School of Nursing, LKS Faculty of Medicine, The University of Hong Kong
Department of Medicine, LKS Faculty of Medicine, The University of Hong Kong
School of Public Health, LKS Faculty of Medicine, The University of Hong Kong

Title:The effects of a Strength-based Tailored-Exercise Program at Home (STEP@Home) on health outcomes of geriatric patients at risk of hospitalization-associated functional decline: A sequential mixed-method study

Information Sheet

You are invited to participate in a research. This is a study conducted by the Department of Medicine, School of Nursing, and School of Public Health, LKS Faculty of Medicine, The University of Hong Kong. Before you decide, it is important that you understand why the research is done and how you will be involved. Please read the information carefully and discuss it with friends, relatives and your family doctor if you wish. Ask if there is anything unclear or if you wish to obtain more information. Take time to decide whether you wish to participate in the research.

A total number of about 256 patients will be recruited from the Department of Medicine, Queen Mary Hospital. Since you are recently hospitalized and at risk of hospitalization-associated functional decline, you are cordially invited to participate in this study.

Purpose of the Study

This study aims to effects of a 20-week Strength-based Tailored-Exercise Program at Home (STEP@Home) on functional outcomes and health-related quality of life (HRQoL) among geriatric patients at risk of developing hospitalization-associated functional decline (HAFD).

Participants Selection:

Patients will be invited to participate in this study, who are

i) aged 60 or above;
ii) has an acute hospitalization and the length of hospital stay is of ≥ 2 day;
iii) has risk of functional decline in 3 months following hospitalization as measured by the SHERPA score of >4.5
iv) discharged home without any referral for exercise-based rehabilitation;
v) has a Smartphone to access video calls ;
vi) consented to participate.

Patients with this following criteria will be excluded

i) admitted with a disabling condition leading to significant functional loss such as stroke;
ii) bed-bound or chair bound;
iii) with conditions contradictory to exercise training (e.g., acute muscular-skeletal problem, acute and unstable cardio-respiratory disease, etc),
iv) engaging in moderate or vigorous exercise (>60min/week) in the past 6 months.

Nature of Participation:

Your participation is absolutely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you refuse to participate, you don't have to give a reason. The treatment and care that you are receiving will not be affected. If you decide to take part in the study, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of treatment and care you receive in present and future. You will be updated timely of new information that may be relevant to your willingness to continue the participation in this study.

If you withdraw from the study, the data collected before withdrawal will be destroyed if we do not have your consent. You may also state in the consent to allow the researcher to continue using the data collected from you for your research purposes after your withdrawal. You will be given enough time to consider whether to participate in this study.

Data collection procedure

After obtaining informed consents, the research assistant (RA) will collect your socio-demographics (e.g. age, gender, education level) and clinical characteristics (e.g. medical history, quality of life) through a face-to-face interview which will takes about 20 minutes.

After collection of the above baseline data, you will be randomly assigned to one program according to a computer generated sequences of equal opportunities (i.e. you will have half of the chance to be assigned to one of the plans named as Program A and Program B). After being assigned to either of the program, you will not be able to request to change to another plan. Also if you could not attend/complete all activities, you are still treated as participants of the study and will not be terminated.

Program A:

If you are assigned to Program A, you are invited to participate in this 20-week Strength-based Tailored-Exercise Program at Home (STEP@Home). The program will be delivered by a trainer (RA with physical education background) and tailored according to your capacity. You are also received exercise log and safety guideline for reference. A set of self-practice exercise manual and video links will also be provided for you to study and exercise.

The program consists of three phases with physical home visits (about 60 mins), video-call visit (about 40 mins) and telephone calls (about 20 mins) to assist your exercise training. Phase 1 (1^{st} -2^{nd} week) consists of two home visits by the trainer (RA) focusing on health counselling, assessing your exercise tolerance level, providing suitable exercise wheels and goal setting; Phase 2 (3rd – 12th week) consists of three video-call visits focusing on multi-component exercise training and goal review; Phase 3 (13th-20th week) consists of one home visit, one video-call visit and two telephone calls focusing on lifestyle-integrated functional exercise to daily life.

You may also be invited into a qualitative interview on exploring your engaging experience in the 20-week Strength-based Tailored-Exercise Program at Home (STEP@Home). The interview will be taken place at your home for about 30 mins. The interview will be recorded anonymously. The data collected will be used to evaluate program outcomes.

Program B:

If you are assigned to Program B, one RA will make a home visit to you and provide with information on the social and health care service. You will continue to receive the usual post-discharge care provided in the hospital setting, including general education on medication, basic knowledge on disease-related self-care and/or attend regular medical follow-up in the specialist out-patient clinics.

No matter you are in Program A or B, there will be three follow-up tests at 12th week (T1), 20th week (T2), and 32nd week (T3) after joining, to evaluate your health-related quality of life. The follow-up tests will be taken about 20 minutes in the interview room of School of Nursing, HKU. Research assistants will inform you the schedule time via phone call.

Alternative treatments if patient opts for not joining the study

All patients will receive appropriate and standardized treatment in the hospital. There will be no difference between study participants and other patients in terms of treatment arrangement. Your participation will not affect your present or future care and treatment received from the hospital or in the community.

Cost and payment of the study

Besides regular hospitalization fee, you will not be charged for participating in the study.
You will receive $50 supermarket coupon as rewards upon the 32-week follow-up test in this study.

Funding source

This study is funded by Health and Medical Research Fund (HMRF).

Risk and Benefits

The assessment will not cause any pain and discomfort or harm to you.
The results of this study will be used in prevention of premature death, promotion of physical well-being among geriatric patients.

Compensation and treatment for study related injury

When there are any mental or physical discomfort raised during the study period, our research team will provide or refer appropriate treatment to you. You will not give up your legal rights by signing this form.

Anonymity and Confidentiality:

All the information which is collected about you during the course of the research will be kept strictly anonymous and confidential. The collected data will be locked up in a secure location and only the researcher can access to them. All the data will be destroyed five years after the study.
Under the laws of Hong Kong [in particular the Personal Data (Privacy) Ordinance, Cap 486], you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your

personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his/her officer (Tel no.: 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By signing the written informed consent form, you are authorizing the Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

Inquiry:

For any questions or enquiries, please feel free to contact the research team:

Clinical Assistant Professor, Dr YUEN, Kwan Yuk Jacqueline
Department of Medicine, LKS Faculty of Medicine, The University of Hong Kong (Tel: 2255 6208)

Prof. YU Doris Sau-Fung , Professor,
School of Nursing, LKS Faculty of Medicine, The University of Hong Kong (Tel: 3917 6319)

If you have questions related to your rights as a research participant, please contact the Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) at 2255 4086.

Please sign the attached consent form if you agree to participate in this study. After signing, a copy of this participant information sheet and signed consent form will be given to you for retention.

You are cordially invited to participate in this study.

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Informed Consent for Participation in a Research Study

This is to certify that I, _____, consent to participate in the above study. I understand that the information obtained from this study may be used in future research, and may be published. However, I will not be in any way identifiable. I have been given a detailed account of the project and have had opportunities to ask questions which have been explained to my satisfaction. I understand that my participation is entirely voluntary and I have the right to withdraw from the study at any time, and will not affect the quality of present or future clinical care I receive in the hospital.

If I request to withdraw from the study, I ☐ agree / ☐ disagree researcher to continue using the data collected from me for research purposes after my withdrawal.

I understand that my identity will be handled confidentially. I also agree Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB) and the relevant statutory bodies to directly review my research data to verify the relevant clinical research data, subject to the appropriate regulations and legislation and without infringing my privacy.

Name of Participant	Signature	Date

Name of Research Assistant	Signature	Date

** After signing, a copy of the participant information sheet and signed informed consent form will be given to me for retention.