

Official Title: Evaluation of an individualized exercise programme plus behavioural change enhancement strategies for managing general fatigue in community dwelling frail older people: A cluster-randomized controlled trial

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

Consent form



THE HONG KONG
POLYTECHNIC UNIVERSITY

香港理工大學

SCHOOL OF NURSING
護理學院



**CONSENT TO PARTICIPATE IN RESEARCH
(Participant)**

**Evaluation of an individualized exercise programme plus behavioural change enhancement
strategies for managing general fatigue in community dwelling frail older people:**

A cluster-randomized controlled trial

Principal Investigator: Dr. Justina Yat Wa Liu

Co-Investigator: Prof. Wai Tong Chien, Dr. Parco Ming Fai Siu & Prof. Keith Hill

I _____ hereby consent to participate in the captioned research conducted by Dr. Justina Yat Wa Liu.

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 to me. I understand the benefits and risks involved. My participation in the project is voluntary.

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

Participant:

Name of Participant/

Signature

Date

Researcher:

INFORMATION SHEET

Evaluation of an individualised exercise programme plus behavioural change enhancement strategies for managing general fatigue in community dwelling frail older people: A cluster-randomized controlled trial

Principal Investigator: Dr. Justina Yat Wa Liu

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We would like to invite you to take part in this research project. It aims to investigate the effects of an individualised exercise programme combined with behavioural change enhancement (BCE) strategies on managing general fatigue in community dwelling frail older people.

If you decide to be in this study, your health-socio-demographic data will be obtained for research purpose. Each participating centre will be randomized to one of the three study groups: the combined group, receiving the 16-week combined intervention consisting of individualized exercise training and BCE programmes; the exercise group, receiving 16-week intervention consisting of exercise training and health talks; or the control group, receiving health talks only. Participants from each centre will be placed in their centre's corresponding group

After the completion of the 16-week programme, the participants of the combined group will receive two booster sessions and the participants of the exercise group and the control group will receive two health talks, which will be held at 2 and 6 months after the programme.

The researcher will conduct face-to-face interviews and assessments before the programme begins, at week 8, 1 week, 6 and 12 months after the programme. The assessments include socio-demographics, levels of fatigue, physical endurance, exercise self-efficacy, subjective and objective physical activity levels and self-efficacy for exercise scale, exercise diary, levels of frailty and mood.

You have the right to withdraw from the study at any time without being discriminated against, treated inhumanely and disrespectfully or penalised. All information will be kept strictly confidential and only the research team will have access to the information. The collected data may be used for future studies, education and academic purposes. During the study, possible side effects such as mild

exercise-induced muscle tiredness may arise. If you feel any discomfort or muscle tiredness during the exercise programme, you have the right to suspend the study immediately and decide whether or not to receive further treatment depending on the circumstances.

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 Dr Justina Liu at 2766-4097.

Thank you for your participation and your contribution in improving the care service for elderly.

Dr. Justina Yat Wa Liu

Principal Investigator