Official Title: Effectiveness of a dyadic e-Health System on enhancing healthy lifestyles of older adults with sarcopenia: A Randomized Controlled Trial

Date of document: 12th October 2023

Approved by the Human Subjects Ethics Sub-committee of
The Hong Kong Polytechnic University on 10th October 2023

Identifier: NCT06088511

INFORMATION SHEET

Effectiveness of a dyadic e-Health System on enhancing healthy lifestyles of older adults with sarcopenia: 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 effectiveness of a e-Health System delivered in a dyadic approach to encourage older adults with sarcopenia to maintain healthy lifestyles.

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 ≥ 60 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;
- Able to communicate, read, and write in Chinese without significant hearing and vision problems to ensure that our instructions are understood;
- Own a smartphone, and able to access the internet at home or elsewhere;
- Reside with family and have at least one daily shared meal (family is defined as an individual who has a significant personal relationship with the participant, such as next of kin, spouse and the individual must be at aged > 18); and
- Able to identify a family member who has a smartphone and is willing to support the participant to use the e-Health System.

Exclusion criteria

- With any form of disease or condition that might affect food intake and digestion (such as severe heart or lung diseases, diabetes, cancer, or autoimmune diseases);
- Currently suffering from acute gouty arthritis or had a gout attack in the past year;
- 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 depressive symptomatology, defined by a Geriatric Depression Scale score of > 8;
- Suffering from dementia (i.e., MoCA<20 or clinical dementia rating ≥1);
- 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. The experimental group will receive a 12-week intervention consisting of a 4-week, group-based, face-to-face supervised sessions conducted by a dietician, plus an 8-week self-management phase. Each supervised session will last for an hour. The features of the e-Health System will be introduced to the participants and their family members in the first two face-to-face sessions. They will then be able to start using the System with the mobile app. In the other two sessions, all participants in the experimental group will learn how to accurately complete their dietary records in the e-Health System and will be provided with nutritional advice.

For the 8-week self-management phase, the participants will be recommended to follow the lifestyle interventions to relieve their problems related to sarcopenia. The participants are required to fill in their dietary record in the e-Health System every day, and will be provided with nutritional advice to improve high-quality protein and leucine intake, which is essential for muscle building. The participants will be also suggested to continually practise exercise training at home for 30 minutes at least 5 times per week. Participants can review the self-learning exercise videos embedded in the System. The exercise trainings include: a) progressive resistance training to improve muscle strength; and b) brisk walking exercise to maintain walkability. Self-reported digital log sheets will also be used to capture the participants' performance and engagement in different interventions. This information will be collected and analyzed to provide feedback to enhance the participants' motivation through the System, which can enhance the participants' and family members' understanding of participants' performance. Thus, the family members can support the participants to adopt and maintain these healthy-lifestyle interventions. The control group will be arranged to receive a 4-week, group-based, face-to-face health talks on the management of sarcopenia. The number and time for the health talks will be matched with the supervised sessions received by the experimental group.

Researchers will conduct a face-to-face interview and assessment at baseline (T0), immediately after the completion of all supervised sessions (T1 at week 4), and after the completion of the eight-week self-management phase (T2 after 12 weeks). 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 HAPA Nutritional Self-efficacy Scale (HAPA), the Dietary Quality International-Index (DQI-I), the Mini Nutritional Assessment scale (MNA), the 7-day self-reported dietary record for dietary adherence, the Strength, Assistance in walking, Rise from a chair, Climb stairs, and Falls (SARC-F), the 9-item Chinese Self-Efficacy for Exercise scale (C-SEES), the Fried Frailty Index (FFI), the Brief Fatigue Inventory (BFI), the 10-point Numeric Rating Scale (NRS), the Geriatric Depression Scale (GDS), the 12-item Short Form Health Survey (SF-12v2), and the step counts, active minutes, moderate to vigorous physical activities (MVPA), and Global Positioning System (GPS) collected by the Actigraph wGT3X wrist-wore accelerometer. These assessments will be used to evaluate the effectiveness of a dyadic e-Health System on enhancing healthy lifestyles of older adults with sarcopenia. Each interview and assessment lasts for approximately 1 hour.

No major risks will be involved throughout the face-to-face regular supervision phase and the self-management phase. 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. Besides, during the 8-week self-management phase, you may contact the Research Associate Ms. Amy Cheung via 5175- 8010 for any enquiries. If you encounter any problems or emergency situations, like fall or sprain, depending on the severity, you are advised to seek medical advice, or call the emergency hotline via 999. The research team will record all incidents, and report them to the Clinical Trials Centre.

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 2766-4097 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 the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University, at 2766-6378 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

CONSENT TO PARTICIPATE IN RESEARCH

(Caregiver)

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_____	_____
Signature of Caregiver	Signature of Researcher
_____	_____
Name of Caregiver	Name of Researcher
_____	_____
Date of Signature	Date of Signature