INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of traditional Chinese herbal medicine combined with HAART in the treatment of HIV/AIDS: a protocol for systematic review and meta-analysis

Qian, Z[1]; Zhang, Y[2]; Xie, X[3]; Wang, J[4].

Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials is to explore the efficacy and safety of traditional Chinese herbal medicine combined with HAART for HIV/AIDS patients.**
Information sources: **We will search the following databases for relevant English and Chinese language literature: PubMed, Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), WanFang Database, China Science and Technology Journal Database (VIP) and Chinese Biomedical Literature Database (CBM).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 November 2021 and was last updated on 23 November 2021 (registration number INPLASY20211100082.

INTRODUCTION

Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials is to explore the efficacy and safety of traditional Chinese herbal medicine combined with HAART for HIV/AIDS patients.**

Condition being studied: **Acquired immunodeficiency syndrome (AIDS), defined as a kind of chronic contagious and inflammatory disease, which is caused by human immunodeficiency virus (HIV) infected with decreased CD4 cell count and abnormal continuous activation of immune system as the main pathological changes. Highly active antiretroviral therapy**

(HAART), acted as the mainstream therapy in the treatment of HIV/AIDS, plays a very important role in reducing HIV viral load, lowering morbidity and mortality of AIDS. However, clinical studies have found that long-term use of antiviral drugs may lead to a series of adverse reactions such as renal dysfunction, osteoporosis, neurocognitive disorder, cancer, and so on, which can directly affect clinical efficacy and medication compliance of patients. Traditional Chinese herbal medicine, as a supplement to HAART, has been applied into the treatment of HIV/AIDS for a long history. It has been showed that Chinese herbal medicine combined with HAART not only can delay the onset of HIV infection, improve clinical symptoms and signs, increase CD4 cell count, promote immune function reconstruction, but also can reduce the incidence of serious opportunistic infections and improve quality of life of patients with less side effects. However, it has not been systematically verified that traditional Chinese herbal medicine in combination with HAART can improve clinical efficacy and reduce adverse reactions. Therefore, the aim of this review is to objectively evaluate the efficacy and safety of Chinese herbal medicine combined with HAART for patients with HIV/AIDS, in order to provide reliable evidences and valuable references for clinical doctors and researchers for better medical decisions and further studies.

METHODS

Participant or population: The population will be composed of individuals who are over 18 years old with HIV/AIDS (as diagnosed by a clinician, or using any recognized diagnostic criteria).

Intervention: The treatment group will receive the therapy of Chinese herbal medicine in combination with HAART.

Comparator: The control group will only accept HAART, placebo, or no intervention.

Study designs to be included: The study style is randomized clinical trials (RCTs).

Eligibility criteria: Adults who are over 18 years old with HIV/AIDS (as diagnosed by a clinician, or using any recognized diagnostic criteria).

Information sources: We will search the following databases for relevant English and Chinese language literature: PubMed, Cochrane Library, EMBASE, China National Knowledge Infrastructure (CNKI), WanFang Database, China Science and Technology Journal Database (VIP) and Chinese Biomedical Literature Database (CBM).

Main outcome(s): CD4+ cell, CD8+ cell, CD4+/CD8+ cell ratio, CD45RO cell, CD45RA cell, quality of life (QoL).

Additional outcome(s): Karnovskey Score, opportunistic infections, adverse effects.

Quality assessment / Risk of bias analysis: Two authors will independently assess the risk of bias of each included study following the domain-based evaluation described in the Cochrane Handbook for Systematic Reviews of Interventions. This assessment tool addresses seven specific items: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete data, selective outcome reporting, and other issues relating to bias. Each item will be evaluated at three levels: low risk, high risk and unclear.

Strategy of data synthesis: We will pool the results into Review Manager 5.4 software to conduct a quantitative analysis (meta-analysis) by using a random effects model, with mean difference (MD) or standardized mean difference (SMD) for continuous outcomes and relative risk (RR) for dichotomous outcomes, and calculate 95% confidence intervals for each outcome. A 2-tailed $P<0.05$ was considered statistically significant.

Subgroup analysis: If there is existing significant heterogeneity, we will analysis the sources clinically in the following themes: (1) Treatment time (e.g., < 6 months or > 6 months); (2) CD4+ T cell

count baseline values (e.g., < 200/μL or > 200/μL).

Sensitivity analysis: **To identify the quality and credibility of the results in this review, we will conduct the sensitive analysis, which is aimed at eliminating the possibility of false positives and investigating the reliability of the composite statistical results in our meta-analysis.**

Country(ies) involved: **China.**

Keywords: **traditional Chinese herbal medicine; HAART; HIV/AIDS; systematic review; meta-analysis.**

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