

INPLASY PROTOCOL

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The authors have no conflicts
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Effects of Qigong, Tai Chi, Acupuncture and Tuina on Cancer- Related Fatigue for Breast Cancer Patients: A protocol of systematic review and meta-analysis

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Review question / Objective: The aim of this systematic review and meta-analysis of randomized controlled trials is to evaluate the effectiveness of Qigong, Tai Chi, Acupuncture and Tuina for cancer-related fatigue by breast cancer survivors.

Condition being studied: Breast cancer (BC) is the most common cancer among women worldwide. Fortunately, despite the increasing incidence of BC, development of cancer diagnosis and treatment technology have made year of survival extended significantly. Cancer-related fatigue (CRF) is one of the most common and disabling outcomes reported by BC survivors during and after treatment. More than 80 percent of BC patients with standardized treatment have fatigue. NCCN defines CRF as a distressing, persistent, subjective sense of physical, emotional and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning. CRF is exacerbated by higher rates of depression, sleep disturbance and pain, it is highly bothersome, interferes with daily activities, and limiting overall quality of life. Besides, CRF can persist for up to 10 years after end of treatment. It is increasingly demanding to improve quality of life.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 October 2020 and was last updated on 02 October 2020 (registration number INPLASY2020100003).

INTRODUCTION

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METHODS

Search strategy: RCTS are being searched in the following electronic databases without language and publication date restrictions: PubMed, Cochrane Library, EMBASE, MEDLINE, Web of Science, Scopus, PsycINFO, PSYINDEX, CINAHL, China National Knowledge Infrastructure (CNKI), WanFang Database, and Chinese Biomedical Literature Database (CBM) until March 2020. Search terms are related to (1)breast cancer, (2)cancer related fatigue, (3)Qigong,(4) Tai Chi, (5)acupuncture and (6)Tuina. The details of the PubMed database search strategy are shown in Table 1, and similar search strategies will be adopted for other databases.

Participant or population: Breast cancer patients suffering from CRF with the following conditions will be included: firstly, age, gender, race, education status, and types of treatment are not restricted. Secondly, definite pathological diagnosis of breast cancer without restrictions related to type and stage. And finally, breast

cancer patients should conform to the diagnosis standards of CRF, which based on International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10).

Intervention: Approaches including Qigong, Tai Chi, acupuncture and Tuina alone or in combination, will be reviewed.

Comparator: The control group could be placebo, blank control, standard care and other body-based practices such as exercise techniques, yoga.

Study designs to be included: RCTs will be included without restriction of publication type or language. Studies should be available in full papers and peer-reviewed.

Eligibility criteria: 1. Types of studies. RCTs will be included without restriction of publication type or language. Studies should be available in full papers and peer-reviewed. 2. Types of participants. Breast cancer patients suffering from CRF with the following conditions will be included: firstly, age, gender, race, education status, and types of treatment are not restricted. Secondly, definite pathological diagnosis of breast cancer without restrictions related to type and stage. And finally, breast cancer patients should conform to the diagnosis standards of CRF, which based on International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10). 3. Types of interventions and comparators. Approaches including Qigong, Tai Chi, acupuncture and Tuina alone or in combination, will be reviewed. The control group could be placebo, blank control, standard care and other body-based practices such as exercise techniques, yoga. 4. Types of outcome measures 4.1 Primary outcomes. The primary outcomes are certain common scales which reflects fatigue severity. We considered the following scales: Piper Fatigue Scale (PFS); the Functional Assessment of Cancer Therapy (FACT)-Fatigue Scale; Schwartz Cancer Fatigue Scale (SCFS); the Multidimensional Fatigue Inventory (MFI).

4.2 Secondary outcomes. The secondary outcome measures are any quality of life, adverse events.

Information sources: 1. Electronic searches: RCTS are being searched in the following electronic databases without language and publication date restrictions: PubMed, Cochrane Library, EMBASE, MEDLINE, Web of Science, Scopus, PsycINFO, PSYINDEX, CINAHL, China National Knowledge Infrastructure (CNKI), WanFang Database, and Chinese Biomedical Literature Database (CBM) until March 2020. Search terms are related to (1)breast cancer, (2)cancer related fatigue, (3)Qigong,(4) Tai Chi, (5)acupuncture and (6)Tuina. The details of the PubMed database search strategy are shown in Table 1, and similar search strategies will be adopted for other databases. 2.Searching other resources: Manual searches will include reviewing reference lists of identified studies, relevant reviews, meta-analyses and journals that have published the most relevant research articles or reviews. Meanwhile, grey literature will be searched. The ongoing RCTS will be searched the WHO International Clinical Trial Registry Platform(ICTRP) and its Registry Network, and we will contact corresponding authors to identify extra studies if necessary.

Main outcome(s): The primary outcomes are certain common scales which reflects fatigue severity. We considered the following scales: Piper Fatigue Scale (PFS); the Functional Assessment of Cancer Therapy (FACT)-Fatigue Scale; Schwartz Cancer Fatigue Scale (SCFS); the Multidimensional Fatigue Inventory (MFI).

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of study bias using the Cochrane Collaboration tool, which consists of the following six items: random sequence generation, allocation concealment, participant and personnel blinding, outcome assessment blinding, incomplete outcome data, selective reporting and other source of bias. The quality of the

reporting will be categorized into 3 levels: low, unclear, and high risk of bias. Any disagreement will be decided by 3rd reviewer.

Strategy of data synthesis: Meta-analysis will be performed using RevMan ver 5.3(Cochrane) statistical software. Relative risk (RR) will be used when the result is dichotomous variables and 95% confidence intervals (CI). For continuous variables, we will use standardized mean difference(SMD) and 95% CI. χ^2 test and I² statistic will be used to confirm the heterogeneity. The former checks for heterogeneity, while the latter reflects the degree of heterogeneity through a specific value. I² of 25%, 50%, and 75%, respectively, indicated low, medium and high heterogeneity. If I² is more than 50%, there is considerable heterogeneity between studies, so a subgroup analysis will be performed to investigate the potential causes.

Subgroup analysis: Considering significant heterogeneity, we plan to carry out a subgroup analysis. The following items will be considered: (1) age, and race of patients, (2) types and stage of breast cancer, (3) course of the intervention.

Sensibility analysis: Sensitivity analysis will be conducted to eliminate the efficacy of low quality studies, provided there is significant heterogeneity after robust subgroup analysis. The meta-analysis will be repeated after low-quality studies are removed. We will compare the results of the two meta-analyses and then decide whether to exclude low-quality studies based on evidence strength, sample size, and influence on the pooled estimate. Nonetheless, sensitivity analysis will not be performed if there is a high risk of bias in all included studies.

Country(ies) involved: China.

Keywords: breast cancer, Qigong, Tai Chi, acupuncture, Tuina, TCM nonpharmacological interventions, cancer-

related fatigue, protocol, systematic review, meta-analysis.

Contributions of each author:

Author 1 - Xue Li - Author 1 drafted the manuscript, made contributions to the conception.

Author 2 - Xueqian Wang - The author drafted the manuscript and made contributions to the conception.

Author 3 - Hongsheng Lin - The author read, provided feedback and approved the final manuscript.

Author 4 - Ying Zhang - The author read, provided feedback and approved the final manuscript.

Author 5 - Lijun Song - The author contributed to the development of the data curation, and methodology.

Author 6 - Jiayue Tian - The author contributed to the development of the data curation, and methodology.

Author 7 - Xuejiao Ma - The author contributed to the development of the investigation.

Author 8 - Qiyuan Mao - The author contributed to the development of the investigation and methodology.