INPLASY PROTOCOL

To cite: Bi et al. Efficacy of Traditional Chinese Medicine-Based Clearing Heat and Laxative Method against Non-alcoholic Fatty Liver Disease: A Systematic Review and Meta-analysis. Inplasy protocol 2022100002. doi: 10.37766/inplasy2022.10.0002

Received: 01 October 2022

Published: 01 October 2022

**Corresponding author:**
**Yan-jing Liu**

**liuyanjing666888@163.com**

**Author Affiliation:**
**Changchun University of Chinese Medicine.**

**Support:** **Jilin Provincial DST.**

**Review Stage at time of this submission:** **Completed but not published.**

**Conflicts of interest:**
**None declared.**

# Efficacy of Traditional Chinese Medicine-Based Clearing Heat and Laxative Method against Non-alcoholic Fatty Liver Disease: A Systematic Review and Meta-analysis

Bi, CR[1]; Sun, JT[2]; Wang, YH[3]; Chu, LY[4]; Liu, JL[5]; Wang, XY[6]; Liu, YJ[7].

**Review question / Objective:** **This study searched the relevant randomized controlled trials (RCTs) literature. After literature screening, a systematic review and meta-analysis of included trials were performed to evaluate the clinical efficacy and safety of the Traditional Chinese Medicine (TCM)-based clearing heat and laxative method in treating non-alcoholic fatty liver disease.**
**Information sources:** **RCTs were retrieved from the China National Knowledge Infrastructure (CNKI; https://www.cnki.net), Wanfang database (https://www.wanfangdata.com.cn/index.html), VIP database (http://www.cqvip.com), China Biomedical Database (CBM; http://www.sinomed.ac.cn), Cochrane Library (https://www.cochranelibrary.com), and Pubmed database (https://pubmed.ncbi.nlm.nih.gov) by three researchers independently according to the inclusion and exclusion criteria.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 October 2022 and was last updated on 01 October 2022 (registration number INPLASY2022100002).

## INTRODUCTION

**Review question / Objective:** **This study searched the relevant randomized controlled trials (RCTs) literature. After literature screening, a systematic review and meta-analysis of included trials were performed to evaluate the clinical efficacy and safety of the Traditional Chinese Medicine (TCM)-based clearing heat and laxative method in treating non-alcoholic fatty liver disease.**

**Condition being studied:** **This study has a multi-person collaborative retrieval team with the retrieval authority of relevant**

databases, and team members are skilled in the use of data analysis software.

## METHODS

**Participant or population:** 1130 Chinese patients.

**Intervention:** The experimental group was treated with conventional therapy and CHL therapy (clearing heat and laxative therapy), or add CHL therapy to the control group program.

**Comparator:** The control group was treated with conventional therapy and chemical medicine.

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

**Eligibility criteria:** (1) Research objects: Literature published in domestic and international journals related to the CHL in treating NAFLD. (The definition of the CHL method: ① the names of the formula include "Clearing Heat and Laxative" ② the total proportion of the Clearing Heat herbs and Laxative herbs should be greater than or equal to 50%) (2) Literature type: The article must be an RCT.(3) Treatment method: The control group was treated with conventional therapy and chemical medicine. The experimental group was treated with conventional therapy and CHL therapy, or add CHL therapy to the control group program.(4) Research indicators (at least one): Alanine aminotransferase (ALT); Aspartate aminotransferase (AST); Glutamyl transpeptidase (GGT); Total cholesterol (TC); Triglyceride (TG); High-density lipoprotein cholesterol (HDL-C); Low-density lipoprotein cholesterol (LDL-C); Efficiency and Adverse events.

**Information sources:** RCTs were retrieved from the China National Knowledge Infrastructure (CNKI; https://www.cnki.net), Wanfang database (https://www.wanfangdata.com.cn/index.html), VIP database (http://www.cqvip.com), China Biomedical Database (CBM; http://www.sinomed.ac.cn), Cochrane Library (https://www.cochranelibrary.com), and Pubmed database (https://pubmed.ncbi.nlm.nih.gov) by three researchers independently according to the inclusion and exclusion criteria.

**Main outcome(s):** Alanine aminotransferase (ALT); Aspartate aminotransferase (AST); Glutamyl transpeptidase (GGT); Total cholesterol (TC); Triglyceride (TG); High-density lipoprotein cholesterol (HDL-C); Low-density lipoprotein cholesterol (LDL-C); Efficiency and Adverse events.

**Quality assessment / Risk of bias analysis:** The literature quality assessment of this study was conducted using the risk of bias tool recommended by the Cochrane Collaboration.

**Strategy of data synthesis:** Review Manager 5.4 software was used for statistical analysis. For continuous variables, the mean difference (MD) was used for statistical analysis; for dichotomous variables, the odds ratio (OR) was used, and the study confidence interval was set to 95%. Heterogeneity analysis was performed using the I2 test. A fixed-effects model was used when no statistical heterogeneity was observed ($I2 \leq 50\%$ or $P \geq 0.05$). A random-effects model was used when high heterogeneity was present ($I2 > 50\%$ or $P < 0.05$ indicated). Sensitivity and subgroup analyses were performed to identify sources of heterogeneity. Finally, funnel plots were generated to identify potential publication bias.

**Subgroup analysis:** The course of treatment < 3 months VS The course of treatment ≥ 3 months; Hepatoprotective intervention VS Non-hepatoprotective intervention; High-ratio laxatives VS Low-ratio laxatives.

**Sensitivity analysis:** The Sensitivity analysis method is to identify the source of heterogeneity by the rule-by-item exclusion method.

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

**Keywords:** Traditional Chinese Medicine, Clearing Heat and Laxative Method, Non-alcoholic Fatty Liver Disease, Systematic Review, Meta-analysis

**Contributions of each author:**

**Author 1 - Chao-ran Bi.**
**Email: bichaoran666@163.com**
**Author 2 - Jia-tong Sun.**
**Author 3 - Yun-he Wang.**
**Author 4 - Li-yuan Chu.**
**Author 5 - Jin-lin Liu.**
**Author 6 - Xin-yang Wang.**
**Author 7 - Yan-jing Liu.**
**Email: liuyanjing666888@163.com**