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Guo, CG¹; Shao, WJ²; Li, FY³; Tan, XF⁴; Xie, YM⁵.**ADMINISTRATIVE INFORMATION****Support** - This research did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.**Review Stage at time of this submission** - Piloting of the study selection process.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202370061**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 July 2023 and was last updated on 15 July 2023.**INTRODUCTION**

Review question / Objective Evidence on the effects of TCM exercise therapy on the cognitive function of the elderly is limited. Specifically, on the one hand, the results of Tai Chi interventions on the cognitive function in the elderly are mixed, and their effectiveness is controversial. On the other hand, studies on the effectiveness of Chinese medicine exercise therapies, such as Badaanjin, Yi Jin Jing and Wu Qin Xi, in intervening in the cognitive function of the elderly are relatively few. This study aims to systematically evaluate the effects of TCM exercise therapies on the cognitive function of the elderly and further propose the best exercise intervention programme to delay the cognitive decline of the elderly.

Condition being studied The prevalence of mild cognitive impairment (MCI) in older adults is reported to be 5.2%–23.4% in Europe and the United States. In addition, studies showed that normal older adults and those with MCI develop Alzheimer's disease (AD) at a rate of 1%–2% and 10%–15% per year, respectively. AD is irreversible and burdens patients and society heavily. According to a WHO survey, approximately 46.8 million people worldwide were living with AD or other types of dementia at the end of 2015. This number is expected to reach 74.7 million by 2030 and 131.5 million by 2050, an increase of 68%. With the accelerated ageing of populations worldwide, dementia has become the third leading cause of health threat to human life after cardiovascular diseases and malignancies. Therefore, how to improve the cognitive function of people with cognitive disorders and improve the

quality of life in later life has become an urgent problem in an ageing society.

METHODS

Search strategy A computer searched six databases: PubMed, EBSCO host, Web of Science, EMBase, China National Knowledge Infrastructure and Wan Fang (Wan Fang). The search period was from January 2000 to July 2022, and the last search date was July 20, 2022. The search strategy was a combination search (subject and free terms) using Boolean operations and was determined after repeated pre-screening, supplemented by manual searches and retrospective inclusion of references to the literature when necessary. The following search items were used: ('Traditional Chinese Medicine' OR 'Tai Chi' OR 'Yi Jin Jing' OR 'BaDuanJin' OR 'Liu Zi Jue' OR 'Qigong' OR 'Wu Qin Xi') AND ('cognitive function' OR 'Executive function' 'visual space' OR 'memory' OR 'attention' OR 'orientation') AND ('elderly' OR 'senior' OR 'aged 60+') AND ('randomized controlled trial' OR 'quasi-randomized controlled trial'). These terms were translated into Chinese when retrieving data from the Chinese databases.

Participant or population The study population was older adults with normal cognitive function, MCI or dementia (AD).

Intervention The intervention was TCM exercise therapy (Tai Chi, Yi Jin Jing, Ba Duan Jin, Liu Zi Jue, Qigong, Wu Qin Xi etc.), not combined with other interventions (e.g. cognitive training).

Comparator The control group consisted of maintaining the same lifestyle, health education, routine care, low-intensity stretching and stretching exercises.

Study designs to be included The study design was randomised controlled trial (RCT) or quasi-RCT.

Eligibility criteria Inclusion criteria: (1) The study population was age range or mean age of 60 years, regardless of race or country. The study population was older adults with normal cognitive function, MCI or dementia (AD); (2) The intervention was TCM exercise therapy (Tai Chi, Yi Jin Jing, Ba Duan Jin, Liu Zi Jue, Qigong, Wu Qin Xi etc.), not combined with other interventions (e.g. cognitive training); (3) The control group consisted of maintaining the same lifestyle, health education, routine care, low-intensity stretching and stretching exercises; (4) The outcome indicators were the

Mini-mental State Examination (MMSE) or Montreal Cognitive Assessment Scale (MoCA) for cognitive performance. MoCA is used to assess the cognitive function in older adults, with the MMSE being preferred if both are present;⁶ (5) The study design was randomised controlled trial (RCT) or quasi-RCT, published from January 2000 to July 2022, with no significant difference in baseline values between the experimental and control groups. Exclusion criteria: (1) literature that did not meet the inclusion criteria; (2) review-type literature or dissertations; (3) literature that was not in English or Chinese; (4) literature with incomplete data on outcome indicators, resulting in unable to extract data.

Information sources A computer searched six databases: PubMed, EBSCO host, Web of Science, EMBase, China National Knowledge Infrastructure and Wan Fang (Wan Fang). The search period was from January 2000 to July 2022, and the last search date was July 20, 2022. The search strategy was a combination search (subject and free terms) using Boolean operations and was determined after repeated pre-screening, supplemented by manual searches and retrospective inclusion of references to the literature when necessary.

Main outcome(s) The outcome indicators were the Mini-mental State Examination (MMSE) or Montreal Cognitive Assessment Scale (MoCA) for cognitive performance. MoCA is used to assess the cognitive function in older adults, with the MMSE being preferred if both are present.

Quality assessment / Risk of bias analysis The risk of bias in the included literature was assessed in seven areas using the risk of bias assessment tool of the Cochrane systematic reviews, in accordance with the guidelines for evidence-based research. These guidelines included random sequence generation, allocation protocol concealment, blinding of subjects and interventionists, blinding of outcome assessors, completeness of outcome data and selective reporting, with each indicator being rated as 'low risk of bias', 'uncertainty of bias', 'high risk of bias' and 'risk of bias'. 'High risk of bias' was used to determine each indicator.

Strategy of data synthesis The Cochrane risk of bias assessment schematic was produced using Review Manage 5.3, and statistical analysis was performed using Stata 12.0 software. The experimental data were continuous variables, and the outcome indicators were two evaluation scales, MMSE and MoCA, with standard mean deviation

(SMD) used as the effect size indicator and 95% confidence intervals (95% CI) calculated. When SMD was used to calculate effect sizes, according to Cohen's (1988) interpretation, $d < 0.2$ was a small effect size, $0.2 \leq d < 0.5$ was a small effect size, $0.5 \leq d < 0.8$ was a medium effect size and $d \geq 0.8$ was a large effect size.

The homogeneity test (Q test) was used to test the overall heterogeneity amongst multiple studies, which is essentially an X^2 test, with $P < \alpha$ (test level $\alpha = 0.1$) indicating heterogeneity amongst studies; conversely, studies were considered homogeneous. The magnitude of heterogeneity was then quantitatively analysed in relation to I^2 , which was classified as low ($I^2 = 25\%$), moderate ($I^2 = 50\%$) and high ($I^2 = 75\%$) heterogeneity. In the Cochrane Handbook, $I^2 \leq 40\%$, a fixed effects model was selected for meta-analysis, and $I^2 > 40\%$, a random effects model was selected for meta-analysis. The moderating variables were analysed for the source of their heterogeneity.

Subgroup analysis A random-effects model was used to test the moderating effects of seven moderating variables in a Traditional Chinese Medicine (TCM) exercise therapy intervention on cognitive function in older adults.

Sensitivity analysis Sensitivity analysis was used to test whether the results of this study were stable and reliable.

Country(ies) involved China.

Keywords Traditional Chinese Medicine (TCM); Elderly people; Cognitive functions.

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