INPLASY PROTOCOL

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Corresponding author:
Lin Zhu

zhulin999999999@126.com

Author Affiliation:
School of Physical Education, Soochow University

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The authors declare no conflict of interest.

Effects of Mind-body Exercise on PTSD Symptoms, Depression and Anxiety in PTSD Patients : A protocol of Systematic Review and Meta-Analysis

Zhu, L[1]; Li, L[2]; Li, XZ[3]; Wang, L[4].

Review question / Objective: **Patientor population: Sample population including a group of adult (18 years of age or older) human, psychiatrist-confirmed DSM-IVTR diagnosis of PTSD; medical clearance to participate in an exercise programme; and cognitively able to provide consent to participate. Intervention: In an experimental group involving mind-body exercise (e.g., mindfulness, yoga, taichi, qigong, meditative movement, etc.) compared with different types of control groups (e.g., usual care, no physical activity, and no-intervention control group). Outcomes: The purposes of our meta-analysis will to evaluate the effect of mind-body exercise on PTSD symptoms, depression and anxiety in PTSD patients. Meanwhile, this study will also explore the internal regulation mechanism of mind-body exercise on the PTSD symptoms, depression and anxiety of PTSD patients to provide a corresponding exercise prescription.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 December 2020 and was last updated on 12 December 2020 (registration number INPLASY2020120072).

INTRODUCTION

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on PTSD symptoms, depression and anxiety in PTSD patients. Meanwhile, this study will also explore the internal regulation mechanism of mind-body exercise on the PTSD symptoms, depression and anxiety of PTSD patients to provide a corresponding exercise prescription.

Condition being studied: Post-traumatic stress disorder (PTSD) is a debilitating psychological condition that occurs after exposure to a single or a series of traumatic events that include military combat, terrorism, abuse, rape, childhood neglect, natural disasters, and witnessing injury or death[1]. In a population survey in the United States, 60.7% of men and 51.2% of women reported experiencing a traumatic event in their lifetime (such as witnessing someone being badly injured or killed, experiencing a flood, fire, a life threatening accident, rape or sexual assault). Recently, a large number of studies have been carried out to evaluate the influence of mind-body exercise on PTSD symptoms, depression and anxiety among PTSD patients. Because of the differences in the intervention samples, timing, frequency, method, and duration, the specific effects on PTSD symptoms, depression and anxiety among PTSD patients could have been different. Therefore, the purposes of our meta-analysis will be to evaluate the effect of mind-body exercise on PTSD symptoms, depression and anxiety in PTSD patients. Meanwhile, this study will also explore the internal regulation mechanism of mind-body exercise on the PTSD symptoms, depression and anxiety of PTSD patients to provide a corresponding exercise prescription.

METHODS

Search strategy: To avoid missing any available literatures, which possibly meet our demands, we will systematically search following electronic databases:PubMed, Web of Science, the Cochrane Library, EMBASE and VIP Database for Chinese Technical Periodicals, China National Knowledge Infrastructure, and Wanfang. These databases were searched to identify randomized controlled trials (RCTs) published in any language between January 1, 1980, and August 30, 2020. The search terms used included “mindfulness” or “mind-body exercise”, and “yoga” or “taichi” or “qigong” or “meditation”, with PTSD terms including “PTSD, Post-traumatic stress disorder”, as well as, “depression, anxiety, depressive disorder, anxiety disorder”.

Participant or population: Sample population including a group of adult (18 years of age or older) human, psychiatrist-confirmed DSM-IVTR diagnosis of PTSD; medical clearance to participate in an exercise programme; and cognitively able to provide consent to participate.

Intervention: Interventions in an experimental group involving mind-body exercise (e.g., mindfulness, yoga, taichi, qigong, meditative movement, etc.).

Comparator: Control groups (e.g., usual care, no physical activity, and no-intervention control group).

Study designs to be included: (1) randomized controlled trial (RCT) (2) sample population including a group of adult (18 years of age or older) human, psychiatrist-confirmed DSM-IVTR diagnosis of PTSD; medical clearance to participate in an exercise programme; and cognitively able to provide consent to participate; (3) interventions in an experimental group involving mind-body exercise (e.g., mindfulness, yoga, taichi, qigong, meditative movement, etc.).

Eligibility criteria: We will only include randomized controlled trials (RCTs), whereas non-RCTs, quasi-RCTs, and any other types of studies will be excluded.

Information sources: PubMed, Web of Science, the Cochrane Library, EMBASE and VIP Database for Chinese Technical Periodicals, China National Knowledge Infrastructure, and Wanfang.

Main outcome(s): PCL (PTSD Checklist),STAI(State Trait Anxiety Inventory), CES-D (Center for Epidemiologic Studies-Depression Scale).

Quality assessment / Risk of bias analysis: Two authors will use the modified the Physical Therapy Evidence Database (PEDro) scale to independently perform methodological quality assessment of each eligible study. This assessment consisted of 9 items (randomization, concealed allocation, similar baseline, blinding of assessors, = <15% dropouts, intention-to-treat analysis, between-group comparison, point measure and measures of variability, isolate exercise intervention), and higher scores indicate better quality of the method. /We will generate funnel plots to assess reporting bias if no <10 studies are available for quantitative analysis. For continuous variables, Egger test will also be taken to test funnel plot asymmetry. However, even when a test does not provide evidence of funnel plot asymmetry, reporting bias (including publication bias) cannot be excluded due to the relatively low test power. Asymmetric funnel plots are usually thought to present publication bias, one type of the reporting biases, but it also means that there may exist other reasons, such as differences in methodological quality or true heterogeneity in intervention effects. We will analyze the possible cause and give reasonable interpretation for asymmetric funnel plots.

Strategy of data synthesis: Stata 14.0 will use to carry out the meta-analysis: mapping overall forest plot, heterogeneity analysis, regression analysis, and sub-group analysis. According to the Cochrane Collaboration handbook for systematic reviews of interventions, selection of fixed- or random-effects meta-analysis should be based on the potential real effect of an intervention on outcome measures. Differences (standard mean difference, SMD) and 95% confidence intervals (95% CIs) will calculate. I2 values of 25%, 50%, and 75% are considered as low, moderate, and high heterogeneity, respectively. When the heterogeneity test I2 ≥ 50%, a random-effects model will be use for meta-analysis. Otherwise, the fix-effect model will be adopted.

Subgroup analysis: Subgroup analyses will be conducted which aims to explain the potential causes of heterogeneity when necessitated. The subgroup analyses will be implemented according to age, gender, frequency, time, duration, and event.

Sensibility analysis: After the data synthesis, we plan to conduct sensitivity analysis through excluding merged studies one by one and observe whether the synthesis result changes significantly. Significant change reflects that the removing study is enough to influence overall synthesized result, so, it is necessary for us to reassess it and decide cautiously whether to merge it. A valid reason must be given before we make a decision. If no significant change arises, we could consider that our synthesized result is firm.

Country(ies) involved: China.

Keywords: Mind-body Exercise; PTSD Symptom; Depression; Anxiety.

Contributions of each author:

Author 1 - Lin Zhu - The author drafted the manuscript.
Author 2 - Long Li - The author provided statistical expertise.
Email: lilong@suda.edu.cn
Author 3 - Xiao-zhi Li - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Email: 101006120@seu.edu.cn
Author 4 - Lin Wang - The author read, provided feedback and approved the final manuscript.
Email: wanglin123@126.com