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Training Grandma/pa against frailty

Submission date 20/07/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/07/2021	**Overall study status** Completed	
Last Edited 22/12/2021	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Frailty is a major problem affecting older people's health. It is associated with disability, hospitalization, nursing home admission, and death. A frail or pre-frail state is common among older people in Hong Kong. Yet, intervention is possible – inexpensive, with proven effectiveness, and no unpleasant adverse effects – simply by exercising.
The goals of GrandMove (GM) is to develop a feasible and sustainable model to address the issue of frailty in the rapidly ageing society of Hong Kong by increasing physical fitness of older people through resistance and aerobic exercises to prevent or improve frailty (exercise intervention); and by promoting lifestyle change for older people to adopt resistance and aerobic exercises as their regular exercise routine through applying the principle of social learning theory (lifestyle intervention). The GM intervention was developed based on psychological principles in health behavior and habit formation, current evidence in geriatric medicine, and theories in social gerontology to keep our older population active and robust. The project aims to generate evidence of the effectiveness of the aerobic and resistance training protocol in preventing and intervening in frailty among Hong Kong Chinese, and to generate evidence of behavioral change and habit formation through a model that combine social gerontological theories and psychological principle of social learning theory.

Who can participate?
To be eligible for the GM Training Programme, older adults had to be screened as frail or pre-frail using the 5-item FRAIL scale and to have a sedentary lifestyle (<20 mins/week of structured physical activity in the month before the assessment).

What does the study involve?
Participants are invited to take part in the GM Training Programme, an 18-month progressive exercise intervention comprising 3 phases: 6 months of aerobic training, 6 months of resistance training, as well as 6 months of lifestyle education. Participants will receive small group exercise practice, supervised home practice, and phone calls to help reinforce exercise routine. They will undergo these training phases in a random sequence. Each group or home exercise session lasts for 45 minutes and will be held between January 2016 and October 2017. In addition, their frailty level, physical performance and quality of life will be measured at four time points: before the programme, at 6 months, 12 months, and 18 months. Each assessment lasts for about an hour.

What are the possible benefits and risks of participating?
Participants will be taught by trained coaches exercises that have been shown to be beneficial for frailty, and receive advice on healthy lifestyle, which may help exercise regularly and improve health. However, they may also experience mild fatigue or physical discomfort during the exercise but they could feel free to take short breaks. If health events take place, participants may suspend or withdraw from the programme at any time.

Where is the study run from?
The Sau Po Centre on Ageing (COA) of The University of Hong Kong (HKU)

When is the study starting and how long is it expected to run for?
July 2015 to June 2018

Who is funding the study?
Simon K.Y. Lee Foundation's Elderly Fund (Hong Kong)

Who is the main contact?
Prof. Terry Lum, tlum@hku.hk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
EA1511048 (HKUCTR)

Study information

Scientific Title
Training Grandma/pa - Promote Robustness against Frailty – Healthy Ageing x Productive Ageing Project

Acronym
GrandMove

Study objectives
Frail and pre-frail elders undergoing the physical exercise programmes will improve in frailty level, physical performance, and quality of life as compared with frail and pre-frail elders undergoing lifestyle education.
Exercising and healthy lifestyle habit developed through a 6-month coaching programme is sustained at 12 months after the active intervention period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/12/2015, Human Research Ethics Committee (HREC), The University of Hong Kong (Research Services, The Registry, The University of Hong Kong, 9th Floor, Knowles Building, Pokfulam, Hong Kong; +852 2241 5267; rssdata@hku.hk), ref: EA1511048

Study design
Single-blind multicenter randomized controlled trial with three intervention arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Exercise training program (including aerobic exercise, resistance exercise and healthy lifestyle education) in prefrail and frail elders with different training sequence

Interventions
There are three arms for the intervention. They are aerobic exercise, resistance exercise, and healthy lifestyle education.

Protocols for aerobic exercise and resistance exercise are designed by the Active Health Clinic of the HKU Institute of Human Performance and tailored for older adults in Hong Kong. Aerobic exercise protocol focuses on stimulating the cardiorespiratory system, while resistance exercise protocol concentrates on the adaptation of the musculoskeletal system. Both protocols are designed to be 'home-friendly', such that they work in small spaces, demand very small training objects – thus can be implemented in a home surrounding and community centre settings. They are also safe – thus elders can perform training exercises easily with low risk, but high potential for improvement.

The exercise programmes incorporate a 5-tier system whereby an elder who reaches a certain standard of fitness and strength is given a ranking. This is to stimulate continued exercise progress and motivate the elderly person to exercise. Thus, each protocol will have five levels, which indicate different levels of intensity and fitness. Depending on their physical capacity, elders can enter the programme at different levels based on the initial assessment. Elders can then progress to advanced levels if they successfully complete promotional assessments. The promotional assessment day will be held by HKU Sau Po Center on Ageing.

Over the three 6-month periods, elderly trainees will receive allocated training in small group format (10 elders per group) plus supervised home practice and/or phone calls to reinforce the new lifestyle. Each 6-month intervention period is designed as follows:

• 1st month: group practice (1/week), home visit (2/week)
• 2nd month: group practice (1/week), home visit (1/week), phone call (1/week)
• 3rd month: group practice (1/week), phone calls (2/week)
• 4th month: phone calls (2/week)
• 5th month: phone calls (1/week)
• 6th month: self-sustaining period

Each group or home session will last for 45 minutes. The schedule is designed to provide active coaching and intervention (with decreasing input from the coach) in the first 3 months, monitoring and supervision in the 4th and 5th months, and weaning for self-sustained behaviour in the 6th month. During the group exercise session, the coach will deliver a group exercise that can specifically challenge each individual regardless of his/her level.
In the healthy lifestyle education condition, group sessions are health talks in a small group format to cover topics such as nutrition, sleep, and exercising; phone calls in the lifestyle education involve health behaviour and environment checking and individual advice.

Intervention Type
Behavioural

Primary outcome measure
Measured at baseline, T1 (6 months), T2 (12 months), and T3 (18 months):
1. Frailty score is measured by the FRAIL scale (Morley et al, 2012) and 32-item Frailty Index (Kwan JSK et al, 2015)
2. Physical performance is measured by Short Physical Performance Battery (SPPB) (Guralnik et

al, 1994), 30-second bicep curl, and 2-minute step test
3. Quality of life is measured by the World Health Organization Quality of Life Instrument – Older Adults Module (WHOQoL-OLD)

Secondary outcome measures
Measured at baseline, T1 (6 months), T2 (12 months), and T3 (18 months):
1. Other physical performance measures (e.g., isometric handgrip strength)
2. Cardiorespiratory function (e.g., blood pressure, heart rate)
3. Social functioning as measured using the Lubben Social Network Scale
4. Cognitive performance
5. Mood as measured using the Patient Health Questionnaire (PHQ-9)
6. Sleep quality as measured using the Pittsburgh Sleep Quality Index (PSQI)
7. Nutrition as measured using the Mini Nutritional Assessment Short Form (MNA-SF)
8. Mobility as measured using the LifeSpace Questionnaire
9. Activities of daily living (ADL) as measured using the Modified Barthel Index (MBI)
10. Instrumental Activities of daily living (IADL) as measured using the Lawton IADL scale
11. Health literacy as measured using the Chinese Health Literacy Scale for Chronic Care (CHLCC)
12. Physical exercise level as measured using the Physical Activity Scale for the Elderly (PASE)
13. Falls
14. Body mass index (BMI)
15. Bioelectrical impedance analysis (BIA)
16. Utilization of healthcare resources

Overall study start date
01/07/2015

Completion date
30/06/2018

Eligibility

Key inclusion criteria
1. Age 65 years or above
2. Screened as frail or prefrail defined using cutoff scores of the 5-item FRAIL scale
3. Living in the community and planning to reside in the area for the duration of the study
4. Give informed consent to participate in the randomized controlled trial

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
Target number of participants: 390 (150 frail and 240 prefrail)

Total final enrolment

390

Key exclusion criteria
1. Have severe heart failure, uncontrolled angina, severe pulmonary disease, or end-stage disease with a life expectancy of less than 18 months;
2. Have been diagnosed as having dementia or falling below the suggested dementia screening cutoff using the clock-face test (Lam et al, 1998).
3. Has another member of the household as a participant in this study;
4. Has difficulty in communication with study personnel due to speech or hearing problems;
5. Has other medical, psychiatric, or behavioural factors that in the judgment of the PI may interfere with study participation or the ability to follow the intervention protocol.
6. Have had stroke, hip fracture, myocardial infarction, major heart surgery, deep vein thrombosis, pulmonary embolus, spinal surgery, or hip or knee replacement within the previous 6 months;
7. Is currently prescribed activity limitation or weight-bearing limitation by a formal healthcare professional;
8. Limited physical activity due to chest pain or dyspnoea without definitive treatment by a healthcare provider;
9. Currently consume more than 14 alcoholic drinks per week;
10. Is currently enrolling in another randomized trial involving lifestyle or pharmaceutical interventions

Date of first enrolment
01/01/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
Hong Kong

Study participating centre
Fong Wong Wun Tei Neighbourhood Elderly Centre
Hong Kong
Hong Kong
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Sponsor information

Organisation
University of Hong Kong

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Funder(s)

Funder type
Charity

Funder Name
Simon K.Y. Lee Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact journal.

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Yat Sang Terry, LUM (tlum@hku.hk) after the trial registration with data anonymisation.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		17/11/2015	21/07/2021	No	Yes
Protocol file			21/07/2021	No	No