INPLASY PROTOCOL

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None declared.

A comparison of the efficacy and safety of complementary and alternative therapies for Hemiplegic gait : A protocol for network meta-analysis

Liu, XX[1]; Han, XY[2]; Zhong, FX[3]; Yin, XP[4]; Wang, YG[5]; Zhang, QM[6].

Review question / Objective: **All clinical randomized controlled studies on the use of complementary and alternative therapies (acupuncture, massage, Tai Chi, yoga and traditional Chinese medicine ironing) in the treatment of post-stroke hemiplegia published since the establishment of the database. There is a precise control group in the test, and the sample size of the test group is ≥ 30 cases. It is limited to published Chinese and English literature. Diagnostic criteria of patients studied in the literature (patients who meet one of the diagnostic criteria of traditional Chinese medicine or western medicine and have clinical symptoms of hemiplegia). Intervention measures 1.The control group was given conventional western medicine or other treatment. Another treatment refers to any drug treatment and non-drug treatment other than traditional Chinese medicine, acupuncture, massage and Tai Chi. 2.The observation group was treated with acupuncture, massage, Tai Chi, yoga and traditional Chinese medicine ironing based on basic therapy; Other interventions used in the treatment group and the control group were the same, and There was no significant difference between the two groups at baseline. Outcomes The leading indicators include Fugl-Meyer balance function assessment (FMA), Holden walking function assessment scale, improved Lovett muscle strength measurement method, and the secondary indicators include Barthel index assessment scale and other indicators.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 March 2022 and was last updated on 16 March 2022 (registration number INPLASY202230075).

INTRODUCTION

Review question / Objective: **All clinical randomized controlled studies on the use of complementary and alternative therapies (acupuncture, massage, Tai Chi, yoga and traditional Chinese medicine ironing) in the treatment of post-stroke hemiplegia published since the establishment of the database. There is a precise control group**

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Condition being studied: Stroke is a disease of brain dysfunction caused by a series of brain hypoxia and ischemia and cerebral vascular rupture of vascular blockage. It is a common clinical disease in middle and the aged. Stroke ranks second or third in the mortality list, and forecasts show that this will continue to be the case in recent years. Limb dysfunction after stroke is one of the greatest clinical manifestations of stroke sequelae. In addition, stroke is the leading cause of disability. At present, the primary treatment is physical rehabilitation therapy. Rehabilitation therapy has been widely used in clinical practice. Although rehabilitation doctors have selective theraphy according to the specific conditions of patients with gait disorder after stroke, there are still unavoidable drawbacks in a certain degrees of treatment. Many randomized controlled trials and systematic evaluations simply evaluate one or two complementary or alternative therapies for gait disorders after stroke. Therefore, in order to better apply this therapy to clinical treatment, it is urgent to further summarize and evaluate this kind of research. Retrieval strategy The English databases searched by the computer include: web of science, Pub Med, the Cochrane Library, Cochrane Center controlled trial registration centre (central), etc. Chinese databases include VIP Chinese Journal Database, China National Knowledge Infrastructure (CNKI), China biomedical database and Wan fang database. Using the method of subject words combined with free words, all the Chinese and English clinical RCT literature on the use of complementary and alternative therapy in the treatment of post-stroke hemiplegia published since the establishment of the database were searched by computer. Statistical analysis Pairwise meta-analysis and Network meta-analysis Firstly, what we need to do is a pairwise meta-analysis. Two researchers will use stata17.0 software notes that the odds ratio and mean difference of dichotomy variables were selected as the basis of counting and measurement data, respectively. Calculate the 95% confidence interval for each impact indicator. We will use I2 and P values to represent the degree of heterogeneity in multiple studies, where $p < 0.05$ is a significant difference. Secondly, we carry out NMA analysis, which is based on Bayes theory to analyze and evaluate all treatment measures comprehensively. In the case of I2 > 50% or

P < 0.05, the random effect model was chosen, whereas the fixed effect model was used instead. Due to the need for more complex data statistics, we will use MCMC in WinBUGS1. 4.3 Bayesian NMA model.

METHODS

Participant or population: All clinical randomized controlled studies on the use of complementary and alternative therapies (acupuncture, massage, Tai Chi, yoga and traditional Chinese medicine ironing) in the treatment of post-stroke hemiplegia published since the establishment of the database. There is a precise control group in the test, and the sample size of the test group is ≥ 30 cases. It is limited to published Chinese and English literature. Diagnostic criteria of patients studied in the literature (patients who meet one of the diagnostic criteria of traditional Chinese medicine or western medicine and have clinical symptoms of hemiplegia).

Intervention: 1.The control group was given conventional western medicine or other treatment. Another treatment refers to any drug treatment and non-drug treatment other than traditional Chinese medicine, acupuncture, massage and Tai Chi.2.The observation group was treated with acupuncture, massage, Tai Chi, yoga and traditional Chinese medicine ironing based on basic therapy; Other interventions used in the treatment group and the control group were the same, and There was no significant difference between the two groups at baseline.

Comparator: The control group was given conventional western medicine or other treatment. Another treatment refers to any drug treatment and non-drug treatment other than traditional Chinese medicine, acupuncture, massage and Tai Chi.

Study designs to be included: This study systematically evaluated and compared the efficacy and safety of complementary and alternative therapy in the treatment of post-stroke gait disorder.

Eligibility criteria: All clinical randomized controlled studies on the use of complementary and alternative therapies (acupuncture, massage, Tai Chi, yoga and traditional Chinese medicine ironing) in the treatment of post-stroke hemiplegia published since the establishment of the database. There is a precise control group in the test, and the sample size of the test group is ≥ 30 cases. It is limited to published Chinese and English literature. Diagnostic criteria of patients studied in the literature (patients who meet one of the diagnostic criteria of traditional Chinese medicine or western medicine and have clinical symptoms of hemiplegia).Exclusion criteria1.Non-Chinese and English literature and non-randomized controlled trials;2. Repeated and incomplete data, animal test and in vitro study;3.The sample size of the test control group was less than 30 cases, no descriptive study of the control group or unreasonable design of the control group affected the judgment of curative effect;4. Literature on alternative and complementary therapies as interventions in the control group;5.Review, conference papers, literature duplication, unable to extract data, medical case reports, systematic evaluation and personal diagnosis and treatment experience, etc.

Information sources: The English databases searched by the computer include: web of science, Pub Med, the Cochrane Library, Cochrane Center controlled trial registration centre (central), etc. Chinese databases include VIP Chinese Journal Database, China National Knowledge Infrastructure (CNKI), China biomedical database and Wan fang database. Using the method of subject words combined with free words, all the Chinese and English clinical RCT literature on the use of complementary and alternative therapy in the treatment of post-stroke hemiplegia published since the establishment of the database were searched by computer.

Main outcome(s): The leading indicators include Fugl-Meyer balance function assessment (FMA), Holden walking

function assessment scale, improved Lovett muscle strength measurement method, and the secondary indicators include Barthel index assessment scale and other indicators.

Quality assessment / Risk of bias analysis: Evaluation of literature quality with Jadad scale.The Jadad score of the competition shall be ≥ 3 points (if the score is higher, the literature quality is better and the reference value is more valuable). If we have any objections, please consult the third party for a decision.

Strategy of data synthesis: What we need to do is a pairwise meta-analysis. Two researchers will use stata17.0 software notes that the odds ratio and mean difference of dichotomy variables were selected as the basis of counting and measurement data, respectively. Calculate the 95% confidence interval for each impact indicator. We will use I2 and P values to represent the degree of heterogeneity in multiple studies, where $p < 0.05$ is a significant difference.

Subgroup analysis: If there is heterogeneity among the research results, we will comprehensively and systematically analyze the causes of heterogeneity, and classify it according to various sources of heterogeneity. For example, different clinical research design schemes, the quality of retrieved literature, published journals and years, etc. the data are further subdivided and then compared Sensitivity analysis.

Sensitivity analysis: The literatures included in the study were removed by stata17.0 software, and the changes of heterogeneity and effect quantity before and after removing one item of included research data were compared and analyzed to further analyze the source of heterogeneity and test the stability of the analysis results.

Country(ies) involved: China.

Keywords: complementary and alternative therapies, post-stroke gait disorder, protocol, systematic review.

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