# ORIGINAL ARTICLE

## Cystic Fibrosis—Children and Adults Tai Chi Study (CF CATS2): Can Tai Chi Improve Symptoms and Quality of Life for People with Cystic Fibrosis? Second Phase Study Protocol

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**ABSTRACT** **Background:** Cystic fibrosis (CF) is a genetic disorder affecting respiratory and digestive systems. People with CF experience physical symptoms; cough, poor lung ventilation, recurrent infections, poor weight gain, diarrhoea, and malnutrition, as well as lower quality of life. Tai Chi, a Chinese form of meditative movement, may help with the symptoms of CF and help people with CF to exercise. However, there is very little research in this area. **Objective:** To evaluate the feasibility of studying Tai Chi for CF and to compare the effectiveness of Tai Chi to standard care and face-to-face Tai Chi with online Tai Chi for people with CF. **Methods:** This is a comparative effectiveness trial with 72 people with CF over 6 years old and a patient at the Royal Brompton Hospital, London, UK. Participants receive 8 Tai Chi sessions, then home practice with a DVD. Sessions are one-on-one for group A, online for group B. Group B is a no treatment standard care control (first 3 months). At baseline, 3, 6 and 9 months, questionnaires will be used to measure quality of life, mindfulness and sleep, and medical data health and respiratory function. At Tai Chi sessions and at 4 follow-up points, the Borg Scale and healthcare use data will be collected. At 9 months online focus groups will assess participants' experience, Tai Chi feasibility, perceived health impact, and study participation. Recruitment will use adverts in hospital clinics and website, and letter/phone for non-regularly attending patients. Block randomisation will use random number tables. The two groups will be compared for: weeks 1 to 12 (Tai Chi *vs*. standard care); before and after intervention (differences in delivery method); week 1 (of intervention) to month 9 (long-term impact). Qualitative data will use Framework analysis. **Discussion:** We believe this is the first trial of Tai Chi for CF. Tai Chi may help with the physiological symptoms of CF and increase levels of exercise by providing a self-management technique and low stress activity. This study will provide data on the feasibility of a randomized controlled trial of Tai Chi for CF, including data for a sample size calculation and will inform future study design.

**KEYWORDS** cystic fibrosis, Tai Chi, study protocol, quality of life

Cystic fibrosis (CF) is a genetic disorder which particularly affects the respiratory and digestive systems and is the most common life-threatening inherited disease in the United Kingdom, affecting over 9,000 people in the UK.[1] People with CF experience physical symptoms of cough, poor lung ventilation, recurrent infections, poor weight gain, diarrhoea, and malnutrition as well as lower quality of life (QOL) than those without the disease.[2,3] CF can also affect emotional and mental health and impact school or work.[2,4-6]

Complementary and alternative medicine (CAM) appears popular for people with CF in the USA, 65% of children used CAM (excluding prayer) and 49% mind-body approaches, particularly for symptoms, mucous clearance, anxiety, and general health.[7] Most (77%) reported finding it useful.[7] One form of CAM is Tai Chi. Tai Chi (also known as taiji) is a Chinese exercise based on martial practice. Recent evidence suggests health benefits for a variety of chronic conditions.[8]

People with CF are encouraged to be physically active, to develop fitness, social skills, relationships and improve QOL.[9,10] However, prolonged exercise (and chronic illness) may strain the metabolism and reduce immunity through stimulation of the sympathetic nervous system. Compared with many forms of exercise, Tai Chi is low impact and low stress, using gentle yet demanding movements, practiced


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with respiratory control and mental awareness.

We have conducted a systematic review of the literature, and there appears to be no previous research on Tai Chi and CF.[11] Findings from our feasibility study indicate that Tai Chi may improve the treatment constraints and respiratory symptoms domains of the well-validated Cystic Fibrosis Questionnaire-Revised (CFQ-R), and have a relaxing and calming effect, in particular when experiencing breathlessness, and may improve sleep.[12] The aims of this trial are to compare the effectiveness of Tai Chi to standard care for people with CF, and face-to-face and online Tai Chi sessions.

## METHODS

### Study Design, Ethical Approval and Registration

This study will be a comparative effectiveness trial with a delayed start control group. It will take place in London, UK, with recruitment from the paediatric and adult CF clinics at the Royal Brompton Hospital, London. The study has been approved by the National Research Ethics Committee London – Harrow with reference No. 14/LO/0327, and is registered at Clinicaltrials.gov with registration No. NCT02054377.

### Inclusion and Exclusion Criteria

Seventy-two patients with CF will be recruited to allow for 30% dropout, leaving a sample size of 50. We do not anticipate any problems recruiting this number based on our experience in the feasibility phase.[12]

Inclusion criteria will be: (1) diagnosis of CF;[13] (2) able to learn and practice the Tai Chi movements and commit to a 9-month study; (3) living in or near London; (4) able to complete questionnaires in English; (5) 6 years old and above; (7) have internet access.

Exclusion criteria will be: (1) participant in the feasibility phase; (2) currently taking part in another interventional research study.

### Intervention and Control

The Tai Chi intervention, developed in the feasibility study, is based on the "eternal spring" Tai Chi-qigong set, which uses various animal movements. It is a form of Wu style Tai Chi-qigong, which comprises movements from the Wu style Tai Chi form, and Tai Chi-qigong movements practiced in accordance to therapeutic Tai Chi-qigong principles. The intervention uses a short sequence of movements adapted from the traditional Tai Chi forms for specific use with CF patients, selected for their specific effect on the respiratory organs or a holistic all round benefit for patients. Every session will begin and end with mindful breathing—jing gong (still meditation). The movements—dong-gong (moving meditation)—facilitate skeletal muscle movements and aim to improve circulation, respiration and mucus clearance. At the end of the set participants will be shown traditional "closing methods" including self-massage, to reduce tension and aid peripheral circulation.

The intervention will be taught individually, by a team of teachers who have all trained in Wu style Tai Chi-qigong and are experienced in teaching a range of age groups and variety of health problems. They will attend a training session with the lead instructor, to ensure the intervention is consistently taught (Mian A).

The face-to-face sessions (group A) will be delivered individually in participants' homes or a mutually convenient location. The online sessions (group B) will be delivered using webcams and online video conferencing facilities such as Skype™. Face-to-face sessions will be one-on-one rather than group (due to risks of infection), online sessions will also be one-on-one. Parents/carers will be present for all sessions with children under 16 and will be invited to participate in Tai Chi sessions and home practice for all participants.

In addition to the taught sessions, a DVD and handout will be given to all participants. Two versions will be created, one for adults and one for children of 16 years and under. The adult version of the DVD was developed in the feasibility phase and includes demonstration of the movements and a voiceover describing the movements. The paediatric DVD has been developed with the help of local school children. During the home practice periods teachers will encourage participants to practice the exercises they have learnt for 5 to 10 min, up to 5 times a week.

At the end of the 9 months, local Tai Chi classes can be recommended if requested by participants. The control period will have no Tai Chi intervention but patients will access their routine hospital care. All participants will continue with their usual treatments

throughout the study, including encouragement to undertake regular exercise.

## Outcome Measures

Primary outcome is the health related QOL (HRQOL) as measured by the CFQ-R or CFQ-Child, a validated disease-specific instrument.[14,15] The CFQ uses 5 point Likert Scales in 9 QOL domains (physical, role/school, vitality, emotion, social, body image, eating, treatment burden, health perceptions), 3 symptoms (weight, respiratory, and digestion) and health perception.

Secondary outcomes include: (1) Five Facets Mindfulness Questionare (FFMQ) for over 16 years, which has construct validity,[16] and Child and Adolescent Mindfulness Measure (CAMM) for under 16 years which is internally consistent.[17] The FFMS is a 39-item questionnaire about awareness of thoughts, anxieties, self-management. CAMM is a 10-item questionnaire about awareness of thoughts, anxieties, self-management. (2) Pittsburgh Sleep Quality Index (PSQI), a 10-item questionnaire about sleep quality and duration which is validated and reliable.[18] This will be proxy-completed by the parent/carer for children under 12. Table 1 clarifies the questionnaires completed for the different age groups. (3) Changes in general health and respiratory function will be measured using routine clinical data from hospital records, including body mass index (BMI), medications, antibiotic use, forced expiratory volume ($FEV_1$), forced vital capacity (FVC), and oxygen saturation (amount of oxygen in red blood cells).

In addition the modified Borg Dyspnoea Scale before and after Tai Chi sessions will be administered. This is a one-item, 10-point scale that rates comfort of breathing and has been validated.[19,20] At the start of each Tai Chi session: details of any changes in medication, exacerbations, antibiotic use, clinical trial participation, or care provision (start of session only) will be collected by the instructor and recorded on a proforma. The instructor will ask about details of Tai Chi practice in the intervening week.

At the end of the study qualitative research will obtain feedback on participants' experience, feasibility of learning and practicing of Tai Chi, engagement with the process, levels of concentration and perceived health impact, as well as feedback on their participation in the study. Online focus groups will be conducted with 50% of the sample, using Skype, as used successfully in the previous study.

## Procedure

As shown in Figure 1, participants will be block randomised to group A (intervention group) or B (control group), using a random number table and blocks of 6 from each of the three age groups (6–11; 12–16 and over 16 years). In the first 3 months group A will receive face-to-face Tai Chi (8 sessions) and group B routine care only. In months 4 to 6 group B will be offered online remote Tai Chi (8 sessions) and group A will continue with home practice. Both groups will be followed up for 9 months, to ensure the important long-term effects of Tai Chi are captured. Recruitment is planned to commence in June 2014 and the study is scheduled for completion in May 2016.

## Data Analysis

Frequency data of demographic characteristics (collected by CFQ-R) will be generated for demographic variables. Data will be analysed using appropriate statistical tests comparing groups A and B to determine the effect of: (1) changes following face-to-face teaching of Tai Chi (group A) compared with standard care (group B) from time point (TP) 1 to TP2; (2) changes following face to face teaching (group A) from TP1 to TP2 will be compared with changes following web based learning (group B) from TP2 to TP3; (3) feedback from focus groups at the end of the study to determine whether there are any differences in delivery method of Tai Chi; (4) long-term impact of face-to-face teaching (group A) from TP2 to

**Table 1. Questionnaires to be Used in the Study**

| Outcome | Child (6–11 years) | Child (12 or 13 years) | Carer of 6–13-year-old child | Child (14 or 15 years) | Adult (≥16 years) |
|---|---|---|---|---|---|
| CF QOL | Child CFQ (parent as interviewer) | 12–13 CFQ | Parent CFQ (about the child's health) | Adolescent/adult CFQ | Adolescent/adult CFQ |
| Sleep | PSQI (with parent's help) | PSQI | PSQI for child (proxy completion) | PSQI | PSQI |
| Mindfulness | CAMM | CAMM | None | CAMM | FFMQ |

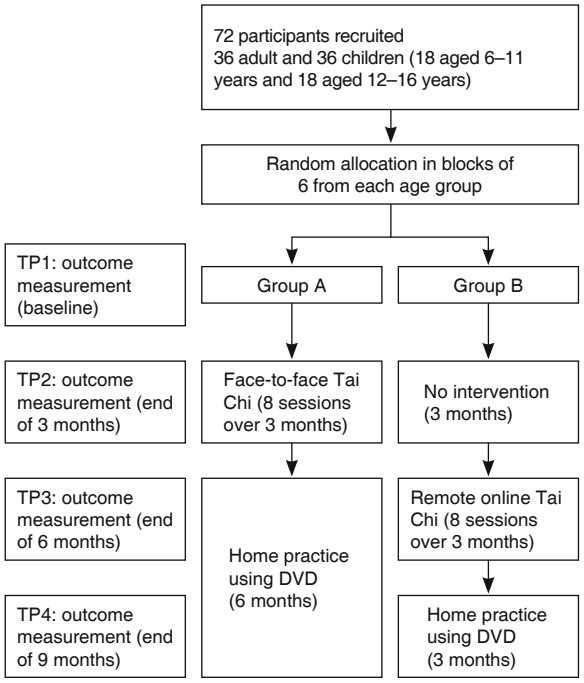


**Figure 1. Participant Flowchart**

TP3 will be compared with long-term impact of web-based learning (group B) (changes from TP3 to TP4, i.e. both groups at 3 months after the end of the taught intervention). In addition, data from before and after the intervention at the 9-month follow-up will be compared to determine the long-term effects of Tai Chi, continued adherence to Tai Chi practice and any transfer effects.

These analyses will be performed for the whole group and, if appropriate, sub-analyses will be carried out. Subgroup analysis may also be conducted, if appropriate, for the three cohorts of participants according to CF severity (mild, moderate, severe), as determined by lung function and for the three age groups.

Qualitative data from the focus groups will be analysed using Framework analysis;[21] the research team have experience in this method of analysis.[12,22,23] Themes will be drawn both from the literature and inductively from the data.

## DISCUSSION

The anticipated benefits of Tai Chi for CF are mainly based on its potential physiological effects and providing a form of low-impact exercise.

There is some evidence that meditative movement (which includes Tai Chi) may have an effect on respiratory function in terms of improving $FEV_1$, as compared with either no treatment or exercise. Studies have found that Tai Chi/qigong may improve pulmonary function in children with asthma,[24] benefit children with special educational needs[25] and is feasible to teach to children.[26] As a form of moving meditation, Tai Chi is thought to calm the sympathetic nervous system and engage the parasympathetic systems. This may lead to improvements in cardiovascular, pulmonary and immune function, and reduced inflammation and infection rate.

Exercise is recommended for people with CF but is often limited by the complex symptoms experienced and frequent exacerbations and periods of hospitalization. Provision of a self-management approach such as Tai Chi may help to address these challenges. Physiotherapists have a key role in encouraging patients with CF to maintain exercise levels.[27] A comprehensive exercise programme combining aerobic and strength training is encouraged. Depending on the individual's exercise capacity and lung function, the level of breathlessness experienced whilst exercising will differ, and Tai Chi may improve the sensation and control of breathlessness coupled with traditional physiotherapy techniques of breathing control. More recently physiotherapists focus on core stability to positively influence symptoms of stress incontinence and postural control. Core stability training is therefore incorporated into an individual's exercise regime for CF, and because of this Tai Chi may be complementary to the exercise regimes already practised. Tai Chi provides a low impact form of physical and mindful exercise which may be useful for the symptoms of CF and QOL.

A further aspect of teaching Tai Chi to people with CF, which this study will evaluate, is the utility of online technology to deliver Tai Chi sessions. Due to the risk of cross-infection, people with CF are not able to physically meet face to face. This means the Tai Chi must be taught one-on-one, as in our pilot study,[12] which is resource intensive. We therefore propose to test online video teaching of Tai Chi, which, if feasible for individual sessions, has the potential to provide a virtual group environment for teaching people with CF. Video-conferencing technology such as Skype can provide an effective,[28] convenient and cheap method for delivering healthcare, although evidence of cost-effectiveness is very limited.[28,29] Most studies

of telemedicine/video-conferencing technology in health are from mental health—a few have found that exercise such as video-conferencing is useful for delivering Tai Chi (for older people)[30] and breathing techniques (for people with chronic obstructive pulmonary disease),[31] although these are small uncontrolled studies.

In terms of research design, as this area of research is relatively new, feasibility data is needed on the best way to study the effects of Tai Chi, as well as information on how best to recruit, improve compliance, and the intervention. The study design of the proposed study has been heavily influenced by the results of our pilot study,[12] including feedback from participants on the relevance and acceptability of various outcome measures [FFMQ; Multidimensional Health Locus of Control (MHLC); Perceived Stress Scale; Modified Borg Dyspnoea Scale; Dyspnoea-12 Scale; PSQI; and MYMOP2]. The feedback suggested that: the CFQ was useful and acceptable, so was retained; the MHLC would not capture effects of Tai Chi; the Perceived Stress Scale was not focused enough; MYMOP2 was perhaps not appropriate for CF; both dyspnoea questionnaires were useful but the Borg Scale was much quicker to complete. Based on this data we chose the CFQ, FFMQ, Borg Scale, and PSQI. In addition we added child-friendly versions of questionnaires where available.

We anticipate the results of this study to include: (1) the feasibility of conducting a randomized controlled trial of Tai Chi for CF, including recruitment, retention, compliance and data collection; (2) data on the effect of Tai Chi on HRQOL to inform a sample size calculation for a full trial; (3) feedback from participants on the outcome measures used; (4) the acceptability and success of teaching Tai Chi online to people with CF; (5) the acceptability and success of teaching Tai Chi to people with CF of different ages, and the potential adaptations needed for different age groups.

As the area of Tai Chi for respiratory function and cystic fibrosis is new,[11] this feasibility work could provide evidence to inform clinical practice and patient self-management, and input for the design of future randomised trials.

## Conflict of Interest

None to declare.

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