INPLASY PROTOCOL

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Conflicts of interest: None declared.

Astragalus membranaceus (Huang Qi) for cancer-related fatigue: A protocol for systematic review and meta-analysis

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Review question / Objective: We will systematically analyze the therapeutic effect of Chinese medicine containing Astragalus on CRF.

Condition being studied: Cancer-related fatigue (CRF) is one of the most common complications of cancer patients, which significantly reduces patients' quality of life. The incidence of CRF varies with tumors, treatments, and evaluation methods.2 80% of patients who have received chemotherapy and/or radiotherapy suffered CRF.3 32% to 90% of advanced cancer experience fatigue.4 Therapeutic drugs are still under development, and the current intervention methods include exercise, psychology, and psychotropic drugs, as well as treatments for mood, anemia, nutrition, and soon.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 December 2021 and was last updated on 15 December 2021 (registration number INPLASY2021120069).

INTRODUCTION

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received chemotherapy and/or radiotherapy suffered CRF.3 32% to 90% of advanced cancer experience fatigue.4 Therapeutic drugs are still under development, and the current intervention methods include exercise, psychology, and psychotropic drugs, as well as treatments for mood, anemia, nutrition, and soon.

METHODS

Search strategy: We will search the following databases without language limitation: China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Chinese Biomedical Literature Database (CBM), Wanfang Database, EMBASE, MEDLINE, the Cochrane Registry of Controlled Clinical Trials (CENTRAL). We will search the literature from the databases' inception to the present. We will use a combination of subject terms and free words: "Astragalus," "Huang Qi," "Bei Qi," "Huangqi," "Astragali radix," "Astragalus membranaceus," "membranous milkvetch root," "Radix Astragali," "Fatigue," "Asthenia," "Fatigue Syndrome, Chronic," "Cancer Related Fatigue," "Quality of Life," "Neoplasm," "Leukemia," "Lymphoma," "Tumor," "Cancer," "Neoplasm," "Randomized controlled trial," "Randomized," "Placebo," "Controlled clinical trial," "Meta-analysis," "Review."

Participant or population: Adults histologically diagnosed with any cancer (including all stages and treatments of cancer).

Intervention: The intervention mode is any oral Chinese medicine preparation containing astragalus. Studies in combination with other therapies can be included in the analysis.

Comparator: Placebo, blank control, or other nonpharmacological therapies: sleep, exercise, music therapy, usual care, and so on.

Study designs to be included: Only randomized controlled trials (RCT) are included in the analysis.

Eligibility criteria: Inclusion criteria(1) Adults histologically diagnosed with any cancer (including all stages and treatments of cancer). (2) The intervention mode is any oral Chinese medicine preparation containing astragalus. Studies in combination with other therapies can be included in the analysis. (3) Reported CRF assessment as a primary or secondary research result. (4) Only randomized controlled trials (RCT) are included in the analysis. Exclusion criteria(1) Screen articles that meet the inclusion criteria to ensure that the same participant does not appear in more than one article. (2) Full text or key data is not available. (3) Other drugs given to CRF as research interventions. (4) Lack of extractable CRF scores.

Information sources: Mainly electronic databases, trial registers. Ongoing clinical trials and the reference list of published related articles will also be browsed for a supplement.

Main outcome(s): We take the severity of CRF as the primary outcome.

Quality assessment / Risk of bias analysis: The risk of bias in the included RCTs will be independently assessed by two investigators (JD and DDW) by the Cochrane risk-of-bias tool. The Jadad scale will also be used to evaluate the quality of reporting, and if a trial with a score of 3 or more will be considered "high quality."

Strategy of data synthesis: Review Manager 5.4 will be used for the statistical analysis. Since the CRF evaluation results are continuous variables, If the included studies use the same scale, the mean difference (MD) will be used for meta-analysis, otherwise, standardized mean difference (SMD) analysis will be performed to merge data from different scoring scales. 95% confidence interval will be adopted. If the heterogeneity is low, use the fixed effects model, otherwise the random effects model.

Subgroup analysis: If the studies are sufficient, we will conduct a subgroup

analysis. Relevant subgroups may include: baseline treatment status, such as during primary treatment, after primary treatment, etc. Baseline cancer, such as nonmetastatic, metastatic, etc.

Sensitivity analysis: We will conduct a sensitivity analysis by including only studies with a low risk of bias to see if the results of the meta-analysis are consistent under different assumptions.

Language: Language limits will not be imposed on the search.

Country(ies) involved: China.

Keywords: astragalus membranaceus; cancer-related fatigue; therapeutic effect.

Dissemination plans: Astragalus membranaceus; cancer-related fatigue; therapeutic effect.

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