Relationship between Tai Chi and clinical outcomes in elderly patients with COVID-19: a protocol for systematic review and dose-response meta-analysis

Jinfeng Yang,1,2 Yang Wang,1 Sheng He,3 Xiao Peng,4 Chun Wang,1 Na Li,5 Yuanpeng Liao1,6

ABSTRACT

Introduction COVID-19 has posed a serious threat to people worldwide, especially the older adults, since its discovery. Tai Chi as a traditional Chinese exercise that belongs to traditional Chinese medicine has proven its effectiveness against COVID-19. However, no high-quality evidence is found on the dose–response relationships between Tai Chi and clinical outcomes in patients with COVID-19. This study will evaluate and determine the clinical evidence of Tai Chi as a treatment in elderly patients with COVID-19.

Methods and analysis The following electronic bibliographical databases including PubMed, EMBASE, Web of Science, Cochrane Library, China National Knowledge Infrastructure, VIP Database and Wanfang Database will be screened from their inception date to 30 June 2022. All eligible randomised controlled trials or controlled clinical trials related to Tai Chi for elderly patients with COVID-19 will be included. The primary outcomes are forced expiratory volume in 1 s (FEV1), forced vital capacity (FVC) and FEV1/FVC ratio (FEV1%). The secondary outcomes are the time of main symptoms disappearance, length of hospital stay, serum levels of interleukin (IL)-6, IL-1β and tumour necrosis factor-α, and adverse event rate. Two independent reviewers will select the studies, extract the data, and analyse them on EndNote V.X9.0 and Stata V.12.1. The robust error meta-regression model will be used to establish the dose–response relationships between Tai Chi and clinical outcomes. The heterogeneity and variability will be analysed by I² and τ² statistics. Risk of bias, subgroup analysis and sensitivity analysis will also be performed. The quality of evidence will be assessed by the Grading of Recommendations Assessment, Development and Evaluation.

Ethics and dissemination This study will review published data; thus, obtaining ethical approval and consent is unnecessary. The results will be disseminated through peer-reviewed publications.

PROSPERO registration number CRD42022327694.

INTRODUCTION

The novel coronavirus SARS-CoV-2 has rapidly spread to all continents of the world since its discovery in China in December 2019, forming a global pandemic, and has been named COVID-19 on 11 February 2020 by the WHO. To date, COVID-19 has formed many variants over time, further exacerbating the threat to humanity. Patients with COVID-19 are divided into four clinical classifications: mild cases, moderate cases, severe cases and critical cases.1 Therefore, patients with COVID-19 have a series of clinical features ranging from mild to severe due to different clinical classifications.2 These clinical features include common symptoms such as fatigue (1.38%), cough (7.67%) and fever (9.87%), and rare symptoms, such as diarrhoea (7.3%) and vomiting (5%).3 In addition to respiratory symptoms such as dyspnoea, patients with COVID-19 can experience musculoskeletal symptoms including fatigue, arthralgia, myalgia and muscle weakness, which can persist from infection to weeks to months after recovery.4 5 Thus, decreased exercise capacity is the most common functional impairment (61.4% of mildly discharged patients).2 Older adults, especially those over the age of 65 years, are a high-risk patient population for COVID-19.1 A meta-analysis showed that age is a key factor in determining

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ In addition to searching English databases, this review will also search major Chinese databases.
⇒ This review will use the Physiotherapy Evidence Database Scale to assess the risk of bias in the included studies.
⇒ This review will quantify the exercise dose of Tai Chi programmes with different exercise intensities and duration in metabolic equivalents of task (hours/ week).
⇒ Grading of Recommendations Assessment, Development and Evaluation will be used to assess the strength of the body of evidence.

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the prognosis of patients with COVID-19, and age has a remarkable positive correlation with mortality. The main reason is the presence of fragility in addition to comorbidities, such as cardiovascular, respiratory and renal diseases, malignancies, diseases of the nervous system, sarcopenia, dysphagia and diabetes, which are extremely common in the older adults, thereby increasing the rate of COVID-19 infection in older people and affecting their recovery from COVID-19 infection.

Exercise training has emerged as an expert consensus in recovery planning for patients with COVID-19. A pulmonary rehabilitation regimen consisting of multiple exercise training methods has been shown to improve exercise capacity measured by 6-minute walk test among patients with mild-to-moderate lung impairment after COVID-19. Exercise training also has a positive effect on the human immune system and inflammation, which can increase the levels of stress hormones and reduce excessive inflammation by increasing neutrophil and natural killer (NK) cell counts. Tai Chi, an ancient exercise derived from traditional Chinese medicine (TCM), has a broad base among the older adults. Regular Tai Chi exercise can increase the percentage of NK, NK T cells and cytokine interferon-γ-producing T cells, thereby promoting the development of T helper 1 immune responses and improving age-associated immune imbalance. A meta-analysis by Morgan et al. provided evidence that Tai Chi has a moderate effect on the reduction of C reactive protein. Irwin and Olmstead confirmed that Tai Chi can reduce the circulating levels of interleukin (IL)-6 in older adults. Compared with usual care, Tai Chi can effectively improve 6-minute walk distance and forced expiratory volume in 1 s (FEV1) in patients with chronic obstructive pulmonary disease. Tai Chi has been proven to improve mood (ie, State Trait Anxiety Inventory and Perceived Stress Scale 14). These features of Tai Chi allow it to be applied to patients with COVID-19 with positive effects. In a COVID-19 case report as early as May 2020, a woman in her late 40s was recommended by doctors to practise ‘Tai Chi’ as a rehabilitation therapy. Castro et al. began to call for Tai Chi as an effective and suitable recovery tool for patients with COVID-19, and Tai Chi has proven its effectiveness against COVID-19.

However, different exercise regimens have different effects on immune function, and excessive exercise can lead to a higher level of inflammatory mediators, which can impair immune function and exacerbate the spread of COVID-19. Compared with excessive exercise, moderate-intensity exercise can maximise immune function and can be considered as a non-pharmacological rehabilitation treatment for COVID-19. Tai Chi is the most representative traditional Chinese exercise (TCE), which belongs to the low-to-moderate-intensity exercise. Although two systematic reviews of Tai Chi for COVID-19 were published in 2020 and 2022, they still did not evaluate the effects of different doses of Tai Chi for COVID-19. No robust evidence high-quality meta-analyses have been published on the association between different doses of Tai Chi and clinical outcomes in patients with COVID-19. Based on this reason, we will perform a comprehensive dose-response analysis to determine the relationship between Tai Chi and clinical outcomes in elderly patients with COVID-19 and to identify the most appropriate Tai Chi treatment programme for elderly patients with COVID-19 through this systematic review and dose-response meta-analysis.

METHODS AND ANALYSIS

This systematic review protocol is designed in accordance with the guideline of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P), and has been registered in PROSPERO with the registration number CRD42022327694. The PRISMA-P checklist is provided in online supplemental table S1. The planned start date for this review is 1 March 2023, and the planned end date for this review is 1 October 2023.

Eligibility criteria

Study designs

All published randomised controlled trials (RCTs) or controlled clinical trials of Tai Chi for elderly patients with COVID-19 will be considered for inclusion, regardless of blinding. We will only include studies written in English or Chinese.

Participants

Older adults (≥60 years) diagnosed with COVID-19 and exercising Tai Chi will be included, without restrictions on gender, race, nationality, disease stage and clinical classification.

Interventions and comparisons

The experimental intervention is Tai Chi and the control interventions are no treatment, placebo or other interventions (ie, acupuncture, TCM, Western medicine, health education, etc.), which will be included in our study. No limitations will be set on the frequency, duration and type of treatment.

Outcome measures

The primary outcomes will include FEV1, forced vital capacity (FVC) and FEV1/FVC ratio (FEV1%). The secondary outcomes will include the time of main symptoms disappearance, length of hospital stay, serum levels of IL-6, IL-1β and tumour necrosis factor (TNF)-α, and adverse event rate. The main symptoms of COVID-19 are fever, dry cough and fatigue. Adverse events include bleeding, pain, haematoma and syncope.

Exclusion criteria

Duplicate literature and studies with unavailable data will be excluded in our study. We will also exclude clinical trials without a comparative group, relevant non-randomised controls, reviews and case reports.
Search strategy
Relevant studies from their inception to 30 June 2022 will be searched in the following electronic databases: PubMed, EMBASE, Web of Science, Cochrane Library, China National Knowledge Infrastructure, VIP Database and Wanfang Database. We will also search the potential studies in the reference lists of eligible studies and international trial registry websites. The specific clinical trial registries include: the WHO International Platform for Clinical Trials Registry (https://www.who.int/trialsearches), the National Institutes of Health clinical registry (https://clinicaltrials.gov/ct2/home) and the Chinese clinical trial registry (http://www.chictr.org.cn/index.aspx). The PubMed search strategy is summarised in table 1 and applied to other electronic databases after adjustment, as shown in online supplemental table S2.

Study selection and data extraction
For all the retrieved studies, two independent reviewers (SH and XP) will perform the screening and eligibility assessment process, blinded to each other. Two reviewers will import the retrieved studies into EndNote X9 (Thomson Reuters, USA), where duplicates will be deleted. Two reviewers will screen the titles, abstracts and full texts of selected studies with the eligibility criteria. Any disagreements will be resolved by discussion with a third reviewer (JY). Two authors will synthesise their screening results and determine the preliminary study pool. The filter operation process will be depicted in a flow chart under the guideline of PRISMA-P (online supplemental figure S1).

Two reviewers (CW and NL) will independently extract the data using a self-designed data acquisition form by Excel V.2013 (Microsoft, USA). This form includes the study characteristics (first author, publication year, country and study design), population demographics (number, age, gender, disease stage and clinical classification), intervention characteristics (type, frequency, duration of Tai Chi) and outcomes (primary and additional outcomes). Any disagreements will be resolved by inviting a third reviewer (YW) to discuss or consult together. If any data are missing, then we will try to contact the corresponding author by email or telephone to obtain the complete data.

Assessment of risk of bias
The risk of bias for the included studies will be evaluated by two reviewers (SH and XP) using the Physiotherapy Evidence Database Scale independently, which includes 11 items developed from the Delphi list to identify the quality of RCTs. The 11 items include (1) eligibility criteria and source, (2) random allocation, (3) concealed allocation, (4) baseline comparability, (5) blinding of participants, (6) blinding of therapists, (7) blinding of assessors, (8) adequate follow-up (>85%), (9) intention-to-treat analysis, (10) between-group statistical comparisons, and (11) reporting of point estimates and

<table>
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<th>Table 1</th>
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<td>2</td>
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<td>3</td>
<td>&quot;SARS-CoV-2 Infection&quot; [Title/Abstract]</td>
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<td>4</td>
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<td>5</td>
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<tr>
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<td>47</td>
<td>&quot;Ji Quan, Tai&quot; [Title/Abstract]</td>
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variability. The first item is different from the other scale items because it is related to external validity, so item 1 is not counted. This assessment categorises the studies on a scale from 0 (high risk of bias) to 10 (low risk of bias). A third reviewer (JY) will resolve cases of variation in opinion between initial reviewers.

**Exposure quantification**

Considering that the Tai Chi regimens included in the included studies may vary, we will unify the Tai Chi programmes with different exercise intensities and duration in metabolic equivalents of task (METs) (hours/week) to integrate different Tai Chi programmes. In accordance with the WHO’s guidelines, the quantified Tai Chi programmes will be divided into three categories: light intensity (between 1.5 and 3.0 METs), moderate intensity (between 3.0 and <6.0 METs) and vigorous intensity (6.0 or more METs). In the sensitivity analysis, we will subtract the resting metabolic rate of 1 MET from the original Tai Chi dose.

If the study only reported Tai Chi practice frequency on a weekly or monthly basis, then we will use the equation $X$ ($\text{MET} \times \text{hour}$)/$Y$ (kcal) = 4.5 hour/week ($X$), then we will use the equation $X$ ($\text{MET} \times \text{hour}$)/$Y$ (kcal) = 4.5 MET$\times$2.5 hours/550 kcal to convert between the two units.

### Data synthesis

Stata V.12.1 (StataCorp, USA) will be used for synthesising and analysing all the efficacy data. For dichotomous variables, the data will be analysed by using the risk ratio with 95% CIs. For continuous results, the mean difference (MD) or standard MD with 95% CIs will be calculated for the effect sizes. The heterogeneity and variability between studies will be assessed by using the $I^2$ and $\tau^2$ statistics. Applying the Cochrane Handbook, heterogeneity will be interpreted as follows: 0%–40% ‘might not be important’, 30%–60% ‘may represent moderate heterogeneity’, 50%–90% ‘may represent substantial heterogeneity’ and 75%–90% ‘considerable heterogeneity’. In addition to the $I^2$ statistic, the $\tau^2$ statistic measure of ‘between-study variance’ is considered a more suitable method for assessing heterogeneity mainly because the $\tau$ values are not affected by the size of the studies included in the meta-analysis. When $I^2 \leq 50\%$, the fixed-effect model was employed for combined analysis. Otherwise, the data will be combined by using the random-effect model.

We will select the robust error meta-regression model to establish the possible non-linear or linear relationships between Tai Chi and clinical outcomes, which focuses on inverse variance-weighted least-squares regression and cluster robust error variances to deal with the synthesis of correlated dose–response data from different studies. P<0.05 was considered statistically significant.

### Subgroup analysis

The subgroup analysis will be conducted to detect the potential high heterogeneity across RCTs after the statistical heterogeneity is established. Subgroup analysis will be performed on the basis of participant characteristics, such as gender, disease stage and clinical classification.

### Sensitivity analysis

When identifying statistical effects in the primary analysis, we will perform sensitivity analyses to verify the robustness of the results and to check whether any particular study accounted for a remarkable portion of the heterogeneity.

### Assessment of reporting bias

If at least 10 studies are included for the synthesised outcome, then the potential publication bias will be visually assessed by the funnel plots.

### Grading the quality of evidence

Two reviewers (CW and NL) will use the Grading of Recommendations Assessment, Development and Evaluation to assess the quality of evidence independently. The quality of evidence will be evaluated as ‘high’, ‘moderate’, ‘low’ and ‘very low’, with the participation of a third reviewer (YW) when a discrepancy occurred.

### Patient and public involvement

Patients or members of the public were not involved in the design of this study.
Ethics and dissemination

This study will be based on the results of previous studies and does not require ethical approval. This dose–response meta-analysis will be disseminated through a peer-reviewed journal for publication.

DISCUSSION

Methodological issues regarding the treatment of patients with COVID-19 have been a hot topic of concern for healthcare professionals due to the highly contagious COVID-19 worldwide. 15, 46 The availability of safe and effective drugs for the treatment of infections caused by COVID-19 is still limited, and a large number of additional clinical trials are needed for evaluation. 47 On this basis, we need to further enrich the treatment strategies for COVID-19. These effects can help control the potential effects of COVID-19 on the human body.

The theory of TCM holds that Tai Chi, a whole-body exercise including mindfulness, can transport Qi to various internal organs of the human body through the meridians during practice to play a better role and strengthen the immune system. This process is called ‘defensive Wei Qi’ and represents the strength of the body’s immune function. 48 The Wei Qi of older adults often has obvious deficiencies, which is reflected in low immunity, making older adults a prone group for COVID-19. Considering that Tai Chi can improve Wei Qi and better Wei Qi indicates better prognostic ability, Tai Chi is beginning to be used in the treatment of COVID-19. One hundred elderly patients with COVID-19 were equally divided into a Tai Chi intervention group and a control group. After 3 months of Tai Chi intervention, the Tai Chi intervention group had remarkably lower rates of severe illness and mortality than the control group without Tai Chi intervention. 39 From another perspective, the immune system will produce an excessive inflammatory response due to COVID-19, thereby activating the coagulation response, resulting in the excessive production of proinflammatory cytokines including IL-6, IL-1β and TNF-α, and then causes multiorgan injury in the human body. 30, 51 The elderly patient group, often with other comorbidities, has become the highest-risk population. Tai Chi as a TCE can reduce the level of proinflammatory cytokines, such as IL-6, 34 increase the level of anti-inflammatory cytokines, such as IL-10, 52 and reduce the expression of proinflammatory genes effectively. 53 Healthcare professionals need advice on effective doses for the use of Tai Chi during the rehabilitation of elderly patients with COVID-19. However, existing studies do not provide clear recommendations on the optimal dose of Tai Chi, and the dose–response effect of Tai Chi on the clinical outcomes of COVID-19 remains unknown. Therefore, this study will evaluate the dose–response relationship between Tai Chi and clinical outcomes in elderly patients with COVID-19. The emergence of this type of research will provide evidence-based medical support for the use of Tai Chi in elderly patients with COVID-19 with high-quality evidence.

However, this study has some limitations. Whether all patients were proficient in Tai Chi practice and whether different proficiency levels will bias the results remain unclear. Second, it is unclear whether all studies carefully divided the age of participants, which may have led to the exclusion of some potentially relevant studies. Third, whether participants of different ages and genders can affect the study results and cause selection bias needs to be determined. If the number of high-quality RCTs included in this study is insufficient, then the quality of the evidence for our findings may be compromised.

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Contributors JY, YW and YL conceived and designed the study. JY drafted the manuscript of the protocol. YW and YL revised the protocol. JY, SH and XP will search and select the eligible studies. YW, CW and NL will extract the data from the included studies. JY, SH and XP will assess the risk of bias. YW, CW and NL will assess the quality of evidence. JY and YW will perform the data synthesis. All authors contributed to the article and approved the submitted version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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