

INPLASY PROTOCOL

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Baduanjin exercise for patients with breast cancer: a systematic review and meta-analysis

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Review question / Objective: Is Baduanjin exercise effective for the treatment of breast cancer?

Condition being studied: Breast cancer, one of the most common cancers among women, is responsible for physical and mental problems. Breast cancer survivors experience a variety of side effects from cancer treatment, including cognitive impairment, sleep disturbance, depression and anxiety, pain weight gain, and chronic fatigue. 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. However, critical evidence which confirms the clinical value of Baduanjin in patients with breast cancer is still insufficient. Therefore, This systematic review and meta-analysis will summarize the current evidence of TCE used as an intervention for Patients with Breast Cancer.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2020 and was last updated on 15 April 2020 (registration number INPLASY202040083).

INTRODUCTION

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the clinical value of Baduanjin in patients with breast cancer is still insufficient. Therefore, This systematic review and meta-analysis will summarize the current evidence of TCE used as an intervention for Patients with Breast Cancer.

METHODS

Search strategy: To ensure inclusion of all relevant articles, the following search items will be used: “Baduanjin” OR “ba duan jin” OR “eight section brocades” and “breast neoplasm” OR “breast neoplasms” OR “breast cancer” OR “breast cancers” OR “breast tumor” OR “breast tumors.” These terms were translated into Chinese when retrieving Chinese database.

Participant or population: Patients diagnosed with Breast cancer of all ages, stage and racial groups.

Intervention: The studies must have examined Baduanjin exercise as the only intervention. Baduanjin exercise interventions combined with non-exercise interventions, or other exercise interventions, such that the individual effects of Baduanjin exercise cannot be assessed.

Comparator: Control: 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: Only RCTs were considered eligible.

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.

Information sources: The following electronic bibliographic databases will be searched to identify relevant studies: Pubmed, Embase, Cochrane Library, web of science Chinese National Knowledge Infrastructure (CNKI), Wanfang Data Information Site, Chinese Biomedical Database (CBM), and Chinese Science and Technique Journals Database (VIP). In addition, clinical trial registries, such as the Chinese Clinical Trial Registry (ChiCTR), and ClinicalTrials.gov, will also be searched for ongoing trials with unpublished data. 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.

Main outcome(s): Primary outcomes: Quality of life (measured using the Functional Assessment of Cancer Therapy-Breast , Functional Assessment of Chronic Illness Therapy-Fatigue survey, Health-related quality of life 36, and medical outcomes study short form, and so on), psychological symptoms (stress, anxiety, and/or depression). Secondary outcomes: treatment-related symptoms (e.g., pain and/or fatigue symptoms), limb dysfunction, heart rate, weight, body mass index.

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 'unclear risk of bias' according to Higgins (2011). 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 assessed 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.

Sensibility analysis:

Sensitivity analysis may be performed by removing low quality studies, or trials with a short-term follow-up.

Language:

No language restrictions will be applied.

Country(ies) involved:

China.

Keywords:

Baduanjin; breast cancer; systematic review.