Official Title: Effects of an Individualized Dietary Behavioural Change (IDBC) Programme and Exercise Training in combination or separately on managing sarcopenic obesity in community-dwelling older adults: A Randomized Controlled Trial

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# INFORMATION SHEET

## Effects of an Individualized Dietary Behavioural Change (IDBC) Programme and Exercise Training in combination or separately on managing sarcopenic obesity in community-dwelling older adults: A Randomized Controlled Trial

Principal Investigator: Dr. Justina Yat-Wa Liu
（School of Nursing, The Hong Kong Polytechnic University）

We would like to invite you to take part in a research project conducted by Dr. Justina Yat Wa Liu, Associate Professor from the School of Nursing, The Hong Kong Polytechnic University and her team. This project aims to evaluate the effects of an IDBC intervention and exercise training in combination and separately for older adults with sarcopenic obesity.

After participating in the research project, you will undergo a screening process conducted by researchers for eligibility checking. Your information will be collected for research purposes. Eligibility to take part in the study will be decided based on the following criteria:

**Inclusion criteria**

- Community-dwelling older people aged > 65 years;
- Meeting the diagnostic criteria of sarcopenic obesity according to the Asian Sarcopenia Working Group (ASWG) and the WHO definition of obesity for the Asian population respectively:
  - Early-stage sarcopenia refers to the fulfillment of one of the following criteria: low handgrip strength < 28 kg for men and < 18 kg for women, low muscle quality as reflected by low appendicular skeletal muscle mass (ASM) /height squared < 7 kg/$m^2$ for men and <5.7 kg/$m^2$ for women, or low physical performance with a Short Physical Performance Battery (SPPB) score of < 9;
  - Obesity refers to the fulfillment of one of the following criteria: Body Mass Index (BMI) ≥ 25kg/$m^2$ or waist circumference ≥ 90 cm in men and ≥ 80 cm in women, or percentage of body fat > 30%.
- Able to communicate, read, and write in Chinese without significant hearing and vision problems to ensure that our instructions are understood.

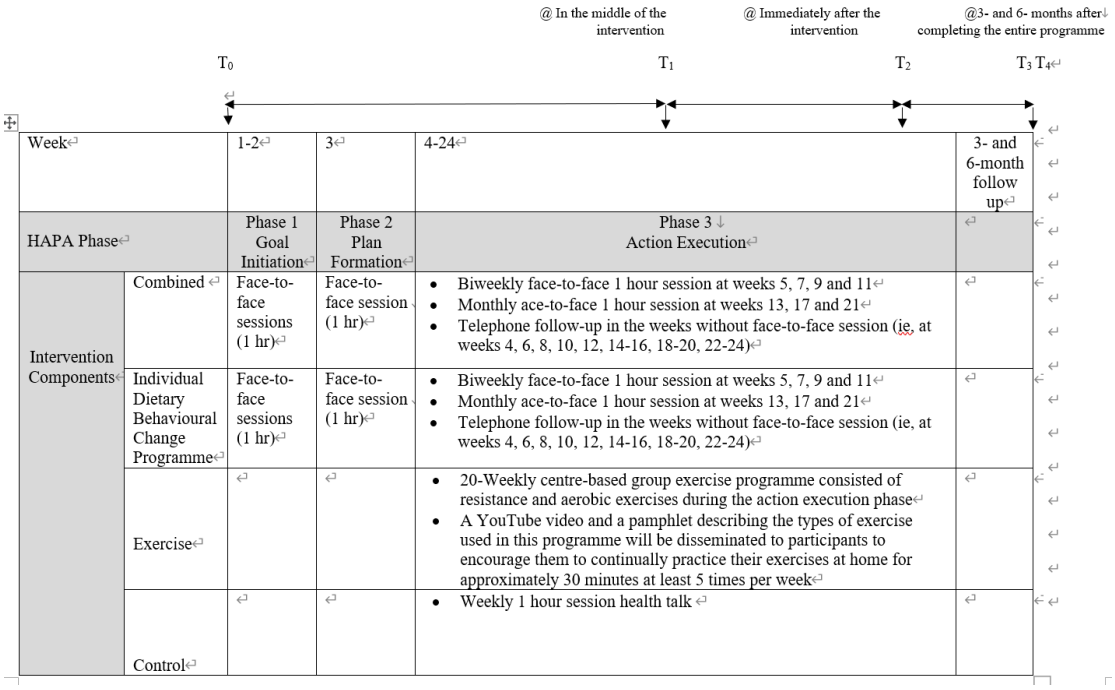
**Exclusion criteria**

- With any form of disease or condition that might affect food intake and digestion

(such as severe heart or lung diseases, renal diseases, diabetes, cancer, or autoimmune diseases);

- Taking medications that may influence eating behaviour, digestion, or metabolism (such as weight loss medication)
- Being addicted to alcohol, which might affect the effort to change dietary behaviour;
- Having impaired mobility, which might affect participation in exercise training, as defined by a modified Functional Ambulatory Classification score of < 7;
- Having renal impairment, based on the renal function blood test which will be screened by a geriatrician
- Having any medical implant device such as a pacemaker, because low-level currents will flow through the body when doing the bioelectric impedance analysis (BIA by InBody 270, Korea), which may cause the device to malfunction.

You will be randomized to the combination group, IDBC group, exercise training group or control group. The combination group and IDBC group will receive a 24-week intervention consisting of 1 hour per session for a total of 10 sessions of nutritional consultation either face-to-face or by telephone interview. Participants will attend a 1-hour nutrition consultation within 1-2 weeks of the start of the programme and another 1-hour nutrition consultation in week 3. The remaining 8 sessions of nutrition consultations will be completed during week 4-24 of the programme. Only participants in the combination group will be scheduled to receive the exercise training in 20 weeks with 1 hour per week after week 4. Participants in the exercise training group will be given the same exercise training as the combination group. Participants will also be required to do 30 minutes of exercise training at home for at least 5 days a week. Participants in the IDBC group and the control group will be arranged to receive health talks. The number and time for the sessions will be matched with exercise training. The Control Group will not receive any nutrition consultations. You may refer to the following diagrams for each study group:




| Week | | 1-2 | 3 | 4-24 | 3- and 6-month follow up |
|---|---|---|---|---|---|
| HAPA Phase | | Phase 1 Goal Initiation | Phase 2 Plan Formation | Phase 3 ↓ Action Execution | |
| Intervention Components | Combined | Face-to-face sessions (1 hr) | Face-to-face session (1 hr) | • Biweekly face-to-face 1 hour session at weeks 5, 7, 9 and 11<br>• Monthly ace-to-face 1 hour session at weeks 13, 17 and 21<br>• Telephone follow-up in the weeks without face-to-face session (ie, at weeks 4, 6, 8, 10, 12, 14-16, 18-20, 22-24) | |
| | Individual Dietary Behavioural Change Programme | Face-to-face sessions (1 hr) | Face-to-face session (1 hr) | • Biweekly face-to-face 1 hour session at weeks 5, 7, 9 and 11<br>• Monthly ace-to-face 1 hour session at weeks 13, 17 and 21<br>• Telephone follow-up in the weeks without face-to-face session (ie, at weeks 4, 6, 8, 10, 12, 14-16, 18-20, 22-24) | |
| | Exercise | | | • 20-Weekly centre-based group exercise programme consisted of resistance and aerobic exercises during the action execution phase<br>• A YouTube video and a pamphlet describing the types of exercise used in this programme will be disseminated to participants to encourage them to continually practice their exercises at home for approximately 30 minutes at least 5 times per week | |
| | Control | | | • Weekly 1 hour session health talk | |

Researchers will conduct a face-to-face interview and assessment at baseline (T0), in the middle of the intervention (T1), immediately post-intervention (T2),3 months (T3) and 6 months (T4) after the programme. The assessments include socio-demographic and health-related data, upper limb strength, appendicular skeletal muscle mass (ASM / height$^2$), Short Physical Performance Battery (SPPB), Body Mass Index (BMI), waist circumference, percentage of body fat, HAPA Nutritional Self-efficacy Scale, Dietary Quality International-Index (DQI-I), Mini Nutritional Assessment scale (MNA), diet adherence and exercise adherence. These assessments will be used to evaluate the effectiveness of IDBC and exercise training. Each interview and assessment lasts for approximately 1 hour.

There are possible risks from this study such as fatigue induced by exercise and uncommon mild gastrointestinal discomfort. If you have any discomfort or muscle fatigue during exercise training or nutrition consultation, you have the right to suspend your participation in this study immediately and decide whether to receive possible treatment as appropriate.

You have the right to withdraw from the study at any time without being discriminated against, treated inhumanely or disrespectfully, or penalized. All information will be kept strictly confidential and only Dr. Justina Yat-Wa Liu and delegated researchers will have access to the information. Your name will be coded and only delegated researchers will be able to identify the code. All information collected will be kept for 7 years until 2030. The collected data may be used for future studies and for educational and academic purposes. If you would like to know more

about this study, please contact Dr. Justina Yat-Wa Liu at 27664097 or via justina.liu@polyu.edu.hk. 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, at 27666378 or via institutional.review.board@polyu.edu.hk.

Thank you for your participation.

Dr. Justina Yat-Wa Liu
Principal Investigator
School of Nursing
The Hong Kong Polytechnic University

**CONSENT TO PARTICIPATE IN RESEARCH**

**(Participant)**

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I _____ (Participant's name) hereby consent to participate in the captioned research conducted by Dr. Justina Yat-Wa Liu.

I understand that the 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 part of the project and/or conversation and can withdraw from the study at any time without penalty of any kind.

| | |
|---|---|
| _____ | _____ |
| Signature of Participant | Signature of Researcher |
| _____ | _____ |
| Name of Participant | Name of Researcher |
| _____ | _____ |
| Date of Signature | Date of Signature |