

INPLASY PROTOCOL

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None declared.

Effects of mindfulness-based intervention on cognitive function, depression and quality of life in stroke patients: Protocol for systematic reviews and meta-analyses

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Review question / Objective: (1) **Participants.** For participants, we included studies of patients with stroke as defined by the World Health Organization (WHO) or diagnosed by imaging. There were no restrictions on sex, age, race, nationality, duration of disease, type of functional impairment, or type of ischemic versus hemorrhagic stroke. (2) **Interventions and controls.** The intervention for stroke patients in the experimental group used mindfulness-based intervention, including tai chi, yoga, qigong, and meditation. There were no restrictions on the type of tai chi, yoga, or qigong. Stroke patients in the control group had to receive conventional treatment or other clearly described treatment options. (3) **Outcome.** The primary outcome was mainly assessed by the cognitive function evaluation scale MMSE, MoCA, RBANS. **Information sources:** This study systematically searched English databases (e.g., PubMed, Physiotherapy Evidence Database, Web of Science (WOS), Cochrane Library and WHO International Clinical Trials Registry) and Chinese databases (e.g. China Knowledge Infrastructure, Wanfang, and China Clinical Trials Registry). There is no restriction on publication date, and the language of the literature includes only Chinese or English.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 January 2022 and was last updated on 27 January 2022 (registration number INPLASY202210126).

INTRODUCTION

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were no restrictions on sex, age, race, nationality, duration of disease, type of functional impairment, or type of ischemic versus hemorrhagic stroke. (2) **Interventions and controls.** The intervention for stroke patients in the experimental group used mindfulness-based

intervention, including tai chi, yoga, qigong, and meditation. There were no restrictions on the type of tai chi, yoga, or qigong. Stroke patients in the control group had to receive conventional treatment or other clearly described treatment options. (3)Outcome. The primary outcome was mainly assessed by the cognitive function evaluation scale MMSE, MoCA, RBANS.

Condition being studied: Stroke has a high morbidity, mortality and disability rate, with approximately two million people suffering from stroke each year. As a result, 70-80% of stroke victims are unable to live independently due to disability. Stroke is reported to be the second leading cause of death following myocardial infarction and one of the leading causes of disability, and this will continue until 2030. One third of these stroke survivors will suffer from depression, and depressed mood and inability to live independently largely affect quality of life. In 2012, 6.7 million people died of stroke worldwide, and the increasing proportion of stroke survivors aged 20 to 64 years underscores the importance of preventive measures. Stroke can lead to increasing socioeconomic costs (e.g., medications, hospitalization, unemployment/reduced productivity), placing a tremendous strain on families and society. Many studies in the past have shown that balance and gait dysfunction are common problems in stroke patients, and these problems can affect the patient's ability to walk and quality of life. To help patients improve their quality of life, physical therapy is often prescribed as the primary method of medication to help stroke survivors regain motor function and control of balance. According to some reviews of the literature over the years, one third of stroke patients experience depression, anxiety and stress. A number of stroke patients may experience sleep disturbances along with apathy and social retardation compared to the pre-stroke period. The presence of mental disorders such as these may not only lead to delayed functional recovery and reduced quality of life, but also increase the risk of stroke recurrence. Some studies suggest that yoga, tai chi, or qigong may be a

complementary rehabilitation method for stroke survivors for balanced recovery. Taiji not only improve gait and balance, but also increase muscle strength for motor system function, which can be beneficial for stroke patients to recover and even healthy adults. Mindfulness-based intervention are cheap to learn and safe for beginners with no foundation, while mindfulness-based intervention effectively combine mental relaxation and physical activity to help improve cognitive performance and depression in stroke patients. For example, there is growing evidence to support that tai chi can be very helpful for balance, recovery of neuromuscular conditions and improvements in cognitive function and mental health, and can be effective in improving patients' quality of life. Therefore, mindfulness-based intervention may have a positive impact on cognitive function, depression, and quality of life in stroke patients, and has been shown to be effective as an adjunctive therapy for stroke survivors.

METHODS

Participant or population: For participants, we included studies of patients with stroke as defined by the World Health Organization (WHO) or diagnosed by imaging. There were no restrictions on sex, age, race, nationality, duration of disease, type of functional impairment, or type of ischemic versus hemorrhagic stroke.

Intervention: The intervention for stroke patients in the experimental group used mindfulness-based intervention, including tai chi, yoga, qigong, and meditation.

Comparator: There were no restrictions on the type of tai chi, yoga, or qigong. Stroke patients in the control group had to receive conventional treatment or other clearly described treatment options.

Study designs to be included: Only randomized controlled trials (RCTs) of psychosomatic exercise interventions on cognitive function, depression, and quality of life in stroke patients were included in this review.

Eligibility criteria: (1) duplicate publications; (2) non-randomized controlled trials, cross-sectional studies, case reports/series, and systematic evaluations or meta-analyses; (3) incomplete data in the literature; and (4) animal experiments.

Information sources: This study systematically searched English databases (e.g., PubMed, Physiotherapy Evidence Database, Web of Science (WOS), Cochrane Library and WHO International Clinical Trials Registry) and Chinese databases (e.g. China Knowledge Infrastructure, Wanfang, and China Clinical Trials Registry). There is no restriction on publication date, and the language of the literature includes only Chinese or English.

Main outcome(s): The primary outcome was mainly assessed by the cognitive function evaluation scale MMSE, MoCA, RBANS.

Additional outcome(s): Secondary outcomes were evaluated by DASS 21, GDD, BDI-II, IADL, BADL.

Quality assessment / Risk of bias analysis: Two researchers independently checked the titles and abstracts of the search results and performed an initial screening of the articles based on the screening criteria. Studies that met the criteria were further identified after reading the full text. Finally, the articles screened by the two independent reviewers were integrated. When there was a disagreement between the two researchers, a third researcher was added and the final decision was made through discussion./If more than 10 studies are included, we will assess reporting bias by generating funnel plots. For continuous variables, Egger's test will be used to test the symmetry of the funnel plot. If the data in the resulting funnel plot are symmetrically distributed then there is no publication bias. If there is no symmetry, we will further analyze the causes of bias.

Strategy of data synthesis: Stata 14.0 (Manufacturer, City, US State abbrev. if applicable, Country) will be used for quantitative analysis of the data, including

assessment of bias, mapping of the overall forest, heterogeneity, sensitivity analysis, and subgroup analysis. Where I² was used to determine the heterogeneity of effect sizes in the RCT: large = 75%, medium = 50%, and small = 25%.

Subgroup analysis: We will explore the sources of high heterogeneity through subgroup analyses that include, for example, both the individual characteristics of the sample and the intervention situation. The individual characteristics of the sample include the age, gender, disease duration, and degree of illness of the stroke patients, and the intervention characteristics include the type of mindfulness-based intervention, frequency of intervention, duration of each intervention, and intervention period.

Sensitivity analysis: Sensitivity analysis will be used to assess the reliability of the results by looking for changes in the composite results through an exclusion-by-exclusion approach. If there is a significant change in the results indicating that the excluded studies have a significant impact on the results, they should be reassessed. If the change is not significant then it indicates that the data synthesis results are reliable.

Country(ies) involved: China.

Keywords: mindfulness-based intervention, stroke, cognitive function, depression, quality of life, protocol, meta-analysis.

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