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Seated and lying Tai Chi model for stroke patients

Submission date	Recruitment status	[_] Prospectively registered
25/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/09/2016	Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a serious, life-threatening medical condition that occurs when the blood supply to part of the brain is cut off. The injury to the brain caused by a stroke can lead to widespread and long-lasting problems. Tai chi is a health-promoting exercise that combines deep breathing and relaxation with slow and gentle movements. A seated and lying Tai Chi model has been developed that is easier for the elderly, people with disabilities, and especially for stroke patients. The aim of this study is to find out whether the easy Tai Chi exercise could improve stroke patients' mental condition, muscle power, and quality of life.

Who can participate?
Stroke patients aged 18 and over who have had disabilities of the limbs for longer than 6 months

What does the study involve?
Participants attend 12 practice sessions (90 minutes per session) led by a Tai Chi master and practice at home for 60 minutes per day for three months. The participants' mental condition, muscle power, and quality of life are assessed before practicing Tai Chi and after practicing Tai Chi for three months.

What are the possible benefits and risks of participating?
The participants may improve their mental condition, muscle power, and quality of life. Although Tai Chi is not a heavy exercise, the body is still moving during exercise. When the patients practice Tai Chi in a sitting position, the participants have to be in a better condition to move and keep balanced, or the patients could choose Tai Chi in a lying position.

Where is the study run from?
The study has been set up by the Department of Neurology, E-Da Hospital in collaboration with Kaohsiung Medical University and Chang Gung Memorial Hospital-Kaohsiung Medical Center (Taiwan)

When is the study starting and how long is it expected to run for?
October 2014 to June 2015

Who is funding the study?
E-Da Hospital (Taiwan)

Who is the main contact?
1. Dr Lian-Hui Lee (brucel-k@yahoo.com.tw)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EMRP17103N

Study information

Scientific Title
Development of a Direction-Oriented Motion and Short-Seated and Lying Tai Chi (DOM-SSLTC) model for stroke patients

Acronym
DOM-SSLTC Model for Stroke Patients

Study objectives
A Direction-Oriented Motion and Short-Seated and Lying Tai Chi (DOM-SSLTC) model can be performed easily, for stroke patients, and is helpful for their mental, muscle strengthening, and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the E-Da Hospital, 10/09/2014, ref: EMRP17103N

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Stroke

Interventions
18 stroke patients were recruited to perform the patient-based DOM-SSLTC model. The Direction-Oriented Motion and Short-Seated and Lying Tai Chi (DOM-SSLTC) model is composed of nine typical movements of the Yang-style Tai Chi form divided into Ma Bu and Gong Bu posture, and four motion directions (medial-lateral, forward-backward, rotation, and upward-downward) in sitting and lying positions. All patients received 12 practice sessions (90 minutes per session) led by a Tai Chi master to ensure a uniform technique and consistent experience and practiced at home for 60 min per day for three months.

Intervention Type
Behavioural

Primary outcome measure
Outcomes are measured before practicing Tai Chi (baseline) and after practicing Tai Chi for three months.
1. The National Institutes of Health Stroke Scale (NIHSS): a systematic assessment tool that provides a quantitative measure of stroke-related neurologic deficit, has 15 items, 3 to 5 grades with 0 is normal
2. Modified Ashworth Scale: evaluated muscle spasticity, from grade 0 (No increase in muscle tone) to grade 5 (Affected part(s) rigid in flexion or extension)
3. Modified Rankin Scale: commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of

neurological disability, The scale runs from 0-6, running from perfect health without symptoms to death
4. Barthel Index: the scoring point for the statement that most closely corresponds to the patient's current level of ability for each of the 10 activities of daily living
5. Psychology test with Taiwanese Depression Questionnaire: evaluated depression scale, a 4-point scale with 18 items, is a culturally specific depression self-rating instrument for effective screening of depression in Taiwan

Secondary outcome measures
Outcomes are measured before practicing Tai Chi (baseline) and after practicing Tai Chi for three months.
1. Muscle power of the trunk flexor muscles, assessed via sit-ups with knee bended and hand alternately touching the opposite bended knee.
2. Muscle power of the rectus femoris, assessed by the leg alternately stretched on sitting.
The repetitions of both motions were measured for one min with same height chair for leg test and lying with 10 cm hard mat as pillow with knee bending.

Overall study start date
15/10/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Disability status based on the modified Ranking scale 2-4 (mild-to-moderately severe disability)
3. Post-stroke disabilities of the limbs longer than 6 months
4. Cleared for major cardiac and respiratory medical diseases
5. No contraindications for doing Tai Chi exercises

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
18

Key exclusion criteria
1. Disability status on modified Ranking scale is 1
2. Cannot do the Tai Chi exercises

Date of first enrolment
15/10/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Taiwan

Study participating centre
E-Da Hospital
Kaohsiung
Taiwan
824

Sponsor information

Organisation
E-Da Hospital

Sponsor details
No.1, Yida Road
Jiaosu Village
Yanchao District
Kaohsiung
Taiwan
824

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00eh7f421

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/09/2016	22/09/2016	No	No