Official Title: Effects of the EatWelLog App on Enhancing Daily Diet Management for Community-dwelling Older Adults with Sarcopenic Obesity:

A Pilot Randomised Controlled Trial

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INFORMATION SHEET

Effects of the EatWelLog App on Enhancing Daily Diet Management for Community-dwelling Older Adults with Sarcopenic Obesity: A Pilot Randomised 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 effectiveness of the EatWelLog App on enhancing daily diet management for community-dwelling 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 sarcopenia according to the Asian Sarcopenia Working Group (ASWG):
  - 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; and
- Own a smartphone, and able to access the internet at home or elsewhere.

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);
- With alcohol use disorder as defined by DSM-5, potentially hindering dietary behaviour changes; and
- 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 S10, Korea), which may cause the device to malfunction.

You will be randomized to either the **experimental group** or the **control group** based on the screening results. Both the **experimental** and **control groups** will receive a 8-week, group-based, face-to-face supervision sessions conducted by a dietician and an exercise coach. Participants will attend 2 times of an hourly nutritional consultation in Weeks 1-2, 1 hour nutritional consultation in Week 3, and the remaining

5 sessions of nutritional consultation will be completed during Weeks 4-8. Meanwhile, both the **experimental** and **control groups** will receive a weekly, 1-hour physical training. Participants will also be required to do 30 minutes of exercise training at home for at least 5 days a week.

In addition to that, only the **experimental group** will be instructed on how to use the EatWellLog app to enhance their daily diet management. Participants will be required to fill in the dietary record in the app on a daily basis to understand the nutritional information of the food they eat, thereby knowing whether their diet is appropriate, whether they have absorbed enough protein and appropriate amount of calories. These data will be collected and analyzed, and the EatWellLog app will provide relevant recommendations to enhance participants' engagement. Participants will also be encouraged to watch educational animations and play video games in the app to understand more about sarcopenic obesity, and how to choose heathly food wisely. Family members of participants will be able to review participants' dietary record and nutritional information in the app, and when necessary, they can leave messages to the participants for reminders. You may refer to the following diagram for each study group:

<table>
<tr><th colspan="2">Week</th><th>1-2</th><th>3</th><th>4-8</th><th>3- and 6-month follow-up</th></tr>
<tr><td colspan="2">Study Phase</td><td>Phase 1 Goal Initiation</td><td>Phase 2 Plan Formulation</td><td>Phase 3 Action Execution</td><td></td></tr>
<tr><td rowspan="3">Intervention Components</td><td rowspan="3">Experimental Group</td><td>2 sessions of individual face-to-face nutritional consultation (2 hours in total)</td><td>Individual face-to-face nutritional consultation (1 hour)</td><td>Weekly individual face-to-face nutritional consultation at weeks 4, 5, 6, 7, and 8 (5 hours in total)</td><td rowspan="3"></td></tr>
<tr><td colspan="3">• 8 weekly sessions of a center-based group exercise programme consisting of resistance and aerobic exercises (8 hours in total).
• A YouTube video and a pamphlet describing the types of exercises used in this programme will be disseminated to the participants to encourage them to continually self-practice at home for approximately 30 minutes at least 5 times per week.</td></tr>
<tr><td colspan="3">• Participants will be instructed to use the EatWellLog app for diet self-management on daily basis.
• The EatWellLog app enables participants to monitor their dietary habits by logging meals and snacks from a food list, receive automated feedback on their diet adherence, obtain health information on managing sarcopenic obesity, and learn how to make healthy food choices through video game.</td></tr>
<tr><td></td><td>Control Group</td><td>2 sessions of individual face-to-face nutritional</td><td>Individual face-to-face nutritional</td><td>Weekly individual face-to-face nutritional consultation at</td><td></td></tr>
</table>

		consultation (2 hours in total)		consultation (1 hour)	weeks 4, 5, 6, 7, and 8 (5 hours in total)		
		• 8 weekly sessions of a center-based group exercise programme consisting of resistance and aerobic exercises (8 hours in total). • A YouTube video and a pamphlet describing the types of exercises used in this programme will be disseminated to the participants to encourage them to continually self-practice at home for approximately 30 minutes at least 5 times per week.					
Focus group interview and assessment		Baseline (T_0)				2nd assessment (T_1)	3rd and 4th assessments (T_2 & T_3)

Researchers will conduct assessments at baseline (T0) and immediately after the completion of the 8-week supervised sessions (T1). To explore the possible long-term effects of the intervention, assessments will also be conducted at 3 months (T2) and 6 months (T3) after the supervised program, which will be compared with those conducted at T0. 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, the Nutritional Self-efficacy Scale, the Dietary Quality International-Index (DQI-I), the Mini Nutritional Assessment scale (MNA), the 3-day self-reported dietary record for dietary adherence, the EuroQoL 5D (EQ-5D) for health-related quality of life, and data on app users experience based on the Technology Acceptance Model (TAM). Researchers will also collect and analyze the app usage, including app usuage duration, frequency, feature utilization, and retrention rates during the entire data collection period from T0 to T3. In addition to that, researchers will conduct interviews with all participants in the experimental group at 3 months (T2) after the supervised program. The interview will be group-based, with 6-8 participants in each group. All outcome measurements and qualitative data collected will be used to evaluate the effectiveness of the EatWellLog App on enhancing daily diet management for community-dwelling older adults with sarcopenic obesity. Each interview and assessment lasts for approximately 1 hour.

No major risks will be involved throughout the program. Possible minimal risk that may arise from the project is muscle fatigue during exercise training and uncommon mild gastrointestinal discomfort for the experimental group. Exercise precautions and safety guidelines will be provided to participants and they are advised to follow before doing physical activity training. Nutrition consultation will also be arranged for the participants if they have any gastrointestinal discomfort. In case of any problems or emergency, you have the right to suspend your participation in this study immediately and decide whether to receive possible treatment as appropriate.

In case of serious adverse events (SAE) during participation of the research study, which means any adverse event that:

- Results in dealth;
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred;
- Requires or prolongs hospitalization;
- Causes persistent or significant disability or incapacity;

- Results in congenital anomalies or birth defects;
- Is another condition which investigators judge to represent significant hazards

you are advised to immediately notify the Principal Investigator Dr. Justina Yat-Wa Liu at 2766-4097 or via justina.liu@polyu.edu.hk about the situation(s).

You have the right to withdraw from the study at any time without being discriminated against, treated inhumanely or disrespectfully, or penalized. You also have the right to request access to and correction of the personal data supplied for this study. 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 2031. 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. If you have any complaints about the conduct of this research study, please do not hesitate to contact The Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University at 2766-6378 or via institutional.review.board@polyu.edu.hk / address: Research and Innovation Office, The Hong Kong Polytechnic University.

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 request access to and correction of the personal data supplied for this research.

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