INPLASY

Buzhong Yiqi prescription on cancer-realted fatigue for cancer patients: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202430025

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 March 2024 and was last updated on 07 March 2024.

INTRODUCTION

Review question / Objective Does Buzhong Yiqi prescription intervention have ameliorative effects on cancer-related fatigue?

Condition being studied Cancer-related fatigue(CRF)is a subjective fatigue that is inconsistent with recent activity in patients with maligant tumors, which is related to the maligant tumor itself and its treatment. CRF seriously disrupts the daily life and quality of life of cancer patients, and even shortens the overall survival of cancer patients. Western medicine treatment can improve CRF to some extent, but the teatment cost is high and the effect is not exact. The theory of Traditional Chinese Medicine(TCM) syndrome differentiation and treatment thinks that CRF is caused by the deficiency of qi in the spleen. Buzhong Yiqi prescription can tonify qi and strengthen the spleen, which can paly the effect of raising Yang and lifting trap. Through systematic review and meta-analysis, we can evaluate whether Buzhong Yiqi prescription has an important effect on patients with CRF, so as to help the clinical treatment of CRF.

METHODS

Participant or population Patients have confirmed diagnosis of cancer and with the symptom of CRF will be considered. There is no restriction on gender, age, types of cancer, tumor grade or post-treatment.

Intervention A group was teated with Buzhong Yiqi decoction on the basis of the control group.

Comparator A group of people with cancer-related fatigue symptom exposed to any other conventional or unconventional therapies apart from Buzhong Yiqi will be eligible as comparators.

Study designs to be included Only randomized controlled trials (RCTs) will be included in this study.

Eligibility criteria All adults aged≥18 years and with a diagnosis of cancer and with the symptom of CRF at any stage, type or phase of cancer treatment pathway.

Information sources RCTS are being searched in the following electronic databases without language and publication date restrictions: PubMed, Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure(CNKI), WanFang Database, and Chinese Biomedical Literature Database(CBM) until Feb.2024. Search terms are related to cancer-related fatigue, Buzhong Yiqi.

Main outcome(s) The primary outcome was KPS score, Piper fatigue scale and TCM syndrome score.

Quality assessment / Risk of bias analysis We will use the Cochrane Collaboration Risk of Bias Tool to evaluate the RCT design of these studies included in the review. Two reviewers will judge the risk of bias assessment for each study independently as high, low or unclear, with discrepancies being resolved through discussion, and the third author being involved if necessary.

Strategy of data synthesis Data will only be pooled if it is clinically meaningful and appropriate to do so. Otherwise, a narrative synthesis of the data will be conducted. Count data will be summarized using risk ratio (RR). Continuous data will be combined using mean difference with 95% confidence intervals (CI). If qualified studies shared the same scale, we will calculate mean difference (MD), otherwise standard mean difference (SMD) will be adopted. If the direction of CRF scale among studies are different (e.g. some scales had positive correlation with CRF while others were negative), the mean values measured by negative-correlated scale should multiply by -1 to ensure the consistency. Heterogeneity was tested by I2 test. If statistical heterogeneity is low (I2= 50%), fixed-effects model will be adopted, otherwise random-effects model will be adopted (I2> 50%). Then we will conduct sensitivity analyses based on study quality. All statistical analyses will be calculated in Review Manager 5.4(the Cochrane Collaboration, Copenhagen, Denmark).

Subgroup analysis If there is significant heterogeneity, we should firstly examine the causes and then carry out subgroup analysis. We will undertake subgroup analysis based on different diseases, different measurement tool and different intensity or follow-up period according to the details of included studies.

Sensitivity analysis Based on sample size, study design, heterogeneous quality, methodological quality, and statistical model, sensitivity analysis will be performed to exclude trials with quality defects and ensure the stability of the analysis results.

Country(ies) involved China.

Keywords Buzhong Yiqi;cancer-related fatigue.

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