INPLASY PROTOCOL

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

Conflicts of interest:
The authors declare no conflict of interest.

The efficacy of Qigong exercises for Nonalcoholic fatty liver disease： Protocol for a systematic review and meta-analysis

Liu, Y[1]; Zou, J[2]; Dan, L[3]; Zhang, R[4]; Feng, Q[5].

Review question / Objective: **We will include patients with NAFLD irrespective of gender, race, age, and setting. We excluded patients with any signs of mental illness or organic disease. Using Qigong exercises for NAFLD patients. Included variation in intensity, frequency and duration will be accepted. Conventional treatment or exercise according to relevant guideline, or other forms of Qigong such as Tai Chi, Baduanjin, etc. Studies that compared Qigong plus another therapy with the same another therapy alone will be tolerated. The main outcomes are Alanine aminotransferase (ALT) (U/l) and Aspartate aminotransferase (AST) (U/l). The secondary outcomes are disappearance of radiological steatosis, NAFLD fibrosis score, the Fibrosis-4 test, the BARD index, the AST-to-platelet ratio, the FibroMeter, and the FibroTest.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 September 2020 and was last updated on 08 September 2020 (registration number INPLASY202090034).

INTRODUCTION

Review question / Objective: **We will include patients with NAFLD irrespective of gender, race, age, and setting. We excluded patients with any signs of mental illness or organic disease. Using Qigong exercises for NAFLD patients. Included variation in intensity, frequency and duration will be accepted. Conventional treatment or exercise according to relevant guideline, or other forms of Qigong such as Tai Chi, Baduanjin, etc. Studies that compared Qigong plus another therapy with the same**

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Condition being studied: NAFLD has become the most common liver disease worldwide.It constitutes a spectrum ranging from simple steatosis through to NASH and cirrhosis of the liver. NASH can cause liver cirrhosis, liver failure and liver cancer. The overall prevalence of NAFLD worldwide continues to increase due to the large-scale spread of obesity, especially in Western countries. Although genetic factors play an important role in the pathogenesis of NAFLD, detrimental lifestyle, prolonged sedentary periods or limited physical activity have major metabolic implications. The cornerstone of the treatment of mild or nonadvanced forms NAFLD, is lifestyle changes, including modifications to diet and physical activity, to reduce body weight and liver fat. Qigong, a traditional fitness method that originates from ancient China. The practice of qigong aims to cultivate energy via systematic training exercises, including the coordination of different breathing patterns, rhythmic movements, and meditation, in contrast to conventional exercise.Qigong is practiced by chinese people to improve health, explore the latent ability of humans, prevent disease, and prolong life in the context of a wide range of conditions. In this study, we will evaluate the safety and efficacy of Qigong for NAFLD, so as to provide evidence for treating NAFLD.

METHODS

Search strategy: We will perform a comprehensive literature search from the following resources: electronic databases including PUBMED, Web of Science, Scopus, the Cochrane Library, Embase, SinoMed, Chinese Science and Technology Periodicals Database, Chinese National Knowledge Infrastructure, and Wanfang Database for papers published from inception to September 2020. We will search manually for additional studies by cross-checking the reference lists of all included primary studies and lists of relevant systematic reviews. Grey literature sources including International clinical trials registry platform and 2 Qigong associations (China association of medical Qigong: http://www.cmqg.cn/, World Academic Society of Medical Qigong: http://www.wasmq88.com/sy) will be contacted for recent or unpublished papers. The search strategy will be developed by the research team in collaboration with an experienced librarian and checked by a referee according to the Peer Review of Electronic Search Strategy guidelines.

Participant or population: Patients with NAFLD irrespective of gender, race, age, and setting.

Intervention: Using Qigong exercises for NAFLD patients.Included variation in intensity, frequency and duration will be accepted.

Comparator: Conventional treatment or exercise according to relevant guideline, or other forms of Qigong such as Tai Chi, Baduanjin, etc. Studies that compared Qigong plus another therapy with the same another therapy alone will be tolerated.

Study designs to be included: We will include patients with NAFLD irrespective of gender, race, age, and setting. We excluded patients with any signs of mental illness or organic disease.

Eligibility criteria: Studies that report randomized controlled trials (RCTs) and quasi-RCTs of comparison between qigong and other treatment for NAFLD are considered for inclusion in this study. Studies involving non-RCTs, animal experiments, case reports, reviews will be excluded.

Information sources: We will perform a comprehensive literature search from the

following resources: electronic databases including PUBMED, Web of Science, Scopus, the Cochrane Library, Embase, SinoMed, Chinese Science and Technology Periodicals Database, Chinese National Knowledge Infrastructure, and Wanfang Database for papers published from inception to September 2020. We will search manually for additional studies by cross-checking the reference lists of all included primary studies and lists of relevant systematic reviews. Grey literature sources including International clinical trials registry platform and 2 Qigong associations (China association of medical Qigong: http://www.cmqg.cn/, World Academic Society of Medical Qigong: http://www.wasmq88.com/sy) will be contacted for recent or unpublished papers. The search strategy will be developed by the research team in collaboration with an experienced librarian and checked by a referee according to the Peer Review of Electronic Search Strategy guidelines.

Main outcome(s): The main outcomes are Alanine aminotransferase (ALT) (U/l) and Aspartate aminotransferase (AST) (U/l).

Additional outcome(s): The additional outcomes are disappearance of radiological steatosis, NAFLD fibrosis score, the Fibrosis-4 test, the BARD index, the AST-to-platelet ratio, the FibroMeter, and the FibroTest.

Data management: Endnote V.X9 will be used to manage literature and remove duplications.

Quality assessment / Risk of bias analysis: We will use the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) system to assess the quality of evidence for each outcome.According to the GRADE rating standards, four levels of evidence quality (high, moderate, low, or very low) will be used.The quality of the included evidence will be assessed by 2 reviewers independently according to GRADE approach. Reviewers will take into account limitations of the study, inconsistencies, indirect evidence, inaccuracies, and publication bias.

Strategy of data synthesis: When I2 <75% comes from the heterogeneity test, the data will be synthesized and analyzed. When the heterogeneity test shows slight or no statistical heterogeneity in these trials (I2 value is not less than 40%), we will use a fixed-effects model for the combined data. When significant heterogeneity is detected (I2 40%, <75%), a random effects model will be used for data synthesis. If there is considerable heterogeneity in the trial, no meta-analysis will be performed.Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) are continuous outcomes, so the mean difference or the standardized mean difference are used for meta-analysis. All the results for risk ratios are displayed in the form of forest plots. If there is considerable heterogeneity in the trial, no meta-analysis will be performed. In this case, we will try to determine the source of heterogeneity from both clinical and methodological aspects and will provide a qualitative summary.

Subgroup analysis: We will perform subgroup analysis based on various study characteristics and sample size, such as study type, study quality, adjustment (or not) for confounders.

Sensibility analysis: We will perform sensitivity analysis based on various study characteristics and sample size, such as study type, study quality, adjustment (or not) for confounders.

Country(ies) involved: China.

Keywords: Nonalcoholic fatty liver disease, Qigong, meta-analysis, protocol, systematic review.

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