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State-of-the-art evidence of traditional Chinese medicine for treating coronavirus disease 2019

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ABSTRACT

Traditional Chinese medicine has widely been used internationally in the treatment of coronavirus disease 2019 (COVID-19) since January 2020. There has been great interest in initiating clinical studies testing different Chinese medicine therapies for COVID-19, but the majority of registered studies have yet to move forward due to a lack of COVID-19 patients in mainland China. The aim of this article was to systematically review the current clinical research evidence on Chinese medicine for treating COVID-19 from international and domestic bibliographic databases to reflect on the advances in this field.

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1. Introduction

Traditional Chinese medicine (TCM) has a long history of preventing and controlling infectious diseases, and it has widely been used in the treatment of coronavirus disease 2019 (COVID-19) in China. COVID-19 is an acute respiratory disease caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), with typical manifestations, such as fever, cough, fatigue, and dyspnea, as well as a runny nose, sore throat, diarrhea, and a lack of taste and smell.¹ At present, no specific antiviral drug exists for the treatment of COVID-19. Although COVID-19 vaccination has achieved great success in reducing the number of severe cases, the global pandemic is still ongoing, with new variants of the virus emerging (Lambda, Delta, and Omicron), and all countries are vulnerable to imported variants.

Historical classical records on TCM have shown that Chinese medicine was used to prevent and treat infectious disease, and more recently in the past decades it was used against severe acute

respiratory syndrome (SARS) and H1N1 influenza. Thus, from the third to the eighth version of the national guidelines of the prevention and control of COVID-19 issued by the National Health Commission in China, Chinese medicines have been recommended for the treatment of COVID-19. A large number of clinical studies on COVID-19 have been registered in trial registries, but the majority of these studies could not be conducted due to the effective control of the virus in China. This review summarizes the current evidence on clinical studies of TCM for COVID-19 and aims to describe the characteristics of TCM therapies in the prevention and treatment of COVID-19 and post-COVID-19 syndrome.

2. Data sources and study inclusion criteria

We searched PubMed, the Web of Science, Wanfang, the China National Knowledge Infrastructure, ClinicalTrials.gov, and the ChiCTR electronic databases, from their respective dates of inception to December 2021, using the following keywords: “COVID-19,” “2019-nCoV,” “novel coronavirus pneumonia,” “NCP,” “SARS-CoV-2,” “TCM,” “herbal medicine,” “acupuncture,” “treatment,” “prevention,” and “rehabilitation.” We then established a literature database related to COVID-19. Randomized controlled trials (RCTs) of TCM for COVID-19 from peer-reviewed journals were included.

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Table 1
Existing randomized controlled trials on Chinese medicine for the treatment of coronavirus disease 2019.

Study ID	Participants (n)	Intervention	Control	Outcomes and main findings
Yu P 2020 ⁸	Mild and moderate cases (148 + 147)	Lianhua Qingwen granules + arbidol	Arbidol	Lianhua Qingwen combined with arbidol relieved symptoms, increased the curative effects, and reduced the rate of progression to severe disease
Duan C 2020 ⁹	Mild case (82 + 41)	Jinhua Qinggan granules + routine care	Routine care	Jinhua Qinggan significantly improved symptoms of fever, cough, fatigue, and expectoration, and relieved anxiety
Sun HM 2020 ¹⁰	Mild and moderate cases (32 + 25)	Lianhua Qingke granules + routine care	Routine care	Lianhua Qingke significantly improved symptoms of cough and expectoration; shortened the duration of cough and expectoration; reduced lung inflammation; improved lung function; and relieved symptoms of fever, fatigue, dry pharynx, and sore throat
Fu XX 2020 ^{a11}	Mild and moderate cases (32 + 33)	Toujie Quwen granules + arbidol	Arbidol	Clinical symptoms and inflammation were alleviated by early and timely use of Toujie Quwen granules
Fu XX 2020 ^{b12}	Mild case (37 + 36)	Toujie Quwen granules + arbidol	Arbidol	Symptoms of COVID-19 patients were alleviated by early and timely combined use of Toujie Quwen granules and arbidol
Ding XJ 2020 ¹³	Mild, moderate, severe/critical cases (51 + 49)	Qingfei Touxie Fuzheng Fang + routine care	Routine care based on NHC-China guidelines (5th edition)	Qingfei Touxie Fuzheng Fang in combination with Western medicines was more effective than Western medicine alone in terms of alleviating fever, coughing, and expectoration; chest tightness and shortness of breath; promoting absorption of pulmonary lesions; and improving oxygenation
Ye YA 2020 ¹⁴	Severe case (28 + 14)	CHM recommended in NHC-China guidelines (4th edition) + routine care	Routine care	The odds of a shift toward death were lower in the CHM plus routine care group than the routine care group
Qiu M 2020 ¹⁵	Moderate case (25 + 25)	Maxing Xuanfei Jiedu decoction + interferon + lopinavir/ritonavir	Interferon + lopinavir/ritonavir	Maxing Xuanfei Jiedu decoction significantly improved symptoms of fever, cough, and chest tightness, and accelerated the absorption of lung inflammation
Zhang CT 2020 ¹⁶	Moderate case (22 + 23)	Jiawei Dayuan Fang + routine care	Routine care	Jiawei Dayuan formula significantly improved symptoms for COVID-19 patients with “Yibing Bifei” pattern, increased the percentage of lymphocytes, and accelerated absorption of lung inflammation
Hu K 2021 ¹⁷	COVID-19 cases without classification (142 + 142)	Lianhua Qingwen capsules + routine care	Routine care	Lianhua Qingwen improved recovery of symptoms, shortened the time to symptom recovery, and improved recovery of chest radiologic abnormalities
Xiao MZ2020 ¹⁸	Suspected and diagnosed cases of COVID-19 (94 + 95 + 94)	Group 1: Lianhua Qingwen granules + Western medicine Group 2: Huoxiang Zhengqi dropping pills + Lianhua Qingwen granules + Western medicine	Western medicine	Use of Huoxiang Zhengqi dropping pills and Lianhua Qingwen granules combined with Western medicine may have clinical benefit for COVID-19 patients by improving symptoms, reducing the utilization rate of anti-infective drugs, and improving patient prognosis
Zeng CC2021 ¹⁹	Mild or moderate case (30 + 29)	Maxing Shigan–Weijing decoction + routine care	Routine care	Maxing Shigan–Weijing decoction increased the rate of symptom recovery and shortened the time to recovery of symptoms without deterioration to death or needing critical care
Xu XL2021 ²⁰	COVID-19 cases without classification (77 + 80)	Reduning injection + routine treatment (NHC-China guidelines, 5th edition)	Routine treatment (NHC-China guidelines, 5th edition)	Compared to routine care, Reduning injection ensured a shorter median time to resolution of symptoms, shorter to negative nucleic acid test results, shorter hospital stay, and shorter time to defervescence
Zhang XY2021 ²¹	Mild or moderate case (65 + 65)	Xiyanping injection + routine care (NHC-China guidelines, 5th edition)	Routine routine care (NHC-China guidelines, 5th edition)	Xiyanping injection significantly reduced the time to cough relief, fever resolution, and virus clearance; also, fewer patients receiving Xiyanping injection experienced progression to severe disease during the treatment process

(continued on next page)

Table 1 (continued)

Study ID	Participants (n)	Intervention	Control	Outcomes and main findings
Wen L2020 ²²	Severe type (20 + 20 + 20)	Group 1: Xuebijing injection (50 mL twice daily) + routine treatment Group 2: Xuebijing injection (100 mL twice daily) + routine treatment	Routine treatment	Compared to routine care, the WBC count in the Xuebijing group 2 was significantly increased and the levels of CRP and ESR in the Xuebijing 50 mL and 100 mL groups were significantly decreased; also, compared to the Xuebijing 50 mL group, the increase in WBC and the decreases of CRP and ESR levels were more significant in the Xuebijing 100 mL group

Notes: CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; NHC–China guidelines: clinical guidelines for the management of COVID-19 developed by the National Health Commission in China; WBC: white blood cell count. ^{a,b} refer to the same first author but from two articles.

3. TCM for the prevention of COVID-19

TCM for the prevention of epidemic diseases includes both specific and non-specific procedures. In terms of specific prevention, TCM is used for prevention and control, isolation and avoidance of evil, disinfection and insecticide. Non-specific prevention refers to the enhancement of the healthy qi—that is, immunity—of humans to prevent infection. By improving the self-healing capacity to expel external evil from the body, performing daily exercise and keeping emotions calm are non-specific measures. In the early days of the COVID-19 pandemic in Wuhan, our team published the article “Can Chinese medicine be used for prevention of corona virus disease (COVID-19)? A review of historical classics, research evidence and current prevention programs,” in which we analyzed the potential role of Chinese medicines for the prevention of COVID-19.² As of December 27, 2021, the article has obtained a citation count of 238 in the Web of Science, reflecting international attention toward the use of TCM in combatting COVID-19. In this article, we collated and analyzed research evidence from previous SARS and influenza outbreaks. The rate of infection with H1N1 influenza was brought significantly lower by using Chinese medicine than non-Chinese medicine (relative risk, 0.36; 95% confidence interval, 0.24–0.52; $n = 4$).² For the prevention of COVID-19, 23 guidelines from different provinces in China recommend the use of Chinese medicine. The main principles of Chinese medicine use are to tonify qi to protect humans from external pathogens, disperse wind and discharge heat, and resolve dampness.

4. TCM for the treatment of COVID-19

National Health Commission in China officially recommended TCM herbal decoctions (4 patterns, basic formulae) in the third version of the COVID-19 Diagnosis and Treatment Guidance. From the fourth version onward, it was clearly pointed out that COVID-19 patients can be treated by pattern differentiation according to their physical conditions, local climate characteristics, and variable geographical features. Different herbal formulae were recommended according to the different patterns. Also, from the fourth version onward, Chinese patent medicines (e.g., Huoxiang Zhengqi capsule, Jinhua Qinggan granule, Lianhua Qingwen capsule, Shufeng Jiedu capsule, and Fangfeng Tongshen pill) have been recommended, while, beginning with the fifth version, herbal injections began to be recommended. It was not until the eighth version, however, that recommendations of TCM were made for prevention. Chinese experience and guidance on COVID-19 were shared with the international community through publications and webinars.³

In an effort to consider clinical research on TCM treatments for COVID-19, our research team previously reviewed published study characteristics and offered guidance for future trials to avoid duplicated efforts.⁴ We also reviewed the existing TCM clinical trial

registrations and identified potentially promising and available TCM therapies.⁵

As of May 14, 2020, a total of 161 TCM clinical trials for COVID-19 were registered (<https://clinicaltrials.gov/> and <http://www.chictr.org.cn/enIndex.aspx>), including 94 (58.4%) RCTs, 25 non-randomized studies, and 18 case series. Of these, 70.8% evaluated therapeutic effects, focusing on Chinese medicine decoctions, Chinese patent medicine, and herbal injections. However, most of the TCM therapies recommended in the national guidelines are not supported by clinical evidence, and a persistent gap has remained between their wide use and research evidence.

For the prevention, control, and treatment of COVID-19 cases, China has been adhering to the combined use of Chinese and Western medicines. In the process of epidemic prevention and control, three medications (Lianhua Qingwen capsules, Jinhua Qinggan granules, and Xuebijing injection) and three prescriptions (Lung Clearing and Detoxifying decoction, Huashi Baidu Fang, and Xuanfei Baidu Fang) have been selected as the recommended Chinese medicines for the treatment of COVID-19. These three medications are all herbal drugs approved for sale, and all three play an important role in the treatment of COVID-19 and have significant clinical effects in patients with COVID-19.⁶ The National Medical Products Administration in China gave fast-track approval for the treatment of COVID-19 to be included in the treatment indications of the aforementioned three prescriptions. Among the three medications and three prescriptions listed above, Jinhua Qinggan granules and Lianhua Qingwen capsules are recommended for use by contacts of COVID-19 cases during the medical quarantine period, the Lung Clearing and Detoxifying decoction is recommended for all types of COVID-19 patients, Xuanfei Baidu Fang is used to treat moderate cases, and Huashi Baidu Fang and Xuebijing injection are prescribed for severe and critical cases. The potential molecular mechanisms of the active components in the six TCM formulations targeting ACE2,3CL (pro) and inteleukin-6 have been fully revealed by molecular biological studies and/or network pharmacology prediction/molecular docking analysis/visualization analysis.⁷

As of December 26, 2021, 15 RCTs on TCM treatment in the Clinical Guidelines for the Management of COVID-19 developed by National Health Commission in China have been published (Table 1).

In our previous systematic review,²³ we analyzed the use of Chinese herbal medicine (CHM) and estimated the effectiveness and safety of CHM in the treatment of COVID-19. Considering the updated RCTs included in Table 1, we found that TCM in combination with conventional therapy has more potential benefits compared to conventional therapy alone, such as a reduced rate of progression to severe COVID-19; increased resolution rate, shortened duration of fever, cough, and fatigue; negative conversion rate of nucleic acid test results; and an increased number of patients

with inflammatory disappearance or shortening of the time between receiving treatment and inflammation absorption. The evidence of TCM was mainly for COVID-19 patients with mild and moderate cases. From the reporting of adverse events in three systematic reviews,^{23–25} it was suggested that the use of TCM appears to be safe.

5. TCM clinical trials for long COVID-19

Several clinical studies reported that more than half of COVID-19 patients experience persistent symptoms, such as fatigue and chest pain after viral clearance; these symptoms have come to be known as long COVID or post-COVID syndrome (Box 1).^{26–30}

Box 1

Multi-organ systems and variable manifestations of long coronavirus disease 2019.

- ◆ Neurological or psycho-psychiatric symptoms: fatigue, headache, insomnia, anxiety, depression, post-traumatic stress disorder, and epilepticus
- ◆ Respiratory symptoms: lung fibrosis, fever, cough, sputum, dyspnea, and chest tightness on exertion
- ◆ Endocrine symptom: thyroid dysfunction
- ◆ Gastroenterological symptoms: diarrhea and poor appetite
- ◆ Cardiovascular symptoms: high blood pressure and palpitations on exertion
- ◆ Genitourinary symptoms: male infertility, male sexual dysfunction
- ◆ Oral and sensory symptoms: persistent salivary gland ectasia, olfactory and gustatory dysfunction, and macroglossia
- ◆ Skin and hair symptom: alopecia

Table 2
Characteristics of registered clinical trials for patients with long coronavirus disease 2019.

Title	Status	Conditions	Interventions	Locations
Cardiorespiratory exercise & Chinese medicine for rehabilitation of discharged coronavirus disease (COVID-19) patients	Not yet recruiting	COVID-19	Cardiorespiratory exercise, modified Kong, Bahe Gujin decoction	Hong Kong, China
Special Chinese medicine out-patient program for discharged COVID-19 patients	Recruiting	Post-COVID-19	Individualized-Chinese herbal medicine	Hong Kong, China
Moxibustion plus cupping in convalescent patients with COVID-19	Recruiting	COVID-19 convalescence	Moxibustion plus cupping	Hubei, China
Treatment of pulmonary fibrosis due to COVID-19 with Fuzheng Huayu	Recruiting	Pulmonary fibrosis due to COVID-19	Fuzheng Huayu tablet, vitamin C, placebo, lung function rehabilitation training	Shanghai, China

A systematic review of current data on post-COVID-19 syndrome showed that, by February 15, 2021, a total of 145 studies had reported long-term COVID-19 symptoms, including abnormal lung function (20.70%), neurologic complaints and olfactory dysfunction (24.13%), and systemic symptoms such as fatigue and pain (55.17%).³¹ TCM has many approaches to deal with long-term symptoms, including CHM, acupuncture, moxibustion, Taichi, Qigong (i.e., six-character formula, Baduanjin), Tuina, and mental therapy. As of December 27, 2021, there were four clinical trial protocols testing Chinese medicine therapies for long COVID that were registered with ClinicalTrials.gov (Table 2).

As of December 22, 2021, 30 protocols of clinical trials testing CHM or Chinese patent herbal drugs (26, 86.7%), Taichi (1, 3.3%), and Qigong (3, 10.0%) were registered for COVID-19 convalescent patients. Here, study designs include RCTs (25, 83.3%), pilot non-randomized controlled studies (1, 3.3%), and prospective case series (4, 13.3%).

The lack of COVID-19 patients and international cooperation are the main current limitations placed on TCM research for long COVID-19. We encourage future international collaborative trials on the most potential patent herbal drugs.

6. Conclusion

TCM therapies have widely been used in the treatment of COVID-19, either alone or in combination with conventional therapy in China, and they have achieved significant achievements. There have been some randomized clinical trials completed and published demonstrating benefits of CHMs in the areas of symptom relief and lung inflammation. However, due to the lack of double-blind, placebo-controlled trials and endpoint outcomes such as mortality, the beneficial effects still need to be verified in rigorous trials. There might be great value to explore the potential of TCM for long persistent symptoms after COVID-19.

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CRediT authorship contribution statement

Jianping Liu: Conceptualization, methodology, funding acquisition, and writing—review & editing. **Fei Dong:** Data curation, investigation, and writing—original draft, and writing—review & editing. **Nicola Robinson:** Funding acquisition and writing—review & editing.

Declaration of competing interest

Professor Jianping Liu is an outstanding evidence-based medicine expert and acts as an executive deputy editor-in-chief of the *Journal of Traditional Chinese Medical Sciences*. He was excluded from the review process of this paper.

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