INPLASY PROTOCOL

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Corresponding author:
Junwen Wang

wangjunwen_1963@126.com

Author Affiliation:
Hunan University of Chinese Medicine

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None declared.

Effect of moxibustion combined with HAART on CD4(+) T cells in HIV/AIDS patients: a meta-analysis

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

Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluate the effect of moxibustion combined with HAART compared to HAART on CD4(+) T cells in HIV/AIDS patients.**
Condition being studied: **Highly Active Anti-retroviral Therapy (HAART) is the primary treatment for HIV/AIDS in the world. It significantly reduces HIV viral load, the morbidity and mortality of HIV/AIDS. However, HAART can cause serious adverse reactions, which reduces the life quality of patients and affects the medication compliance. The combined treatment of TCM and western medicine has the effect of reducing toxicity and increasing effectiveness in HIV/AIDS patients. This integrated therapy includes Chinese herds combined with HAART or non-drug therapy (acupuncture and moxibustion) combined with HAART. Traditional Chinese Medicine can be an adjuvant therapy of HAART in the clinic treatment of HIV/AIDS.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2021 and was last updated on 17 April 2021 (registration number INPLASY202140086).

INTRODUCTION

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METHODS

Search strategy: We will search, with no time restrictions, the following databases for relevant English and Chinese language literature: PubMed, the Cochrane Central Register of Controlled Trials, EMBASE, CNKI, WanFang, VIP, CBM. The search includes the following relevant MeSH terms, in various combination: Acupuncture, Acupuncture Therapy; Moxibustion; HIV, HIV Infections; Acquired Immunodeficiency Syndrome. The electronic databases search will be supplemented by a manual search of the reference lists of included articles.

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 highly active anti-retroviral therapy (HAART) is a three-drug regimen containing a nonnucleoside reverse transcriptase inhibitor (NNRTI), a protease inhibitor (PI), or an integrase strand transfer inhibitor (INSTI) plus two nucleoside/tide reverse transcriptase inhibitors (NRTIs). The moxibustion therapy includes the mild moxibustion and other moxibustions by acting on Shenque Point, Zhongwan Point, Guanyuan Point, and other acupoints.

Comparator: The compared intervention is taking the antiviral drugs alone.

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: PubMed, the Cochrane Central Register of Controlled Trials, EMBASE, CNKI, WanFang, VIP, CBM.

Main outcome(s): CD4(+) T cells.

Additional outcome(s): Clinical symptoms and signs, HIV viral load, WHOQOL-HIV, Karnovskey Score.

Data management: Two authors will independently extract data. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. The following data will be extracted: author, year of publication, country where the study was conducted, study period, original inclusion criteria, study design, population, details of moxibustion therapy, details of HAART regimen used, outcome descriptions and outcomes measures.

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. The Cochrane 'Risk of bias' tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other issues relating to bias. The evaluation results include of 'low risk', 'high risk' and 'unclear'.

Strategy of data synthesis: For the extracted data, a qualitative synthesis will be performed. If there are at least five studies with the same comparisons, a meta-analysis will be performed. The outcomes will be analyzed: CD4(+) T cells, clinical symptoms and signs, HIV viral load, WHOQOL-HIV, Karnovskey Score. Where studies have used the same type of

intervention and comparator, with the same outcome measure, we will pool the results using a random-effects meta-analysis, with mean differences for continuous outcomes, and calculate 95% confidence intervals and two sided P values for each outcome. Heterogeneity will be assessed using the I^2 statistic. We will consider an I^2 value greater than 50% indicative of substantial heterogeneity.

Subgroup analysis: We anticipate clinical heterogeneity in the effect of the intervention and we propose to conduct, where possible, the following sub-group analyses: 1. Treatment time (e.g., < 6 months or > 6 months); 2. CD4(+) T cells baseline values (e.g., < 200/μL or > 200/μL); 3. Different moxibustion methods (e.g., the mild moxibustion vs other moxibustions); 4. TCM syndrome (e.g., spleen-kidney yang deficiency vs other syndromes).

Sensitivity analysis: In this review, only subgroup analysis will be performed to explain the heterogeneity and no sensitivity analysis will be conducted.

Language: English.

Country(ies) involved: China.

Keywords: Systematic review; meta-analysis; HIV/AIDS; moxibustion; HAART; CD4(+) T cells.

Dissemination plans: We intend to publish the review on completion.

Contributions of each author:

Author 1 - Zhenzhen Qian.
Email: qianzhenzhendoctor@126.com
Author 2 - Yujin Zhang.
Email: 346281180@qq.com
Author 3 - Xiaoli Xie.
Email: 809742111@qq.com
Author 4 - Junwen Wang.
Email: wangjunwen_1963@126.com