

# INPLASY PROTOCOL

To cite: Zhang et al. Meta-analysis of the clinical efficacy of Lingguizhugan decoction in the treatment of non-alcoholic fatty liver disease. Inplasy protocol 2021100039. doi: 10.37766/inplasy2021.10.0039

Received: 13 October 2021

Published: 13 October 2021

**Corresponding author:**  
Zhenhua Zhou

jinghua1220@163.com

**Author Affiliation:**  
Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine ; Shanghai University of Traditional Chinese Medicine.

**Support:** National Natural Science Found.

**Review Stage at time of this submission:** Preliminary searches.

**Conflicts of interest:**  
None declared.

## Meta-analysis of the clinical efficacy of Lingguizhugan decoction in the treatment of non-alcoholic fatty liver disease

Zhang, Q<sup>1</sup>; Fu, L<sup>2</sup>; Qiao, F<sup>3</sup>; Zhou, Z<sup>4</sup>.

**Review question / Objective:** To systematically evaluate the clinical efficacy of Linggui Zhugan Decoction combined with conventional therapy in the treatment of non-alcoholic fatty liver disease (NAFLD) by Meta analysis.

**Condition being studied:** Non-alcoholic fatty liver disease (NAFLD) refers to the clinical pathology characterized by fatty degeneration of liver parenchymal cells and excessive accumulation of fat in liver cells, which are caused by in vitro alcohol and other clear liver damage factors. Syndrome. With the improvement of people's living standards, the number of people with high-fat diets continues to increase, coupled with poor living habits, the prevalence of obesity and related metabolic syndrome is increasing rapidly. The occurrence of NAFLD is mainly related to metabolic factors, and the disease has become the most common disease in China. One of the common chronic liver diseases. Related investigations show that the prevalence rate of NAFLD in China is 31%, which exists in all age groups, and the incidence rate increases with age. At the same time, NAFLD is also the main cause of cryptogenic cirrhosis, and severe cases require liver transplantation. Therefore, NAFLD threatens human health and safety, and further research on effective treatment methods is needed.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 October 2021 and was last updated on 13 October 2021 (registration number INPLASY2021100039).

### INTRODUCTION

**Review question / Objective:** To systematically evaluate the clinical efficacy of Linggui Zhugan Decoction combined with conventional therapy in the treatment

of non-alcoholic fatty liver disease (NAFLD) by Meta analysis.

**Condition being studied:** Non-alcoholic fatty liver disease (NAFLD) refers to the clinical pathology characterized by fatty

degeneration of liver parenchymal cells and excessive accumulation of fat in liver cells, which are caused by in vitro alcohol and other clear liver damage factors. Syndrome. With the improvement of people's living standards, the number of people with high-fat diets continues to increase, coupled with poor living habits, the prevalence of obesity and related metabolic syndrome is increasing rapidly. The occurrence of NAFLD is mainly related to metabolic factors, and the disease has become the most common disease in China. One of the common chronic liver diseases. Related investigations show that the prevalence rate of NAFLD in China is 31%, which exists in all age groups, and the incidence rate increases with age. At the same time, NAFLD is also the main cause of cryptogenic cirrhosis, and severe cases require liver transplantation. Therefore, NAFLD threatens human health and safety, and further research on effective treatment methods is needed.

## METHODS

**Participant or population:** There were a total of 728 participants, and all patients met the diagnostic criteria for NAFLD in the "Guidelines for the Diagnosis and Treatment of Non-alcoholic Fatty Liver Disease" formulated by the Chinese Society of Liver Diseases.

**Intervention:** Linggui Shugan Decoction combined with conventional therapy.

**Comparator:** Conventional treatment.

**Study designs to be included:** By searching for clinical randomized controlled trials of Linggui Zhugan Decoction in the treatment of non-alcoholic fatty liver disease, after statistics related data, the clinical treatment efficiency and liver function indexes after treatment were meta-analyzed to prove that Linggui Zhugan Decoction is in the treatment of non-alcoholic fatty liver disease. Safety and effectiveness in fatty liver disease.

**Eligibility criteria:** (1) The patients in the included literature meet the diagnostic

criteria for NAFLD in the "Guidelines for the Diagnosis and Treatment of Non-alcoholic Fatty Liver Disease" formulated by the Chinese Society of Liver Diseases; (2) The type of study is a randomized controlled trial (RCT); (3) Intervention measures: Under the premise of giving patients moderate exercise and low-fat diet behavior intervention, the experimental group was treated with Linggui Zhugan decoction combined with conventional therapy, and the control group was treated with Western medicine or conventional therapies; (4) Outcome indicators: this article mainly selects alanine aminotransferase (ALT), aspartate aminotransferase (AST), triglycerides (TG), and total cholesterol (TC) as clinical efficacy evaluation indicators.

**Information sources:** Independent search by two researchers, after selecting keywords, matching free words, formulating search styles, searching and extracting documents from Chinese and English databases such as CNKI, Wanfang, Weipu, PubMed, SinoMed, EMBASE, Science Direct, Cochrane Library, etc. Chinese search terms: Linggui Zhugan Decoction, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis, randomized controlled trial, clinical efficacy. English search terms: Linggui Zhugantang, Nonalcoholic Fatty Liver Disease, Nonalcoholic Steatohepatitis. Taking PubMed as an example, the search formula is as follows: #1 non-alcoholic fatty liver disease [Mesh] , #2 Nonalcoholic Fatty Liver Disease OR Non-alcoholic Fatty Liver Disease OR Nonalcoholic Steatohepatitis OR Non-alcoholic Steatohepatitis OR NAFLD [Title/Abstract], #3 #1 OR #2#4 Linggui Zhugan [Title/Abstract] #5 #3 AND #4.

**Main outcome(s):** A total of 102 documents were retrieved, and 40 documents were obtained after removing duplicate documents. According to the literature retrieval strategy, the searched documents will be filed and summarized separately in the database unit, and the document name, author, publication period, affiliated

institution and journal will be marked. One researcher compares, removes duplicate documents, and then pools them together. Two researchers read the titles independently and then remove the documents that do not meet the inclusion criteria. After the preliminary screening, the results are exchanged and unified, and then the content of the literature is intensively read. Determine the literature included in this study. The two researchers independently completed the literature screening throughout the entire process, and in case of objections, the third researcher will discuss together to ensure the accuracy of the included literature. After reading the title, after the abstract, 18 documents that were obviously not in line with the study were screened out. The remaining 22 documents after the preliminary screening were passed through the intensive reading of the full text and the quality evaluation was eliminated. 8 articles with incomplete data, 3 animal experiments, 3 non-clinical randomized controlled experiments, and finally 8 articles were included.

#### **Quality assessment / Risk of bias analysis:**

Evaluation is based on the RCT bias risk assessment standard provided by the Cochrane Collaboration. The evaluation content includes: (1) random sequence generation; (2) allocation hiding; (3) blinding to patients and experimenters; (4) blinding to outcome assessors; (5) completeness of outcome data; (6) Selective reporting; (7) Other bias.

**Strategy of data synthesis:** To evaluate the effective rate of Lingguizhugan decoction combined with conventional therapy in the treatment of non-alcoholic fatty liver disease using dichotomous variables, and to evaluate the changes of various physiological indicators using continuous variables.

**Subgroup analysis:** No subgroup analysis.

**Sensitivity analysis:** Due to the different intervention measures adopted by some control groups, the analysis results showed

high heterogeneity. After sensitivity analysis, the results showed homogeneity.

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

**Keywords:** Linggui Zhugan Decoction; Non-Alcoholic Fatty Liver Disease; Clinical Efficacy; Meta Analysis.

#### **Contributions of each author:**

**Author 1 - Qiuyi Zhang -** The author drafted the manuscript.

**Email:** 857301571@qq.com

**Author 2 - Lihong Fu -** Author 2 responsible for finding and screening documents.

**Email:** 575917708@qq.com

**Author 3 - Fengjie Qiao -** Author 3 responsible for the statistics of the data.

**Email:** 3502548474@qq.com

**Author 4 - Zhenhua Zhou -** Author 4 is corresponding author.

**Email:** jinghua1220@163.com