INPLASY PROTOCOL

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

Conflicts of interest:
No ethical statement will be required for the performance of this review and meta-analysis.

Traditional Chinese mind-body exercises for low back pain: a protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this systematic review is to evaluate the effects of traditional Chinese mind-body exercises in the management of low back pain.**
Condition being studied: **Low back pain (LBP) and associated disability are one of the most common health problems worldwide and result in a substantial socioeconomic and healthcare burden.The prevalence of LBP is high and approximately 10% of acute LBP progress to chronic pain for 3 months or more. About 50% of LBP sufferers experienced symptom relapse within 1 year, and the lifetime prevalence was estimated up to 85%.Therefore, appropriate treatments are very important for LBP sufferers especially in reducing its recurrence rate.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 August 2020 and was last updated on 22 August 2020 (registration number INPLASY202080093).

INTRODUCTION

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METHODS

Participant or population: Studies will be eligible if they include participants with a diagnosis of LBP. There were no limitations on age, gender, or nationality of patients with LBP.

Intervention: In this review, traditional Chinese mind-body exercises include Tai Chi, Qigong, Baduanjin, Wuqinxi, and Yijinjing. The included studies use one of them to treat LBP.

Comparator: The control interventions include medicine, observation, manual therapy, acupuncture, traction, education, and any treatments without traditional Chinese mind-body exercises.

Study designs to be included: Randomized controlled trials will be included.

Eligibility criteria: Randomized controlled trials(RCT) of traditional Chinese mind-body exercises for LBP were included in the analysis. Case reports, observational studies, and cross-sectional design studies will be excluded. The study protocol and conference abstract of RCTs will also be excluded, if the corresponding author could not provide detailed information.

Information sources: The electronic databases (PubMed, Embase, Web of Science, Cochrane Library, China Knowledge Resource Integrated Database, and Wanfang Data) will be searched from their inception to December 2020.

Main outcome(s): For eligible studies, pain should be assessed by Visual Analogue Scale, Brief Pain Inventory, Numerical Rating Scale, etc. disability should be assessed by Roland–Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI), etc.

Quality assessment / Risk of bias analysis: The quality assessment of the included studies will be independently conducted by two reviewers using the Physiotherapy Evidence Database (PEDro) scale. The PEDro scale is a tool developed to measure the methodological quality of RCTs of physiotherapy interventions.The scale involves an 11-domain assessment: 1) study eligibility criteria specified, 2) random allocation of subjects, 3) concealed allocation, 4) measure of similarity between groups at baseline, 5) subject blinding, 6) therapist blinding, 7) assessor blinding, 8) less than 15% dropouts, 9) intention- to-treat analysis, 10) between-group statistical comparisons, and 11) point measures and variability data. The PEDro score will be calculated by criteria 2) to 11) according to meeting the criteria or not. From these scores, the studies are considered as excellent (9–10 points), good (6–8 points), fair (4–5 points), and poor (less than 4 points) quality. The overall quality of evidence will be assessed using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) framework including the risk of bias, inconsistency, indirectness, imprecision, and publications bias. Any disagreement will be resolved through discussion.

Strategy of data synthesis: The meta-analysis will be conducted using Review Manager Version 5.3 software. For continuous data, the change between baseline and the end of interventions will be used in the meta-analysis. The mean difference (MD) and 95% confidence intervals (CI) will be calculated. In the case of different outcome measure scales, the standardized mean difference (SMD) and 95% CI will be calculated. For the expected heterogeneity, the Continuous data will be pooled using a more conservative random-effects model. According to the recommendations of the Cochrane handbook for systematic reviews of

interventions, the heterogeneity will be assessed using the statistic and Q statistic. Three levels of heterogeneity are < 25% (low heterogeneity), < 50% (moderate heterogeneity) and > 75% (high heterogeneity). It will be considered to be statistically significant when P<0.10.An Egger's test was performed to examine publication bias, and publication bias will be determined from a corresponding p-value less than 0.05.

Subgroup analysis: The subgroup analysis will be conducted based on different traditional Chinese mind-body exercises, control interventions and subpopulations if there are more than three eligible studies. The subgroup analysis will also be conducted according to different intervention time. The session time is defined as ≤ 30 min and > 30 min. The duration of exercise is coded as short (≤ 12 weeks), medium (13–24 weeks) or long (> 24 weeks). The weekly frequency is coded as low (≤ 2 sessions), medium (3–4 sessions), or large (> 4 sessions). If relevant data are not reported, the corresponding authors will be contacted to get detailed information. If the meta-analysis is not possible, a narrative synthesis of the available data will be conducted.

Sensibility analysis: The sensitivity analysis will be used to assess the quality of the included studies based on sample size, statistical method, and missing data. The risk of bias in the review process, as indicated by the results of the sensitivity analysis, will be discussed.

Country(ies) involved: China.

Keywords: Traditional Chinese mind-body exercises, low back pain, meta-analysis, systematic review.

Dissemination plans: The results of this review will be published in an international peer-reviewed journal.

Contributions of each author:
Author 1 - Yufeng Wang - Conceptualization.
Author 2 - Jing Bian - Funding acquisition.
Author 3 - Chengfu Quan - Methodology.
Author 4 - Fei Xu - Project administration.
Author 5 - Yanan Zhao - Writing –original draft.
Author 6 - Li Dong - Writing –review & editing.