Title:

The effects and cost-effectiveness of a technology-based family-centered empowerment (T-FAME) program on health and health service utilization outcomes of post-discharged patients with advanced heart failure: A sequential mixed method study

Last Update: 2021, June 15
School of Nursing, Li Ka Shing Faculty of Medicine, 
The University of Hong Kong
Information sheet (English version)

Study Title
The effects and cost-effectiveness of a technology-based family-centered empowerment (T-FAME) program on health and health service utilization outcomes of post-discharged patients with advanced heart failure: A sequential mixed method study

Purpose of the study
The purpose of the study hopes to arise the quality of life among patients who are just discharged from hospital admission. The aims of the study are to investigate the effects of the technology-based family-centered empowerment program for heart failure (T-FAME-HF) on hospital readmission, mortality, event-free survival, HF-related self-care, family functioning and health-related quality of life (HRQL) among patients admitted with HF; to investigate whether the T-FAME-HF is a cost-saving strategy in improving post-discharge outcomes; to explore the patients’ and families’ experience of engaging in the T-FAME-HF.

Procedure
You will be randomly assigned to receive either technology-based family-centred empowerment program for heart failure (T-FAME-HF) or HF education program. Before you are assigned to either of these care programs, the research assistant/nurse will use standardized questionnaires to assess your conditions during your hospitalization period.

For participants who join technology-based family-centred empowerment program for heart failure (T-FAME-HF), you and your family member(s) are invited to join a 16-week transitional care program. The program comprises three phases for self-care empowerment activities followed by two bi-weekly telephone call. Each phase lasts four-week period. In each phase, you and your family member(s) will have a specified goal of care to guide the care activities, and be commenced with a post-discharge family-centered home visit by HKU nurse. During each home visit, the nurse will conduct family health conversation with you and your family member(s) to identify the disease management needs at the family level. Then, the you and your family member(s) will be engaged in a goal setting process to set up family-centered goals and the corresponding action plan to address the identified needs for effective disease management. These goals will be reviewed in the subsequent home visit and adjustment will be made if necessary. The nurse will then orientate you and your family member(s) to the different features of the patients’ interface of the online platform (Chinese name: 「戶心易 EASY」) via a mobile Apps and wearable clinical monitoring device (blood pressure monitor) over the three care
phases so that you and your family member(s) can gradually develop the care competency. Audio-enabled videos relevant to each phase of care will be assigned to you and your family member(s) for review through the online platform at home. The nurse will give two telephone calls to the family during each 4-week care phase to support your engagement in the goal-attainment process and on the online platform. After the three phase of self-care empowerment at the dyadic level, the nurse will give two bi-weekly telephone call to the care dyads and to support you to consolidate the self-care to everyday life. Any problems and concerns of the care dyads will be addressed accordingly.

For participants who join HF education program, you will receive a 16-week HF education program that comprises a home visit by HKU nurse, five bi-weekly video-based training sessions, and two subsequent telephone follow-up for the care dyads. The nurse will first assess how you manage HF in terms of medication compliance, fluid and dietary control, symptom monitoring and responses in a home visit and clarify your major misconceptions in self-care. This will be followed by five bi-weekly video-based training sessions on heart failure and symptom monitoring and responses, dietary and fluid modification, exercise and heart health, and stress management. For each video-based training session, the nurse will send out the online video to the smart-phone of the care dyad through the instant message platform available to you (e.g. Whatapps/ WeChat) and prompt you to preview the video. This would be followed by a telephone call to the care dyads through speaker phone and to clarify any concerns and questions. Upon the completion of the five training sessions, the nurse will give two bi-weekly phone calls to resolve any questions raised by the care dyads on HF management.

No matter which type of programs you are assigned to, another research assistant will give you telephone calls for another 4 times, at 8th, 16th, 24th, 32th weeks to access your health outcomes by standardized questionnaires. The data collection procedure will take approximately 20 to 25 minutes to complete. The information will be used to conclude the effects of the program you have received.

**Risk and Benefits**

All activities related to this study will not make any pain, discomfort and harm to participants. Participants benefit from receiving health education and information on disease management, daily care with aims of controlling a stable health condition and relieving the stress from the disease.

**Anonymity, confidentiality and nature of participation**

All the collected data will be subject to strict anonymity and confidentiality. Your name will not appear on any data record sheets. They will be locked up in a secure location and only the researcher can have access. All the data will also be destroyed after use. Your participation is voluntary. You may refuse to participate or may withdraw consent and discontinue the participation in the study at any time.
Your decision will not affect the quality of present or future care you receive in the hospital.

**Inquiry**
This study is undertaken by Prof. Doris YU (School of Nursing, The University of Hong Kong) and Dr. Wong CW (Consultant (Cardiology), Department of Medicine & Geriatrics, Pok Oi Hospital).

For any inquiry, please feel free to contact Prof. YU at 3917 6319, or Dr. Wong at 2486 8985.

You are cordially invited to participate in this study.
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I hereby agree to participate in the above study. I understand that the information obtained in the study will be used for future research and maybe published in academic literature.

I also know that if I disagree with the information obtained in the public study, I can continue to participate in the study. However, all personal data is kept strictly confidential and will not be made public. I understand all the benefits and risks associated with this study.

The researcher has explained the study to me in detail and asked me to ask questions and get a satisfactory reply. If I am involved in this study and cause any physical discomfort or emotional fluctuations, the researcher will treat or refer to my treatment. I will not waive any legal rights by signing this consent form.

I hereby sign this consent form to prove that all the information provided by me is correct. I understand that participation in this study is voluntary and I may withdraw this consent at any time without any reason, without affecting my current and future treatment.

I understand that my identity will be treated confidentially. I also allow the Hospital Authority New Territories West Cluster Research Ethics Committee and the relevant statutory bodies to directly check my research data to verify the relevant clinical research data, subject to the appropriate regulations and legislation and without infringing my privacy.

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<th>Participant’s signature</th>
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<td>Witness/ Research assistant Signature</td>
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After signing, I will receive a copy of the participating academic research materials page and signed informed consent for reservation.