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The authors have no conflicts of interest to disclose.

The Effect of Tai Chi Practice on immunological function in cancer survivors: A systematic review protocol

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Review question / Objective: **The aim of this systematic review and meta-analysis of randomized controlled trials (RCT) is to evaluate current evidence and estimate the pooled effects of Tai Chi on the immune system, as well as adverse events.**
Condition being studied: **Cancer is a leading cause of global mortality and is responsible for 13% of all deaths. However, the estimated 5-year survival rate across all cancers has risen to about 65% today. Due to in a large part, the dramatic advances in cancer treatment and management, growing attention to multidisciplinary post-treatment care, and healthier lifestyles, there is a steady increase in the number of cancer survivors, that is people diagnosed with cancer, worldwide.Some studies have found that Tai Chi shows some favorable effects on the promotion of immune system. Additionally, the pro-inflammatory cytokines IL-12, IL-6, TNF-α, and the anti-inflammatory cytokinesIL-10 and IL-4 are reported by researchers to be major cytokines and have implications for chronic disease and cancer-related outcomes. Up to now, there are 18[1-18]systematic reviews about the Effect of Tai Chi practice on cancer related symptoms. The primary outcome measures of the reviews included short and long-term cancer-related fatigue, quality of life, aerobic capacity, muscular strength, and flexibility. Although boosting the immune system can offer potential benefits to cancer survivors, there is no systematic review evaluating the effect of Tai Chi on immune system in cancer patients thus far.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 June 2020 and was last updated on 12 June 2020 (registration number INPLASY202060042).

INTRODUCTION

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METHODS

Search strategy: All relevant RCTs will be identified regardless of language or publication status (e.g. published, unpublished, in press or in progress). The English search terms will include 'Tai Chi', 'Tai Chi Chuan','Tai ji', 'Tai-ji', 'Tai Ji Quan', 'taijiquan','neoplasms', 'cancer', 'carcino', 'tumor','randomized controlled trial', 'randomised controlled trial', 'controlled clinical trial', 'randomly', 'clinical', 'trial, 'random', 'randomised'and 'randomized'. The Chinese searching terms will include Tai Chi ('Tai_ji', 'Tai_ji_yun_shou', 'Tai_ji_cao'or 'Tai_ji_chuan'), cancer('ai', 'ai_zheng', 'ai_zhong'or 'zhong_liu')and randomized ('sui_ji', 'dui_zhao').

Participant or population: This review will include cancer survivors regardless of age, sex, tumor site, tumor type, tumor stage, and type of anticancer treatment received.

Intervention: Studies that use any form of Tai Chi regardless of the form (e.g. 24-form, 54-form, 83-form Tai Chi) in any styles (e.g. Chen, Yang, Wu and Sun) with a minimum frequency of once per week.

Comparator: Studies with no treatment, other treatment forms like usual medical care, health education, pharmacotherapy, psychological therapy, cognitive behavioral therapy, and exercises other than Tai Chi such as walking, stretching, yoga, and dancing will be eligible.

Study designs to be included: RCTs assessing the effects of Tai Chi in cancer survivors will be included. Reviews, case reports, editorials and study protocols will be excluded.

Eligibility criteria: Applicable diagnostic criteria including European Society for Medical Oncology (ESMO) 2014; The World Health Organization (WHO) 2017, et, al.

Information sources: The following databases will be searched until March 9, 2019: Cochrane Library, Excerpta Medica Database (EMBASE), PubMed, Amed, CINAHL, Sprotdicus, American Association for Cancer Research Journals, Sino-Med database, China National Knowledge Infrastructure (CNKI).

Main outcome(s): All biomarkers related to the immune system including immunerelated cytokines and immune cells will be recorded including but not limited to pro-inflammatory cytokines IL-6, TNF-α, C-reactive protein (CRP), anti-inflammatory cytokines IL-4 and IFN-γ, cortisol and so on.

Additional outcome(s): Not planned.

Data management: Two authors (XJ Wang and XZ Luo) will extract the data from the included trials independently using a predesigned form. Any disagreements will be resolved by discussion with a third author (N Dai). The extracted data will include the following information: (1)publication information: authors, country, journal, title and year of publication. (2)study designs: multiple/single centre(s), parallel/cross-over, etc. (3)participants: sample size,diagnostic criteria,

characteristics of participants (e.g. age, gender, duration of disease and severity of disease), etc; (4)intervention: type and/ or form of TC, details of treatment and control, duration of treatment; (5) outcome: outcomes measures, main data of the outcomes, time point of measurement, etc. In case of missing data or having unclear information, we will contact the authors to clarify the information. If the data is not accepted, we will record the study as unclear.

Quality assessment / Risk of bias analysis: Studies quality will be assessed using the risk of bias tool provided by the Cochrane Handbook for Systematic Reviews of Interventions. This will assess the the categories of bias for each study: selection bias (random sequence generation and allocation concealment), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting) and other bias (unbalanced base line, early termination). We will not report performance bias, considering the difficulties of blinding the participants and personnel in Tai Chi intervention studies. For each item, there are three potential bias judgements: 'low risk', 'high risk', or 'unclear risk'. Trials that meet all criteria will be judged to have low risk of bias. A high risk of bias if at least one domain is assessed as at high risk of bias, and trials with insufficient information to judge will be classified as unclear risk of bias. Any disagreements will be resolved by discussion, with involvement of a third author where necessary.

Strategy of data synthesis: Data will be summarized by using risk ratios with 95% confidence interval (CI) for dichotomous outcomes or mean difference with 95% CI for continuous outcomes. It is anticipated that different scales may be used to report the same outcomes, in which case we will use the standardised mean difference (SMD). Statistical heterogeneity will be assessed using the I2 statistic (on the bases of characteristics of the included studies and the participants, details of the intervention or control, and types of outcome measurements). If the I2 statistic is <50% and the clinical heterogeneity among trials is acceptable, data will be pooled for statistical analyses using the Cochrane' Review Manager software (V.5.3). Fixed effects model will be used to conduct the meta-analysis when the I2 statistic is<25%, otherwise random-effects model. When there is clinical heterogeneity or statistical heterogeneity (I2 > 50%), subgroup analysis or descriptive analysis will be conducted.

Subgroup analysis: Where data are available, subgroup analyses will be conducted to determine if effectiveness of CM is influenced by: different phrases of treatment, such as undergoing treatment, or in the post-treatment phase. Studies including patients receiving chemotherapy or radiotherapy as the initial cancer treatment or as treatment in the presence of metastasis or cancer recurrence will be classified as 'undergoing cancer treatment stage', while those studies including patients currently have gone through chemotherapy or radiotherapy will be defined as 'post-cancer treatment stage'. Also we will conduct subgroup analyses for time frame, intervention duration, cancer type and so on if needed.

Sensibility analysis: To ensure the robustness of evidence, we will perform sensitivity analysis to assess the impact of studies depending on study characteristics identified during the review process.

Language: No.

Country(ies) involved: China.

Keywords: cancer; tai chi; systematic review; immunological function.

Dissemination plans: The findings will be disseminated through a peer-review publication.

Contributions of each author:
Author 1 - Xuejiao Wang - Xuejiao Wang contributed to the conception of the study and wrote the draft of manuscript.

Author 2 - Lei Xu - Lei Xu will revise the draft.
Author 3 - Xingzhe Yang - Methodology.
Author 4 - xin zhao - Project administration and supervision.
Author 5 - Juanmei Li - Project administration and supervision.
Author 6 - Feng Li - Funding acquisition and validation.