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 naive 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
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 moderating stress; 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
specific e-mail account created for screening purposes, and an e-mail response containing additional information on inclusion and exclusion criteria will be sent. Those individuals who potentially meet the given criteria will be screened in person to determine eligibility.

Potential participants who meet the screening criteria will be required to complete the Lifestyle Appraisal Questionnaire (LAQ) [26] and the STAI [24] to determine if they fulfill the requirements for the study. The LAQ assesses health risks and perceived stress of participants and asks questions regarding smoking habits, family history of severe medical conditions, current medical conditions if any, medication use and serves to identify if potential participants are suitable for the study in terms of physical, mental and social health [26]. A cut-off score of 50 in the STAI was selected because this would place participants in the 90th percentile or higher as "stressed" [27]. Those participants who qualify for inclusion will have the trial explained to them in detail and informed consent will be obtained prior to commencing the trial. Participants will also be asked to sign a declaration stating that they will participate fully to the best of their ability and will continue their involvement in the TC program once commenced. A log book will be given to each participant to monitor involvement and home practice of either TC or exercise as well as any reporting of adverse events.

4.1. Inclusion criteria

The inclusion criteria are: (1) between 18 and 60 years of age with no serious medical conditions, screened using the LAQ [26]; (2) must be English literate and able to read and sign the consent form; and (3) score above the threshold of 50 on the STAI [27].

4.2. Exclusion criteria

The exclusion criteria are: (1) currently suffering from a major illness; (2) currently taking antidepressant medication; (3) currently training or have trained in Tai Chi in the past 12 months; (4) currently exercising on a regular basis (greater than 5 hours of exercise per week on a regular basis); and (5) currently pregnant.

(SPIRIT items 10, 11c, 15, 18b, 22 and 26a)

5. Data collection location

All participants will be recruited from the Sydney region and all outcome measures will be collected on the Sydney city campus of the University of Technology, Sydney (UTS). The TC sessions will be conducted at the University of Technology, and at least 2 hours of exercise per week for the exercise group will be completed at the UTS Fitness Center.

(SPIRIT item 9)

6. Ethical considerations

This trial has the UTS Human Research Ethics Committee approval (HREC 2011-107A) and is registered with Australian New Zealand Clinical Trial Registry (ACTRN12611000810910).

(SPIRIT items 2a and 24)

7. Intervention

7.1. Tai Chi rationale

TC is believed to enhance mood and improve psychological well-being. Although stress is generally nonpathological in nature, an inability to cope with an increase of stress may lead to pathological psychosomatic presentations, which are commonly self-reported as "feeling stressed". Feeling stressed is becoming more prevalent in modern society affecting both the "healthy" and the sick [23]. Past research has shown that TC practice has significantly reduced both trait anxiety and state anxiety from baseline after a 12-week TC trial [28]; however, there are very few trials which use the STAI as a primary measure for conducting TC research on stress. For this trial, the simplified 24 stance Taiji Quan is chosen as the TC intervention. Although there are various other styles of TC (i.e., Chen, Yang, Sun, Wu), the simplified 24 stance Taiji Quan was chosen for its simplicity and ease of learning [5]. This style was also chosen because it is the most well-known form of TC internationally [5] and provides the participants access to self-research materials in terms of books and internet video clips.

7.2. Tai Chi instruction method

The TC sessions will involve group practice with instruction given in both verbal and visual form to demonstrate both the movements and the basic theory behind each action. The TC component will be taught in sets of movements and will, over the period of the trial, accumulate into the entire 24 stance form.

Each TC session will consist of 10 minutes of warm up, 45 minutes of TC practice and 5 minutes of cooling down. The TC will be led by a skilled instructor who has been practicing TC for more than 15 years. The TC practice component will consist of TC meditative stance for 10 minutes followed by the set of progressive movements each session.

A DVD of the 24 stance sequence will be given to each participant of the TC group to encourage home practice and act as a prompt in case the participant fails to remember a movement during home practice. The DVD consists of the instructor completing the entire TC set to ensure that movements are exactly identical to the face-to-face TC session.

During this time participants may continue their normal lifestyles (based on the initial inclusion criteria that they were not exercising on a regular basis) and to not commence any regular exercise regime or participate in other mind—body exercises, such as yoga or qigong.

A log book will be given to each participant to record practice times and home practice will be reinforced by writing reflective entries on their practice and thoughts on various stances in the TC form as well as recording any adverse events.

(SPIRIT items 11a and 11d)

7.3. Tai Chi dosage

TC sessions will take place initially during first 6 weeks and during this period there will be five TC sessions (1 hour
each) each week available for participants to attend. It is required that participants must complete at least 5 hours of TC a week (minimum 1800 minutes during the initial 6 weeks) and at least two of these must be face-to-face sessions with the instructor. There is no restriction on how many TC sessions any individual attends, but the minimum two must be completed. Remaining sessions will be recorded in the log book to ensure sufficient hours are completed.

The 6 weeks only of face-to-face instructions is designed to assess if the efficacy of TC is limited only to the condition that participants must have an instructor present or if the efficacy of TC will be reflected and maintained through self-directed practice. This can potentially lead to self-empowerment of participants without the need to attend specific classes once the basics of TC have been learnt.

Home practice will be expected throughout the 12 weeks (6 weeks contact and 6 weeks noncontact) and will be reinforced by logging time and frequency of practice. The total minimum dosage of TC practice for the 12 weeks is 3600 minutes with 720 minutes of face-to-face class time. Study staff will contact participants via e-mail during the study to maximize adherence to protocol, especially during the last 6 weeks of noncontact TC.

8. Active controls

The exercise group will be an active control group and they will be provided with gym membership for the duration of the trial (12 weeks), and during the study participants in this group will be asked not to undertake any form of mind—body exercises.

As with the intervention group, they will be given a log book to record the amount of time spent, frequency and type of exercise undertaken, as well as recording any adverse event. It is also expected that they complete a total of 5 hours of exercise per week including at least 2 hours at the UTS Fitness Center. The participants will be assessed by the staff at the UTS Fitness Center and will be required to attend at least one of the scheduled exercise classes inclusive in the minimum 2 hours they are required to spend at the UTS Fitness Center. The total dosage for the active control group is also 3600 minutes with a total of 720 minutes of face-to-face class time over the period of 12 weeks similar to the TC group. This arm will control for attention and exercise equivalence.

9. Nonactive controls

The nonactive control group involves a wait-list group. The wait-list group will be idle for the 12 weeks of the trial; during this time, participants may continue their normal lifestyles (based on the initial inclusion criteria that they were not exercising on a regular basis) and are requested not to commence any regular exercise regime or participate in other mind—body exercises, such as yoga or qigong.

At the completion of the study they will be given the same 6 weeks of TC practice and DVD after the 12 weeks as appreciation for their involvement. This group will control for time-tied factors.

10. Adverse events and discontinuation from the study

Participants will be asked to record any adverse events in the log books and will be asked to withdraw from the study if: (1) due to any physical ailments or injury they are unable to complete the study; or (2) stress in participants is unmanageable without medical intervention. (SPIRIT items 11b and 22)

11. Outcome measures

The trial will measure the level of anxiety in healthy but stressed individuals with the STAI as the primary measure. Secondary measures are PSS-14 (Perceived Stress Scale 14 Questions), heart rate variability (HRV), blood pressure (BP), Short Form 36 Health Survey (SF36) and a Visual Analog Scale (VAS).

All outcome measurements will be taken at three points in time, prior to the commencement of the intervention phase (week 0), at the completion of contact intervention (week 6) and at the conclusion of the study (week 12). (SPIRIT items 12, 13 and 18a)

12. State Trait Anxiety Inventory

The STAI consists of two subtests which collect subjective data from participants on their State and Trait Anxiety in the form of two questionnaires consisting of 20 questions each [24]. The State Anxiety (Y-1) section is designed to assess an individual’s reaction to stress and their emotional state at a particular time, whereas Trait Anxiety (Y-2) is related to an individual’s personality trait and how they perceive stress [27]. The questions require the participant to rank their current and general feelings towards certain statements between four options of increasing frequency ranging from “almost never” to “almost always”.

The STAI is a highly reliable measure for both stress and anxiety, which is also reflected by internal consistency coefficients ranging from 0.87 to 0.92 for Y-1 and 0.89 to 0.90 for Y-2 [27].

13. Perceived Stress Scale 14

The PSS-14 is a 14 question instrument requiring participants to rank the frequency in which they felt or thought about various statements with response descriptors ranging from “never” to “very often” [29]. The questions are designed to measure perceived stress and the coefficient reliability for the PSS-14 ranges from 0.84 to 0.86 [29].

14. Heart rate variability

HRV will be assessed because anxiety generally influences these cardiac parameters adversely. Individuals experiencing anxiety symptoms have elevated levels of circulating cortisol, controlled by the hypothalamic—pituitary—adrenal axis. Cortisol is known to elevate sympathetic nervous system activity [30]. Although results on anxiety effects on HRV
are variable, most indicate a reduction in the high frequency component of HRV or total HRV due to anxiety [31–33]. For the measurement of HRV, a three electrode electrocardiogram (ECG) will be obtained using the Flexcomp Infinity (Thought Technology Ltd, model SA7550, Montreal West, Quebec, Canada). ECG will be analyzed to derive HRV measures. The two active ECG electrodes will be placed level in the fourth intercostal space, approximately 2 cm lateral to the sternum. The reference electrode will be placed on the left shoulder [34]. A three lead ECG is sufficient to obtain the R-R measures required for HRV analysis [35].

HRV provides a measure of sympathetic (low frequency) and parasympathetic (high frequency) activities of the autonomic nervous system [36]. The entire area under the HRV spectrogram also provides a measure of total HRV. Sympathovagal balance, a measure of the equilibrium between the sympathetic and parasympathetic arms, can also be derived as a ratio of low frequency to high frequency activity [37].

Participants will be required to fast from food and caffeinated beverages (4 hours) and alcohol (24 hours) prior to the collection of HRV data to reduce possible confounders that may affect results. The ECG for the HRV will be obtained for 10 minutes at each data collection session with the participant in a seated position with limited contact with the technician.

Low frequency activity, high frequency activity, total HRV activity and sympathovagal balance will be analyzed to identify the effects of the intervention compared across the three arms. This will provide a measure of change in autonomic activity prior to and after the entire experimental phase.

15. Blood pressure

BP will be taken as anxiety increases peripheral BP and has been shown to do so in studies [38–40]. BP will be taken using a digital sphygmomanometer (A&D Medical, model UA-851, Tokyo, Japan). Systolic (SP) and diastolic (DP) BP will be taken a total of six times per data collection period, three times prior to conducting HRV and three times after. Individual systolic and diastolic data will be collected and from it the mean arterial pressure will be estimated using the following formula [41]:

\[
\text{Mean arterial pressure} = \frac{\text{DP} + (\text{SP-DP})}{3}.
\]

16. Short Form 36 Health Survey

The SF36 Health Survey (English version) is a commonly used generic health questionnaire for adults which measures eight domains of health comprising physical functioning, role — physical, bodily pain, general health, vitality, social functioning, role — emotional and mental health [42]. This questionnaire includes 36 main questions which contain several subset questions, with questions relating to the various domains nested into the instrument with the deliberate intention that the participant will need to carefully read and assess each question prior to responding [42]. Because there is no common consensus on stress stimuli [43], various factors which affect the quality of life of participants can contribute directly or indirectly to perceived stress and the ability to cope with stress. This demonstrates the need to collect holistic data from participants regarding their quality of life.

The reliability of the different domains are 0.93 for physical functioning, 0.89 for role — physical, 0.90 for bodily pain, 0.81 for general health, 0.86 for vitality, 0.68 for social functioning, 0.82 for role — emotional and 0.84 for mental health [42].

17. Visual Analog Scale

The VAS consists of a 100 mm line with the terms "not stressed at all" and "very stressed" on either ends of the line. The participant will be asked to mark on the VAS their current stress levels.

18. Sample size and randomization

Sample size required is 42 participants, with 14 individuals equally and randomly allocated to each group. The sample size is based on Y-1 results of the pilot study completed in 2011 (difference of means from baseline to week 12 between TC and wait-list groups = 17.143, standard deviation = 5.96) and will provide a power of 0.8. Similarly with a noninferiority limit of 10 for Y-1, based on standard deviation for norm scores [27], the minimum sample size requirement is 11 per group at a power of 0.8 (difference of means from baseline to week 12 between TC and active control groups = 6.17 standard deviation = 9.02). To account for drop-outs or loss to follow-up, the sample size needs to be inflated by 30% (based on pilot data) resulting in 57 participants needing to be recruited (n = 19 individuals per group).

The randomization process will be conducted by a third party not involved in the study. The third party will employ the "sealed envelope" method to randomize participants (sealed opaque envelopes which contain the allocation information written on a piece of folded paper which is not visible when held up to a light source) in permuted blocks of six.

(SPIRIT items 16a, 16b)

19. Data management and statistical analysis

All personal information from participants will be de-identified and coded. Data will be entered by outcome assessors and analyzed by a blinded data analyst.

This will be an intention to treat study and participants who either drop out from the study or fail to adhere to the protocol will have their last known data carried forward. The statistical method will be a two-way analysis of variance with repeated measures followed by Bonferroni’s post-hoc test.

(SPIRIT items 19, 20a and 20c)

20. Timeline

Participants who meet the inclusion criteria will be evaluated using the outcome measures prior to the commencement of the trial, at the completion of the contact
intervention (end of Week 6) and at the completion of the trial (Week 12). After this time the wait-list participants will take part in 6 weeks of TC practice, which will not be included in the trial data, as appreciation for their participation in this trial. (SPIRIT item 13)

21. Discussion

This trial will investigate the efficacy of TC on anxiety in healthy individuals implementing three parallel arms and using the STAI as the primary measure. The trial design seeks to test the clinical efficacy of TC both as an intervention administered to an individual under guidance as well as to evaluate if the results can be sustained without the ongoing assistance and supervision of an instructor.

The STAI was chosen as the primary outcome measure because it is a highly reliable measure for both stress and anxiety, which is also reflected by internal consistency coefficients ranging from 0.87 to 0.92 for State Anxiety and 0.89 to 0.90 for Trait Anxiety [27]. The importance of the relationship between State and Trait Anxiety to an individual is vital for an individual’s ability to cope with stress as an individual’s Trait Anxiety can very well determine the ability to respond to and influence the intensity of a State Anxiety reaction [27]. This is because State Anxiety is an individual’s reaction to stress and their emotional state at a particular time and this can fluctuate based on a specific event or situation. Trait Anxiety (Y-2), however, is related to an individual’s personality trait and how they perceive stress.

The use of HRV serves as an objective measurement for the study. It is an indirect measure of stress through measuring changes to the autonomic nervous system and the equilibrium of the sympathetic and parasympathetic nervous system, the results are variable [34] and as such there are correlations between stress and the autonomic nervous system [45], thereby causing abnormal autonomic and cardiovascular responses [46]. Although it is established there are correlations between stress and the autonomic nervous system, the results are variable [34] and as such HRV will only be included as a secondary outcome measure.

The inclusion of an active control group is to control for the physical or exercise component within TC. This is to ensure that the study does not take measurements solely concerning the physical exercise aspects of TC but also takes into account the nonexercise components that contribute to the purported holistic benefits of practicing TC. As such, the active control group is designed to match TC in total hours required and also the total hours of supervised group interactions within both groups over the period of 12 weeks. The dosage of intervention time prescribed has been compared to the 2008 report by Sannes et al [47], and it exceeds the average hours reported in past TC studies. Although the study is not powered to establish a difference between the TC group and exercise group number of participants to determine statistically whether there may be a difference between these two groups, TC is invariably less physically demanding on the body and does not require specialized equipment present in a gymnasium.

The SPIRIT statement forms a guide for the content required for reporting a clinical trial protocol [25]; however, not all 33 items were covered in this protocol due to the limitations in reporting. This study design has fulfilled and reported the relevant SPIRIT items for both the study as well as the medium for reporting.

Disclosure statement

The author affirms there are no conflicts of interest and the author has no financial interest related to the material of this manuscript.

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