

PROTOCOL

Long-Term Effects of Tai Chi on Exercise Capacity and Quality of Life in Chronic Obstructive Pulmonary Disease: A pilot study

Introduction

This pilot study aims to investigate the effects of a maintenance Tai Chi intervention on exercise capacity and quality of life in people with chronic obstructive pulmonary disease (COPD). This will be a prospective cohort study where people with COPD will be recruited from two sites in Sydney – Concord Repatriation General Hospital and Terrey Hills Community Centre. All participants will be asked to undertake an eight week, twice weekly, supervised Tai Chi exercise program using Sun-style Tai Chi at one of the sites. On completion of the supervised program, participants will then be asked to continue with a home-based, unsupervised maintenance Tai Chi exercise program five times weekly for a six month period. Outcomes will be measured at baseline, at eight weeks following the supervised Tai Chi program and again at three and six months into the maintenance Tai Chi program. Outcomes will include exercise capacity, quality of life, physical activity, balance, participants' attitudes to management of their health care, compliance with short and long-term Tai Chi training, and satisfaction with the maintenance Tai Chi training.

Participant Selection

People with COPD will be recruited from referrals to the pulmonary rehabilitation programs at Concord Repatriation General Hospital, Sydney, NSW and Terrey Hills Community Centre, Sydney, NSW.

Participant Inclusion Criteria

People will be eligible for inclusion if they:

- have a medical diagnosis of COPD (forced expiratory volume in one second (FEV_1) / forced vital capacity ratio of < 0.7 ; FEV_1 between 20% to 80% predicted normal)

Participant Exclusion Criteria

People will be excluded if they:

- have had an acute exacerbation of COPD in the last month;
- musculoskeletal, cardiovascular or neurological conditions likely to adversely affect performance during assessments or training;
- participation in any supervised exercise training within the last 12 months;
- limited English language skills which might hinder their understanding of the Tai Chi instructions;
- require supplemental oxygen during testing or training procedures.

Participants with co-existing cardiac conditions such as controlled atrial fibrillation and controlled heart failure will be included to ensure that the sample population is representative of patients referred to clinical pulmonary rehabilitation programs.

Study Design

This study is a prospective cohort study with long-term measures. All participants will be asked to complete a program of supervised Tai Chi training for 8 weeks and an unsupervised home maintenance program of Tai Chi training for a further 6 months. Outcome measures will be assessed at baseline, 8 weeks (i.e. end of the supervised Tai Chi program), and three and six months into the maintenance program.

Primary Outcome Measures

Exercise Capacity: This will be measured by the **six minute walk test (6MWT)** where distance walked in six minutes will be measured. Two tests will be performed at each assessment to account for a learning effect. The test that yields the greatest distance will be recorded as the test outcome. During these walk tests, oxygen saturation and heart rate will be monitored using a pulse oximeter while dyspnoea and rate of perceived exertion will be assessed before and after each exercise test using the modified 0–10 point Borg category-ratio scale [1]. The threshold for a clinically important change to six-minute walk distance has been determined as an improvement of 30 m [2].

Health-Related Quality of Life (HRQoL): The St George's Respiratory Questionnaire (SGRQ) will be used [3]. It has 53 items examining the impact of respiratory disease across three domains (symptoms, activity limitations and impact of disease) of HRQoL. Together these domains provide a total score which will be used as the primary outcome for HRQoL. The threshold for a clinically important change to the total score has been determined as an improvement of 4 points [4].

Secondary Outcome Measures

Physical Activity: Daily activity level will be measured in both groups by the **SenseWear Armband** (Bodymedia, Pittsburgh, USA). This device provides information on activity intensity (via energy expenditure) and duration as well as the number of steps taken. The Armband has been shown to provide a reproducible and valid measure of physical activity in people with COPD [5]. The Armband will be worn continuously (except bathing) on the final seven days of the initial testing period to provide a baseline measure of activity level, and again over a seven day period at all subsequent assessments. Our group has extensive experience applying the armband to people with COPD for this length of time with data indicating that it is well tolerated. This measure will determine whether supervised Tai Chi training improves physical activity and whether a maintenance Tai Chi program can sustain any improvements.

Balance: This will be measured by the brief version of the Balance Evaluation Systems Test (BESTest) [6]. The brief-BESTest is a comprehensive balance assessment tool which designed to assess six different aspects contributing to postural control in standing and walking. There is a total of six items which covers six different balance control systems (biomechanical constraints, stability limits, anticipatory postural responses, postural responses, sensory orientation and stability in gait) [7]. Each item is scored on a 3 points scale (0 representing severe impairment and 3 representing no balance impairment) with a total score of 24 points (with 2 items include both a right and left component). Brief-BESTest was the revised version of the BEST test which is a reliable and responsive test to detect improvement in balance in people with balance impairments [8]. Impairment of balance has been demonstrated in people with COPD compared with a healthy, age-matched population so it is essential to include balance measures in the current study as Tai Chi has been shown to improve balance in the short-term [9]. It remains unknown whether improvements are sustained with a maintenance Tai Chi program.

Patient Activation Measure (PAM): PAM is a survey which assesses an individual's knowledge, skill and confidence for managing one's health and healthcare [10]. A higher score indicates that an individual has a better understanding of the importance of taking a pro-active role in managing their health and have the skills and confidence to do so. The PAM survey measures individuals on a 0-100 scale and can segment them into one of four activation levels along an empirically derived continuum. Each activation level reveals insight into an array of health-related characteristics including attitudes (such as self-efficacy), motivators, behaviors, and outcomes. It will be important to determine whether Tai Chi activates participants to manage their health and behaviours in the maintenance phase.

Compliance with Supervised and Unsupervised Tai Chi Training: This will be measured through the supervised Tai Chi training by the number of total attended supervised training sessions and total duration of home practice. Training duration at home will be self-recorded in a diary. Compliance with home training during the maintenance phase will also be self-recorded by the home diary and determined objectively by the SenseWear recordings at the times the armband is worn.

Satisfaction with Tai Chi Training: At the end of the six month maintenance period, participants will complete a purpose-designed survey to ascertain their experience and perception of the maintenance Tai Chi program. Our group has previously reported high satisfaction levels with a short-term supervised Tai Chi program [11] but it remains unknown the level of satisfaction when using Tai Chi as a maintenance form of exercise training.

Additional Measures

Lung Function: Spirometry will be measured at baseline using standard techniques and will be repeated at all subsequent assessments. Lung function data will be used to define disease severity and to assess whether lung function remains stable during the study period.

Intervention

Initial Tai Chi Training (first 8 weeks): Participants will complete the initial Tai Chi training program using the Sun-style Tai Chi as previously reported by our group [9]. Participants will attend two supervised Tai Chi training sessions each week for one hour over eight weeks. Each participant will aim to train at a moderate level of breathlessness or exertion, equating to a score of three on the modified Borg (0–10) scale. To increase the training demand of Tai Chi, participants will be asked to imagine pushing against resistance during all movements or to squat lower in certain movements. In participants for whom dyspnoea or exertion does not reach a moderate level during training, wrist weights of between 0.5 and 1.5 kg will be worn. The weight will be determined by the individual's symptoms of dyspnoea or exertion. In addition to the two supervised training sessions each week, all participants will be asked to practice at home for 30 minutes, on the other five days of the week. A Tai Chi training booklet and DVD (developed by our group) will be provided to facilitate home training. Home diaries will be used to record completion of these unsupervised sessions.

Maintenance Tai Chi Training (8 weeks to 8 months): On completion of the eight week exercise interventions described above, the participants will be advised to continue home training at least five times per week for a further 6 months at the same intensity they achieved at the end of their initial training. The group will be advised to continue to practice the Sun-style Tai Chi training following the DVD and Tai Chi booklet provided. Strategies for progression to ensure exercise remains at a moderate intensity, i.e. moderate breathlessness or fatigue, will be provided to each participant. During this six-month period, participants will also receive monthly “booster” sessions of supervised Tai Chi training. There will be six one-hour “booster” sessions in total. The intensity of Tai Chi training may be adjusted during “booster” sessions to ensure that participants are exercising at a moderate level of breathlessness or exertion.

Sample Size

A total of 48 participants will be enrolled to ensure that 40 participants complete the study (accounts for a 20% drop-out rate). Forty participants will be sufficient to provide 80% power to detect as significant, at the (two-sided) 5% level, a minimum 30 m improvement in the mean six minute walk distance (i.e. which is the minimum important difference for six-minute walk distance) following short-term Tai Chi training and 6 months Tai Chi maintenance, assuming a standard deviation of 48 m for the test.

Analysis of Results

The effects of the initial supervised Tai Chi training program will be determined by calculating the mean differences within the group for all outcomes from baseline to the eight week time point using a paired t test. Uncertainty about the size of the mean differences within groups will be quantified with 95% confidence intervals. The effects of the unsupervised maintenance Tai Chi training program will be determined by calculating the mean differences within the group for all outcomes from the eight week time point to the three and six month time points respectively using a paired t test to identify whether any improvements have been sustained. The three and six month time points will also be compared to baseline using a paired t test to determine if the combination of the supervised and unsupervised Tai Chi program resulted in improvements being better than baseline for all outcome measures.

References:

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