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Effects of a nurse-led Tai Chi programme on improving quality of life, mental wellbeing, and physical function of women with breast cancer: Protocol for a randomized controlled trial

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Abstract

Objectives: Quality of life, mental wellbeing, and physical function deteriorate among women with breast cancer. Tai Chi is a moderate form of exercise that may be effective in improving the mental and physical wellbeing, therefore, the quality of life of women with breast cancer. This protocol paper outlines a trial to determine the therapeutic effects of a Tai Chi programme on breast cancer management.

Methods: The study will be an interventional, single-blind, double-armed, randomized, and controlled trial involving a 12-week Tai Chi programme for women with breast cancer. Forty participants aged 18 years and above who are diagnosed with breast cancer from the general community will be recruited. All participants will be randomized to either a Tai Chi programme or a waiting list control group. The Tai Chi programme will involve 12 weeks of group Tai Chi sessions, with 45 min per session, twice a week. The primary outcome will be potential improvements to the quality of life, and secondary outcomes will be potential improvements in mental wellbeing (anxiety and depression), and physical function (pain, flexibility, obesity, and vital signs). These outcomes will be assessed via self-administered online assessments and physical examinations pre-and post-intervention. Linear mixed modelling will be used to assess changes in outcomes.

Discussion and dissemination: Tai Chi is a safe, easy to learn, inexpensive, and low-intensity exercise with increasing popularity worldwide. If the intervention improves the quality of life in women with breast cancer, this study will build research capacity and increase awareness of the potential for Tai Chi to empower patients and engage them in self-management of breast cancer symptoms. Research findings will be disseminated to the public, health professionals, researchers, and healthcare providers through conference presentations, lay summaries, and peer-reviewed publications.

Keywords

chronic disease, clinical trial, community-based research, exercise, mental health, oncology, Qigong, women's health

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Introduction

Globally, breast cancer (BC) is the most diagnosed cancer and the leading cause of cancer mortality. It represents a significant health challenge in all resource settings and unmet health needs, with an estimated 2.3 million cases recorded in 2020.¹ By 2030, the global estimated number of diagnosed cases and resulting deaths from BC will reach 26.4 million and 1.7 million, respectively.² Approximately 55 Australians are diagnosed with BC each day, which equates to over 20,000 Australians in 2021.³ Owing to the advancements made through research, the 5-year survival rate for women diagnosed with BC is 91.5%.⁴ With longer survival rates, however, symptoms such as fatigue, insomnia, and depression often co-occur in BC patients and can significantly affect functional status and quality of life (QoL).^{5–7} These symptoms cannot usually be managed satisfactorily by pharmacological treatments alone.⁸ Thus, non-pharmacological adjuvant approaches are recommended,⁹ and community-engaged, sustained, and accessible initiatives to improve the QoL, physical function, and mental wellbeing of women with BC are urgently required.

There is strong evidence for body–mind meditative exercise to manage cancer-related symptoms. Recent studies have identified that regular Tai Chi practice may help symptom management in cancer patients.^{10,11} Tai Chi, a moving meditation, is a moderate body–mind exercise that integrates breathing into body movement. The central mechanism of Tai Chi emphasizes the unity of mind and body and the coordination of breathing and body movement.¹² This proposed study will, therefore, examine the effectiveness of a 12-week Tai Chi programme as a promising additional approach to help promote QoL, mental wellbeing, and physical function of women with BC. The proposed programme will be the first community-engaged, nurse-led Tai Chi programme specifically targeting BC patients.

Methods

Study design

This study will be an interventional, single-blind, double-armed, randomized, and controlled trial on the therapeutic effect of a 12-week Tai Chi programme for women with BC. While this trial protocol will be reported adhering to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting template, the trial report will be guided by the principles of the CONSolidated Standards of Reporting Trials (CONSORT) reporting template for clinical trials.¹³

Sample size estimation

Calculation of a sample size is centred on the desired effect size, level of significance, power, and expected attrition rate.¹⁴ Oh and colleagues¹⁵ reported a significant difference

($t(144)=5.761, p<0.001$) in the total QoL (mental and physical aspects) between the control (-0.13 ± 10.92 pre-to-post difference) and intervention group ($+8.86 \pm 11.13$ pre-to-post difference), from the data collected in their study, which corresponded to a large effect (Cohen's $d=0.91$). Within the QoL metric, emotional wellbeing component saw the smallest change but still achieved a medium effect (Cohen's $d=0.58$). With this statistic in mind, we estimated the sample size using G*Power Version 3.1.10,¹⁶ based on a mixed model design (two groups and two time-points) to detect at least a medium Group \times Time interaction effect (Cohen's $f=0.25$) for QoL (therapeutic effect) at an α of 0.05 (two-tailed) and an 80% power and 5% level of significance. Therefore, the calculated required sample size for this study is 34 participants. Considering a potential drop-out rate of 15%, the adjusted required sample size has been adjusted to 40.

Randomization and blinding

Each participant will be assigned a computer-generated sequence number using a randomized block approach. To safeguard concealment, the block sizes will not be disclosed, and the allocation will be conducted blindly by an independent statistician. The randomization list will be controlled by the researcher who performed the intervention. Participants will be randomly assigned to one of the two groups: (1) intervention group, who will be enrolled in a 12-week Tai Chi programme (45 min per session, twice a week one the same days each week) led by a qualified Tai Chi practitioner. The programme combines mild to moderate physical intensity exercise with deep breathing and meditation. It is a mixture of different Tai Chi styles (e.g. Chen, Yang, Wu, and Kung Fu) combining meditation and martial arts; or (2) waiting list control group, who will receive usual care consisting of other types of moderate exercise (e.g. walking) or medication. Outcome assessors and team members who perform data entry and data analysis will be blinded to the randomization.

Setting

This proposed study will be conducted in Western Australia, where BC is the most diagnosed cancer. The Tai Chi programme is an ongoing community programme led by nurses at multiple locations in the Perth metropolitan area.

Study population and recruitment

Participants will be recruited from the community by the research team via mass mailings, social media advertising, flyers, and 'snowball' subject recruitment, which includes word of mouth referrals. After expressing an interest in participating in this trial, each potential participant will be

contacted and screened for inclusion by the investigators. Inclusion criteria consist of adults (1) aged 18 years and above, (2) diagnosed with BC, (3) having no physical or cognitive limitations prohibiting exercise, and (4) willing and able to commit to the 12-week trial. BC patients who have had recent (< 3 months) experience in Tai Chi or are experienced Tai Chi practitioners will be excluded from the trial.

Public involvement

A consumer representative with lived experience of BC will be involved in this study by providing input on study design, how best to connect with potential study participants, and interpreting findings and dissemination of research outcomes. Consumer involvement in this project can help consider the implications of the research and how it will lead to practical benefits for women with BC in the future.¹⁷

Concomitant care

The 12-week Tai Chi programme is an ongoing initiative. Participants can continue to attend Tai Chi classes at no charge after completion of the study. Tai Chi is a safe, low intensity, and enjoyable exercise, there is no anticipation of any adverse events (physical or psychological) that will occur during the sessions. Participants can stop at any time if they experience discomfort.

Study procedure

All participants (intervention and control groups) will complete self-reporting questionnaires at the start of the programme (T_0) and at its end (week 12; T_1). Physical assessments of all participants will also be conducted at T_0 and T_1 . Figure 1 summarizes the schedule of enrolment, interventions, and assessments.

Outcome measures

Primary and secondary outcomes. The primary outcome will be QoL as measured by mean scores on the 12-item short-form health survey (SF-12)^{18,19} and the Euro QoL (EQ-5D).²⁰ This outcome will be obtained via two online surveys from all participants: at baseline (T_0) and post-intervention (T_1).

Secondary outcomes include anxiety as measured by mean score on generalized anxiety disorder survey (GAD-7);²¹ depression as measured by mean score on the patient health questionnaire (PHQ-9);²² pain (if any) as measured by mean scores on the visual analogue scale (VAS)^{23,24} and the McGill pain questionnaire (MPQ).^{25–28} These outcomes will be measured via two online surveys (T_0 and T_1). Questions on participants'

non-pharmacologic therapy preferences and experiences of participating in the trial will also be captured and measured at T_0 and T_1 , respectively.

In addition to these self-reported online questionnaires, physical assessments will also be conducted by the research team at the research clinic site. These assessments include flexibility as measured by finger to floor distance (FFD); obesity as measured by mean scores on body mass index (BMI); vital signs (blood pressure, heart rate, respiratory rate, temperature, and oxygen saturation) as measured by a blood pressure monitor, tympanic, and pulse oximetry device. These outcomes will be measured at T_0 and T_1 .

QoL assessment

SF-12. The SF-12 is a self-reported outcome measure across eight domains (physical, social, usual role due to physical issues, bodily pain, mental health, usual role due to emotional issues, vitality, and health perceptions) that assesses the impact of health on an individual's QoL.^{18,19} The SF-12 is a validated tool,^{29–31} and scores on these eight domains are aggregated to form two final components: physical and mental wellbeing scores. An algorithm is used to generate the two components for comparison to normative data: the mean score is set to 50, scores > 50 indicate better physical or mental health than the mean, whereas scores < 50 indicate worse physical or mental health than the mean.^{18,19}

EQ-5D. The EQ-5D is the most commonly used health-related QoL questionnaire in adults.²⁰ It consists of five questions that assess functions in five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with three possible levels of disability (3, severe; 2, moderate; 1, none). EQ-5D is commonly used to make evidence-based decisions in analyses of cost-effectiveness. Therefore, the EQ-5D can be used for health outcomes studies and economic analyses. Extensive research has shown EQ-5D to be valid, reliable, and responsive.^{32,33}

Anxiety assessment

GAD-7. The GAD-7 is a gold-standard measurement tool for generalized anxiety disorder.²¹ It is a quick, user-friendly, concise, and self-administered screening and diagnostic tool. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to the response categories of 'not at all', 'several days', 'more than half the days', and 'nearly every day', respectively. GAD-7 total score, the sum of the response scores for the seven items, ranges from 0 to 21. Scores of 5, 10, and 15 represent cut-off points for mild, moderate, and severe anxiety, respectively.

Depression assessment

PHQ-9. The PHQ-9 is a self-administered diagnostic instrument for depression severity.²² It is calculated by

| | Enrolment | Baseline (T0) Randomisation | Post-allocation 12 weeks trial period | | Close-out (T1) |
|--|-----------|--------------------------------|--|---|---------------------|
| Time point | Week -1 | Week 0 | Week 1—Week 12 | | Post-trial, week 13 |
| Enrolment: ✓ Randomisation ✓ Informed consent | | X | | | |
| | X | | | | |
| Intervention: 12-week Tai Chi program + usual care | | | X | X | |
| | | | ←————→ | | |
| Control: Waiting list (usual care, e.g., other exercise) | | | X | X | |
| | | | ←————→ | | |
| Assessments: All participants (Intervention & Control groups) | | | | | |
| Quality of life | | | | | |
| SF-12 | | X | | | X |
| EQ-5D | | X | | | X |
| Anxiety assessment | | | | | |
| GAD-7 | | X | | | X |
| Depression assessment | | | | | |
| PHQ-9 | | X | | | X |
| Pain assessment | | | | | |
| VAS | | X | | | X |
| SF-MPQ | | X | | | X |
| Flexibility | | | | | |
| FFD | | X | | | X |
| Obesity | | | | | |
| BMI | | X | | | X |
| Vital signs | | | | | |
| BP, RR, HR, Temp., O2SAT | | X | | | X |
| Non-pharmacologic therapy preference | | | | | |
| Past 3-month choice of non-pharmacologic therapy | | X | | | |
| Participant's experience (Intervention group only) | | | | | |
| Participants' experiences of the intervention | | | | | X |

Figure 1. Schedule of enrolment, interventions, and assessments.

BP: blood pressure; RR: respiratory rate; HT: heart rate; Temp.: temperature; O2SAT: oxygen saturation; BMI: body mass index; EQ-5D: EuroQoL (EQ-5D); FFD: finger to floor distance; GAD-7: generalized anxiety disorder 7; PHQ-9: patient health questionnaire; SF-12: 12-item short form health survey; SF-MPQ: short-form McGill pain questionnaire; VAS: visual analogue scale.

assigning scores of 0, 1, 2, and 3 to the response categories of ‘not at all’, ‘several days’, ‘more than half the days’, and ‘nearly every day’, respectively. PHQ-9 total score for the nine items ranges from 0 to 27. Scores of 5, 10, 15, and 20 represent cut-off points for mild, moderate, moderately severe, and severe depression.

Pain assessments

VAS and SF-MPQ. The VAS and the SF-MPQ are commonly used clinically to assess pain.³⁴ VAS is a reliable, validated tool with adequate sensitivity^{23,24} that is often used to assess pain intensity. The MPQ is the most well-known and popular multi-dimensional pain assessment tool. The SF-MPQ consists of 15 pain descriptors: 11 that assess the sensory dimension of pain and 4 that assess the affective dimension of pain. Descriptors are rated on an intensity scale of none (=0), mild (=1), moderate (=2), and severe (=3). Three pain scores are derived from the sum of the intensity rank values of the chosen sensory, affective, and total descriptors.³⁴ This questionnaire is used to measure the quality (i.e. using words to describe the pain, such as ‘sharp’, ‘dull’, ‘stabbing’, ‘burning’, ‘crushing’, ‘throbbing’, ‘nauseating’, ‘shooting’, ‘twisting’, or ‘stretching’) as well as the intensity of the pain.^{25–28}

Flexibility. The FFD will be measured with the patient bending forward maximally with knees straight. We will use a ruler to assess flexibility by measuring the FFD. Two measurements will be made and averaged.

Obesity. The BMI is an internationally recognized standard for classifying overweight and obesity in adults. BMI is calculated by dividing a person’s weight in kilograms by the square of their height in metres. A BMI of 25.0–29.9 is classified as overweight but not obese, a BMI of 30.0 or over is classified as obese, while a BMI of greater than 35.0 is classified as severely obese.³⁵

Vital signs. Vital signs indicate the status of the body’s vital functions. These measurements are taken to assess the general physical health: body temperature (Temp), heart rate (HR), respiratory rate (RR), blood pressure (BP), and oxygen saturation (SpO₂).³⁶

Body temperature. Temperature is how hot or cold a person is, and a normal range is between 36.6 to 37.5 degrees Celsius. Temperature is measured via a tympanic device.

Heart rate. HR is the number of heart beats per minute. The normal range is between 60 to 100 beats per minute. This result can be influenced by fitness level, age, illness, and emotion.

Respiratory rate. RR is the number of breaths a person takes per minute. It is measured through watching the rise and fall of the chest and counting breaths for a full minute.

The normal limit for an adult RR is between 12 and 20 breaths per min. A person’s RR is influenced by factors such as resting or moving.

Blood pressure. BP consists of systolic pressure (the first number) indicates the pressure of blood within the arteries during a contraction of the left ventricle of the heart. The diastolic reading (the second number) indicates the pressure within the arteries when the heart is at rest. According to the Heart Foundation of Australia, as a general guide, BP can be classified as ‘optimal’ (<120/80), ‘normal’ (120/80–129/84), and ‘high-normal’ (130/85–139/89). High BP is further classified as mild (140–159/ 90–99), moderate (160–179/100–109), or severe (\geq 180/110).

Oxygen saturation. SpO₂ estimates the level of oxygen blood carries. A pulse oximetry device is used to present the measurement with a percentage. If the red blood cells contain 95% oxygenated haemoglobin, the SpO₂ would be 95%. Normal pulse oximeter readings usually range from 95% to 100%. Values under 90% are considered low and indicate the need for supplemental oxygen. This condition is often referred to as hypoxemia, and its symptoms include severe shortness of breath, increased heart rate, and chest pain.

Data analysis

Descriptive statistics for continuous variables will be described by the mean and standard deviation (SD) for normal data and by the median and interquartile range (IQR) for non-normal data. Categorical data will be summarized by frequencies and proportions. Linear mixed modelling with an unstructured covariance matrix will be conducted to assess changes in outcomes throughout the study. This modelling approach allows for the inclusion of missing data in an intention-to-treat analysis without imputations. Post hoc tests will be conducted on all pairwise comparisons. The analysis will be adjusted for potential confounding factors such as age, gender, education levels, and any other potentially relevant variables where data are available. The corrected Akaike Information Criterion (AICc) will be used to assess model fit when covariates are added to the model. Normality assumptions will be assessed using the Shapiro–Wilk test. If required, non-linear transformations such as the square root and log-transformations will be applied to normalize the data. Statistical significance will be set at an alpha level of 0.05. Effect sizes, defined by partial eta squared, will be reported and interpreted, with 0.01, 0.06, and 0.014, respectively, identified as small, medium, and large effects.³⁷ All analyses will be conducted using R version 4.1.

The qualitative data collected via open-ended questions from the post-intervention online survey will be used to help explain or elaborate the quantitative data. Qualitative data will be analysed using thematic analysis. Thematic analysis uses ‘a priori’ code frame to analyse and report on

the data.³⁸ The analyses will be conducted using NVivo version 12.

Discussion

Evidence has shown that Tai Chi can improve both physical and mental status of people with chronic diseases.³⁹ It is a safe, easy to learn, inexpensive, and moderate-intensity exercise with increasing popularity worldwide.⁴⁰ The results from this study will provide updated knowledge on treatment options with the potential for women with BC to self-manage to improve their QoL. Our recommendations will inform healthcare policy and priorities in this area. The results will provide insight into the potential alternative management strategies to support the improvement of QoL, decision-making, and ultimately help women with BC to enhance their QoL.

If the intervention improves the QoL of women with BC, this study will build research capacity and increase awareness of the potential for Tai Chi to empower patients and engage them in self-management of BC symptoms to improve the QoL.

Declarations

Ethics approval and consent to participate

Ethical approval has been obtained from the corresponding author's University Human Research Ethics Committee (No. 2021-03042-WANG; ACTRN12622000042741p <https://www.anzctr.org.au/ACTRN12622000042741p.aspx>; Issue date: 17 January 2022; Protocol Amendment No: 02; Author: Dr Carol Chunfeng Wang). A Participant Information Letter will be provided to all participants to explain the study, including the purpose and procedures, the voluntary nature of participation, and the option to withdraw participation at any time. Participants will also be guaranteed confidentiality. Any adverse events arising will be reported and managed by the investigators. Data will be securely stored in the university's secure cloud location, and no unauthorized persons will have access to the collected data. The results from this study will be shared in various forms to engage broader audiences, including at national and international conferences presentations, in open-access peer-reviewed journal publications, and at local community workshops with healthcare professionals. Protocol modifications will be undertaken by the principal investigator and submitted to the Ethics Committee for approval following any change requirements, and no changes will be made before the approval is granted.

Consent for publication

Not applicable.

Author contribution(s)

Carol Chunfeng Wang: Conceptualization; Data curation; Investigation; Methodology; Project administration; Resources; Software; Validation; Visualization; Writing – original draft; Writing – review & editing.

Sadie Geraghty: Investigation; Project administration; Resources; Validation; Visualization; Writing – review & editing.

Caitlin Fox-Harding: Investigation; Project administration; Validation; Writing – review & editing.

Calvin Wang: Conceptualization; Investigation; Methodology; Resources; Validation; Visualization; Writing – review & editing.

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Competing interests

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Availability of data and materials

Not applicable.

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Supplemental material

Supplemental material for this article is available online.

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