Official Title: The Effects of Simplified 10-step Tai-chi Programme on the Motor Performance and Fall Prevention of Community-dwelling Older People With Dementia: a Pilot Cluster Randomized Control Trial

Date of the document: 16 May 2016

Approved by the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University on 15-Jan-2016
Proxy Consent Form

CONSENT TO PARTICIPATE IN RESEARCH

The effects of a simplified 10-step Tai-chi programme on the motor performance and fall prevention of community-dwelling older people with dementia (PWD):
A pilot cluster RCT study
Principle Investigator: Dr Justina Yat Wa Liu
Co-Investigator: Prof. Claudia Kam Yuk Lai & Prof. Keith Hill

I ______________________ (elderly participant) and my caregiver ________________ hereby consent to participate in the captioned research conducted by Dr. Justina Liu Yat Wa.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any parts of the interview and/or conversation and can withdraw from the study at any time without penalty of any kind.

________________________________________  ______________________________
Name of participant                  Signature of participant

________________________________________  ______________________________
Name of caregiver                    Signature of caregiver

________________________________________  ______________________________
Signature of researcher              Date
The effects of a simplified 10-step Tai-chi programme on the motor performance and fall prevention of community-dwelling older people with dementia (PWD): A pilot cluster RCT study

Principle Investigator: Dr Justina Yat Wa Liu
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The purpose of the study
The study is conducted under the supervision of Dr Justina Liu of the School of Nursing, The Hong Kong Polytechnic University. The study aims to find out the effect a 16-week simplified 10-step Tai-chi programme in enhancing the motor performance and reducing fall risks among community-dwelling older people with dementia.

About the Project
Participants will be randomized into either the Tai-chi group or the control group after they and their caregivers have been screened for eligibility. The Tai-chi group will receive the 16-week simplified 10-step Tai-chi programme and home practice sessions. An experienced Tai-chi instructor will conduct the Tai-chi sessions twice weekly (an hour per session) where each session includes 5 minutes of warm up and cool down exercise. Each week, participants are encouraged to have three 30-minute home practice sessions. During the programme, two workshops will be offered to the caregivers during which the aim and their roles in the programme (e.g. being a supportive exercise partner during the Tai-chi sessions and home practice sessions and help log their fall incidence and home practice) will be informed and positive emotional motivation techniques will also be taught. The control group will only take part in group recreational activities.

The research team will collect data for assessments two weeks before the programme begins, midway through the study (week 8), and after the completion of the programme (week 16). The assessments include timed up and go test, sit to stand test, functional reach test and step test to evaluate the effect of the 10-step Tai-chi programme on mobility enhancement and fall risks prevention among PWD. Besides, feedback from the participants (caregivers) will be collected through group interviews within two weeks after completion of the programme. In addition, a HK$100 coupon will be given to the participants in the control groups who have completed all assessments in 3 different time slots so as to thank for their supports and contributions to the study.
To better assess the learning progress and participation of older people with dementia, photographs and videos will be taken during the sessions. All the data from the video tapings and will be used for research purpose and scholarly writing and kept confidential. There will be no penalty to you if you decide to withdraw from the study.

There may be risks of falling during Tai-chi practice. Therefore, participants will receive instructions regarding exercise safety, safety checklist for home exercise, ways to deal with fall accidents during the training and at home. Besides, there will be students from the School of Nursing and research assistant monitor your safety during the training sessions in order to reduce your fall risks.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss Cherrie Mok, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in writing (c/o Research Office of the University) stating clearly the responsible person and department of this study.

If you would like to know more details of this study, please contact Ms Wong at 2766-6759 or Dr Justina Liu at 2766-4097.

Thank you for your interest in participating in this study. It is hoped that this study would contribute to the understanding of improving the physical conditions among older people with dementia.

Dr. Justina Liu Yat Wa

Principal Investigator
Guidelines for Exercise Safety and Fall Management in Elderly

The effects of a simplified 10-step Tai-chi programme on the motor performance and fall prevention of community-dwelling older people with dementia (PWD): A pilot cluster RCT study

Guidelines for Exercise Safety

For the elderly, attention to exercise safety is important to avoid accidents.

Before exercise:

1. Do not exercise on an empty stomach or just after a big meal.
2. Wear comfortable clothing, socks and shoes. Wear correct size and non-slippery, shock-absorbing shoes. Bring some water with you.
3. Avoid exercise in extreme weather.
4. Remember to have 5 to 10 minutes warm up and stretching exercise before starting.
5. Do not forget to repeat the cool down and stretching after exercise.

Exercise Precautions

1. Choose appropriate exercise according to your ability and interest. Never exceed your limit. Remember that it is NOT the harder the better.
2. If you have acute medical problem (such as fever, or pain), stop exercising.
3. If you have chronic medical condition (such as hypertension, diabetes mellitus, ischaemic heart disease and arthritis), it is better to seek advice from your doctor or physiotherapist beforehand.
4. If there is dizziness, fainting, shortness of breath, chest pain, vomiting, nausea and severe pain during exercise, stop exercising and seek medical advice as soon as possible.
5. For prolonged exercise like hiking, drink water from time to time to supplement the loss of body fluid due to sweating. Do not wait until you are thirsty. Take appropriate breaks during exercise. Do not over-exert yourself.
6. Keep up with the exercise! At least 3 times per week, 20-30 minutes or more each time so as to derive the maximum benefit.
7. Exercise with friends. Company provides enjoyment, mutual encouragement and support.

Proper management of injuries

1. When there is an accident like sprain or injury, stop exercising right away to prevent any further damage.
2. Keep calm and rest in a safe place.
3. If there is muscle cramp, you can stretch the muscle gently and gently massage it, but do not bounce or stretch it too forcefully.
4. The proper treatment for sprain is RICE, R (rest the injured part), I (ice-pack application), C (compression by applying an elastic bandage), and E (elevate the swollen parts). Do not massage as it would make it worse.
5. Extreme pain, rapid swelling, severe bruising, decreased range of movement or deformity may be signs of fracture, seek help from a doctor immediately.

Dealing with falls during class

If an elderly person has a fall accident, his/her family or caregiver should:

1. Immediately report to the researcher, class instructor or centre-in-charge.
2. If the person is conscious and has visible wound(s), the researcher will administer first aid treatment promptly (e.g. wound dressing) and contact his/her family or caregivers. If necessary, the participant will be sent to hospital for further treatment.
3. If the participant is conscious but without any visible wounds, he/she will be asked to sit down and rest for a while and may join the class later. The researcher will contact his/her family or caregiver.
4. If the participant is conscious and show no visible wound(s) but reports injuries (e.g. feel painful and swollen), the researcher will administer immediate first aid treatment (e.g. apply ice on the injured part) and contacts his/her family or caregiver.
5. If the person becomes unconscious, the researcher will start cardiopulmonary resuscitation and send him/her to hospital for treatment promptly. The research will contact his/her family or caregiver.
6. After the fall incidence, the researcher will follow up on that by phone.

Dealing with falls at home

Elders should assess the risk of falls, no matter they have experienced falls or not. Once slip and fall, elders should take appropriate steps to help themselves as follows:

1. Keep clam
2. Assess the level of injury, move slowly if not severe
3. Move along the ground to walls or stable furniture, then climb up with the support of furniture
4. If you cannot stand up, you may make a call by using the Personal Emergency Link Service, open the main door and ask for help loudly
5. Clean the wound first if you get an abrasion
6. Consult a doctor quickly if you note any problems. You may have fracture if you have difficulty in moving or in severe pain, even without obvious wound.
7. If the elders become unconscious, the caregiver should call the ambulance and report the details of the fall to relevant officer.
8. Any accidental falls should report to the researcher, who will follow up on that by phone.

Reference:
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Home Safety Checklist before Exercise

- Keep floors clutter-free
- Keep the floor dry
- Flat and safe floor surface
- Remove tripping hazards such as rugs
- Good lighting in buildings
- Remove furniture with sharp edges/ Place padding on any of the sharp edges of furniture

Reference: