INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest: **None.**

Baduanjin exercise on quality of life for cancer survivors: a protocol for systematic review and meta-analysis

Gong, XG[1]; Rong, G[2]; Wang, ZY[3]; Liu, F[4]; Song, HZ[5]; Wang, LP[6]; Zhang, AY[7].

Review question / Objective: **What is the effect of Baduanjin exercise on quality of life of cancer survivors?**
Condition being studied: **Cancer cure and care. Baduanjin (also called Eight Section Brocade), a traditional Chinese mind-body exercise routine, has been frequently reported to be a useful complementary and alternative therapy. This systematic review and meta-analysis wil summarize the current evidence of Baduanjin used as an intervention on quality of life for cancer survivors.**
Information sources: **Clinical trial registries, such as the Chinese Clinical Trial Registry (ChiCTR), and ClinicalTrials.gov, will also be searched for ongoing trials with unpublished data. The search period will be recorded for each database. Describe all intended information sources (e.g., electronic databases, contact with authors, trial registers, or grey literature.In addition, a manual search will also be carried out to supplement the electronic searches, and the references of relevant studies will be investigated for any further material for inclusion.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2020 and was last updated on 16 April 2020 (registration number INPLASY202040095.

INTRODUCTION

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Condition being studied: **Cancer cure and care. Baduanjin (also called Eight Section Brocade), a traditional Chinese mind-body exercise routine, has been frequently reported to be a useful complementary and alternative therapy. This systematic review and meta-analysis wil summarize the current evidence of Baduanjin used as an intervention on quality of life for cancer survivors.**

METHODS

Search strategy: The following search items will be used: “Baduanjin” OR “ba duan jin” OR “eight section brocades” and “neoplasm” OR “neoplasms” OR “cancer” OR “cancers” OR “ tumor” OR“tumors.” These terms were translated into Chinese when retrieving Chinese database.

Participant or population: Survivors and patients diagnosed with all kinds of cancer.

Intervention: Inclusion: Baduanjin exercise Exclusion: Baduanjin exercise interventions combined with non-exercise interventions, or other exercise interventions, such that the individual effects of Baduanjin exercise cannot be assessed.

Comparator: Interventions other than Baduanjin exercise (e.g. usual care, or other standard interventions including health education, psychological support, and daily exercise.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Eligibility criteria were detailed using the Participants, Interventions, Controls, Outcomes, and Studies (PICOS) framework. Participants were adults aged 18 years or older with a diagnosis of cancer; of any race, nationality, or language background; had previously received cancer treatment; and without major concomitant chronic disease or mental illness that precluded them from participating in Baduanjin exercise.

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Main outcome(s): Primary outcomes: quality of life (QOL) , included all QOL outcomes measured by the Functional Assessment of Cancer (FACT), the Functional Assessment of Chronic Illness Therapy-Fatigue survey (FACIT-F), the Medical Outcomes Study 36-item short-form health survey (SF-36), and the World Health Organization quality of life brief questionnaire (WHOQOL-BREF).Secondary outcomes: fatigue, sleep function, anxiety, and depression.Outcome evaluation before and after intervention.

Additional outcome(s): Safety measurements and adverse events.

Data management: Two reviewers will assess the eligibility of the studies retrieved during the searches independently against the inclusion and exclusion criteria, and those studies meeting the criteria will be selected for use in the review. The following data will then be extracted from the studies selected for inclusion using a data collection form, and recorded in an Excel file: first author and year, study design, sample, cancer stage, intervention, control group, type of measures, risk of bias assessment and findings. The results will be cross-checked by the two reviewers, and any disagreements will be resolved by consensus, with any ongoing differences in opinion being arbitrated by a third reviewer. We may also contact the original authors to provide additional relevant information, if necessary.

Quality assessment / Risk of bias analysis: Two reviewers independently assessed the quality of each trial according to the Cochrane risk of bias tool, which contained 7 domains: random sequence generation, allocation concealment, blinding of participants and investigators, blindness of outcome assessments, incomplete outcome data, selective outcome reporting, and other biases. We will judge the each of the domains as ’low risk of

bias', 'high risk of bias', or 'uncertain risk of bias' according to Higgins. Disagreements were rechecked by discussion with a third reviewer. We will illustrate the potential biases within each of the included studies by presenting a 'risk of bias' table or graph and summary.

Strategy of data synthesis: Meta analysis was performed using RevMan 5.3 software provided by the Cochrane Collaboration. For continuous outcomes, data will be analyzed by using a standard mean difference (SMD) with 95% CIs or a weighted mean difference (WMD).The WMD will be used for the same scale or the same assessment instrument; SMD will be used for different assessment tools. If subsets of studies are sufficiently homogeneous, we will perform a meta-analysis to combine their results for our primary outcomes. Statistical heterogeneity will be assessing using a standard χ^2 test, with a significance level of $P<0.10$ regarded as significant, and the I^2 statistic will also be used. The fixed-effects model will be utilized if the heterogeneity test indicates no significant difference ($I^2$0.1); otherwise, the random-effects model will be used.

Subgroup analysis: A subgroup analysis will be performed to determine the potential heterogeneity and inconsistency clinically and statistically. This include age, gender and disease duration of patients, trial blinding, evidence quality and so on. Meta-regression analysis will be implemented to quantify the inter-subgroup difference and explore statistical significance. A meta-regression analysis will be implemented to quantify the inter-subgroup differences, and to explore statistical significance.

Sensibility analysis: Sensitivity analysis will be performed by removing low quality studies, or trials with a short-term followup.

Language: No language restrictions will be applied.

Country(ies) involved: China.

Keywords: Baduanjin; quality of life; cancer survivor; systematic review.