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PROTOCOL

Protocol: The Effect of 12 Weeks of Tai Chi Practice on Anxiety in Healthy but Stressed People Compared to Exercise and Wait-list Comparison Groups: A Randomized Controlled Trial

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Abstract
Stress is a major problem in today's fast-paced society and can lead to serious psychosomatic complications. The ancient Chinese mind–body exercise of Tai Chi may provide an alternative and self-sustaining option to pharmaceutical medication for stressed individuals to improve their coping mechanisms. The protocol of this study is designed to evaluate whether Tai Chi practice is equivalent to standard exercise and whether the Tai Chi group is superior to a wait-list control group in improving stress coping levels. This study is a 6-week, three-arm, parallel, randomized, clinical trial designed to evaluate Tai Chi practice against standard exercise and a Tai Chi group against a nonactive control group over a period of 6 weeks with a 6-week follow-up. A total of 72 healthy adult participants (aged 18–60 years) who are either Tai Chi naïve or have not practiced Tai Chi in the past 12 months will be randomized into a Tai Chi group ($n = 24$), an exercise group ($n = 24$) or a wait-list group ($n = 24$). The primary outcome measure will be the State Trait Anxiety

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Inventory with secondary outcome measures being the Perceived Stress Scale 14, heart rate variability, blood pressure, Short Form 36 and a visual analog scale. The protocol is reported using the appropriate Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) items.

1. Introduction

Stress is a major problem affecting the health of many individuals in today's society. The World Health Organization states that mental problems, such as stress will probably become the second most common disability by the year 2020 [1]. According to the Australian Institute of Health and Welfare, 2169 hospital episodes in psychiatric hospitals in Australia in 2001—2002 were for neurotic, stress-related, and somatoform disorders [2]. Furthermore, a poll recently conducted in 2011 by Lifeline, a nongovernment organization, showed that 93% of Australians were stressed, up from 90% in 2010. In addition, a similar survey conducted by the Australian Psychological Society [3] in 2011 also found that 12% of Australians reported experiencing stress in the severe range, with one in three Australians reporting that they were suffering from depressive symptoms, and one in four from anxiety.

Patients with severe anxiety are generally treated with pharmaceutical medications, psychotherapy, or a combination of both [4]; however, prior to treatment being administered careful diagnoses must be undertaken, which could present as a social stigma for healthy individuals who have not yet developed pathological or somatoform anxiety conditions. This may partially explain why people with anxiety are also beginning to explore complementary and alternative options for treating their anxiety, with one such option being Tai Chi.

Taiji 太极 or *Tai Chi* (TC), as it is more commonly known outside of Asia, is an ancient Chinese mind—body exercise that is practiced worldwide by millions of people daily with the belief that it has potent healing effects upon the practitioner and is a fundamental path for longevity [5]. Although the mechanisms behind TC are not fully understood, it is purported that TC calms the mind and benefits health [5]. More recently, there has been growing interest in the scientific community to evaluate the efficacy of TC for various physiological and psychological conditions ranging from fear of falling in the elderly [6—8], balance [9—11], metabolic disorders [12—14], arthritis [7,15—20] to psychological health [13,21,22].

The recent reporting in 2011 of eight clinical trials investigating anxiety and two investigating stress reflect the growing interest in the use of TC for psychological conditions [21]. However, these studies showed mixed results. More recently, a systematic review of the effects of TC on psychological well-being appraised 40 clinical trials conducted between March 2009 and May 2010 with a total of 3817 participants [23]. The authors concluded that TC significantly decreased anxiety levels [effect size (ES) = 0.66; 95% confidence interval (CI = 0.29, 1.03), reduced depression (ES = 0.56; 95% CI = 0.31, 0.80) and significantly improved mood (ES = 0.45; 95% CI = 0.20, 0.69). Despite this conclusion, the claim that TC benefits psychological well-being is still contentious because many of the reported studies were poorly designed and lacked statistical power [23].

The trial described in this protocol will evaluate whether TC can enhance stress coping mechanisms by reducing levels of stress-related anxiety as measured by the State Trait Anxiety Inventory (STAI) [24]. Furthermore, the Perceived Stress Scale 14 and the physiological measures of blood pressure and heart rate variability will measure changes to generalized stress levels.

This protocol has been developed using the 2013 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [25] with SPIRIT item numbers included in parentheses where appropriate.

(*SPIRIT items 6a and 7*)

2. Hypothesis

This study is designed to test two hypotheses: (1) TC is statistically noninferior to exercise in moderatingstress; and (2) TC is statistically superior to doing nothing (nonactive wait-list control) in moderating stress.

The study design also allows for further comparisons to be made for both within- and between-group changes, namely to assess if supervised TC practice performs as well when unsupervised as well as how unsupervised TC practice compares to both the exercise and wait-list groups at 12 weeks.

(*SPIRIT item 7*)

3. Methods and design

The design is a prospective parallel three-arm randomized controlled trial with repeated measures. Participants will be randomly allocated to three equally sized groups, comprising a TC intervention group, an exercise group and a wait-list group. The TC intervention group will be the primary intervention group with the exercise group acting as an active comparison group and the wait-list group as the nonactive control group. The use of a three-arm design is to differentiate between the benefits of physical movements and the mind—body aspects unique to TC. The wait-list group controls for regression to the mean and other time-tied factors.

(*SPIRIT items 6b and 8*)

4. Participant recruitment

Individuals will be recruited from the general Sydney metropolitan area in Australia through various media advertisements. General information will be provided on both posters and in e-mails sent to interested participants. Individuals who are interested will be asked to reply to a