INPLASY PROTOCOL

To cite: Hou et al. Efficacy and safety of acupuncture and moxibustion combined with Shenmai injection in the treatment of Cancer related fatigue:a systematic review protocol. Inplasy protocol 202140129. doi: 10.37766/inplasy2021.4.0129

Received: 25 April 2021

Published: 25 April 2021

Corresponding author:
xianbing hou

houxianbing007@126.com

Author Affiliation:
Fenghua District Hospital of Traditional Chinese Medicine, Ningbo City, Zhejiang Province

Support: **None.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Efficacy and safety of acupuncture and moxibustion combined with Shenmai injection in the treatment of Cancer related fatigue: a systematic review protocol

Hou, XB[1]; Chen, DD[2]; Cheng, TF[3]; Wang, D[4]; Dai, XJ[5]; Wang, Y[6]; Cui, BX[7]; Wang, YY[8]; Xu, H[9]; Chen, HZ[10].

Review question / Objective: **Population: cancer patients Intervention: non-pharmacological interventions Comparison: any intervention Outcome: cancer-related fatigue Study design: RCTs.**
Condition being studied: **According to the survey, in recent years, the cancer is increasing gradually, and the cancer-related fatigue increases too. The causes of cancer-related fatigue are mostly due to cancer or cancer treatment and other reasons. In the majority of studies, majority of patients report moderate to severe fatigue during treatment, which in some cases may lead to treatment discontinuation. In recent years, there are many randomized controlled trials that show that acupuncture is effective for cancer-related fatigue. However, acupuncture alone may have limitations. Therefore, this study hopes to provide evidence-based support for acupuncture and moxibustion combined with Shenmai injection in the treatment of Cancer related fatigue through this systematic evaluation.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 April 2021 and was last updated on 25 April 2021 (registration number INPLASY202140128).

INTRODUCTION

Review question / Objective: **Population: cancer patients Intervention: non-pharmacological interventions Comparison: any intervention Outcome: cancer-related fatigue Study design: RCTs.**

Condition being studied: **According to the survey, in recent years, the cancer is increasing gradually, and the cancer-related fatigue increases too. The causes of cancer-related fatigue are mostly due to cancer or cancer treatment and other reasons. In the majority of studies, majority of patients report moderate to severe**

fatigue during treatment, which in some cases may lead to treatment discontinuation. In recent years, there are many randomized controlled trials that show that acupuncture is effective for cancer-related fatigue. However, acupuncture alone may have limitations. Therefore, this study hopes to provide evidence-based support for acupuncture and moxibustion combined with Shenmai injection in the treatment of Cancer related fatigue through this systematic evaluation.

METHODS

Participant or population: Patients diagnosed with cancer-related fatigue will be included regardless of gender, age, race, education and source.

Intervention: Acupuncture combined with Shenmai injection.

Comparator: Conventional treatment.

Study designs to be included: RCTs.

Eligibility criteria: There are clear and recognized diagnostic criteria and efficacy criteria, and all patients are diagnosed as CRF, regardless of gender, age, and origin of the case.

Information sources: We will start electronic searches from PubMed, MEDLINE, Embase, Web of Science, Cochrane Central Register of Controlled Trials (Central), China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM), China Science Journal Database (VIP) and Wanfang Database. The search date is from the database to March 30, 2021, and the search language is limited to Chinese and English. In addition, we will manually retrieve other resources, including reference lists of identified publications, conference articles and grey literature.

Main outcome(s): Clinical efficacy, including total effective rate or cure rate and fatigue scale score will be accepted as the primary outcomes.

Additional outcome(s): The KPS score, TCM syndrome score, adverse events, will be used as secondary outcomes.

Data management: Data extraction and analysis will be performed independently by two researchers. When differences and opinions are inconsistent, they should be resolved through discussion. If the differences encountered cannot be resolved through discussion, a third author will be invited to resolve them.

Quality assessment / Risk of bias analysis: We will use the "deviation risk" tool in Cochrane Manual v.5.1.0 to assess the deviation risk of each article in the literature. Assessments include sequence generation, allocation sequence hiding, blindness of participants and people, and outcome evaluators, incomplete outcome data, selective outcome reporting and other sources of bias. If the risk of bias is high in the literature, we will try to explain and discuss the causes of bias.

Strategy of data synthesis: For dichotomous data, we will denote the outcomes as relative risks (RRs) with 95% CIs. If the I^2 test is less than 50%, the fixed-effects model will be used for data synthesis. If the I^2 test is between 50% and 75%, the random-effects model will be conducted for data synthesis. If the I^2 test is higher than 75%, we will investigate possible reasons from both clinical and methodological perspectives, and provide a descriptive analysis or conduct subgroup analysis. For continuous data, if no heterogeneity is detected, we will use mean difference (MD) or standard MD (SMD) to measure the therapeutic effect of 95% CIs. If significant heterogeneity is found, we will use the random-effects model instead.

Subgroup analysis: If there are obvious heterogeneity, we will conduct subgroup analysis to identify the sources of heterogeneity. We will conduct subgroup analysis according to different combinations of acupuncture, different course time or different outcome indicators.

Sensitivity analysis: When sufficient trials are available, sensitivity analysis will be performed by sequentially eliding each trial to check the robustness of the final results.

Country(ies) involved: China.

Keywords: Cancer-related fatigue; Moxibustion; Acupuncture; Systematic review.

Contributions of each author:

Author 1 - Xianbing Hou.
Email: houxianbing007@126.com
Author 2 - Dandan Chen.
Email: 819328570@qq.com
Author 3 - Tongfei Cheng.
Email: 20964891@qq.com
Author 4 - Dan Wang.
Email: 2537493@qq.com
Author 5 - Xiaojun Dai.
Email: 2398431959@qq.com
Author 6 - Yao Wang.
Email: wangy198302@sohu.com
Author 7 - Bixian Cui.
Email: 459397003@qq.com
Author 8 - Yuanyuan Wang.
Email: wagnyy9208@163.com
Author 9 - Hui Xu.
Email: 598702325@qq.com
Author 10 - Hongzhou Chen.
Email: 2352326376@qq.com