**A mobile based multidisciplinary virtual clinic for patients with HF: A Controlled Randomised Trial, MoTER-HF**

**Background**

Chronic cardiac diseases such as Heart Failure (HF) represent complex health problems and feature debilitating symptoms which adversely influence morbidity (Barnason, Zimmerman, Hertzog, & Schulz, 2010). Despite advanced medical, pharmacological and surgical treatment of HF, patient outcomes are poor and hospital readmissions remain high(Dickson, Deatrick, & Riegel, 2008). Patients often experience symptoms such as dyspnoea, chronic fatigue and oedema (Bisognano, Baker, & Early, 2009). Lack of symptom monitoring and seeking treatment when necessary may result in hospital readmissions in this population. Hence, being diagnosed with HF not only has a major impact on quality of life, but is also a key elevator of healthcare expenditure (Bisognano et al., 2009). In seeking to address these complexities, HF patients are encouraged to modify their lifestyles and constantly monitor symptoms related to their condition. Furthermore and to effectively manage HF, intensive inpatient and community based interventions are required along with a high level of participation by patients and health care professionals (Barnason et al., 2010).

As a cardiovascular disease HF, represent as one of the most common causes of acute medical admissions to Australian hospitals (National Heart Foundation Australia & The Cardiac Society of Australia and New Zealand, 2011). This high number of potentially preventable hospital admissions and readmissions could be reduced with providing education, constant monitoring and support. However, due to service staffing workload, time intensive nature of health services to provide face to face appointments, and high volume of patients to be seen, health services can only provide phone follow up for the majority of patients with HF. This places limitations on conducting the full assessment of patients and efficient follow-up related to patients’ condition and progress.

The impact of Remote Patient Monitoring (RPM) in improving clinical outcomes of patients with chronic disease has been extensively studied (Scherr et al., 2009; Zan et al., 2015). RPM may include distance communication with a healthcare provider, ongoing remote measurement of vital signs or automated or phone-based follow-ups of physical and mental well-being (American Telemedicine Association, 2013). Furthermore, patients could receive education and reminders on the required lifestyle choices at the most appropriate times.

The use of mobile phone is currently proposed as suitable technology for RPM system as it provides not only the capacity for monitoring and communication but an especially attractive, lifestyle-media option to support home-based health and chronic disease management programs (Varnfield et al., 2011). As a technology platform, it integrates sufficient computing power, user interface, memory, and communication capabilities to run applications needed for personal health management (Klasnja, Consolvo, McDonald, Landay, & Pratt, 2009). From an individual user’s perspective, it has become a personal appendage to be considered as a sufficiently personal and trusted device to store personal messages, conduct daily errands (such as carry out bill payments or monetary transactions while on the move, and it portable during exercising or other daily tasks). Furthermore, Mobile phones are attractive tools from health service providers’ perspective because they have the capacity to deliver multimedia communication and information for feedback at a personal level to the patient in combination with a very high penetration rate in most countries (e.g. in Australia 99% and in many countries significantly higher than for example broadband internet penetration). Furthermore, the mobile phone is a relatively well accepted device, which makes it potentially a non-discriminating service media (Klasnja et al., 2009; Mattila et al., 2008).

Investigating mobile phone systems for RPM is a logical next step because they enable greater scalability of remote monitoring due to their relatively low cost compared to traditional systems, and because they provide more freedom for the patient due to their portability (Mattila et al., 2008). There are number of studies that investigated the impact of mobile based remote monitoring systems on the clinical outcomes of patients with CVD particularly heart failure (Blasco et al., 2012; Mattila et al., 2008; Seto et al., 2012; Varnfield et al., 2014). However, little is known about the feasibility and effects of mobile phone-based remote monitoring on the outcomes of patient with HF. The aim of this research is to develop a mobile based virtual clinic (MBVC) model of care based on the existing MoTER platform and to investigate the impact of such a clinic on health outcomes and clinical management of patients with HF. This protocol will describe the methods, integrated solution, clinical trial procedure and expected outcomes.

**Methods**

This study consists of pre-study survey, phase one and two. The objective of the pre study survey is to conduct short structured interviews with a small group of patients and one session of focus group with healthcare professionals. The results of the pre-study survey will be used to design the virtual clinic platform and to address its components and materials. The first phase of this study will focus on the development of a MoTER-HF and the second phase will be evaluating the clinic effectiveness in a Randomised Controlled Trial (RCT).

**Study design**

**Pre study Survey**

The pre-study survey aims to gather consumer information into the needs and preferences of patients with HF to receive technology-based intervention and to develop tools and materials to process and display clinically relevant information for both patients and healthcare professionals.

**Study population**

Patients with a clinical diagnosis of HF (N=30) will be invited to participate in the pre study survey at the time of their scheduled clinic appointment by their nurse practitioner (NP). For this stage of the study, purposive sampling is used to identify patients with a range of patient characteristics including sex, age, and years with HF. Thus, purposeful sampling allows for the selection of the participants who have the capacity to provide relevant information required for the study.

**Procedure**

Nurses from HF service at Metro North Health Service (MNHS) District Queensland, Australia will briefly explain the research concept to eligible participants and introduce them to the researcher. The researcher will explain the research objectives and the interview process. The researcher will provide written participant information sheet and consent form to patients who agree to participate. Participants are required to spend maximum 30 minutes to answer structured interview with open response questions.

**Instrumentation**

In addition to demographics information, participants will be asked to answer two surveys including Australian version of Short Test of Functional Health Literacy (STOFHLA) and the HF patients’ learning needs and styles (HFLNI).

***Australian version of Short Test of Functional Health Literacy (STOFHLA)***

Health literacy will be assessed with the Test of Functional Health Literacy in Adults, short version (S-TOFHLA). In this study the S-TOFHLA Australian version (Barber et al., 2009) is used, a modified version that is more appropriate for the Australian setting and language. Patients’ knowledge related to read­ing comprehension of health-related materials will be assessed via the S-TOFHLA 36-item. The scale measures understanding of functional health literacy and tests a patient’s ability to read passages using real materials from the health setting. While score between (0-16) indicates inadequate health literacy, score (17–22) indicates marginal health literacy and (23–36) adequate health literacy respectively. The S-TOFHLA is widely used in the assessment of health literacy and is a relia­ble and valid measure of reading comprehension in the healthcare environment (Barber et al., 2009; Dennison et al., 2011).

***Learning style and learning needs of heart failure patients***

To investigate HF patients’ learning needs and styles, we will use the Clark and Lan's questionnaire (OHFLNI) which was modified by Boyde et al (2009). Boyde et al (2009) changed the wording of three items to reflect current vocabulary and make it applicable to Australian populations. The OHFLNI covers eight educational topics and consists of 46 closed-response items and 1 open-ended question. Participants are asked to rank each item from not important to very important on a 5-point Likert scale. The questionnaire topics include general heart failure information, psychological factors, risk factors, medications, diet, activity, prognosis, and signs and symptoms. Cronbach's alpha coefficient for the OHFLNI (JC & VM, 2004) was 0.86 (N=33), with each of the subsets having a Cronbach's alpha coefficient range within 0.65–0.96 (Boyde et al., 2009).

***Health Tracking Survey (2012)***

This survey has been developed by Princeton Survey Research Associates International for the Pew Research Center’s Internet & American Life Project to explore the phenomenon of tracking for health, limiting questions to those who use online tools.

**Focus Group**

A group of healthcare professionals (N=10) including nurse practitioner, clinical nurse consultant, cardiologist and research scientists will attend a session (60 minutes) to investigate their perspective on facilitators and barriers of using cell-phones to provide health care services. A list of questions will be prepared by investigators to discuss in the focus group.

**Statistical analysis**

***Patient survey:*** All statistical analyses will be performed using Statistical Package for the Social Sciences (SPSS) version 19 for Windows (SPSS Inc., Chicago, IL, USA). The S-TOFHLA results will be scored into inadequate (0–16 correct answers), marginal (17–22) and adequate health literacy (23–36).

To investigate patients learning needs based on their age and language, we use four subgroups including age under 70, age above 70, English as primary, and English as secondary language. Mean and standard deviations for each group will be calculated. Furthermore, the means for each educational topic (question) are ranked from highest to lowest. Spearman's rho coefficients will be obtained to determine if there is a linear relationship between the educational topics and the age of the patients, the educational topics and the language, and also the educational topics and the educational level.

***Focus group:*** Based on established methods of qualitative research (Kotler, Roberto, & Lee, 2002), a thematic analysis will be conducted on each question, using a note-based strategy. The Researcher will analyse the notes and transcripts across the group and enter the data into tables. Data tables will be organised by question, capturing the frequency of topics, extensiveness of the response across participants, and the intensity of the response. The notes will be supplemented as needed with the audiotapes to glean details from the focus group discussions.

**Phase one: Customising the platform (MoTER) for HF patients**

MoTER is a platform designed for home-based monitoring in cardiac rehabilitation using smartphone application and the Internet (Varnfield et al., 2014). We aim to customise the platform for delivering care in patients with HF as a comprehensive virtual clinic. MoTER-HF will be offered to patients as an alternative program to a hospital-based follow-up. The mobile phones are used for providing education and personalised feedback, monitoring physiological data as well as recording patients’ self-observations on their health-related behaviour and virtual consultation via audio or video. All the data is synchronised daily to a portal on a remote server. Mobile prepaids including 3 GB data will be provided without cost to participants in the intervention group which covers all the required communications (unlimited text and talk) and mobile internet.

**Phase two: Evaluating the MoTER-HF (RCT)**

The study is an open randomized controlled trial of Information Technology (IT) enabled virtual clinic utilizing mobile phones (MoTER-HF) compared to traditional community-based management program (Usual Care). The study design is displayed in Figure 1. The trial will be conducted at HF service, MNHHS, Queensland, Australia. The enrolment process includes baseline measurements; training to use the mobile application software; education on avoiding risks; and briefing on details such as contact persons.

**MoTER-HF intervention**

The MoTER-HF pedagogical principals are based on key elements of the self-efficacy theory; mastery experience, role modelling, and verbal persuasion. Role modelling through observing others actions is considered effective in increasing self-efficacy (Bandura, 2006). Examples of peer role modelling will be used through video-clips to resemble role models and to help patients engage with educational materials. Mastery experience is implemented by asking participants to monitor and record their signs and symptoms related to their condition. A further source of self-efficacy, verbal persuasion, is applied in the MBVC intervention through encouraging short SMS messages and feedback from healthcare professionals. The MoTER-HF will include number of software tools such as multimedia educational materials, goal setting, and e-diaries.

***Educational materials:*** The smartphone application includes multimedia educational materials on topics related to the HF condition including hear failure educational information, healthy eating and body, heart and mind. Nutritional education has beneficial impact on dietary habits, and nutritional knowledge of patients with CVD(Jeong-Ah, JeeWon, & Chun-Ja, 2018). Hence, to encourage healthy eating, we developed diet related instructions, which cover topics including foods better for heart health, daily meal plan, tips to prepare daily foods and recipes. Healthy eating was developed with collaboration of Professor Manny Noakes former director of the Commonwealth Scientific and Industrial Research Organization (CSIRO) food and nutrition department. The rest of educational information were linked to the related webpages of the National Heart Foundation of Australia website(Australia, 2019).

***Goal setting:*** Following the enrolment, each patient set goals (Smoking, Alcohol intake) with the help of Clinical Nurse (CN) to start the program. The mentor (CN) will discuss the patient’s progress in comparison to the set goals and assist in setting the new goals on lifestyle modifications during the intervention. Both the patient and mentor will document the agreed goals.

***Health measures:*** Patients allocated to the MoTER-HF intervention arm will receive Bluetooth enabled monitoring devices for measuring body weight, blood pressure and, if required, glucose monitoring.

***Weekly diaries***: In addition to monitoring daily health measures patients will be asked to answer weekly questions on the signs and symptoms related to HF exacerbation.

***Body Pain Map:*** Body Map is a tool designed for patients to identify the location of her/his pain and score their pain level from 0 to 10. Participants will be asked to identify their pain characteristics by answering questions about pain cause, intensity, aggravation factors, frequency and duration.

***Relaxation audio:*** To decrease patients’ emotional stress, the MoTER-HF app consists of relaxation audio. The audio developed by the Australian Cancer Council and the research team purchased licence to use the audio in the MoTER-HF app. The audio consists of ten tracks, which provides exercises for relaxation, practical tips and types of relaxation.

***Motivational messages:*** Based on healthcare professionals’ input, a collection of motivational messages was developed to deliver to patients as SMS throughout the program. Message content was adapted from previous study(Varnfield et al., 2014). Messages aim to enhance patients’ self-management, competence, and relatedness. Messages are sent daily and can be reviewed at any time.

***Video or audio consultation:*** Patients will receive information related to their condition via video or audio consultation from their healthcare professionals. Furthermore, health care professionals will be able to encourage patients to achieve their goals and follow healthy lifestyle.

**Primary and secondary outcome measures**

The primary endpoint is participants’ uptake and adherence to the smartphone-based intervention. Participants’ uptake and adherence are scored based on the pattern developed for patients’ adherence to clinical interventions(Riekert, 2006). Several secondary outcomes will also be assessed. The outcome measures and the corresponding measurement tools are listed in Table 1.

**RCT protocol**

**Population**

HF patients will be recruited to participate in this study. Inclusion criteria include patients diagnosed with HF, able to read and write in English, and interested in Information Technology (IT). Potential participants are excluded if they have ejection fraction less than 50, diagnosed with ischemic cardiomyopathy, require titration clinic, are unable to participate in virtual clinic due to medical care needs, unable to operate a Smartphone for purposes of the trial (e.g. vision, hearing, cognitive or dexterity impairment), had no experience with mobile/smartphones, or were involved in another trial.

**Procedure**

Participants will be recruited from HF service at MNHS, Queensland, Australia. Prior to recruitment, information sheets are distributed to patients by their nurse practitioner (NP). Eligible patients were then introduced to the project officer (PO). The PO will explain the purpose of the research, the procedures and the time required for using the mobile application and will obtain consent prior to commencing data collection. The time required for randomisation and completion of base line data will be approximately one hour. Randomisation will be conducted prior to baseline assessment by computer-generated random numbers to one of two parallel groups including control (Usual Care) and intervention (MoTER-HF) Figure 1. The intervention group will receive intervention via cell phone and the control group will receive usual care. Usual care for patients with HF in the Australian health care settings includes 30-45 minutes NP consultation including physical assessments, medication and blood test review and health education.

**Instrumentation**

Individual participant will be clinically reviewed, to collect baseline demographic information, previous clinical history and procedural data. Furthermore, modifiable risk factors will be assessed to set individual goals for lifestyle behaviour modification and clinical assessment (Table 1) at baseline, and 12 weeks. In addition, patient HF knowledge, QOL, self-efficacy and psychosocial factors will be measured using*Minnesota HF knowledge****,*** European Quality of Life-5 Dimensions (EQ-5D)(EuroQol Group, 1990), DASS21 (Lovibond & Lovibond, 1995) and Self-efficacy for managing chronic disease(Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001) respectively.

**Power**

Sample size for the study was determined using the power method for binary outcome non-inferiority trial. Using this method, we used the adherence rate of patients as the primary outcome measure for the two randomised groups MoTER-HF (Intervention) and UC (Control). For our study, we considered 90% attendance rate of participants (i.e. completing follow-up), as the null hypothesis and a non-inferiority limit of 25% (i.e rate of intervention group’s attendance being better than traditional). So, with power of 90% and α = 5%, sample size of 25 per group is required. Accounting for the addition of 10% dropout rate (from previous study), the sample size is 27 per group, which equates to a total sample size for the study to be N = 54.

**Statistical analysis**

***Descriptive Analysis***

Data will be analysed using Microsoft EXCEL 2008 and IBM SPSS Statistics version 19.0 software. Baseline data and sample characteristics for both the MBVC and traditional groups are compared using Chi-square, Fishers exacttests and *t*-tests. Univariate statistical techniques are used to investigate distributions (frequencies), central tendencies (mean, mode or median) and dispersion (standard deviation and range). To examine the categorical variables, count and percentage are employed (Kirkwood & Sterne, 2003).

### *Main Analysis*

Prior to the conduct of statistical tests, empirical distribution of continuous variables will be evaluated for normality. To do this, histograms, skewness and kurtosis indices and Shapiro-Wilk tests will be used. Furthermore, boxplot are used to identify any outliers. ANCOVA assumptions are tested including homogeneity of variances and homogeneity of regression slopes. Homogeneity of variances will be tested for outcome variables using Levene’s test. If variables did not violate normality, hypothesises are tested using the analysis of co-variance (ANCOVA). Using ANCOVA maximises group equivalence prior to assessing the effect of independent variables on dependent variables. Potential covariates should be variables that significantly correlate with the dependent variable. For instance, pre-intervention scores would likely be highly correlated with post intervention scores. Regardless of the intervention some participants may have better scores than others (Polit & Beck, 2010). The effects of confounding variables like pre-intervention scores are removed in the context of ANCOVA. As a result, ANCOVA has greater statistical power to detect the treatment effect and allows a more sensitive test for real group differences. It also can increase the power of analysis and reduce the risk of type II error(Polit & Beck, 2010).

**Discussion**

We hypothesize that the use of MBVC offer effective healthcare management tools for both the patients and health care professionals. The main strengths of the model include true mobility and reliance on existing mobile phone and networking technologies which allows potentially cost-efficient implementation in various geographical settings. This study will provide evidence on the effectiveness of the MBVC on the health outcomes of patient with HF. The study may be limited by the ability of the relatively aged cardiac patients to use given technologies in real life settings, which is currently an open issue and considered as a potential barrier for applying modern technology tools in outpatient care. Therefore, we may be able to identify a sub-group of patients that prefer and benefit from a home-based care over the traditional model.

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**Conflict of interest**

The authors report no competing interests

**Table 1, outcome measures**

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| --- | --- |
| **Primary outcome measures** Uptake and adherence (Participants’ uptake and adherence to the smartphone-based intervention) | **Measurement tool**Participants’ uptake and adherence are scored based on the pattern developed for patients’ adherence to clinical interventions (Riekert, 2006) |
| **Secondary outcome measures** | **Measurement tool** |
| New York Heart Functional Classification | NYHA class I, II, III, IV |
| Blood pressure (SBP and DBP) | All measures will be transferred from devices via Bluetooth to the mobile application and then will be stored in a master web-portal for data extraction. |
| Heart Rate (Resting) |
| Weight |  |
| Smoking |
| Alcohol intake |
| Major Adverse Cardiovascular Event (MACE) | MACE is defined as MI, stroke, or death. MI is defined as symptoms of chest pressure and elevation of troponin with evidence of infarct by stress imaging or cardiac catheterization. Stroke is defined as focal neurologic deficit with computed tomographic or magnetic resonance imaging evidence of cerebral ischemic or hemorrhagic infarct. All mortalities will be confirmed by direct hospital chart documentation (Armstrong et al., 2014). |
| EQ5D | *European Quality of Life-5 Dimensions (EQ-5D)(EuroQol Group, 1990),* |
| HF Knowledge | *Minnesota HF knowledge* |
| Self-efficacy | Self-efficacy for managing chronic disease (Lorig et al., 2001) |
| DASS21 | Depression, anxiety and stress of participants will be meausred using DASS21 (Lovibond & Lovibond, 1995). |
| All cause hospital readmission  | The data will be extracted from Queensland Health Hospital Based Computer Information System (HBCIS). |
| Cardiovascular related readmission  |
| All cause Emergency visits |
| Cardiovascular related Emergency visits |
| IT survey  | The survey has been developed and used in the CAP study (Varnfield et al 2014). |

**Figure 1, Study design**

HF Patients refer to the MBVC

Patient will sign the consent form (N=54).

Patient will be allocated to Intervention group (MBVC) and will be trained to use the MoTER-HF intervention (N=27).

Patient will be allocated to the control group and receives usual care (N=27).

Allocation

Assessment following 12-weeks

Randomisation

 Enrolment

Outcome evaluation and analysis

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