

# INPLASY PROTOCOL

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None declared.

## A Meta Analysis of the Efficacy of Tonic Method in Traditional Chinese Medicine for AIDS Immunological Nonresponses

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**Review question / Objective:** To evaluate the efficacy of tonic method in treating AIDS immunological nonresponses.

**Eligibility criteria:** ① **Study type:** RCT based on tonic method in TCM for AIDS INRs. The language was limited to Chinese and English. ② **The research object:** HIV/AIDS patients with any disease stage; the intervention objects were adults with no gender restrictions. ③ **Intervention measures:** The treatment group was treated with tonic prescriptions combined with ART, including four types of prescriptions for nourishing qi, nourishing blood, nourishing yin, or nourishing yang; the dosage, frequency, and method were not limited. The control group was treated with ART or mock agent and placebo. ④ **Outcome indicators:** The observation indicators reported in the included studies should include at least one of the following indicators: 1) **Effective rate of immune function reconstruction:** formulated in accordance with "AIDS (Adult) Chinese Medicine Diagnosis and Treatment Program" (2016 Edition), effective: CD4 + T lymphocyte counts increased by  $\geq 50$  cells/l or  $\geq 30\%$ , invalid: CD4+ T lymphocyte counts decreased by  $\geq 50$  cells/l or  $\geq 30\%$ ; total effective rate = effective number/total number; 2) CD4+T lymphocyte counts level.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2022 and was last updated on 14 April 2022 (registration number INPLASY202240077).

### INTRODUCTION

**Review question / Objective:** To evaluate the efficacy of tonic method in treating AIDS immunological nonresponses.

**Condition being studied:** Acquired immunodeficiency syndrome (AIDS) is a chronic infectious disease caused by human immunodeficiency virus (HIV), which affects the immune system CD4+ T

lymphocyte counts decreased, is prone to various opportunistic infections and tumors, and finally presents a complex infection state. Reconstruction of immune function refers to the process in which the body's immune function is severely damaged and gradually recovers with corresponding treatment of immune abnormalities. Antiretroviral therapy(ART) can effectively inhibit HIV virus replication, reduce viral load, improve immune function, and promote immune reconstruction etc.. However, studies have found that under the premise of ensuring good compliance, there are still some infected patients who have achieved good control of HIV viral load, but have not achieved ideal immune function reconstruction. These infected patients are called immunological non-responders(INRs), most studies believed that the incidence of INRs is about 9-45%. Since 2004, China has implemented the "Four Frees and One Care" policy for HIV/AIDS patients. Studies had shown [9-23] that the prescriptions based on the tonic method in traditional Chinese medicine(TCM) have a certain effect on INRs. Therefore, this study conducted on the clinical efficacy of the prescriptions based on the tonic method on INRs. A Meta Analysis is to provide further evidence-based medical evidence supporting for the treatment of HIV/AIDS with TCM.

## METHODS

**Participant or population:** ①Study type: RCT based on tonic method in TCM for AIDS INRs. The language was limited to Chinese and English. ②The research object: HIV/AIDS patients with any disease stage; the intervention objects were adults with no gender restrictions.

**Intervention:** The treatment group was treated with tonic prescriptions combined with ART, including four types of prescriptions for nourishing qi, nourishing blood, nourishing yin, or nourishing yang; the dosage, frequency, and method were not limited.

**Comparator:** The control group was treated with ART or mock agent and placebo.

**Study designs to be included:** RCT.

**Eligibility criteria:** ①Study type: RCT based on tonic method in TCM for AIDS INRs. The language was limited to Chinese and English. ②The research object: HIV/AIDS patients with any disease stage; the intervention objects were adults with no gender restrictions. ③Intervention measures: The treatment group was treated with tonic prescriptions combined with ART, including four types of prescriptions for nourishing qi, nourishing blood, nourishing yin, or nourishing yang; the dosage, frequency, and method were not limited. The control group was treated with ART or mock agent and placebo. ④Outcome indicators: The observation indicators reported in the included studies should include at least one of the following indicators: 1) Effective rate of immune function reconstruction: formulated in accordance with "AIDS (Adult) Chinese Medicine Diagnosis and Treatment Program" (2016 Edition), effective: CD4 + T lymphocyte counts increased by  $\geq 50$  cells/l or  $\geq 30\%$ , invalid: CD4+ T lymphocyte counts decreased by  $\geq 50$  cells/l or  $\geq 30\%$ ; total effective rate = effective number/total number; 2) CD4+T lymphocyte counts level.

**Information sources:** Chinese database (CBM, CNKI, Wanfang Database) and English Database (PubMed, Web of Science, Cochrane Library).

**Main outcome(s):** Effective rate of immune function reconstruction; CD4+T lymphocyte counts level.

**Quality assessment / Risk of bias analysis:** Revman 5.4.1 and Stata17.

**Strategy of data synthesis:** Revman 5.4.1 and Stata17 were used to carry out the data synthesis. Mean difference(MD) was used for continuous data. Dichotomous data utilized relative risk (RR). Both were used 95% confidence interval (CI).

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Statistical heterogeneity was analyzed by chi-square test. If  $P > 0.10$  and  $I^2 < 50\%$ , it could be considered that multiple similar studies were statistically homogeneous, and a fixed-effect model was adopted for meta-analysis; if  $P < 0.10$  or  $I^2 \geq 50\%$ , there was statistical heterogeneity, and clinically when it was judged that there was clinical consistency between the studies and needed to be merged, a random effects model was adopted for meta-analysis; descriptive analysis of the data that could not be merged and analyzed. Carry out sensitivity analysis for methodological heterogeneity.

**Subgroup analysis:** Effectiveness Rate after 3months, 6months, 9months, 12months, 15months, 18months of treatment; CD4 T cell counts after 3months, 6months, 9months, 12months, 15months, 18months of treatment.

**Sensitivity analysis:** Count data utilized relative risk (RR) or odds ratio (OR) and its 95% confidence interval (CI) to represent statistical indicators; measurement data used mean difference or standardized mean difference and its 95% CI to represent statistical indicators.

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

**Keywords:** HIV/AIDS, TCM, Immunological Nonresponses, Meta Analysis, Tonic Method.

**Contributions of each author:**

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Author 2 - HanQing Zhao.

Author 3 - Jian Wang.