.

Sensitivity analysis: Sensibility analysis will be conducted by excluding studies with high risk of bias. When more than ten articles are included in the same outcome, funnel plots will be drawn to determine potential publication bias.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Moxibustion, fatigue, dialysis.

Dissemination plans: The results will be reported as journal article.

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