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Tai Chi-Qigong improves physiological and psychosocial health in people with chronic obstructive pulmonary disease

Submission date	Recruitment status	[_] Prospectively registered
30/12/2011	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
06/01/2012	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
21/05/2015	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and aims
People with chronic obstructive pulmonary disease (COPD) have difficulties breathing due to the narrowing of their airways. Tai Chi Qigong is a form of Chinese meditative exercise. This study aims to find out about the benefits of a Tai Chi Qigong program on the health of COPD patients. We wish to determine if such exercises could help to improve their quality of life.

Who can participate?
COPD patients.

What does the study involve?
You will be randomly allocated to one of the three groups: the Tai Chi Qigong group, the exercise group or the routine activity group. If you are allocated to the Tai Chi Qigong group you will receive Tai Chi Qigong exercise training, which consists of two 60-minute sessions each week for 3 months.
If you are allocated to the exercise group, you will be taught the breathing techniques and the coordination of breathing and walking exercise. You are advised to perform outdoor walking daily for 3 months. If you are allocated to the routine activity group, you need to maintain your routine activities during the 3-month study period. You are expected to come to the general outpatient clinic at the beginning of study, at 6 weeks and at 3 months. You will need to answer two questionnaires and receive a physical check-up which includes a breathing test and a 6-minute walk test. You will receive a follow-up assessment at 6 months after the start of the study.

What are the possible benefits and risks of participating?
The findings from this study will allow healthcare professionals to better understand the effectiveness of Tai Chi Qigong in people with COPD. During the study your health will be very closely monitored. Both the exercise group and routine activity group will join free community activities weekly for 3 months. All participants will then be given a DVD at the end of study,

which teaches you the modified 13 forms of Tai Chi Qigong. Side effects arising from Tai Chi Qigong are rare. Normal reactions include breathlessness and tiredness, which are easily resolved by resting.

Where is the study run from?
The study takes place at five general outpatient clinics at Shatin district in the New Territories East cluster (Hong Kong).

When is the study starting and how long is it expected to run for?
From October 2008 to February 2010.

Who is funding the study?
This study is funded by the Health and Health Services Research Fund (HHSRF) from the Hong Kong government.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Tai Chi-Qigong improves physiological and psychosocial health in people with chronic obstructive pulmonary disease (COPD): a randomised controlled trial

Study objectives
Null hypothesis:
There are no significant differences in the change of lung functions, exercise tolerance, quality of life and perceived social support among the three study groups: Tai Chi-Qigong (TCQ), exercise and control groups, across a period of six months.

On 17/01/2012, the overall start date and end date were amended.
The pilot study was carried out from 27/02/2007 to 15/06/2007. The main study was carried out from 10/11/2007 to 29/08/2009.

On 22/02/2012 the following changes were made to this record:
1. The overall trial start date was changed from 27/02/2007 to 01/03/2008.
2. The overall trial end date was changed from 29/08/2009 to 28/02/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint The Chinese University of Hong Kong Clinical Research Ethics Committee, 18/10/2007 ref: CRE-2006.361

Study design
Single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
The subjects were randomly assigned to one of the three groups: TCQ, exercise, or control.

TCQ Group:
The subjects in the TCQ group completed the 60-minute TCQ practice sessions twice a week for three months. The TCQ intervention routine consisted of the 13 movements of TCQ. The TCQ class was led by a qualified TCQ master. Participants were required to coordinate their breathing with the prescribed movements, and were also advised to practice TCQ exercises for an hour everyday apart from the two TCQ sessions. In addition, DVD and TCQ pictures were given to each subject to facilitate daily self practice. A diary was also provided to the subjects to record the frequency of their self practice.

Exercise Group:
The subjects in the exercise group were taught pursed-lip breathing and diaphragmatic breathing techniques. They coordinated breathing with walking as their physical exercise. Return demonstrations of breathing techniques were performed to ensure proper practice. The subjects were advised to perform breathing and walking exercises for one hour everyday for three months. In addition, leaflets with pictures and instructions were provided to facilitate daily self practice. A diary was also given to the subjects to record the frequency of their self practice.

Control Group:
The subjects in the control group were advised to maintain their routine activities.

Intervention Type

Behavioural

Primary outcome(s)
1. Spirometry results
2. Six-minute walking distances (6MWD)
3. Responses to the St. George's respiratory questionnaire (SGRQ)
4. Scores on the multidimensional scale of perceived social support (MSPSS)

Key secondary outcome(s))
1. Number of exacerbations
2. Hospital admission
3. Borg scale for dysnoea and fatigue level
4. Saturation level of oxygen in hemoglobin (SaO2)

Completion date
28/02/2010

Eligibility

Key inclusion criteria
1. Subjects clinically diagnosed with COPD as defined by the American Thoracic Society (ATS)
1.1. Predicted post-bronchodilator Forced Expiratory Volume 1 (FEV1) of < 80%
1.2. FEV1/Forced Vital Capacity (FVC) ratio of < 70% (which does not change markedly over several months)
2. Subjects able to walk independently

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Subjects who had suffered from severe sensory or cognitive impairment
2. Subjects who had suffered from symptomatic ischemic heart disease
3. Subjects who had had practiced TCQ within a year prior to the commencement of the study

Date of first enrolment
01/03/2008

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
Hong Kong

Study participating centre
The Nethersole School of Nursing
New Territories
Hong Kong
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Sponsor information

Organisation
Health and Health Services Research Fund (Hong Kong)

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Government

Funder Name
The Health and Health Services Research Fund (Hong Kong) ref: 06070201

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration