
# Children and Adults Tai Chi Study: a randomised feasibility study comparing internet delivered with face to face Tai Chi lessons in cystic fibrosis

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# Children and Adults Tai Chi Study (CF-CATS2): a randomised controlled feasibility study comparing internet delivered with face to face Tai Chi lessons in cystic fibrosis

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**Abstract**

Virtual health care is fast entering medical practice. Research into the feasibility of using it to teach treatment regimens such as exercise has not been explored. Maintaining an exercise regime can be difficult in cystic fibrosis: group classes risk potential infection yet motivation is hard to maintain when alone. Tai Chi is low impact and involves gentle, demanding movements. This study aimed to assess the feasibility, safety and acceptability of learning Tai Chi via an internet based approach and compared patient reported outcomes.

Methods: Children and adults with cystic fibrosis were recruited to a randomised, comparative effectiveness trial. Participants learnt eight Tai Chi movements, teaching was delivered in eight lessons over 3 months: either internet delivered or face to face. Assessments were at three monthly intervals over nine-months. Outcomes included health status, quality of life, sleep, mindfulness and instructor-led questions.

Results: Forty adults and children completed the eight sets of Tai Chi lessons. The median age was 22.8 years (range 6.1 to 51.5). Twenty-seven were female. Twenty-six adults (>16 years), six teenagers and eight <12 years. The groups were well matched. Feasibility and safety were demonstrated. Participants showed significant improvements in self-reported sleep, cough (both day and night time), stomach ache and breathing. No differences in lung function, health status, QoL, sleep or mindfulness was shown before or after completing the lessons.

Conclusions: Tai Chi was safe well tolerated, it was feasible to deliver individual lessons via the internet reducing concerns regarding cross infection and appeared to improve self-reported symptoms.

**Key Words (3-6):** Cystic Fibrosis, Tai Chi, randomised controlled trial, Internet-delivered, exercise, cross-infection

## 1. Introduction

The importance of the role of exercise and physical activity for people with cystic fibrosis (CF) has been emphasized since the 1970s and is now a well-established recommendation in clinical care (1). Although the specific therapeutic effects of exercise in CF are still under investigation, correlations between aerobic fitness and survival, alleviation of dyspnoea, reductions in the rate of decline in lung function and improvements in quality of life scores have been reported (2). The ability to practice and access instruction for more gentle exercises may be key to maintaining a regime that is suitable and beneficial to maintain quality of life during times of poor health. Tai chi can be highly adaptable in nature and intensity.

A Cochrane review on CF concluded that there is evidence for beneficial effects on aerobic fitness and no negative side effects (3). It is clear from the literature that individuals with CF who increase their activity levels have a reduction in their decline in $FEV_1$ compared with those who are not as active, supporting the view that even low-intensity activity is able to preserve lung function (4) this is important as many people with CF cannot sustain high intensity training.

Tai Chi is a low impact exercise that involves gentle, yet demanding movements. It is practiced with respiratory control, postural awareness and mental awareness (mindfulness). It can be practiced standing or sitting (5). Recent evidence suggests Tai Chi benefits a variety of chronic conditions (6,7), including chronic obstructive pulmonary disease (COPD) (8,9), cardio-cerebrovascular and musculoskeletal problems (10). It is suitable for a variety of age groups and fitness levels.

Cross infection is a concern in CF, this has led to recommendations for total segregation in both clinical and social settings (1). Group activities are actively discouraged to lower the risk for cross

infection, this is isolating for patients. In parallel, and may be because of segregation advice, social media and web-based engagement is becoming utilized by both the paediatric and adult CF population, although research into delivery of care or treatments over the internet has not been well studied.

The literature for use of Tai Chi in CF is sparse (11). A previous pilot study in adults with CF was carried out to assess the feasibility and usefulness of individual Tai Chi sessions taking cross infection into consideration (12). The small group of ten participants not only reported improvements in breathing, sleeping and reduced anxiety, but also the positive benefits of face to face contact with the Tai Chi teacher. The aims of this study were to assess the feasibility of delivering Tai Chi over the internet, to compare the effectiveness of Tai Chi to standard care and to compare two methods of delivering individualised Tai Chi lessons: either by face-to-face lessons or online "internet delivered" lessons using Skype.

## 2. Methods

### *2.1 Participants*

Participants with CF, aged six years or older were recruited from The Royal Brompton Hospital specialist adult and paediatric CF centres. Participants were required to have the time to complete the study, be within reasonable distance of the centre for teachers to travel to lessons and have internet access. Individuals were excluded if they were taking part in any other interventional study or if they had been in the pilot study (12). They were recruited opportunistically from outpatient clinics after responding to posters or approach by researchers and had no prior experience of practicing Tai Chi. A power calculation suggested 72 participants were needed, with the expectation

that 60 would complete the study given an anticipated withdrawal rate of 17% based on the previous study (12).

*2.2 Study Design*

A comparative effectiveness randomized trial design was conducted by dividing participants into two groups: Tai Chi lessons via Skype (the internet delivered group (ID)) or lessons in a face to face format (F2F). After providing informed, written consent (parental consent for children and assent for older children), participants were randomised to either the F2F or the ID group. Random number tables were used to generate random sequencing for blocks of six participants in three age groups (6-11; 12-16 and over 16 years). F2F Tai chi sessions were usually delivered at home, but participants could select other suitable venues, including hospital if convenient. All sessions were taught individually, but participants could choose to invite a friend or family member to participate. Individualised F2F sessions were critical to reduce the risk of cross infection. Participants were given a total of eight sessions delivered over a period of three months, timetabled at their own convenience. Parents and/or carers were required to be present for children under the age of 16 years.

The F2F group started their Tai Chi intervention at time zero, the ID group had their intervention started three months later, allowing a three-month period to act as a control group of standard care for the first F2F Tai Chi intervention.

*2.4 Intervention*

Tai chi was taught to both groups by a team of six teachers trained in Wu style tai chi-qigong, who were experienced in teaching people with health problems, they were specifically trained by AM to

deliver the study intervention and were versed with the study protocol. Wu style tai chi is one of the five major family styles of tai chi taught across the world. It's known for its smooth rhythm and can be taught in an adaptable manner to accommodate an individual's needs. They employed a short sequence of eight movements focused on developing key tai chi principles. These were selected for their specific effect on the respiratory system and assumed overall benefit in CF. Movements were adapted from the "Eternal Spring" tai chi-qigong set, which uses animal movements. These included mindful breathing- *jing gong* (still meditation), *dong- gong* (moving meditation) facilitating skeletal muscle movements with the aim of improving circulation, respiration and mucus clearance. The start of each session began with postural and breath awareness and at the end of each session self-massage was included which reduces tension and aids peripheral circulation.

To aid adherence and to serve as reminder a specific DVD and booklet were developed and stickers, diaries and t-shirts were offered. The DVD comprised three separate sections in order to appeal to different ages and abilities: adults, children, and people who may be incapacitated or in hospital experiencing an exacerbation and those who may need to practice seated. Participants were encouraged to practice the exercises for five to ten minutes up to five times a week. Participants continued with their usual routine treatments throughout the study.

*2.5 Outcome measures*

Participants completed validated questionnaires at four main time points: at the start of the study, then three monthly until the nine-month end point. Patient reported outcome measures (PROM) included the health related quality of life measure Cystic Fibrosis Questionnaire- Revised (CFQ-R) (13-15), the Pittsburgh Sleep Quality Index (PSQI)(16), the Five Facets Mindfulness Scale (FFMS) (17)

for adults over the age of 16 and the Child and Adolescent Mindfulness Measure (CAMM)(18,19) for children. Health status was recorded using Body Mass Index (BMI), %Forced Expiratory Volume in one second ($FEV_1$), %Forced Vital Capacity (FVC), and oxygen saturation at the same time points. Participants were not asked to keep a diary of events such as pulmonary exacerbations or admissions in order to keep the burden of the study as low as possible.

During the interventional part of the study Tai Chi teachers administered a short questionnaire developed for the study (Instructor's Questionnaire) just prior to each of the eight taught sessions. This included questions about breathlessness using the modified Borg dyspnoea scale (20), any change in medication, exacerbations, antibiotic use, frequency and timing of practice, the feasibility of learning and practicing Tai Chi, engagement with the process, levels of concentration and perceived health impact, as well as feedback on their participation in the study. Perceived health covered five questions on a Likert scale (1-4 never, sometimes, often, always) asking for recall of symptoms in the last week related to a) trouble sleeping, b) stomach hurting c) cough during the day d) being woken by cough at night and e) trouble breathing. A more general health question was recorded on a visual analogue scale (VAS) with zero being "as bad as it can be" and 100 "as good as it can be" for the question "In the last week where would you put your general health and wellbeing on this scale"?

*2.6 Ethical approval and funding*

The study received ethical approval from the London - Harrow Research Ethics Committee (REC reference no.: 14/LO/0327), was registered on the Clinical trials.gov website (Registration number: NCT02054377) and the study protocol was published (21). The study was funded by research grants from two charitable bodies (The Tracey Lawlor Trust for Cystic Fibrosis (the major grant funder) and

The Cystic Fibrosis Trust, UK), neither contributed to trial design nor this manuscript.

*2.7 Analysis*

Data were analysed using descriptive statistics and multivariate statistical analysis including parametric (t-test), non-parametric (Mann Whitney) and linear regression models. Overall totals, where appropriate, mean numbers and standard deviations were calculated and significant differences, homogeneity and effect sizes calculated. The differences between time points in the study and the groups were used for calculation of these differences in the PROM questionnaires and clinical outcomes. SPSS version 21 and Excel were used.

## 3. Results

*3.1 Demographic data*

A total of 116 children and adults were invited to participate: 65 declined/were not eligible, 51 consented, 40 completed all lessons, age range 6.1 to 51.5 years, 22 in F2F group and 18 in ID group. The Consort diagram (figure 1) shows reasons for withdrawal and table 1 demonstrates there were no statistical differences (t-test) between the two groups at baseline.

**Figure 1: CONSORT 2010 Flow Diagram**

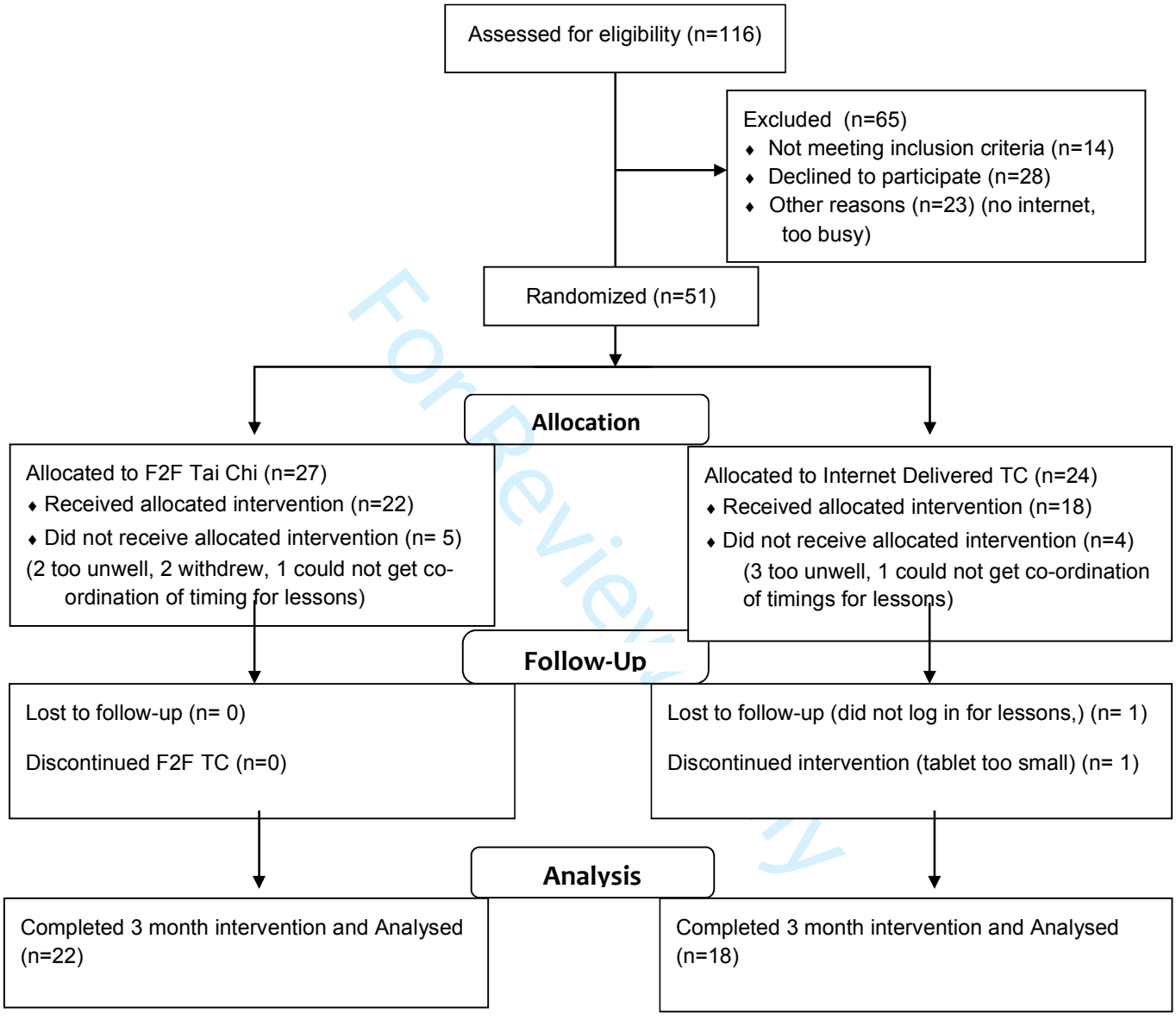


**Table 1: Baseline data at trial entry for both groups completing the 3-month Tai Chi intervention**

Results are presented as mean (standard deviation), unless otherwise stated in table.

FVC % predicted: forced vital capacity % predicted according to age, height, gender and race

FEV1 % predicted: forced expiratory in 1 second % predicted according to age, height, gender and race. BMI: body mass index. CFQ-R: Cystic fibrosis Questionnaire – Revised. CAMM: Child and Adolescent Mindfulness Measure.

| Participants | Face to Face | Internet Delivered |
|---|---|---|
| **Number (n)** | 22 | 18 |
| **Male (n)** | 6 | 7 |
| **Female (n)** | 16 | 11 |
| **Adults (>16 years) (n)** | 15 | 11 |
| **Teen (12-15 years) (n)** | 3 | 3 |
| **Child (6-11 years) (n)** | 4 | 4 |
| **$FEV_1$ % predicted:** | | |
| **<40%** | 3 | 1 |
| **40-70%** | 9 | 5 |
| **>70%** | 13 | 12 |
| | | |
| **Age median (range)** | 22.75 (7.1-45.7) | 22.8 (6.1-51.5) |
| **FVC% predicted** | 87 (18.1) | 94 (14.1) |
| **$FEV_1$ % predicted** | 69 (21.6) | 77 (21.8) |
| **Height (m)** | 1.56 (0.2) | 1.57 (0.21) |
| **Weight (kg)** | 52.5 (18.3) | 52.4 (17.7) |
| **BMI** | 20.4 (4.1) | 20.4 (3.2) |
| | | |
| **CFQ-R (Resp)** | 64.5 (25.2) | 59.4 (26.5) |
| **CFQ-R (Digest)** | 74.8 (25.4) | 75.9 (28.1) |
| **Pittsburgh Sleep** | 11.7 (8.1) | 11.8 (8) |
| **Five Facet Mindfulness (adult)** | 112.5 (14.3) | 107.5 (18.9) |
| **CAMM (child)** | 36.5 (3.9) | 34.9 (5.2) |

*3.2 Clinical Outcome Measures*

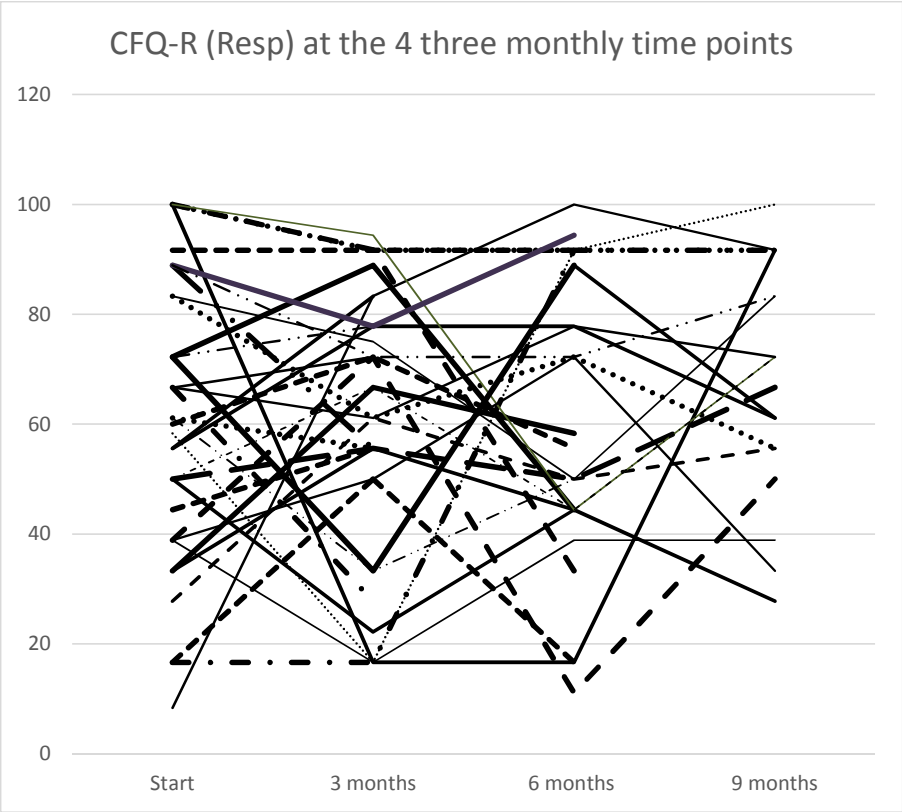
There were no significant differences in the clinical outcome measures (FVC, $FEV_1$, oxygen saturation and BMI) for the first three months of the study when F2F Tai Chi was compared to

standard care (with no Tai Chi) during the three months run in period for the ID Tai Chi group. For the whole group of 40 individuals taught by either method the scores before starting Tai Chi compared to after the end of the three months of the Tai Chi intervention showed no statistically significant changes in FVC% predicted (-0.24%), $FEV_1$ % predicted (1.47%) or BMI (0.006). When comparing these changes between the F2F and ID groups before starting and after ending the Tai Chi intervention there was no significant change.

*3.3 PROM Questionnaires*

There were no significant differences between the two intervention groups pre and post the delivery of the Tai Chi intervention for the questionnaires: CFQ-R, PSQI, FFMS or CAMM. Neither were there differences in these outcomes between the F2F group when compared to the no intervention/standard care control group, at three months. The individual patient variation over the nine months of the trial for the CFQ-R was marked with some individuals showing large variations from 8.33 to 100 and others reporting the same score over the entire duration of the nine months. Figure 2. shows the substantial individual variation over time for the duration of the study for the Respiratory domain for all study participants. Returns of the questionnaire at nine months were low and no further analyses of the difference at this time were performed.

**Fig 2. CFQ-R Respiratory Domain results at three monthly intervals during the study. Each line represents an individual (dashed lines are Face 2 Face TC, solid lines are Internet delivered TC)**




*3.4 Instructor Questionnaires*

The Instructor Questionnaires were conducted on the day of the TC lessons, prior to the start of the session. A definite trend to improvement across the three months of the intervention was shown across the eight taught TC sessions. The graphs show the reducing symptom scores broken down into the three age groups (adults, teenagers and children) in fig 3 a-e. The adults reported worse scores for all areas apart from 'stomach hurting in the last week', where teenagers appeared to have more problems. Children did not score any of the symptoms highly. The linear regression analysis for all five symptom domains on perceived health showed statistically significant trends of improvement when time of questionnaire was used as the independent variable (Table 2). The Visual Analogue Scale asking for general health and wellbeing did not show any change over time, children tended to report better scores than the adults (fig 3f). The Borg scores pre and post

individual lessons did not show any significant change. Antibiotic use did not differ between the groups during the 3-month intervention period with 14 in the F2F group and 13 in the ID group receiving additional oral antibiotic courses. Six people required a hospital IV course in the F2F group and 5 in the ID one.

**Figure 3.**

**Self-reported symptom scores immediately prior to each of the eight individual Tai Chi lessons for all participants. a. Trouble sleeping, b. Waking due to cough, c. Day time cough, d. Trouble breathing and e. Stomach hurting. Scale: (0 – never, 1= sometimes, 3=often, 4= always). f. Visual Analogue Scores.**

*(fig 3 attached separately)*

**Table 2.**

**Linear Regression Coefficients for Instructor Questionnaire domains, with time as the independent variable**

| **Dependent variable** | | **Unstandardized Coefficients** | | **Standardized Coefficient** | **t** | **Significance** |
|---|---|---|---|---|---|---|
| | | B | Std Error | Beta | | |
| | | | | | | |
| Trouble sleeping | (Constant) | .881 | .113 | | 7.830 | .000 |
| | Time | -.065 | .022 | -.160 | -2.897 | .004 |
| | | | | | | |
| Stomach ache | (Constant) | .786 | .114 | | 6.88 | .000 |
| | Time | -.051 | .023 | -.126 | -2.258 | .025 |
| | | | | | | |
| Day Cough | (Constant) | 1.317 | .104 | | 12.651 | .000 |
| | Time | -.060 | .021 | -.161 | -2.913 | .004 |
| | | | | | | |
| Wake with cough | (Constant) | .638 | .096 | | 6.630 | .000 |
| | Time | -.055 | .019 | -.160 | -2.882 | .004 |
| | | | | | | |
| Trouble breathing | (Constant) | .843 | .098 | | 8.561 | .000 |
| | Time | -.062 | .019 | -1.74 | -3.158 | .002 |

## 4. Discussion

Data from this study shows that it is feasible to give personalised Tai Chi lessons over the internet allowing patients to engage in an original way to help them exercise. It is also possible to deliver this teaching across a wide age range with the youngest subject being six years old and to patients with severe lung disease with four subjects having lung function below 40%. There were no significant differences between the internet and face to face teaching for the PROM analysis (the CFQ-R, PSQI, FFMS for adults over the age of 16 and the CAMM for children). Participants reported benefits in self- perceived health for breathing, day and night time cough, abdominal pain and sleep to the Instructor during the three-month intervention, irrespective of the way the Tai chi was delivered. There were no statistical differences in the clinical outcome measures before and after the lessons finished, nor between the different teaching groups.

It is common knowledge that large numbers in the region of 200 are required in trials of CF interventions to show a significant change in lung function change, so this finding is not surprising; however, these secondary outcomes were used in the study to ensure safety and make sure there were no significant detrimental effects associated with Tai Chi.

The focus of this relatively small scale randomised controlled trial was to assess the feasibility of delivering Tai Chi via an online service such as Skype. We did not know whether people with CF would be willing to learn Tai Chi over the internet, nor did we know how well it could be taught as we could not find any previous models for this approach. This study confirmed that a technically difficult and novel exercise intervention could be taught and successfully learnt over the internet allowing the possibility that future studies could be conducted this way. Although participants were randomised into F2F or ID lessons, some pre-selection bias may have been present; we do not know whether a prior belief around the benefits of Tai Chi led to more women being enrolled into

the study. We do know that lack of lack of suitable computers or laptops may have excluded some potential participants.

This study was conducted in a largely urban area. This meant that most people had access to super-fast broadband and devices which could support the technology needed for live online teaching. It may be more difficult to conduct a study or make learning over the internet readily available in more rural parts of the country or to people unable to afford internet connections that are fast enough. Only two people reported having no or inadequate technology which precluded participation or was a reason for withdrawal. One of the younger participants withdrew because of difficulties following lessons on a small tablet device. Future studies might budget for and plan for the availability of appropriate technology. They could also work towards delivering a more cost effective approach using group classes of Tai Chi delivered over the internet.

The power calculation had been based upon a finding of a significant improvement in the CFQ-R Respiratory domain in our original pilot study of only 10 patients (12). This study did not quite meet the sample size of 60 published in our original study protocol (21), a not uncommon experience in research (22,23), this was partly due to the limited availability of teachers who could travel to participants' homes, slow recruitment from the clinics and time constraints over the duration of the study. There was also some fall out of participants from the time of consent to the start of Tai Chi lessons, there was a very low drop-out rate once lessons had started, suggesting participants engaged well with the Tai Chi intervention in both groups. The remarkable variation for individuals (Fig 2) in CFQ-R over the 9 months of the study suggests it may not have been a suitable measure as a primary outcome and asks the question about the reliability of this outcome over long time periods and suggests that use of it in research over time will need to be restricted to larger studies

if significance is to be demonstrated. This lack of improvement in QoL is still disappointing when a recent study has suggested that it may be associated with physical fitness (24), so should have been a reasonable outcome measure in this type of exercise intervention study. However, as is known in CF, respiratory exacerbations will have played a role in the marked variation of CFQ-R score in this study, pulmonary exacerbations were not recorded and is a limitation of the study.

The instructor led questionnaires on perceived health in the week prior to a lesson, shown in Fig 3 show a significant improvement in reported symptoms over the course of the three months of intervention, with a slight plateau towards the eighth visit. The forms of Tai Chi chosen for the lessons in this study were directed specifically at the common symptoms of CF, including lung and abdominal, although it is not possible to define whether this improvement in reported symptoms in the Instructor Questionnaire is a result of Tai Chi. Participants may have become more comfortable with the teacher, although one would expect them to be able to then express their symptoms more if this were the case, or they may have improved by merit of participating in a clinical trial. However, increasingly there is evidence in both healthy individuals and those with different disease states to suggest that there are a wide variety of both physical and psychological benefits associated with practicing Tai Chi (25,26), some of which may have direct relevance to people with CF (27-29). In addition, it is now shown to be unlikely to result in any serious adverse events (30,31).

**5 Conclusions**

Cystic fibrosis is one of the commonest life limiting, genetic diseases in the United Kingdom. While survival has increased over the past three decades, cross infection and complex treatment demands have led to the need for innovative and flexible healthcare support. Tai Chi appears to be a popular

and useful method of offering an alternative method of exercise with benefits not previously considered, for example improvements in sleep, abdominal pain, and cough. Additionally, TC can be performed by individuals of varying ages, abilities and disease severity with little or no detriment to health.

This study has shown that it is feasible to follow complex instructions over the internet, in this instance using Tai Chi as the model. It can be successfully taught over the internet with no safety or tolerability issues when compared with TC taught face to face. There was some initial scepticism about learning TC over the internet from participants; however, the majority of those who took part were enthusiastic in their reporting. As CF care becomes more complex and the number of people with the disease (particularly of adults) increases over the next two decades, novel methods of care delivery such as innovative use of the internet and technology must be explored and introduced whenever possible or suitable.

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Figure 3.

Instructor Questionnaires

Trend graphs for self-reported symptom scores in the week prior to the 8 individual Tai Chi lessons (a-e). a. Trouble sleeping, b. Waking due to cough, c. Day time cough, d. Trouble breathing and e. Stomach hurting. Scale: (0 – never, 1= sometimes, 2=often, 3= always). f. Visual Analogue Scores.