

INPLASY PROTOCOL

To cite: Tao et al. The Clinical Effect of Integrated Traditional Chinese Medicine and Western Medicine in Immuno-reconstitution Deficiency of HIV/AIDS: A Meta-analysis. Inplasy protocol 202060057. doi: 10.37766/inplasy2020.6.0057

Received: 15 June 2020

Published: 15 June 2020

Corresponding author:
Zhuang Tao

doersTZH@163.com

Author Affiliation:
China Academy of Chinese
Medical Sciences

Support: National Science and
Technology

**Review Stage at time of this
submission:** The review has
not yet started.

Conflicts of interest:
None.

The Clinical Effect of Integrated Traditional Chinese Medicine and Western Medicine in Immuno- reconstitution Deficiency of HIV/ AIDS: A Meta-analysis

Tao, Z¹; Huang, X²; Liu, Y³; Wang, R⁴; Dong, JP⁵; Liang, B⁶; Zou, W⁷; Gao, GJ⁸; Wang, Z⁹; Zhang, K¹⁰; Wang, J¹¹.

Review question / Objective: P: HIV/AIDS; I: integrated traditional Chinese medicine and western medicine; C: single ART; O: the CD4 cell count, the effective rate, the CD45RO cells, the CD45RA cells.

Condition being studied: It has been nearly 30 years since the exploration and practice of traditional Chinese medicine in the prevention and treatment of HIV/AIDS. Traditional Chinese medicine has definite curative effect on HIV/AIDS, which can effectively promote the reconstruction of immune function, reduce the toxic and side effects of ART, and delay the disease process of HIV/AIDS. It is effective to promote HIV/AIDS immune function reconstruction with integrated Chinese and Western medicine, but there is no reliable evidence-based medicine supported. Therefore, this study systematically evaluates the efficacy and safety of integrated Chinese and Western medicine on immuno-reconstitution deficiency of HIV/AIDS, and provide evidence-based medicine for clinical treatment reliably.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 June 2020 and was last updated on 15 June 2020 (registration number INPLASY202060057).

INTRODUCTION

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METHODS

Participant or population: HIV/AIDS.

Intervention: The integrated traditional Chinese medicine and western medicine.

Comparator: Single ART.

Study designs to be included: Randomized controlled trials (RCT).

Eligibility criteria: Randomized controlled trials (RCT) were included in the analysis if they analyzed HIV/AIDS patients who were being treated with integrated Chinese and Western medicine.

Information sources: Relevant studies were identified by searching the CNKI, WANFANG, CMJD, CBM, PubMed, Cochrane Library and EMBASE database, which spans the years from the establishment of database to January 2020 for all Chinese or English-languages. The search terms included medical subject heading (MeSH) terms of "Traditional Chinese Medicine," "HIV," "AIDS," "immuno-reconstitution deficiency," and the general term "CD4". The searches were completed on 1 May 2020.

Main outcome(s): The CD4 cell count, the effective rate, the CD45RO cells, the CD45RA cells.

Quality assessment / Risk of bias analysis: We used the Cochrane risk of bias tool to assess the methodological quality of

eligible studies, including random assignments, blinding, integrity, reporting bias and other biases. Each part of methodological were judged to be of low, unclear, or high risk. Then we judged each trial as a whole to ascertain whether there was low, unclear, or high risk of bias, based on whether the level of bias in each of the defined domains could have led to material biases in the risk estimates. When the two investigators have different opinions, the third investigator decides to solve them.

Strategy of data synthesis: We used Review Manager 5.3 software to make a meta-analyze. I² value is used to evaluate the heterogeneity of the included study. If the heterogeneity between the studies is small, the fixed-effect model is used to calculate the amount of combined effect; if there is obvious heterogeneity between the studies, the random-effect model is used to analyze the combined effect and the source of heterogeneity. P value is used to evaluate whether the results are statistically significant. When P value is less than 0.05, it is considered that there is significant statistical difference. When P value is greater than 0.05, it is considered that there is no significant statistical difference in the results. For binary variable, the relative risk (RR) was used as the efficacy evaluation index; for continuous variables, the mean difference (MD) index was used; both were expressed by 95% confidence interval (95% CI). Funnel plots were used to assess report bias.

Subgroup analysis: The CD4 cell counts after 3 months, 6months and 12 months.

Sensibility analysis: To exclude the excessive influence of any single study, we assessed whether exclusion of any single study substantially altered the magnitude or heterogeneity of the summary estimate.

Language: English.

Country(ies) involved: China.

Keywords: HIV/AIDS; immuno-reconstitution deficiency; the integrated

traditional Chinese medicine and Western medicine; clinical efficacy; Meta analysis.

Contributions of each author:

Author 1 - Zhuang TAO - Responsible for document retrieval, data analysis and draft manuscript.

Author 2 - Xiaojie HUANG - Responsible for research quality supervision.

Author 3 - Ying LIU - Responsible for document retrieval.

Author 4 - Ru WANG - Responsible for data extraction.

Author 5 - Jipeng DONG - Responsible for data extraction.

Author 6 - Biyan LIANG - Responsible for quality assessment.

Author 7 - Wen ZOU - Responsible for quality assessment.

Author 8 - Guojian GAO - responsible for statistical analysis.

Author 9 - Zhuo WANG - Responsible for quality assessment.

Author 10 - Ke ZHANG - Responsible for data extraction.

Author 11 - Jian WANG - Responsible for research quality supervision.