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A systematic review and meta-analysis of the efficacy of Traditional Chinese Medicine formulae in the treatment of Sarcopenia

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ADMINISTRATIVE INFORMATION

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

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 August 2023 and was last updated on 20 August 2023.

INTRODUCTION

Review question / Objective To systematically evaluate the clinical efficacy of traditional Chinese medicine (TCM) formulae in the treatment of sarcopenia in recent 10 years.

Condition being studied Sarcopenia, from the Greek word, was first coined by Rosenberg in 1989 to describe age-related sarcopenia. In addition, the European Working Group on Sarcopenia in Older Statistics (EWGSOP) first published the consensus of sarcopenia in 2010, sarcopenia is a syndrome of progressive, widespread loss of skeletal muscle mass and strength, resulting in decreased muscle function, decreased quality of life, and even death. Studies have found that muscle mass and muscle strength peak at the age of 40 and are higher in men than women. After the age of 50, people's leg muscle mass decreases by 1% to 2% per year, and muscle strength decreases by 1.5% to 5%. With the aggravation of global aging, the

prevalence of sarcopenia has increased from 9%-51% to 15.3%-73.3%, and it is likely to reach 200 million people with sarcopenia in the next 40 years.

The cause of sarcopenia is multi-factorial, and modern medicine considers lack of exercise as the main risk factor, including malnutrition, disease inducement, inflammation, neuromuscular dysfunction, mitochondrial dysfunction and hormone disorders. At present, the mainstream treatment is based on exercise therapy and nutritional support, and drug intervention. Exercise therapy focuses on resistance training such as elastic bands, push-ups, and aerobic exercises such as swimming to improve muscle mass and strength. Nutritional support includes protein intake such as branched-chain amino acids to promote skeletal muscle protein synthesis and vitamin D to improve muscle function. No targeted drugs have been found in drug therapy, but muscles can benefit from other systemic disease drugs, such as testosterone to increase bone mineral density in the elderly, and losartan to

increase skeletal muscle function. In the ancient book Plain question (Su Wen) of traditional Chinese Medicine (TCM), sarcopenia is called as “Wei-flaccidity disorders”, “Muscle flaccidity”, “Wei-flaccidity”, which shows that the muscles and joints are weak, and the muscles are thin. The main cause of the disease is the lack of natural endowments and insufficient nutrition intake during the growth process. The disease is located in the muscles and tendons, and is mainly related to the weakness of the digestive system. In the theory of TCM, the primary treatment principle is “treatment for flaccidity aims at Yang ming meridian”, and the most common treatment method is to replenish Qi and blood and take into account the digestive system. There are many methods of treating “Wei disease” with TCM, such as TCM decoction, acupuncture, Tai Chi, Yi Jin Jing, Baduanjin exercise [,]. Among them, TCM formulae decoction has the best effect and is the most widely used. As early as 4,000 years ago, Yellow Emperor’s Internal Classic (Huang Di Nei Jing,) documented Chinese herbal medicine’s treatment for diseases. With the accumulation of experience and the confirmation of scientific research, TCM decoction has gradually developed from administering a single herb to using compound herbs with a complete theoretical framework. Nowadays, TCM exercises have been shown to have clinical efficacy, but the widely used TCM formulae decoction has not been evaluated in a comprehensive and systematic way. Therefore, the clinical efficacy of TCM formulae on sarcopenia remains controversial. We conducted a meta-analysis of randomized controlled trials (RCTs) to evaluate the efficacy of TCM formulae on sarcopenia and to provide a reference for clinical practice.

METHODS

Search strategy Seven different databases including China National Knowledge Infrastructure (CNKI), Wanfang Database, China Science and Technology Journal Database (CSTJD), PubMed, Embase, The Cochrane Library and Web of Science were searched by computer. The key search terms were (“Sarcopenia” OR “Skeletal Sarcopenia” OR “Senile sarcopenia” OR) and (“Traditional Chinese Medicine” OR “Traditional Chinese Medicine formulae” OR “Chinese Herbal Medicine” OR “Chinese Herbal”) and (“Randomized Controlled Trial” OR “Random Number Table” OR “Random Extraction”). The language is limited to Chinese and English, and the time limit is from January 2013 to April 2023.

Participant or population (i) Patients should be greater than or equal to 60 years of age. (ii) Patients have sarcopenia with diagnostic criteria published by AWGS in 2019. Decreased muscle strength (grip strength, male < 27 kg, female < 16 kg), decreased physical function (5 times sit up time > 12s or 6-meter walk speed < 1 m/s), and skeletal muscle content (male < 7 kg/m², female < 5.4 kg/m²).

Intervention The intervention measures in this study were as follows: (1) use TCM formula decoction as a single intervention measure; (2) use TCM formula decoction combined with conventional therapy. It is essential to note and emphasize that the experimental and control groups must be treated with the same routine therapy for the same duration.

Comparator The control group was treated with conventional treatment.

Study designs to be included This review included studies that met the TCM formula treatment of Sarcopenia and the principle of randomized controlled trials in Chinese or English.

Eligibility criteria (i) Patient age less than 60 years. (ii) Patients with unclear diagnosis, drug-induced sarcopenia or severe bone or muscle disease, severe cardiovascular and cerebrovascular disease, liver and kidney disease, type I diabetes, and mental illness. (iii) Intervention group used TCM external treatment such as exercise therapy, massage, acupuncture and moxibustion. (iv) The study did not specify the type of herb, dosage, or duration of treatment. (v) The control group was treated with TCM formulae decoction. (vi) Sample size less than 10 or incomplete data in the study. (vii) Types of study include non-human or in vitro experiments, reviews, conference abstracts, cases, and books.

Information sources Electronic databases - the China National Knowledge Infrastructure (CNKI), the Wanfang Database, the China Science and Technology Journal Database (CSTJD), PubMed, Embase, Cochrane Central Register of Controlled Trials and Web of Science.

Main outcome(s) Total effective rate, muscle strength is expressed by grip strength (kg), muscle mass divided by square height (kg/m²), and muscle function is expressed using gait speed within 6 m per second (m/s).

Data management According to the eligibility criteria, two researchers (Zebing Ma and Lili Ni)

searched the literature according to the keywords, and initially extracted the data independently. In order to ensure the accuracy of the literature, cross-comparison was carried out. The quality of each study was assessed using bias risk assessment tools recommended in the Cochrane Manual, and the two reviewers evaluated the test methods included in the study with RevMan 5.3 and evaluated the following characteristics: (i) Use random sequences, (ii) Hidden allocation, (iii) Two-way blindness of patients and personnel, (iv) Blind review of results, (v) The sample falls off, (vi) Report data selectively, (vii) Other biases.

Quality assessment / Risk of bias analysis Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: Random sequence generation (selection Bias) Allocation concealment (selection bias) Blinding of participants and personnel (performance bias) Incomplete outcome data (attrition bias) Selective reporting (reporting bias) Other biases Results from these questions will be graphed and assessed using Review Manager 5.3.

Strategy of data synthesis RevMan 5.3 was used to meta-analyze the included data. Relative risk (RR) and 95% confidence interval (CI) were used to describe binary variables. As the units of outcome indicators are consistent, mean difference (MD) and 95% confidence intervals were used to describe continuous variables. If the units of outcome indicators are inconsistent, mean \pm standard deviation (SMD) and 95% confidence intervals were used to describe continuous variables. In the heterogeneity test, if there was no statistical difference between the studies ($I^2 \leq 50\%$), the fixed effect model was used for statistical and sensitivity analyses. The method of eliminating the literature one by one was used to test the stability of the results. By contrast, if there was a difference ($I^2 > 50\%$), subgroup or sensitivity analysis was used for analysis and processing. The random-effects model was used for statistical analysis. Using the random-effects model and the "single item elimination", sensitivity analysis was performed further. Descriptive analysis was performed if the source of heterogeneity could not be found. If the included sample size was greater than 10, the analysis of publication bias was performed by drawing a funnel plot using the R core team 4.1.3 software.

Subgroup analysis We will consider subgroups such as resistance training.

Sensitivity analysis By contrast, if there was a difference ($I^2 > 50\%$), subgroup or sensitivity analysis was used for analysis and processing. The random-effects model was used for statistical analysis. Using the random-effects model and the "single item elimination", sensitivity analysis was performed further. Descriptive analysis was performed if the source of heterogeneity could not be found. If the included sample size was greater than 10, the analysis of publication bias was performed by drawing a funnel plot using the R core team 4.1.3 software.

Language restriction English.

Country(ies) involved China.

Keywords Traditional Chinese medicine formulae; Sarcopenia; Efficacy; Meta-analysis.

Contributions of each author

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