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Effects of Traditional Chinese Medicine exercise therapy on cardiovascular risk factors in patients with metabolic syndrome: A Meta-analysis

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ADMINISTRATIVE INFORMATION

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

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 14 August 2023 and was last updated on 14 August 2023.

INTRODUCTION

Review question / Objective Participants: patients with Metabolic syndrome, aged between 30 to 80 years old, both genders. Intervention: The treatment group was treated with Traditional Chinese Medicine (TCM) exercise therapy (Taijiquan, Baduanjin, Five Animal Play, Yijinjing, or Fitness Qigong), and the control group maintained daily lifestyle or regular health education, without any regular exercise intervention. The control group was treated with oral medication or conventional treatment. Outcome measure: the primary study outcome should include Waist Circumference, BMI, Fasting Glucose, Triacylglycerol, High-density lipoprotein cholesterol, Low-density lipoprotein cholesterol, Total Cholesterol, Systolic blood pressure, Diastolic blood pressure.

Condition being studied Metabolic syndrome (MS) is a clinical syndrome characterized by the

clustering of obesity, high blood sugar, hypertension, and abnormal blood lipids, reflecting a state of multi-system metabolic disorders in the body. Various metabolic disorders occur in the body including proteins, carbohydrates, and lipids, with its pathological mechanism being obesity and insulin resistance.

Epidemiological surveys have shown that the prevalence of MS is increasing globally among different age groups or ethnic populations, with a high incidence rate of 43.49% among people over 60 years old in China. Currently, exercise therapy has been recommended by domestic and foreign experts as an effective non-pharmacological intervention for alleviating the occurrence and development of metabolic syndrome and managing individual risk factors in MS patients. Traditional Chinese medicine exercise therapy not only focuses on local treatment effects but also emphasizes enhancing overall resistance through concepts such as the "holistic view," "yin-yang theory," and "meridian theory." It regulates qi and blood circulation while advocating for movement

and stillness to nourish physical form and spirit. It not only treats existing diseases but also emphasizes prevention before they occur.

In view of this, this study aims to ensure scientific evaluation of outcome indicators by focusing on adult MS patients without complications or other organic diseases as research subjects using rigorous randomized controlled trials (RCTs). The study will systematically evaluate the impact of traditional Chinese medicine exercise therapy on cardiovascular risk factors in MS patients to provide evidence for further exploration into its fitness mechanisms and clinical efficacy. This will guide clinical decision-making for scientifically personalized exercises for MS patients.

METHODS

Participant or population Participants who meet all the following criteria will be recruited: 1. patients with Metabolic syndrome, aged between 30 to 80 years old, both genders. ;2. Meet the diagnostic criteria of MS:① Overweight or Central obesity: BMI cut-off point for obesity (>24.0 kg/m²) or waist circumference ≥ 90 cm for males and ≥ 85 cm for females.② Hyperglycemia: fasting plasma glucose (FPG) ≥ 6.1 mmol/L (110 mg/dl) or 2 hour plasma glucose ≥ 7.8 mmol/L (140 mg/dl), or previously diagnosed type 2 diabetes.③ Hypertensive: systolic blood pressure ≥ 130 or diastolic blood pressure ≥ 85 mm Hg, or treatment of previously diagnosed hypertension.④ Raised TG level: fasting TG level ≥ 1.7 mmol/L (150 mg/dl), or received treatment for this lipid abnormality.⑤ Reduced HDL-c: fasting blood HDL-c < 0.9 mmol/L (35 mg/dl) for males and < 1.0 mmol/L (39 mg/dl) for females. with 3 or all of the above 5 items can be diagnosed as metabolic syndrome. 3. Agree to join this clinical study, volunteer to sign up informed consent form and agree to participate in all visits and inspections in accordance with the requirements of the study protocol.

Intervention The treatment group was treat with exercise therapy of Traditional Chinese Medicine(TCM), including Tai Chi, Wuqinxi, Baduanjin, Yijinjing, Qigong.

Comparator The control group was treated with the original life pattern or conventional medication, not participating in the experimental group exercise.

Study designs to be included (1) The study design was determined to be a randomized controlled trial (RCTs), with or without blinding; (2) The specific diagnostic criteria of adult MS

patients were mainly based on the three mainstream diagnostic criteria in the world. These criteria were formulated by National cholesterol education program (NCEP), International Diabetes Federation (IDF), Chinese Diabetes Society and WHO, respectively. (3) The experimental group was treated with TCM exercise therapy. The control group maintained daily life style or regular health education, without any regular exercise intervention.

Eligibility criteria Exclusion criteria: (1)The subjects were complicated with severe heart, liver, kidney or other lung diseases. People with mental disorders and mental disorders; (2)Minors and pregnant women; (3)No control group study;(4) Case reports, animal experiments, conference abstracts, pathology reports; (5)Literature without accurate numerical data for outcome indicators; (6)Duplicate literatures and literatures whose full text could not be obtained;(7)Date are not presented in the form of average and different.

Information sources We searched and built the database by computer until January 10, 2023. The Cochrane Library, PubMed, Web of Science, Scopus, China Knowledge Network (CNKI), China Biomedical Literature Database (CBM), and Wanfang Data Knowledge Service Platform (Wanfang Data) and other databases. Meta-analysis was completed using Revman 5.3 software.

Main outcome(s) The primary study outcome should include Waist Circumference, BMI, Fasting Glucose, Triacylglycerol, High-density lipoprotein cholesterol, Low-density lipoprotein cholesterol, Total Cholesterol, Systolic blood pressure, Diastolic blood pressure.

Quality assessment / Risk of bias analysis We assessed the risk of bias in the included randomized controlled trials (RCTs) using the Cochrane "risk of bias" assessment tool, including the domains of allocation, blinding, incomplete outcome data, selective reporting, and other bias. Each study was scored according to the selection, comparability, and outcome.

Strategy of data synthesis The data extracted from the literature were systematically analyzed by Review Manager 5.3 software. The outcome indicators of this study were all continuous variable data, so the weighted mean difference (WMD) and its 95%CI were used as the effect size. The heterogeneity of the results among the studies was tested by the Q statistic test and I² test of Review

Manager software. If there was statistical homogeneity ($P \geq 0.1$, $I^2 \leq 50\%$) among the studies, the fixed effect model was used for analysis. Otherwise ($P > 0.1$), it was considered that there was heterogeneity, and the random effect model was used for analysis. A sensitivity test was performed to explore the stability of the results by the one-by-one exclusion method. $P < 0.05$ was considered statistically significant.

Subgroup analysis Our study does not involve subgroup analysis.

Sensitivity analysis We will consider running sensitivity analysis to identify the robustness and stability of merged results by excluding studies with high risk of bias.

Country(ies) involved China.

Keywords Exercise Therapy of Traditional Chinese Medicine; Metabolic syndrome; Meta-analysis; Risk factors.

Contributions of each author

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