**Australia and New Zealand Clinical Trials Registry**

Title: Improving knowledge and self-care through a self-management program with teach-back for people with heart failure: a protocol of a cluster randomised controlled trial

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**Introduction**

This study is a major part of a PhD study in the Queensland University of Technology. The study is a cluster randomised trial to implement a self-management program for Vietnamese people with HF. The self-management intervention was delivered on an individual basis to the intervention group. The control group received standard care. Outcomes were HF knowledge, HF self-care and number of hospital readmissions over three months follow-up.

The unit of randomisation was clusters (wards) in this study, which was chosen for practical reasons and to prevent contamination. If individual randomisation was applied, risk of contamination between participants in the two study groups would have been more likely because in Vietnam patients share hospital beds (typically 2 or 3 per bed) and have lengthy hospitalisation. Hence wards were randomised and all eligible patients in each ward participated in the study.

**Objective**

The main aim of this study was to use the rigour of a cluster randomised controlled trial to compare the effects of a self-management program and usual practice of the care for people with HF in a Vietnamese health care setting. This study aims to explore how an educational intervention using the teach-back method to teach HF self-care can change knowledge and self-care of people with HF. In addition, the study targets to examine if patients participate in the intervention will have less hospital readmissions. Data collection and result interpretation pertains at individual participant level.

**Methods**

**Study design**: This study is a cluster randomised trial. Six inpatient wards in a single large cardiac hospital are randomised into intervention or control arm.

**Sample size:** Sample size is calculated using the sample size for an individually RCT multiplied with design effect. The individual randomised trial is expected to obtain a mean change in knowledge score in a previous study,1 standard type I error = 0.05, type II error = 0.2, there are 20 participants recruited from each ward with intra-cluster correlation coefficient 0.052,3 and drop-out rate of 20%, the sample size is 140 people equally distributed in two study groups.

**Setting and participants**

**Inpatient wards (unit of randomisation)**

Six inpatient wards in a large cardiac hospital in Hanoi, Vietnam were involved in the study. The study screened and enrolled inpatients hospitalised in the Vietnam National Heart Institute, which is one of the largest cardiac hospitals in Vietnam which admits approximately 17,000 – 22,000 cardiac patients annually. The six inpatient wards ranged in bed numbers from 27 to 54, however, average bed occupancy was approximately 200%. Each wad has a separate health care team although routine treatment for people with HF was the same. Patients in these wards come from areas in and surrounding Hanoi, socioeconomic status and literacy levels, therefore it was considered that patients with heart failure in Vietnam National Heart Institute were likely to represent the general HF population.

Eligible participants were adult patients with confirmed New York Heart Association class II-IV diagnosis of HF within the last 3 months. Exclusion criteria were those who were critically ill, waiting for surgery, verbally or cognitively impaired or those unable to communicate in Vietnamese language. Recruitment period has taken place from August 2014 to end of October 2014.

**Primary outcome**

The primary outcome of this study is changes in mean HF knowledge score which is measured repeatedly at one month and three months after commencement of study intervention. Heart failure knowledge is measured by the Vietnamese version of the Dutch Heart Failure Knowledge Scale (DHFKS). The DHFKS is a 15-item self-administered questionnaire that assesses HF symptoms recognition, diet fluid restriction, medication compliance and exercise. For each item, one point is allocated for a correct answer and 0 point if the answer is wrong or missing. The possible total score for knowledge of HF ranges from 0 to 15. The higher the score participants receive the better knowledge they have. The reliability coefficient of the Vietnamese version of DHFKS was 0.72.4

**Secondary outcome**

Heart failure self-care was measured by the Vietnamese version of the Self-care for Heart Failure Index v6.2.5,6 The instrument consists of 22 items divided into 3 scales (i) 10-item self-care maintenance measuring symptom monitoring and treatment adherence (ii) 6-item self-care management scale measuring occurrence of symptoms, symptom evaluation, treatment implementation and evaluation, and (iii) 6-item self-care confidence. The total score of this questionnaire is 100. A score of 70 and over indicates self-care adequacy. The instrument was translated to Vietnamese language and obtained Cronbach alpha coefficients for three subscales were 0.47; 0.57 and 0.82, which were almost equivalent to the original testing.7

The numbers of readmission were assessed at one month and three months after commencing intervention. Hospital readmission is defined if a patient stays at least one night in hospital. Cardiac-cause readmission is defined if patients readmit due to an exacerbation of HF symptoms.

**Randomisation**: Randomisation was conducted at ward level. Inpatient wards where accommodate HF patients (i.e, exept ICU, operation theatre, paediatric ward) were randomly allocated into two groups (three wards in each group). The allocation was conducted by the researcher. Hospitalized participants received either the intervention care or usual care on the basis of their ward allocation.

**Blinding:** Neither participant, outcome assessor were blinded to group allocation, because the nature of intervention blinding is difficult in cluster randomised trials.

**Educational intervention**

The intervention components consisted of an individual educational session, provision of a HF booklet, a diary and a weighing scale to each participant. A trained nurse used the HF booklet to educate about HF self-management with the participants. The booklet particularly focused on HF signs and symptoms, symptom management, advice regarding fluid and weight management, salt restrictions, medication use, exercise, recognition of worsening symptoms and alerting signs to seek help. The nurse discussed common HF symptoms to the participant and taught him/her how to recognise and self-manage symptoms, and to seek help when their symptoms were worsening. The participant was asked to repeat the information to teach-back the nurse. If the patient did not teach-back information accurately the nurse explained again until the patient understood. In addition, each participant received one weighing scale and diary. The participant was taught the steps to measure their weight and was asked to record it in the diary. The diary also provided space for participants to record their existing symptoms, amount of fluid intake, blood pressure and medications being used. A blank page was designated for each participant to write down their personal self-care plan, including salt reduction, fluid intake management, exercise, weight monitoring and recognising warning signs. The nurse explained how to integrate the self-care plan into their daily life. They received a follow-up telephone call from the researcher at two weeks post discharge. The purpose of follow-up telephone was to consolidate the educational session, reinforce adherence and knowledge, and to support self-management.

**Usual care**

Each participant in the control group was provided with the HF self-management booklet and the content was briefly explained by the researcher. Teach-back did not occur. No diary or weighing scales were provided. All participants then continued to receive usual care, which at discharge a physician provided brief education. The contact between participants in the control group and the researcher was at enrolment and two occasions of data collection.

**Statistical methods**

This study approached intention-to-treat principles in data analysis. Participants will be analysed in the intervention arm to which they were allocated, regardless of the treatment they received.8 All participants will be included in the analysis whether or not they provide outcome data. A logistic regression was used to examine if there was any significant factors influencing to people who drop out. Linear mixed effect models were used to examine effects of the intervention in continuous outcomes. Clusters were added in the linear mixed models as a random effect. Any differences at the baseline between two groups would be adjusted in the analysis of outcomes, including HF knowledge and self-care scores. For the hospital readmission or death rate, analysis was conducted by replacing readmission/death variables of missing participants with either “no event” or “at least one event”, while “event” indicated a readmission or death.

**Ethical consideration**

Ethics approvals for the RCT were obtained from relevant institutional ethical committee in Queensland University of Technology (approval number 1400000374) and agreement was sought from director of the study setting. Informed consents were sought for each participant before the study commenced.

**Conflict of interest**

No conflict of interest was foreseen. The study received a minor financial support as part of a PhD scholarship in Queensland University of Technology.

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