School of Nursing

LKS Faculty of Medicine

The University of Hong Kong

Title:

The effects and cost-effectiveness of a Dyadic Empowerment-based Heart Failure Management Program (De-HF) on self-care, HRQL and hospital readmission: A randomized controlled trial

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School of Nursing, The University of Hong Kong

Department of Medicine, Queen Elizabeth Hospital

Department of Medicine, Tseung Kwan O Hospital

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Information Sheet

As you are going to be discharged from the hospital and your family member will take care of your condition of heart failure, you and your family member are invited to participate in a research for about 32 weeks. This is a collaborative study conducted by Queen Elizabeth Hospital and the School of Nursing, 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 100 and 132 dyads (i.e. patients and caregivers) will be recruited from the wards of Department of Medicine at Queen Elizabeth Hospital and Tseung Kwan O Hospital respectively (total: 232 care dyads). With referral from your primary doctor, you are cordially invited to participate in this study

Purpose of the study

The aim of this study is to evaluate the effects of a 16-week dyadic empowerment-based heart failure management program (De-HF) on self-care, health outcomes, and health service utilization among HF patients who require family support after hospital discharge.

Participants Selection:

Patients who are aged 55 or over; have a confirmed medical diagnosis of heart failure by a cardiologist of at least six months standing, with New York Heart Association (NYHA) Class II-IV symptoms; be discharged home after an admission to the hospital setting; have adequate cognitive ability (as indicated by Abbreviated Test Score of >6); and have at least one Smartphone or device to access the online meetings and videos will be invited to participate in this study.

Caregivers who are co-residing with the patients in the same household and be self-identified as the primary caregiver for the patient; who have adequate cognitive ability (as indicated by an Abbreviated Test Score of >6); and have at least one Smartphone or device to access the online meetings and videos will be invited to participate in the study.

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.

Data Collection Procedure

After obtaining informed consents, the research assistant will collect the patient's socio-demographics (e.g. age, sex, education level etc.) and clinical characteristics (e.g. self-management of heart failure, health-related quality-of-life, level of shared care and perceived control in heart failure management) through a face-to-face interview which will takes about 30 minutes. Right after the interview, the research assistant will also collect the caregiver's socio-demographics (e.g. age, sex, education level, etc.) and caregiving characteristics (e.g. health-related quality-of-life, level of shared care, and perceived control in heart failure management) through a face-to-face interview of about 30 minutes. After collection of the above baseline data, you will be randomly assigned to two programs 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 De-HF program and dyadic education program. Both program will be delivered by a registered nurse and comprises one home visit (about 45 minutes) (the 1st to 2nd week), five online meetings (about 30minutes/ each meeting) (3rd to 12th week) and two post-meeting telephone follow-up visits (about 15 minutes) (the 13th – 16th week). The content of these encounters will focus on supporting you and the family members to manage heart failure, particularly on medication compliance, fluid and dietary control, symptom monitoring, symptom recognition and responses. After being assigned to either of the plan, you will not be able to request to change to another plan. Also, if you could not attend/complete all visits, you are still treated as participants of the study and will not be terminated. More details of the two programs are as follow.

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. Also you will receive an incentive of $100 supermarket coupon upon the completion of the study.

Risk and Benefits

The study intervention will not cause any pain, discomfort or harm to you. The 16-week De-HF or dyadic education program is designed in accordance with the practical management recommendations from the Heart Failure Association of the European Society of Cardiology. The major potential benefit is to improve the self-care behavior and reduce rates of hospital re-admission of patients, health-related quality-of-life of the care dyads.

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 within 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 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 Research Ethics Committee (REC) and the regulatory authority(ies) will be granted direct access to your study data for data verification.

Voluntary Participation/ Withdrawal

You are voluntary to participate in this study. Your decision to participate or not will be respected. You have the right to ask any questions, refuse or withdraw from the study at any time and without giving a reason. Your decision of participating in this study will not affect the quality of present or future medical care you receive in the hospital and community. 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.

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.

Inquiry

For any questions or enquiries, please feel free to contact the research team:
Ms. CHAN Miu-Ching, Cecilia, Nurse Consultant, Department of Medicine, Queen Elizabeth Hospital (Tel: 3506 7347).
Dr LEUNG Chun Yu, Associate Consultant, Department of Medicine, Tseung Kwan O Hospital (Tel: 2208 0111).
Prof. YU Doris Sau-Fung, Professor, School of Nursing, The University of Hong Kong (Tel: 3917 6319)

If you have questions related to your rights as a research participant, please contact the Research Ethics Committee (Kowloon Central/Kowloon East) at 3506 8888.

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 the Research Ethics Committee 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.

Participant (Patient) signature	Participant (Patient) name (in BLOCK Letter)	Date
Participant (Caregiver) signature	Participant (Caregiver) name (in BLOCK Letter)	Date
Research assistant signature	Research assistant name (in BLOCK Letter)	Date

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