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Effects and Safety of the Traditional Chinese Exercise Baduanjin on Depression and Anxiety in COVID-19 Patients: A Study Protocol for Systematic Review and Meta-analysis

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ADMINISTRATIVE INFORMATION

Support - N/A.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 August 2024 and was last updated on 16 August 2024.

INTRODUCTION

Review question / Objective Population
The participants included in this study will have a confirmed diagnosis of COVID-19 based on laboratory testing. Depression and anxiety will be either diagnosed by a qualified psychologist or determined through the use of self-administered depression or anxiety questionnaires.

Intervention and comparison
The study will include various types of Baduanjin exercise, whether used alone or in conjunction with other treatment modalities, for the control group. The comparators will include a waitlist control, usual care, health education and supportive counseling, psychosocial support therapy, pharmacotherapies (including antiviral drugs, antitussives, expectorants, antiasthmatic drugs, corticosteroids, α-IFN inhalation, other symptomatic treatments and routine treatments) recommended in COVID-19 international guidelines or the Diagnosis and Treatment Protocol for COVID-19 in local healthcare service centers , as well as other common exercises. The exclusion criteria for trials will be trials comparing different treatment durations, different treatment frequencies, and different types of Baduanjin exercise. Moreover, other traditional Chinese medicine (TCM) therapeutic methods, such as acupuncture, Tuina, moxibustion, Chinese herbal medicine, cupping, auricular acupressure,etc., applied in either the intervention or control group will be also excluded .
Outcome
Primary outcomes
(1) Depression: Depression symptoms will be assessed using validated self-assessment scales, scales administered by medical professionals, or other specific validated scales. Commonly used assessment tools for COVID-19-related depression include the Patient Health Questionnaire (PHQ-9) , the Beck Depression Inventory (BDI) , the Self-Rating Depression Scale (SDS) , the Beck Depression Inventory-II (BDI-II) , the Hamilton Depression Scale , the Depression Anxiety Stress Scale (DASS21) , and the Hospital Anxiety and Depression Scale (HADS) .

(2) Anxiety: Anxiety symptoms will be measured using validated self-rating scales, clinician-rated scales, or other specific validated scales. Commonly used assessment tools for COVID-19-related anxiety include the Self-Rating Anxiety Scale (SAS) , the Hamilton Anxiety Scale , the General Anxiety Disorder 7-item (GAD-7) , and the Beck Anxiety Inventory (BAI) , among others.
Secondary outcome
(1) Adverse events
Adverse events will be recorded by independent researchers.

Condition being studied After a span of 4 years, the novel coronavirus SARS-CoV-2 has resulted in more than 771 million confirmed cases and more than 6 million deaths, leading to substantial societal upheaval globally . Owing to the availability of numerous efficient vaccines and novel treatment options, as well as the reinforcement of testing and monitoring systems and improved comprehension of public health measures, numerous nations are gradually diminishing their quarantine stipulations in an effort to progress toward attaining endemic status for COVID-19 . Numerous studies have shown a high prevalence of depression, anxiety, and other related mental health disorders among COVID-19 patients, likely due to factors such as the fear of infection, prolonged lockdowns, and social isolation. For instance, data from the U.S. Census Bureau reveal that in 2020 , the rate of depression and anxiety among American adults was significantly greater than that in 2019, with three times more adults screened for mental health issues. Another study using online surveys reported that 34% of COVID-19 patients experienced symptoms of anxiety, depression, and risk of suicide. These mental health disorders can have a profound impact on patients' well-being; for example, depression is correlated with longer hospital stays, lower quality of life, and higher hospital readmission rates. Similarly, anxiety is known to be associated with sleep disturbances and suicidal behavior.

METHODS

Participant or population The participants included in this study will have a confirmed diagnosis of COVID-19 based on laboratory testing. Depression and anxiety will be either diagnosed by a qualified psychologist or determined through the use of self-administered depression or anxiety questionnaires.

Intervention The study will include various types of Baduanjin exercise, whether used alone or in conjunction with other treatment modalities, for the control group.

Comparator The comparators will include a waitlist control, usual care, health education and supportive counseling, psychosocial support therapy, pharmacotherapies (including antiviral drugs, antitussives, expectorants, antiasthmatic drugs, corticosteroids, α-IFN inhalation, other symptomatic treatments and routine treatments) recommended in COVID-19 international guidelines or the Diagnosis and Treatment Protocol for COVID-19 in local healthcare service centers , as well as other common exercises.

Study designs to be included Systematic review of randomized controlled trials.

Eligibility criteria The study will include various types of Baduanjin exercise, whether used alone or in conjunction with other treatment modalities, for the control group. The comparators will include a waitlist control, usual care, health education and supportive counseling, psychosocial support therapy, pharmacotherapies (including antiviral drugs, antitussives, expectorants, antiasthmatic drugs, corticosteroids, α-IFN inhalation, other symptomatic treatments and routine treatments) recommended in COVID-19 international guidelines or the Diagnosis and Treatment Protocol for COVID-19 in local healthcare service centers , as well as other common exercises. The exclusion criteria for trials will be trials comparing different treatment durations, different treatment frequencies, and different types of Baduanjin exercise. Moreover, other traditional Chinese medicine (TCM) therapeutic methods, such as acupuncture, Tuina, moxibustion, Chinese herbal medicine, cupping, auricular acupressure,etc., applied in either the intervention or control group will be also excluded.

Information sources The following databases will be searched from their inception until August 2024, without language restrictions. Medline, EMBASE, the Cochrane Infection Group Trials Register, SCOPUS, JBI, CNKI, the Wangfang database, SinoMed, EBSCO, CiNii, KoreaMed, the Cochrane Central Register, CINAHL, AMED, the Department of Health of the Hong Kong Special Administrative Region (https://www.dh.gov.hk/english/index.html), and Serviços de Saúde of the Macau Special Administrative Region (http://www.ssm.gov.mo).
The English search key terms will be used: 'Baduanjin exercise', 'Traditional Chinese exercise', 'Coronavirus Disease 2019' and 'COVID-19'. In addition, we will manually search several important Chinese language journals from their inception to

August 2024 after consulting with the steering committee of the research team. The lists of Chinese-language journals will be listed as follows: Xiandaiyangsheng, Journal of Acupuncture and Tuina Science, Xibuzhongyiyao, Anmoyukangfuyixue, Zhongyiwaizhi, Zhongguoliaoyangyixue, Yixueshiliaoyujiankang, Yangshengbaojianzhinan, Ziwobaojian, Hong Kong Medical Journal, Hong Kong Practitioner, Hong Kong Journal of Emergency Medicine, Macau Journal of Nursing.

Main outcome(s)

Outcome

Primary outcomes

(1) Depression: Depression symptoms will be assessed using validated self-assessment scales, scales administered by medical professionals, or other specific validated scales. Commonly used assessment tools for COVID-19-related depression include the Patient Health Questionnaire (PHQ-9) , the Beck Depression Inventory (BDI) , the Self-Rating Depression Scale (SDS) , the Beck Depression Inventory-II (BDI-II) , the Hamilton Depression Scale , the Depression Anxiety Stress Scale (DASS21) , and the Hospital Anxiety and Depression Scale (HADS) .

(2) Anxiety: Anxiety symptoms will be measured using validated self-rating scales, clinician-rated scales, or other specific validated scales. Commonly used assessment tools for COVID-19-related anxiety include the Self-Rating Anxiety Scale (SAS) , the Hamilton Anxiety Scale , the General Anxiety Disorder 7-item (GAD-7) , and the Beck Anxiety Inventory (BAI) , among others.

Secondary outcome

(1) Adverse events

Adverse events will be recorded by independent researchers.

Quality assessment / Risk of bias analysis The quality of the selected studies will be scored via the quality critical appraisal tool for RCTs from the Cochrane Handbook for Systematic Reviews of Interventions . The tool will includ seven entries concerning sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete data outcomes, selective outcome reporting, and other biases (baseline imbalance, ethical approval, source of funding, etc.). In accordance with the Cochrane Handbook, each entry will be rated as “low risk of bias”, “unclear risk of bias”, or “high risk of bias”.

Strategy of data synthesis A meta-analysis will be performed using the software STATA MP16 (Stata Corporation, TX, USA). Before treatment effects were measured, the I2 statistic will be used to assess the heterogeneity of each outcome. The thresholds of I2 will be based on the Cochrane Collaboration tool:

If I2 was homogeneous or had moderate heterogeneity, a fixed effect model will be selected. Otherwise, we will conduct a sensitivity analysis and re-evaluate the I2 statistic. In addition, a random effects model will be used in the meta-analysis to summarize the data if appropriate, and the articles will be considered clinically similar enough.

The pooled dichotomous data (GAD-7) will be shown as the RR. In addition, we will express the SAS, SDS, PHQ-9 and HAM-A scores as the means with 95% confidence intervals. A significance level of $P<0.05$ will be used to determine statistical significance in this meta-analysis.

Subgroup analysis Subgroup analysis will be conducted based on the following factors: 1) location of Baduanjin exercise, 2) Baduanjin exercise style, and 3) type of intervention in the control group.

Sensitivity analysis In the sensitivity analysis, meta-regression analysis will be employed to investigate potential sources of heterogeneity associated with the intervention protocol, including the treatment duration, frequency, and duration of Baduanjin exercise.

Country(ies) involved China.

Keywords Baduanjin; COVID19; systematic review.

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