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ABSTRACT

DOES USE OF A MOBILE APP AND TELEPHONE SUPPORT PROMOTE
IMPROVED SELF-CARE OF HEART FAILURE?

by

April Christine Chew

Chair: Jochebed Bea Ade-Oshifogun, Ph.D. RN-BC, CNE, CCRN

ABSTRACT OF GRADUATE STUDENT PROJECT

Andrews University

College of Health & Human Services

Title: DOES USE OF A MOBILE APP AND TELEPHONE SUPPORT PROMOTE IMPROVED SELF-CARE OF HEART FAILURE?

Name of researcher: April Christine Chew

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Date completed: March 2020

Background

Heart failure is a complex disease and a growing global epidemic. Symptoms and multiple comorbidities contribute to the overwhelming burden of heart failure, and support people make an important contribution to self-care. Effective self-care maintenance behaviors along with confidence and support can help people living with heart failure to effectively self-manage the disease.

Purpose

This project aimed to determine if use of a mobile app with telephone support calls was an effective intervention to promote improved self-care of heart failure and caregiver contribution to self-care of heart failure compared to the standard of care where the intervention was not used.

Methods

This project used a quantitative quasi-experimental pretest-posttest design with a non-equivalent control group. Participants included people with heart failure and support people. The pretest and posttest were conducted to measure the effectiveness of a 90-day intervention compared to the standard of care. The evidence-based 90-day intervention, used a mobile app to track daily weight and heart failure symptoms with structured telephone support calls, aimed to improve self-care of and caregiver contribution to self-care of heart failure. This project was guided by the situation-specific theory of heart failure self-care.

Results

Thirty-five people completed the 90-day project period. While the small sample size and non-normally distributed variables likely contributed to a lack of significant results comparing the intervention to the standard of care, results within groups were interesting. Control group participants ($n = 17$) made no significant improvements from pretest to posttest in self-care maintenance, management, or confidence. However, intervention group participants ($n = 18$) made significant improvements from pretest to posttest in self-care management, $t(10) = -2.031, p = 0.035$, and confidence, $t(17) = -3.766, p = 0.001$. Examining the level of use of the app in intervention group

households, participants in low-level use households ($n = 10$) made significant improvement from pretest to posttest in self-care confidence, $z = -2.214$, $p = 0.018$, while participants in high-level use households ($n = 8$) made significant improvements from pretest to posttest in self-care management, $z = -1.826$, $p = 0.034$, and confidence, $z = -2.214$, $p = 0.014$.

Conclusions

The intervention resulted in significantly improved self-care management and confidence for intervention group participants and improvement above adequate (70%) in self-care maintenance, management, and confidence for high-level users of the app. The results of this project validated the theory and the literature on evidence-based interventions to promote heart failure self-care. This intervention could be applied in practice as part of an individualized care plan to promote self-care of heart failure and caregiver contribution to self-care of heart failure.

Keywords: caregiver contribution, mobile apps, self-care of heart failure, structured telephone support

Andrews University
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A Scholarly Project
Presented in Partial Fulfillment
of the Requirements for the Degree
Doctor of Nursing Practice

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March 2020

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APPROVAL BY THE COMMITTEE:

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Emmanuel Rudatsikira

Member: Jessica Gingerich

Date approved

DEDICATION

This project is dedicated to my parents. My father died of heart failure one week before I started this program and embarked on my journey to become a doctor of nursing practice and family nurse practitioner. I know he would be proud of me and what I have accomplished with this project in an effort to help other people with heart failure to have a better quality of life. My mother was a model of caregiver contribution to self-care of heart failure for my father, and she has been my biggest supporter through the ups and downs over the past four years while I have focused all of my energy on completing this program. I am looking forward to practicing in primary care, where I can help people with heart failure and other chronic illness to perform better self-care. I am also looking forward to taking care of my mom instead of watching her take care of me and everyone else.

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LIST OF ABBREVIATIONS

AACN	American Association of Colleges of Nurses
App	Mobile application
CC-SCHFI	Caregiver Contribution to Self-Care of Heart Failure Index
Clinic	Heart Failure Clinic
DNP	Doctor of Nursing Practice
DNP Essential s	Essentials of Doctoral Education for Advanced Nursing Practice
EMR	Electronic medical record
FNP	Family Nurse Practitioner
HFHS	Heart Failure Health Storylines
IRB	Institutional Review Board
MANCOVA	Multivariate analysis of covariance
mHealth	Mobile device-based health and well-being interventions
NYHA	New York Heart Association
PCU	Progressive Care Unit
SCHFI	Self-Care of Heart Failure Index
SSU	Short Stay Unit
STS	Structured telephone support
Theory	Situation-specific theory of heart failure self-care

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CHAPTER 1

INTRODUCTION

Overview and Significance

Heart failure is a complex, terminal disease and a growing global epidemic. More than 6.2 million people in the United States have heart failure, and nearly half of them will die within five years of diagnosis (Benjamin et al., 2019; Savarese & Lund, 2017). As the population ages, the heart failure epidemic is growing. By 2030, there will be an increase of 46% of people diagnosed with heart failure in the United States, resulting in greater than eight million cases at a total cost of \$69.8 billion (Benjamin et al., 2019). Many people living with heart failure have multiple comorbidities that contribute to the overwhelming burden of self-care (Koirala et al., 2018). Without self-care confidence and good self-care maintenance behaviors, people and families living with heart failure cannot effectively self-manage the disease (Koirala et al., 2018; Riegel et al., 2016).

Background

Daily weight and symptom tracking in a diary or log is a standard component of effective self-care of heart failure to promote awareness of and early action for signs and symptoms of potential impending exacerbation. Increased tracking of daily weight and symptoms is associated with better outcomes for people with heart failure including reduced ejection fraction, length and cost of hospital stays, and hospital readmissions

(Eastwood et al., 2007; McBain et al., 2015; Park et al., 2017). Unfortunately, many people do not appreciate the value of diaries or logs as an essential aspect of heart failure self-care. Studies involving the use of a daily weight and symptom diary reveal low use of diaries despite the benefits of increased symptom recognition (Koberich, 2016). Reasons for not using a daily diary or symptom log included using a log does not fit their lifestyle, forgetting to use a log, and failing to understand the importance of recognizing small changes in daily weight and symptoms, even on perceived ‘good’ days (White et al., 2010; Koberich, 2016). Healthcare providers have an opportunity to help people change self-care behaviors related to chronic disease to improve self-care management and health outcomes by leveraging technology to augment their interventions to educate, remind, and engage people to participate in their own health and well-being (Hall et al., 2014; Walker et al., 2014; Weaver et al., 2012).

The impact of technology on the world is ever increasing, changing the way people get information, communicate, shop, and drive vehicles. Technology has also changed health and wellness and the delivery of healthcare services, replacing face-to-face consultations with virtual or distance interactions. According to the Pew Research Center (2019), over half of American adults own a tablet computer (52%) and/or a smartphone (81%). Smartphone owners include adults aged 50 to 64 years (79%) and those aged 65 years or older (53%) (Pew Research Center, 2019). The literature indicates that technology, particularly mobile device-based health and well-being interventions (mHealth), that is perceived as practical, helpful, easy to use, and can be conveniently incorporated into daily life, is well-received by older adults and can be an important tool

to increase self-care of heart failure (Cajita et al., 2017; Foster, 2018a, Seto et al., 2012a, 2012b).

Heart Failure Health Storylines (HFHS) is a mobile application (app) which was developed by Self Care Catalysts Inc. in partnership with the Heart Failure Society of America. The HFHS app was ranked in the top three of mobile apps that help people track and monitor heart failure symptoms by Masterson Creber et al. (2016). More recently, Wali et al. (2019) gave the HFHS app the highest functionality score (18/25, 72%) among 74 mobile apps identified to support heart failure self-care. Wali et al. reported that mobile apps with higher ratings were more recently updated, and this was true of the HFHS app, which was updated in March 2017 and August 2018. The HFHS app is convenient and portable, making it an ideal form of symptom and weight log or diary for people living in today's mobile society. The HFHS app also provides customizable, real-time reminders for self-care activities and gives users a colorful, graphic representation of trends in vital signs, daily weight, heart failure symptoms, and adherence to other daily self-care activities.

Hall et al. (2014) reported that people tend to view mobile apps positively but do not often download or use them, concluding that people need instruction on how to use technology to improve self-care along with support and encouragement to use technology consistently. Structured telephone support (STS), monitoring and/or managing self-care via telephone calls, has been shown to have a positive effect on treatment adherence, self-monitoring and self-management of heart failure, depression scores, ejection fraction, hospitalizations for heart failure, and odds of mortality (Inglis, Clark, et al., 2015; Moon et al., 2018; Unverzagt et al., 2016). Personal contact through home visits and regular

telephone calls with a trusted healthcare professional promotes a therapeutic bond that results in more long-term sustainable treatment adherence than use of technology alone (Unverzagt et al., 2016). Use of the HFHS app along with STS calls has great potential to increase symptom monitoring and improve self-care maintenance, management, and confidence in people with heart failure and their support people.

Problem Statement

Tracking daily weight and symptoms is an essential aspect of effective self-care of heart failure, yet many people forget or fail to use a log or diary because it is not convenient or they do not appreciate the value of tracking and recognizing trends in daily weight and heart failure symptoms.

Purpose and Objectives

The purpose of this project was to determine if using the HFHS app with STS calls was an effective intervention to promote improved self-care of heart failure and caregiver contribution to self-care of heart failure compared to the standard of care where the intervention was not used. Project objectives included determining:

- If a 90-day intervention of the HFHS app with STS calls in a household led to improved self-care of heart failure and caregiver contribution to self-care of heart failure.
- If being the actual user of the HFHS app and receiver of the STS calls in a household impacted the effectiveness of the intervention to improve self-care of heart failure and caregiver contribution to self-care of heart failure.

- If the level of use of the HFHS app in a household impacted the effectiveness of the intervention to improve self-care of heart failure and caregiver contribution to self-care of heart failure.
- If having a support person in a household, who participated in the project, impacted the effectiveness of the intervention to improve self-care of heart failure.

PICOT Questions

This project aimed to answer the following questions about the population of people with heart failure who were being treated at a Midwestern hospital and their support people:

- In people with heart failure, what was the improvement in self-care of heart failure after the HFHS app with STS calls was used in the household for 90 days compared with the standard of care where the app with STS calls was not used?
- In support people, what was the improvement in caregiver contribution to self-care of heart failure after the HFHS app with STS calls was used in the household for 90 days compared with the standard of care where the app with STS calls was not used?
- Did being the actual user of the HFHS app and receiver of the STS calls in the household impact the effectiveness of the intervention to improve self-care of heart failure and caregiver contribution to self-care of heart failure compared with the person in the household who was not using the app or receiving the calls?
- Did the level of use of the HFHS app in the household impact the effectiveness of the intervention to improve self-care of heart failure and caregiver contribution to self-care of heart failure?

- In people with heart failure, did having a support person who participated in the project impact the effectiveness of the intervention to improve self-care of heart failure compared with the people with heart failure who had a non-participating support person?

Significance of the Project

The goal of this project was to determine if the implementation of an evidence-based intervention using the HFHS app and STS calls was a more effective way to promote improved self-care of heart failure and caregiver contribution to self-care of heart failure than the standard of care. This project used a research approach guided by a situation-specific theory of nursing practice. The outcomes of this project will be used to inform nursing practice in the care of people with heart failure and their support people and future nursing research.

Summary

Heart failure is a complex, terminal disease, and many people with heart failure and their support people are challenged to cope with self-care. Asking people to track their self-care and symptoms in paper logs or diaries has not been an effective intervention to promote increased self-care of heart failure, but the HFHS app is a more personalized tool than a paper log. This dynamic approach using mobile app technology to promote heart failure self-care could be a valuable tool for nurses to share with heart failure patients and support people. If people can be taught to use the app and provided with ongoing support to encourage continued use, there is great potential to improve the health and well-being of people with heart failure through improved self-care.

CHAPTER 2

CONCEPTS, FRAMEWORK, AND LITERATURE REVIEW

In this chapter, the main concepts of the project will be identified and defined. The theoretical framework and its significance to the project will be discussed. Finally, concepts related to living with heart failure and interventions to promote better self-care of heart failure will be examined in greater detail through a review of the literature.

Concept Identification and Definition

Several main concepts were identified for this project. These concepts will be defined to promote comprehension and readability of this paper. Throughout this project, the concept:

- *90-day study period* was defined as a period of 90 consecutive days from the time of enrollment in the project to completion of participation in the project.
- *Self-care of heart failure* was defined as the ability of people with heart failure to learn to recognize symptoms and manage their condition, independently or with consultation from healthcare providers, without the benefit of daily medical or nursing supervision (Riegel et al., 2016).
- *Caregiver contribution to self-care of heart failure* was defined as the support of spouses, partners, and family members who augment a person's ability to perform self-care of heart failure, providing direct and indirect physical and emotional

support to promote self-care of heart failure (Näsström et al., 2016; Riegel et al., 2016; Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Glaser, et al., 2013).

- *Use of a mobile app* was defined as using the free Heart Failure Health Storylines (HFHS) app on a smartphone or tablet to record weight and other self-care of heart failure maintenance activities and to respond to routine-builder reminders daily for 90 days.
- *Level of use of the mobile app* was calculated as a percentage of the total number of data points possible, which was 19 data points recorded each day for 90 days, or 1,710 data points, low-level ($\leq 30\%$), moderate-level (31-69%), and high-level ($\geq 70\%$). However, due to a low sample size, moderate-level use participants were combined with low-level use participants, and level of use data were recoded into two categories, high-level ($\geq 70\%$) and low-level ($\leq 69\%$) use.
- *Structured telephone support (STS)* was defined as monitoring self-care via regularly scheduled telephone calls to answer participants' questions about and to encourage continued use of the HFHS app.
- *Control group participants* were defined as people with heart failure and support people participating in the project, who lived in households with no exposure to the intervention.
- *Intervention group participants* were defined as people with heart failure and support people participating in the project, who lived in households with exposure to the intervention, meaning at least one participant in the household used the HFHS mobile app and participated in STS calls with the project nurse.

Intervention group participants were divided into two subgroups, users of the mobile app and non-users of the mobile app.

- *Users of the mobile app* were defined as intervention group participants who actually entered information into the HFHS mobile app and participated in STS calls with the project nurse.
- *Non-Users of the mobile app* were defined as intervention group participants who did not actually enter information into the HFHS mobile app and participate in STS calls with the project nurse, but who were exposed to the intervention because the other participant in their household was using the HFHS app and participating in STS calls with the project nurse.
- *Self-care maintenance activities* were defined as routinely weighing oneself, checking ankles for swelling, avoiding illness by getting a flu shot and avoiding sick people, doing some physical activity, exercising for 30 minutes, keeping healthcare appointments, eating a low-salt diet, asking for low-salt items when eating away from home, taking medications as prescribed, and using a pillbox or reminders to take medications (Riegel et al., 2009).
- *Self-care management activities* were defined as recognizing symptoms as related to heart failure; taking action to remedy symptoms by reducing salt in diet, reducing fluid intake, taking an extra water pill, or calling a healthcare provider for guidance; and determining if a remedy helped to relieve symptoms or not (Riegel et al., 2009).
- *Self-care confidence* was measured by confidence in one's ability to keep oneself free of heart failure symptoms, follow treatment advice, evaluate the importance

of symptoms, recognize changes in health status, do something to relieve symptoms, and evaluate how well a remedy worked (Riegel et al., 2009).

- *Self-care adequacy* was defined as a score of 70 or greater in each of the three areas of self-care of heart failure that were measured for this project, i.e., maintenance, management, and confidence (Riegel et al., 2009).

Theoretical Framework

The Situation-Specific Theory of Heart Failure Self-Care

A situation-specific or micro theory is a narrowly defined practice theory; therefore, the situation-specific theory of heart failure self-care (the Theory) is rather self-explanatory (Butts, 2015). Riegel et al. (2016) published a revised version of the Theory which was originally published in 2008. According to the Theory, self-care is defined as a “naturalistic decision-making process that influences actions that maintain physiologic stability, facilitate the perception of symptoms, and direct the management of those symptoms” (Riegel et al., 2016, p. 226). Naturalistic decision-making theory states that every decision is made with a combination of past experience and current information and involves an interaction among the person, problem, and current real-life situation (Riegel et al., 2016). Self-Care requires tactical and situational decision-making skills to make decisions and to know ‘what to do when’ to act on decisions (Riegel et al., 2016). These decision-making skills are developed with practice and experience over time (Riegel et al., 2016).

Self-care of heart failure is a process that consists of three progressive concepts: (a) self-care maintenance; (b) symptom perception; and (c) self-care management (Riegel et al., 2016). People begin at the maintenance level, following a prescribed treatment

plan; progress to symptom perception, learning to listen to their body; and then self-manage by responding appropriately to the messages received from their body (Riegel et al., 2016). All three stages of the self-care process involve autonomous and consultative decisions made collaboratively with support people and healthcare providers and are influenced by internal and external factors (Riegel et al., 2016). Self-care self-confidence is a factor that helps people progress from the maintenance to the management level of heart failure self-care and leads to improved outcomes for people with heart failure (See Figure 2.1) (Riegel et al., 2016). Riegel et al. (2016) stated five assumptions and eight propositions for the Theory (See Table 2.1). In summary, the Theory defines heart failure self-care as a progression from maintenance- to management-level behavior, learning to recognize symptoms and make decisions about how to remedy those symptoms, which is propelled by self-confidence and support from caregivers and healthcare providers.

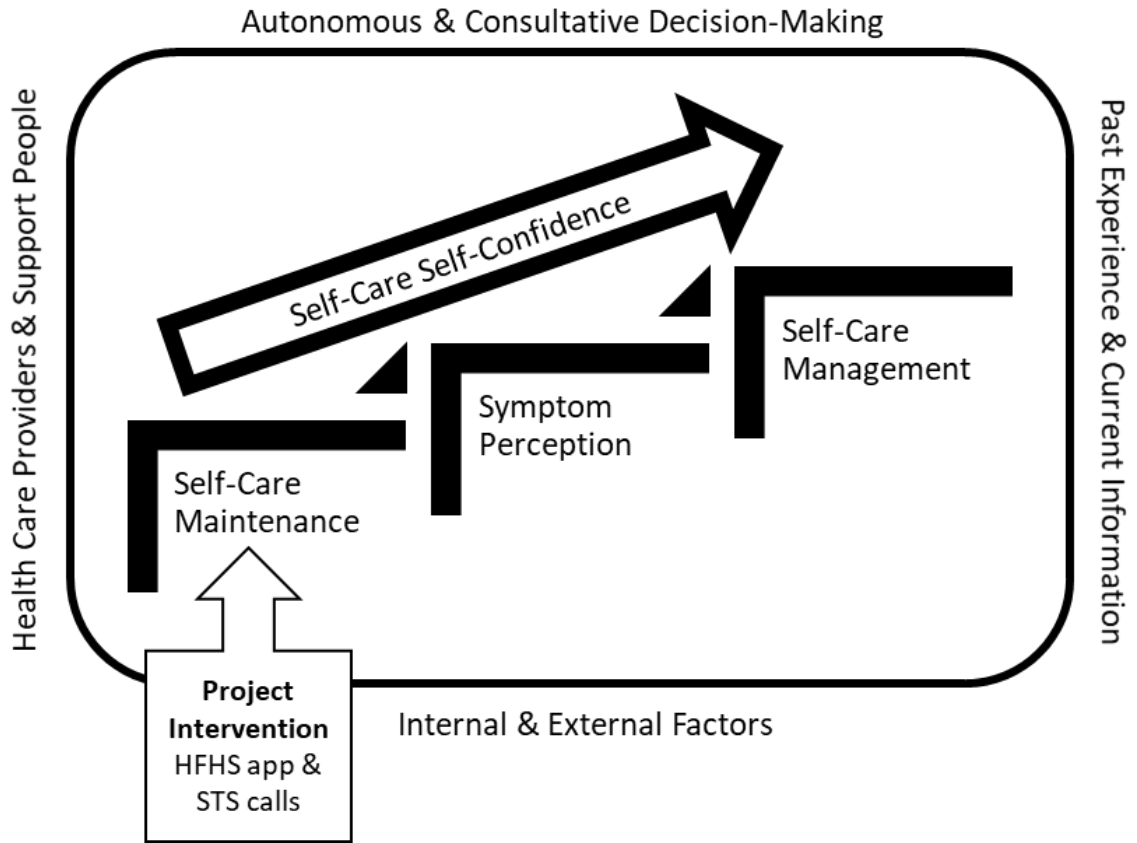


Figure 2.1. Situation-Specific Theory of Heart Failure Self-Care. Adapted from Riegel et al., (2016)

Table 2.1

Theory Assumptions and Propositions

Assumptions

People want to feel well and healthy.

Adults are responsible for their own health.

All self-care involves decision-making.

Self-care can be learned.

Person, problem, and environmental factors contribute to self-care decisions.

Propositions

Specific maintenance-level behaviors are influenced by unique factors.

Physical and emotional symptoms influence self-care.

Decisions about self-care may be conscious or subconscious and reflect choices influenced by person, problem, and environmental factors.

Comorbidities impair abilities and self-care self-efficacy.

Self-care self-efficacy influences the relationship among predictors of self-care, self-care behaviors, and outcomes.

A moderate- to high-level of self-care is required to improve outcomes.

Increased self-care self-efficacy leads to increased autonomous self-care Behavior.

Self-care progresses from maintenance to symptom perception to management.

Application of the Theory to the Project

It was easy to make a connection between the Theory and the DNP project. The Theory described three progressive levels of heart failure self-care, the decision-making process that people experience to advance from one level of self-care to the next, and factors that impact a person's self-care decision-making process (Riegel et al., 2016). The intervention implemented for this project involved use of the HFHS app to record daily weight and self-care activities to help people to consistently perform basic self-care of heart failure at the maintenance level. The project nurse used STS calls to answer

questions and encourage consistent use of the HFHS app. The HFHS app provided a visual record of daily symptom perception and self-care maintenance activities—the ups and downs—in colorful graphs to help people to recognize patterns in their symptoms and self-care activities and progress to the management level of heart failure self-care with increased confidence.

The Self-Care of Heart Failure Index (SCHFI) (Appendix A) and the Caregiver Contribution to Self-Care of Heart Failure Index (CC-SCFHI) (Appendix B) tools were developed using the Theory. Therefore, these tools were the most appropriate measurement of the effectiveness of this project intervention, which aimed to promote improvement in heart failure self-care and caregiver contribution to heart failure self-care. The SCHFI was used to measure self-care of people with heart failure, and the CC-SCHFI was used to measure caregiver contribution to self-care by support people. These two equivalent instruments were used to measure self-care maintenance, management, and confidence separately.

Vellone, Riegel, D'Agostino, et al. (2013) used the SCHFI in a study conducted to test the Theory with structural equation modeling. Vellone, Riegel, D'Agostino, et al.'s (2013) results supported the foundation of the Theory, that symptom monitoring and adherence to the treatment plan are essential for effective self-care of heart failure at the maintenance level. Symptom monitoring and treatment adherence were linked to each other ($p < 0.01$), and both led to improved symptom recognition and evaluation ($p < 0.01$) (Vellone, Riegel, D'Agostino, et al., 2013). Improved symptom recognition and evaluation led to improved self-management ($p < 0.01$), which was defined as implementation of appropriate treatments for symptoms, and evaluation of the treatments

($p < 0.01$) (Vellone, Riegel, D'Agostino, et al., 2013). Vellone, Riegel, D'Agostino, et al. (2013) validated the Theory by concluding that interventions which were guided by the Theory, to help people improve symptom monitoring and adherence to their treatment plan, promoted improved recognition and evaluation of heart failure symptoms as well as a greater probability that people would implement appropriate treatments for their heart failure symptoms and evaluate the outcomes of those treatments. In summary, the Theory with the complimentary measurement tools, the SCHFI and CC-SCHFI, were the ideal framework and assessment for an intervention aimed to promote improved heart failure self-care at the maintenance level.

Review of Literature

Heart failure is a complex, progressive condition. Most people who have heart failure experience multiple comorbid chronic conditions with overlapping symptoms, which makes self-care of heart failure challenging. People with heart failure can benefit from the aid of friends and family who support them in self-care. Interventions aimed to promote improved self-care of heart failure are as varied and complex as the disease itself, but use of a daily weight and symptom diary is an essential component of self-care. Technology is changing how people track health and well-being, including self-care of heart failure. The concepts that were examined in this literature review included the burden of comorbidities and symptoms of heart failure, self-care of heart failure, the contribution of support people, daily weight and symptom diaries, use of technology, and structured telephone support to promote improved self-care of heart failure.

Burden of Comorbidities and Symptoms of Heart Failure

The burden of comorbidities and symptoms associated with heart failure is high and increases as heart failure progresses, which contributes to declining ability to perform self-care (Alpert et al., 2017; Stockdill et al., 2019). Many comorbidities are actually risk factors, which contribute to the development of heart failure and persist over time, intensifying the overall symptom burden (Alpert et al., 2017; Benjamin et al., 2019). Polypharmacy, the long-term use of five or more medications, is another important aspect of the comorbidities and symptoms of heart failure (Page et al., 2016). The burden of comorbidities and symptoms contribute to decreased functioning and quality of life, and increased hospitalizations and mortality for people with heart failure (Alpert et al., 2017; Benjamin et al., 2019; Blecker et al., 2019; Stockdill et al., 2019).

Comorbidities. A majority (86%) of people with heart failure had at least two comorbid conditions, and over half (60%) had three to nine comorbidities (Chamberlain et al., 2015; Manemann et al., 2016; Murad et al., 2015). More than half (52%) of heart failure cases are related to coronary heart disease, hypertension, diabetes, obesity, and tobacco use, which are risk factors for and comorbid conditions of heart failure (Benjamin et al., 2019; Murad et al., 2015).

Cardiovascular conditions, e. g., hypertension, hyperlipidemia, cardiac arrhythmias, and coronary heart disease, are the most common comorbidities of heart failure (Chamberlain et al., 2015; Manemann et al., 2016; Murad et al., 2015). An estimated three to six million people in the US have atrial fibrillation, a cardiac arrhythmia, and that number is expected to reach 12 million by the year 2030 (Benjamin

et al., 2019). Heart failure and atrial fibrillation have many common risk factors, and therefore, they are common comorbid conditions (Benjamin et al., 2019). Approximately 40% of people who have been diagnosed with either heart failure or atrial fibrillation will develop the other condition (Benjamin et al., 2019).

Although cardiac comorbidities affect more than half of all people with heart failure, non-cardiac comorbidities pose a greater threat to their morbidity and mortality (Chamberlain et al., 2015; Manemann et al., 2016; Murad et al., 2015). Non-cardiac comorbidities of heart failure include arthritis, diabetes, cancer, chronic obstructive pulmonary disease, depression and anxiety, kidney disease, peripheral arterial disease, and cerebrovascular disease (Chamberlain et al., 2015; Manemann et al., 2016; Murad et al., 2015). Depression and anxiety, which may be viewed as comorbidities or symptoms of heart failure, alter perception and lead to functional impairment, decline in self-care, heart failure exacerbations, lower quality of life, and greater risk for mortality (Graven et al., 2017; Manemann et al., 2016; Murad et al., 2015; Stockdill et al., 2019). Depression, which can be one of the most difficult conditions to treat in people with heart failure, along with a higher symptom burden are predictors of a poorer one-year health status trajectory for people with heart failure (Bekelman et al., 2018; Flint et al., 2017).

People with numerous comorbidities, particularly non-cardiac comorbidities, most likely see several different healthcare specialists, who may or may not know that a person also has heart failure (Page et al., 2016). Therefore, these providers may not consider the potential impact on heart failure when prescribing medications (Page et al., 2016). Having multiple comorbidities is associated with a greater degree of polypharmacy, which increases the risk for medication interactions and side effects, contributing to the

overall negative impact of heart failure (Page et al., 2016). There is an extensive list of medications that may cause or exacerbate heart failure, contributing to the burden of comorbidities and symptoms (Page et al., 2016). In summary, a higher number of comorbid conditions, particularly non-cardiac conditions, and the related increase in polypharmacy and symptoms, constitute a burden on people with heart failure by contributing to decreased self-care of heart failure and greater morbidity and mortality.

Symptoms. Numerous physical and psychological symptoms which are associated with heart failure and the variety of comorbid conditions constitute the burden of these conditions on people with heart failure. Stockdill et al. (2019) identified four aspects of symptom burden: (a) subjectivity; (b) synergistic association; (c) negative impact on daily life; and (d) exacerbations. Each person experiences symptoms differently, and the sum of multiple symptoms is greater than the individual symptoms (Stockdill et al., 2019). Physical and psychological functioning are impaired by symptoms, particularly during the unpredictable worsening of symptoms in an exacerbation (Stockdill et al., 2019).

In addition to depression and anxiety, fatigue, pain, dyspnea, cough, swelling, weight gain, dizziness, nausea, and decreased appetite are some of the most common symptoms reported by people with heart failure (Alpert et al., 2017; Bekelman et al., 2018; Flint et al., 2017; Gandesbery et al., 2018; Graven et al., 2017; Overbaugh & Parshall, 2017). Pain may include musculoskeletal, neuropathic, or medical device site (Gandesbery et al., 2018). These symptoms can occur with differing patterns and severity making them ambiguous and difficult for people with heart failure to recognize as related to heart failure (Overbaugh & Parshall, 2017). Not recognizing that symptoms may be

related to heart failure can lead to normalization of the symptoms and delayed treatment or behavior change (Alpert et al., 2017).

An important self-care of heart failure maintenance-level behavior is taking prescribed medications consistently, whether or not a person feels symptomatic. Unfortunately, real or perceived medication side effects may also contribute to the symptom burden of heart failure. Heart failure medications associated with more negative side effects include loop diuretics, statins, mineralocorticoid receptor antagonists, and beta blockers (Chin et al., 2018; O'Donovan et al., 2019). As many as 75% of people with heart failure did not take medications as prescribed, and missing doses was the most common deviation (Chin et al., 2018). People may weigh the pros and cons of taking medications, comparing the benefits of controlling their health condition with the added burden that symptoms place on their daily life (O'Donovan et al., 2019). Not taking medications as prescribed and missing doses contributes to worsening of heart failure and a decline in self-care (Riegel et al., 2017). In summary, the burden of symptoms, including the negative effects of polypharmacy, is high for people with heart failure, as it contributes to decreased self-care of heart failure and greater morbidity and mortality.

Self-Care of Heart Failure

The term self-care refers to the fact that people with heart failure and their support people must learn to recognize symptoms and manage their condition, independently or with consultation from healthcare providers, without the benefit of daily medical or nursing supervision (Riegel et al., 2016). Traditionally, self-care has involved following a prescribed plan of care, taking prescribed medications, and keeping medical appointments (Riegel et al., 2017). A more progressive view of self-care requires patients

and family members to partner with healthcare providers and actively participate in their health and well-being, setting goals and developing their plan of care (Riegel et al., 2017).

An understanding of health status, risk factors, basic disease process, prognosis, and treatment options are key concepts of self-care (Riegel et al., 2017). Treatment of heart failure begins with healthy lifestyle practices including diet, physical activity, weight control, smoking cessation, and abstinence or moderation in use of alcohol (Riegel et al., 2017). Basic self-care concepts of heart failure treatment include daily weight and symptom monitoring, and medication and dietary adherence (Riegel et al., 2017). Heart failure medications are most effective when symptoms, especially congestion, are under control (Riegel et al., 2017). Therefore, another key concept of self-care is avoiding heart failure exacerbations, which requires patients and their family members to recognize and evaluate weight and symptoms in a timely manner (Riegel et al., 2017). After recognizing and evaluating symptoms, people who function at the highest level of self-care, which is self-management, are able to appropriately treat their symptoms and evaluate the results (Riegel et al., 2017).

In summary, successful self-care requires constant attention to and decision-making regarding daily weight and symptoms, medications, diet, and numerous other health status indicators guided by their treatment plan (Riegel et al., 2016). Education, support, and encouragement to actively participate in their treatment plan can give people increased confidence and perceived control to improve their self-care of heart failure and optimize their health status (Koirala et al., 2018; Riegel et al., 2016). Effective self-care

of heart failure can decrease symptoms, avoid exacerbations and associated hospitalizations, increase functionality, and improve quality of life (Riegel et al., 2016).

Contribution of Support People

Support people play a very important role in self-care of heart failure. Living with heart failure and managing self-care requires constant vigilance. As the disease progresses and physical and emotional condition worsens, many people with heart failure are overwhelmed and require direct and indirect support (Näsström et al., 2016). Support people are spouses, partners, and family members who augment a person's ability to perform self-care of heart failure, providing direct and indirect physical and emotional support to promote self-care of heart failure (Näsström et al., 2016; Riegel et al., 2016; Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Glaser, et al., 2013). Direct contributions to self-care of heart failure by support people include monitoring symptoms, preparing a low sodium diet, providing transportation to appointments, and administering daily medications as ordered (Näsström et al., 2016). Indirect contributions to self-care of heart failure include emotional support, motivation, communication with healthcare providers, and navigation of the healthcare system (Näsström et al., 2016). In summary, support people provide a variety of direct and indirect support to help people with heart failure to perform essential self-care.

Daily Weight and Symptom Diaries

The use of symptom diaries is associated with improved patient engagement, providing a sense of control and therapeutic benefits from documenting physical experiences and emotions (Hodge, 2013). Symptom diaries can provide visual cues to help people to notice subtle changes in their health condition and identify the triggers,

which can lead to lifestyle or treatment modifications to improve health and well-being (Hodge, 2013). Symptom diaries can also help people to be more organized and focused, which can help them to share more accurate and concise information about their condition with their healthcare providers (Hodge, 2013).

People who have episodic or acute conditions may gain benefit from maintaining a symptom diary intermittently or for a short period of time, but best practice for self-care of chronic conditions like heart failure is to maintain a daily symptom diary indefinitely. Education about heart failure self-care inherently includes the importance of monitoring daily weight and heart failure symptoms, e.g., shortness of breath, leg swelling, and number of pillows used, in a diary or log (Park et al., 2017). The goal of this basic self-care maintenance activity is to help people begin to recognize symptom trends, e.g., symptoms begin to increase when weight has increased, and prompt them to take appropriate action to remedy their symptoms or call their healthcare provider's office for instructions. The ultimate goal of tracking weight and symptoms is to recognize and treat symptoms early to avoid an exacerbation of heart failure that requires hospitalization.

In a 12-month study of adoption of self-management of heart failure behavior using weight and symptom logs conducted by Wright et al. (2003), 76% of intervention group participants ($n = 100$) used the diary. Of the 76 participants who used the diary, 51 (67%) weighed themselves at least once a week, which was associated with increased visits to the heart failure clinic ($p = 0.001$) and telephone calls to providers ($p = 0.002$), and fewer hospital admissions ($p = 0.04$) (Wright et al., 2003). All participants did not have a bathroom scale at home, and the authors concluded that provision of a scale to all participants may have promoted more frequent weighing by more participants (Wright et

al., 2003). DeWalt et al. (2006) also conducted a 12-month study of a heart failure self-management intervention where participants were provided with education, a simple daily tracking worksheet, and a digital scale. Intervention group participants improved in self-efficacy ($p = 0.0026$), self-care behavior ($p < 0.001$), and performance of a daily weight ($p < 0.0001$) compared to the control group (DeWalt et al., 2006). The results of these two studies highlighted the importance of making sure that all participants in this DNP project were provided with a digital bathroom scale.

Eastwood et al. (2007) provided weight and symptom diaries to all participants ($N = 124$), and the 70 (56%) who elected to use the diary for six months, were placed in the intervention group. The control group, those who chose not to use the diary, were more likely to be younger women with a lower ejection fraction (Eastwood et al., 2007). Diary users had a lower ejection fraction at six months ($p < 0.038$) compared with diary non-users whose ejection fraction remained the same (Eastwood et al., 2007). Diary users also had more visits to the heart failure clinic ($p < 0.001$) and telephone contacts with healthcare providers ($p < 0.007$) than diary non-users (Eastwood et al., 2007). Diary users who had a hospital admission during the study period ($n = 40$) decreased their length of stay from baseline by 58% ($p < 0.002$) and cost per case by 56% ($p < 0.011$) (Eastwood et al., 2007).

Jones et al. (2014) compared use of a daily weight log with self-reported recall of weight monitoring over a 12-month period using 80% as a cutoff for adherence. Only 107 (50%) participants ($N = 216$) used a weight diary greater than or equal to 80% of the time, which was associated with fewer hospitalizations (IRR 0.37; 95% CI 0.18-0.75) than participants who used a weight diary less than 80% of the time (Jones et al., 2014).

Self-reported recall of daily weight was not an effective method of weight monitoring as it was not associated with fewer hospitalizations for heart failure (Jones et al., 2014). Self-reported recall greater than or equal to 80% of the time (IRR 1.34; 95% CI 0.24-7.32) compared to self-reported recall less than 80% (Jones et al., 2014). Jones et al. (2014) concluded that use of a weight diary was a higher level of heart failure self-care than self-reported recall of weight, indicating greater engagement in the plan of care.

Lee et al. (2013) conducted a study that used a heart failure symptom log and follow-up telephone calls for three months. The intervention group experienced a longer period of event-free survival ($p = 0.03$) than the control group (Lee et al., 2013). Park et al. (2017) conducted a 24-month study involving the use of a daily diary for weight and heart failure symptoms. Intervention group participants received a bathroom scale and were asked to submit their dairies monthly (Park et al., 2017). Participants who were high ($p = 0.02$) or very high ($p = 0.01$) users of the dairy had significantly reduced incidence of all-cause mortality compared to those who did not use the diary (Park et al., 2017).

Unfortunately, daily weight and symptom tracking is not commonly practiced by people with heart failure. Koberich (2016) reported that many people do not see any point in keeping a weight and symptom diary when they feel good (67.9%), and keeping a diary does not fit into their lifestyle (85.7%). In a three-month study conducted by White et al. (2010), participants ($N = 16$) were asked to record daily weight and symptoms in a diary; the mean adherence was 79.4% with a range of 10.9% to 100%. Although weight logs and symptom dairies have great potential to help people become more actively engaged in self-care of heart failure, White et al. reported a variety of reasons that participants ($N = 16$) cited for non-adherence to daily weight including vacation (57%),

holiday meals (14%), forgetfulness (14%), and not reported (14%). In summary, despite low adherence, tracking daily weight and symptoms is an essential maintenance-level activity for self-care of heart failure, and according to the Theory, this basic self-care maintenance activity can improve symptom perception and self-care management of heart failure.

Use of Technology

Technology, used alone or in conjunction with other methods, can make health and wellness supportive and educational interventions more convenient, accessible, and appealing for people. The literature is filled with evidence of the benefits of using technology, particularly mHealth, to promote self-care of chronic conditions like heart failure. Use of mHealth has resulted in improved adherence to medication schedules, awareness of health condition, and quality of life; and reduced hospital readmissions (Athilingam & Jenkins, 2018; Cajita et al., 2016; Morton et al., 2017; Walker et al., 2014). The focus of this review will be interventions that used mobile phones or mobile apps on smartphones or tablets to promote self-care of heart failure.

Seto et al. (2012a, 2012b) studied a six-month trial of a mobile phone-based telemonitoring intervention with good results. Intervention participants improved significantly in self-care of heart failure maintenance ($p = 0.05$) and management ($p = 0.03$) (Seto et al., 2012a). Participants reported being more motivated to record daily weight, vital signs, and symptoms knowing that their healthcare provider expected to receive the daily information (Seto et al., 2012b). Participants expressed a greater awareness of how their lifestyle choices affected their physical condition with heart failure, e.g., how increased salt intake led to greater fluid retention and increased weight

(Seto et al., 2012b). Participants also appreciated the portability of a mobile phone-based intervention and were reassured by the feeling of connectedness to their healthcare providers even when traveling (Seto et al., 2012b).

Nundy et al. (2013) studied a text message-based intervention to promote self-care of heart failure for 30 days after discharge from hospitalization for a heart failure exacerbation. Although the study did not use a control group, participants showed clinical and statistical improvement in self-care maintenance (posttest scores improved by 29 points, $p = 0.003$) and management (posttest scores improved by 29 points, $p = 0.002$), as measured by the SCHFI (Nundy et al., 2013). Self-care confidence did not improve statistically, but it did improve clinically (posttest scores improved by 18 points) (Nundy et al., 2013). Most participants (83%) thought the intervention was easy to use, and two of the biggest helps were decreasing the number of missed medication doses (66%) and reducing salt intake (66%) (Nundy et al., 2013).

Foster (2018b) used Riegel et al.'s (2012) middle-range theory of self-care of chronic illness to develop a mobile app to support self-care of heart failure, which required users to enter physiologic data and answer questions about symptoms daily. The app also included educational information. Participants in beta testing of the app improved in self-care maintenance ($p \leq 0.05$), management ($p \leq 0.05$), and confidence (posttest score improved by 11 points, $p = 0.037$), as measured by the SCHFI (Foster, 2018b). Participants reported that using the app helped them to become “more aware of their symptoms and the need to self-monitor”, which they perceived as a benefit (Foster, 2018a, p. 93).

Athilingam et al. (2017) studied a mobile app that was developed to engage people with heart failure through educational support and promotion of self-care for a 30-day period. The intervention included daily measurement of weight, collection of vital signs using a wearable device, symptom monitoring, promotion of daily exercise, educational information, and a medication tracker (Athilingam et al., 2017). The app also had the ability to provide feedback to users with alerts on daily measurements and performance (Athilingam et al., 2017). Intervention group participants had greater improvement than the control group in self-care management (posttest scores improved by 8 points, $p = 0.01$) and confidence (posttest scores improved by 7 points, $p = 0.03$), as measured by the SCHFI, and knowledge of heart failure ($p = 0.04$) (Athilingam et al., 2017). Users of the app reported ease of use, but the need for upgrades to the wearable device was noted (Athilingam et al., 2017). In summary, mobile phone-based apps that are quick and easy to use can be an important component of interventions aimed to promote self-care of heart failure.

Structured Telephone Support

Many people with heart failure and their support people are educated, provided with resources and tools, and scheduled for follow-up appointments, but they still struggle to effectively perform self-care to avoid heart failure exacerbations requiring hospitalization. Approximately 900,000 people were discharged from hospitals with a diagnosis of heart failure in 2014, and once a person has been hospitalized for heart failure, there is a higher likelihood that they will require rehospitalization for heart failure (Benjamin et al., 2019). Interventions that include STS calls can promote better self-care by keeping lines of communication open to provide people with the support they need to

continue to learn and stay on track with their prescribed plan of care between office visits with their healthcare providers.

A nurse-led educational support intervention that involved an initial meeting and telephone support for three months resulted in significant ($p < 0.001$) improvement in self-care scores for the intervention group, and the control group's scores did not improve from baseline (Zamanzadeh et al., 2013). Tung et al. (2013) studied an eight-week intervention to promote self-care of heart failure that included training, printed materials, and follow-up calls to assess adherence and promote self-efficacy. The intervention group improved significantly in self-maintenance ($p = 0.049$) and self-management ($p = 0.039$) of heart failure as measured by the SCHFI (Tung et al., 2013). Tung et al. concluded that their intervention helped participants to “feel more capable of dealing with disease-related symptoms” (p. E14) than the control group.

In an intervention to promote self-care in people who had undergone knee surgery, post-surgical patients were asked to do knee exercises at home for one hour per day for 12 weeks (Chen et al., 2016). The use of STS calls with the intervention group resulted in greater exercise time in minutes (54.12) than the control group (48.95) ($p < 0.01$) and for a greater number of days (78.35) than the control group (70.21) ($p < 0.01$) (Chen et al., 2016). Range of motion and functionality also improved significantly ($p < 0.01$) in the intervention group, which the authors stated may have been related to greater adherence to the home exercise plan (Chen et al., 2016). While Chen et al.'s (2016) study did not involve the population of people with heart failure, the concept of adherence to a self-care regimen is relevant to this DNP project.

Moon et al. (2018) studied an intervention of telephone-based self-management support for people with heart failure that measured self-care behaviors, N-terminal pro-brain natriuretic peptide levels, left ventricular ejection fraction, and depression. The intervention included printed educational materials provided in an initial face-to-face meeting, followed by a weekly telephone call to provide support for four weeks (Moon et al., 2018). Intervention group participants had significant improvement in all of the measurements, i.e., self-care behaviors ($p < 0.001$), N-terminal pro-brain natriuretic peptide levels ($p = 0.022$), left ventricular ejection fraction ($p = 0.032$), and depression ($p = 0.001$), compared to the control group (Moon et al., 2018).

In their extensive review of STS and non-invasive telemonitoring studies involving people with heart failure, Inglis, Clark, et al. (2015) reported that interventions involving STS can help people to learn about heart failure, improve self-care behavior and quality of life, and reduce hospitalizations and mortality. In general, study participants enjoyed STS interventions and older age was not a barrier to the benefits of STS (Inglis, Clark, et al., 2015; Inglis, Conway, et al., 2015). Inglis, Clark, et al. concluded that non-invasive telemonitoring and STS “should be considered evidence-based strategies to improve the quality of care and outcomes for people with heart failure” (p. 39).

Treatment of heart failure is continuously advancing, but without adherence to prescribed treatment plans including diet, medication, and lifestyle practices, many people do not receive the full benefit of these advancements (Unverzagt et al., 2016). Improved adherence to their treatment plan was associated with improved clinical outcomes for people with heart failure (Unverzagt et al., 2016). Ongoing contact and

encouragement can help to create a therapeutic bond, an especially important component of technology-based interventions (Unverzagt et al., 2016). In summary, STS calls can promote improved understanding of and adherence to a treatment plan including performance of essential maintenance-level activities for self-care of heart failure.

Summary

As described by the Theory, self-care is an essential component of heart failure treatment. Since heart failure and treatment plans for heart failure are complex and the burden of comorbidities and symptoms is high, self-care of heart failure is challenging and support people play an important role in self-care of heart failure. Likewise, interventions aimed to promote and support self-care of heart failure are numerous and varied in their focus and design. The outcomes of many of these studies suggested that an intervention involving the use of the HFHS app with STS calls may promote significant improvement in self-care for people with heart failure and their support people. These interventions and the efforts of many experienced researchers will serve as a comparison for the intervention examined in this DNP project.

CHAPTER 3

METHODOLOGY

Project Design

This project used a quantitative quasi-experimental pretest-posttest design with a non-equivalent control group. The pretest and posttest were conducted to measure the effectiveness of a 90-day intervention compared to the standard of care. The 90-day intervention by the project nurse aimed to improve self-care of heart failure by people with heart failure and caregiver contribution to self-care of heart failure by support people. The 90-day intervention involved three components: (a) teaching people with heart failure and support people how to use the HFHS app; (b) use of the app by at least one person in a household—the person with heart failure or the support person or both people; and (c) STS calls by the project nurse. Control group participants took the pretest and posttest 90 days apart, and no one in the household participated in the 90-day intervention. The project was guided by the project committee (Appendix C).

Population and Sample

A convenience sample of people with heart failure who were admitted as inpatients to the progressive care unit (PCU) or the short stay unit (SSU) or who visited the heart failure clinic (Clinic) as outpatients and their support people were recruited from the population of heart failure patients at a Midwestern hospital. People recruited

from inpatient units did not participate in the project until after they were discharged to independent living.

Sample Size

The sample size was estimated using G*Power 3.1.9.2, based on the initial plan to conduct a multivariate analysis of covariance (MANCOVA) with 10 levels of the independent variable and three dependent variables for the statistical analysis. A minimum sample size of 35 total participants was estimated assuming a medium (0.25) effect size, an error probability α of 0.05, and a power of 0.95. A minimum sample size of 82 participants was estimated assuming a small effect size (0.10). Therefore, the project nurse made every effort to enroll as many participants as possible over a three-month period of time.

Definition of Participation

People with heart failure and support people were counted as separate participants with a maximum of two participants in each household: (a) one person with heart failure; and (b) one support person. All participants agreed to provide demographic data about themselves. People with heart failure agreed to provide information about their health status and heart failure diagnosis, which was collected from their electronic medical record (EMR) at the project hospital.

Participation Options

All participants, people with heart failure and support people, had the opportunity to choose one of two options: (a) to use the HFHS app with STS calls for 90 days; or (b) to simply take two surveys, 90 days apart. If one person in a household chose to use the HFHS app, then both participants in the household were placed in the intervention group.

If no person in a household chose to use the HFHS app, then both participants in the household were placed in the control group. In both the intervention and control groups, a person with heart failure was able to participate individually, without a support person. However, a support person was not eligible to participate if their person with heart failure was not willing or eligible to participate. See Figure 3.1 for an illustration of participation options. These criteria were established, because if the person with heart failure had not participated, then the project nurse would not have been able to collect health status data from their EMR to confirm their diagnosis of heart failure.

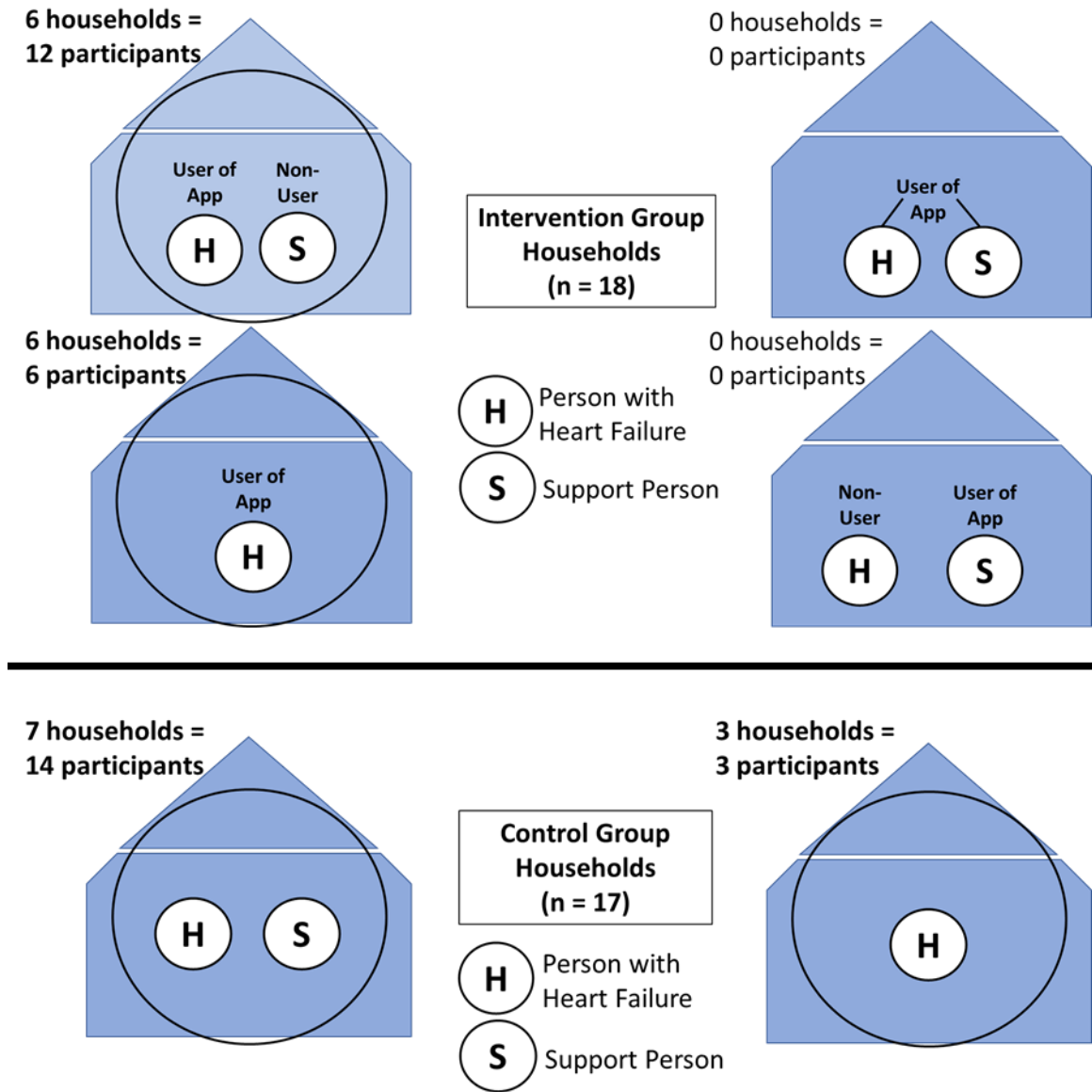


Figure 3.1. Participation Options

Institutional Review Board

The healthcare institution granted consent for the project to be conducted under the supervision of the clinical practice mentor (Appendix D). The project was originally granted expedited approval in December 2017 by the Institutional Review Boards (IRBs) at Andrews University and the healthcare institution where the subjects were recruited (Appendix E). The project protocol was revised in March 2018 to include the use of the

Provider Health Storylines online dashboard, and the amended protocol was also granted expedited approval by both IRBs in March 2018 (Appendix F). Andrews University IRB granted approval for continuation of the project in June 2019, and the healthcare institution's IRB granted approval for continuation in July 2019 (Appendix G).

Recruitment

Nurses (RNs) on the PCU, SSU, and in the Clinic at the healthcare institution were provided with recruitment flyers and a script to use when offering flyers to people with heart failure and support people, who they believed met the project inclusion criteria and might be interested in participating in the project. RNs were asked to collect the name and telephone number for all people who were given a flyer. The project nurse called these people after they were discharged to independent living to assess their interest in the project, screen them for the inclusion/exclusion criteria, and to answer questions about the project. If they were interested and met the inclusion/exclusion criteria, an enrollment meeting was arranged at that time.

The project nurse also received a list of all current Clinic patients, and she called these people to assess their interest in the project, to screen for inclusion/exclusion criteria, and to answer questions about the project. Again, if appropriate, an enrollment meeting was arranged at that time. Recruitment and enrollment were conducted intermittently for a total of three months during April and May 2018, and August 2019.

Inclusion-Exclusion Criteria

To qualify for participation in this project, a person either had to have received a diagnosis of heart failure or have been a support person for someone who had received a diagnosis of heart failure. Five additional inclusion criteria were:

- a. the person with heart failure had to be able to stand on a digital bathroom scale;
- b. one participant per household had to be in possession of and have the ability to use a smartphone or tablet;
- c. all participants had to be living independently and able to participate in self-care or contribute to self-care;
- d. all participants had to be alert, oriented, and able to provide consent to participate for themselves; and
- e. the person with heart failure had to be at least 55 years old.

People were excluded from participation if either the person with heart failure or the support person in a household had previous experience using the HFHS app.

Enrollment and Intervention

Enrollment Meeting

Enrollment meetings were scheduled for mutually agreeable dates, times, and places. Some meetings took place in participants' homes, but most meetings took place at the Clinic, located in the hospital. The project nurse provided and demonstrated a digital bathroom scale to participants in every household who wanted one.

Each individual participant received a copy of the informed consent form and the enrollment form (Appendix H). Each participant with heart failure also received a HIPAA authorization form to grant access to their EMR to the project nurse (Appendix I). All forms were explained and all questions were answered by the project nurse. Each individual participant completed a pretest to assess their baseline self-care of heart failure or caregiver contribution to self-care of heart failure. Before the end of all enrollment

meetings, a conclusion meeting was scheduled. Control group participation in the project included only an enrollment meeting and a conclusion meeting.

Enrollment meetings for participants in intervention group households included additional time to download and customize the HFHS app on one participant's mobile phone or tablet and to train participants how to use the app. Intervention group participants were provided with a folder containing a quick reference guide with a list of the 19 data points to be recorded in the HFHS app every day, the project nurse's contact information for any questions that might come up between STS calls, and a schedule of the dates and times for their six STS calls and the conclusion meeting. Once intervention group participants were comfortable using the HFHS app, the enrollment meeting ended.

Intervention

Intervention group participation included using the HFHS app on a mobile phone or tablet and engaging with the project nurse on six STS calls over a period of 12 weeks by at least one participant in the household. The person using the app and taking the STS calls could be either the person with heart failure, the support person, or both.

Participants who used the app were asked to record eight heart failure symptoms and self-care activities and respond to 11 routine-builder reminders daily (See Table 3.1).

Routine-builder reminders were timed to accommodate each participant's schedule.

Table 3.1

Use of the HFHS App

HFHS App Function	How Data Was Recorded
Self-Care of Heart Failure Activities	
Daily Weight	Actual number from digital scale
Ankle/Leg Swelling	Slide bar from 0-No Symptoms to 10-Most Severe
Shortness of Breath	Slide bar from 0-No Symptoms to 10-Most Severe
Impact of Symptoms on Day	Slide bar from 0-No Symptoms to 10-Most Severe
Physical Activity – Level	Slide a bar from 1-Light to 2 to 3-High
Physical Activity – Length of Time	Slide a bar from 0-120 Minutes
Sodium Intake	Slide a bar from 1-Light to 2 to 3-High
Daily Mood	Pick one of three face icons—frowning, neutral, or smiling. Choosing the frowning or smiling face icon leads to a choice from several mood-specific face icons. All mood options allow for comments to be entered if desired.
Routine-Builder Reminders	
Record Daily Weight	Pick either Completed or Missed
Take Breakfast Medications	Pick either Completed or Missed
Avoid Getting Sick Today – Wash Hands, Avoid Ill People	Pick either Completed or Missed
Eat a Low Salt Diet, Even When Eating Away from Home	Pick either Completed or Missed
Check for Ankle/Leg Swelling	Pick either Completed or Missed
Check for Shortness of Breath	Pick either Completed or Missed
Record Impact of Symptoms on Day	Pick either Completed or Missed
Take Lunch Medications	Pick either Completed or Missed
Take Dinner Medications	Pick either Completed or Missed
Record Level and Length of Physical Activity	Pick either Completed or Missed
Take Bedtime Medications	Pick either Completed or Missed

STS calls were scheduled every two weeks beginning one week after the enrollment meeting to provide support and encouragement. During these calls, the project nurse asked participants how they were doing in their daily use of the HFHS app, answered any questions they might have had about the app, and encouraged daily use of the HFHS app. The project nurse used information about participants' use of the HFHS app, which she viewed on the Provider Health Storylines online dashboard, to inform these calls.

Conclusion Meeting

Conclusion meetings were scheduled for mutually agreeable dates, times, and places approximately 90 days after enrollment. All participants concluded the 90-day project period with a posttest, the SCHFI for people with heart failure and the CC-SCHFI for support people. Intervention group participants were encouraged to continue using the free HFHS app. See Figure 3.2 for an overview of the project protocol.

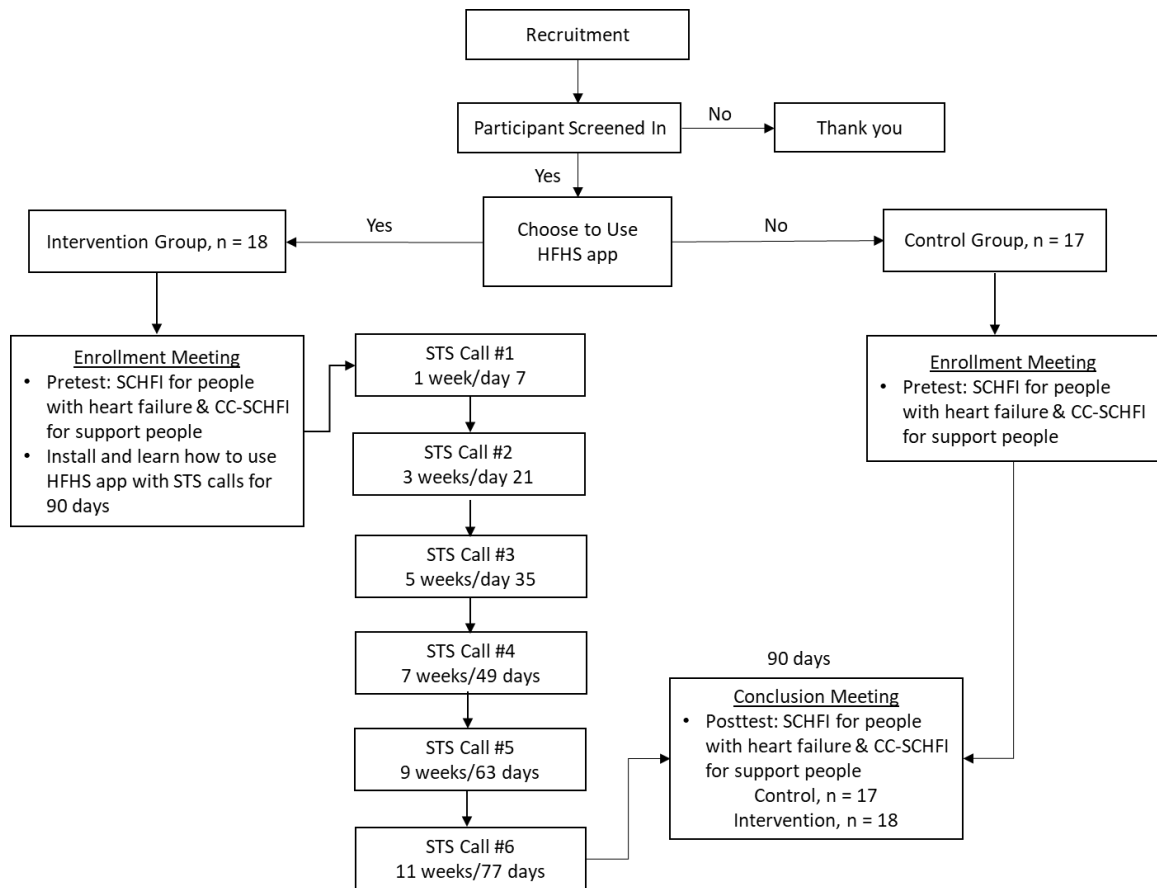


Figure 3.2. Project Protocol

Instrument

Two equivalent pretest and posttest instruments were used to assess the effectiveness of the project intervention. The SCHFI was used to measure self-care of heart failure by people with heart failure, and the CC-SCHFI was used to measure caregiver contribution to self-care of heart failure by support people. These equivalent tools contained the same 22 questions in the same three sections: (a) maintenance; (b) management; and (c) confidence, assessing self-care of heart failure over the past month or since the last assessment.

In section A, there were 10 questions about self-care maintenance activities, which were scored on a four-point Likert scale with ratings of 1 to 4, for a total possible

score of 10 to 40. Questions in section A of the SCHFI asked people with heart failure how routinely they did self-care maintenance activities like weigh themselves daily, check their ankles for swelling, try to avoid getting sick, do some physical activity, keep doctor appointments, eat a low sodium diet, and remember to take medications. These same questions were addressed to support people in section A of the CC-SCHFI, by asking how often they recommended that the person with heart failure do the same 10 self-care maintenance activities.

Section B included a pre-question about whether or not the person with heart failure had experienced trouble breathing or ankle swelling in the past month. If the answer was no, the person skipped section B, which was not scored, and moved on to section C. If the answer to the pre-question was yes, the person scored 1 point and continued to answer six questions about self-care management activities in section B. Questions about self-care management activities included how quickly the person recognized that symptoms were related to heart failure; what remedies the person tried, or recommended that the person with heart failure try, to treat the symptoms; and how sure they were that the remedy worked or did not work. Possible remedies for symptoms included reduce salt in diet, reduce fluid intake, take an extra water pill, and call a healthcare provider for guidance. In section B, four questions were scored on a four-point Likert scale with ratings of 1 to 4, and two questions were scored on a five-point Likert scale with ratings of 0 to 4, for a total possible score of 7 to 25.

Section C contained six questions about self-care confidence which were scored on a four-point Likert scale with ratings of 1 to 4, for a total possible score of 6 to 24. Section C asked people with heart failure how confident they were that they could do

things like keep themselves free of heart failure symptoms, evaluate the importance of their symptoms, recognize changes in their health condition, do something to remedy symptoms, and evaluate how well a remedy worked. These same questions were addressed to support people in section C of the CC-SCHFI, asking how confident they were that they could help the person with heart failure to do these things. Both tools were available in the public domain, and Dr. Barbara Riegel clearly stated that individual permission was not needed to use them (Self-Care Measures, n.d.).

The standardized scores of the SCHFI and the CC-SCHFI have been proven to be valid measures of self-care of heart failure and caregiver contribution to self-care of heart failure. Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Antonetti, et al. (2013) established excellent construct validity of the SCHFI; high internal consistency reliability, 0.74 to 0.90 using factor score determinacy; and test-retest reliability of 0.64 to 0.89 computed by intraclass correlation coefficient. Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Glaser, et al. (2013) established statistically and clinically significant discriminant validity of the CC-SCHFI; high internal consistency reliability, greater than 0.80 for most scales using factor score determinacy; and test-retest reliability of 0.87 to 0.94 computed by intraclass correlation coefficient.

Standardized scores of different versions of the SCHFI tool can be compared (Riegel et al., 2009; Self-Care Measures, n.d.). Although, a standardized score of 70 in each of the three sections of the SCHFI and CC-SCHFI tools has been commonly considered statistically adequate, people can realize benefits from self-care at lower levels of adherence (Riegel et al., 2009). In the absence of statistically significant results, it is important to note that one-half standard deviation or an eight-point increase in a

standardized score of the SCHFI tool is considered clinically significant improvement in self-care of heart failure (Riegel et al., 2009).

Data Collection

Demographics

All demographic and health status data were collected using the enrollment form. Demographic data were provided by participants at enrollment meetings including date of birth, gender, and education level. Health status information on all participants with heart failure was obtained from their EMR at the healthcare institution by the project nurse after both the enrollment and conclusion meetings. Health status information for people with heart failure included their New York Heart Association (NYHA) classification for heart failure; the presence of six major comorbidities, i.e., coronary artery disease, chronic obstructive pulmonary disease, chronic kidney disease, diabetes mellitus, arrhythmia, and active cancer of any kind; ejection fraction; number of hospitalizations for heart failure in past 12 months; number of hospitalizations for heart failure during the 90-day project period; and the date of their most recent hospitalization for heart failure within the past 12 months.

Level of Use of the HFHS App

Self Care Catalysts Inc. provided a report to the project nurse that contained all of the data points entered by each intervention group participant who used the HFHS app during their 90-day use period. The project nurse used this report to verify how many data points were entered by each user of the app. The actual personal information entered into the HFHS app, e.g., daily weight or mood, was not collected.

Level of use of the HFHS app was calculated as a percentage of the total number of data points possible, which was 19 data points recorded each day for 90 days, or 1,710 data points. Three levels of use were defined by the number of data points recorded: (a) low-level use was less than or equal to 513 data points ($\leq 30\%$); (b) moderate-level use was 514 to 1,196 data points (31-69%); and (c) high-level use was greater than or equal to 1,197 data points ($\geq 70\%$). However, due to a low sample size, moderate-level use participants were combined with low-level use participants, and level of use data were recoded into two categories, high-level ($\geq 70\%$) and low-level ($\leq 69\%$) use. A brief review of the literature revealed 70% as a minimum cutoff point for adequate adherence to treatment or self-care (Mantovani et al., 2015; Riegel et al., 2009; Silva et al., 2015; Vellone, Riegel, Cocchieri, Barbaranelli, D'Agostino, Antonetti, et al., 2013).

Pretest/Posttest Scores

Pretest and posttest scores were collected using the SCHFI for people with heart failure and the CC-SCHFI for support people at the enrollment and conclusion meetings, respectively. Individual scores were standardized according to the scoring algorithm and recorded in an Excel spreadsheet (Self-Care Measures, n.d.). All project related data will be securely maintained for three years per the Andrews University IRB handbook.

Data Analysis

Descriptive statistics including frequency tables were used to describe characteristics of the sample population, and Chi square test was used to compare demographic characteristics of the two groups. The initial analysis plan was to use MANCOVA to compare statistical differences by the 10 levels of the independent variable on three dependent variables. However, because some assumptions, e.g., the

sample size in each independent variable group, the linear relationship between the dependent variables, and the normality distribution of the dependent variables, were not met, MANCOVA was not used.

Data was analyzed between groups and within groups of participants. Between groups, the independent t-test was used to make comparisons, pretest to pretest and posttest to posttest, when data were normally distributed, and the equivalent nonparametric Mann-Whitney U test was used to make comparisons when data were not normally distributed. Within groups, the paired t-test was used to examine pretest to posttest improvement when data were normally distributed, and the equivalent nonparametric Wilcoxon signed-rank test was used when data were not normally distributed. The project nurse manually entered all data into an Excel spreadsheet from the paper-based enrollment forms and self-care of heart failure index tools and verified the data for accuracy. After the SCHFI and CC-SCHFI scores were standardized, all data were imported to SPSS, version 25, for analysis.

Objective One

The intervention group and the control group were the two groups analyzed for objective one (See Figure 3.3). The Mann-Whitney U test was used to make comparisons between the pretest and posttest scores of these two groups of participants in self-care maintenance, and independent t-tests were used to make comparisons between the pretest and posttest scores of these two groups of participants in self-care management and confidence. The Wilcoxon signed-rank test was used to examine the improvement from pretest to posttest in self-care maintenance within each group. Paired t-tests were used to

examine the improvements from pretest to posttest in self-care management and confidence within each group.

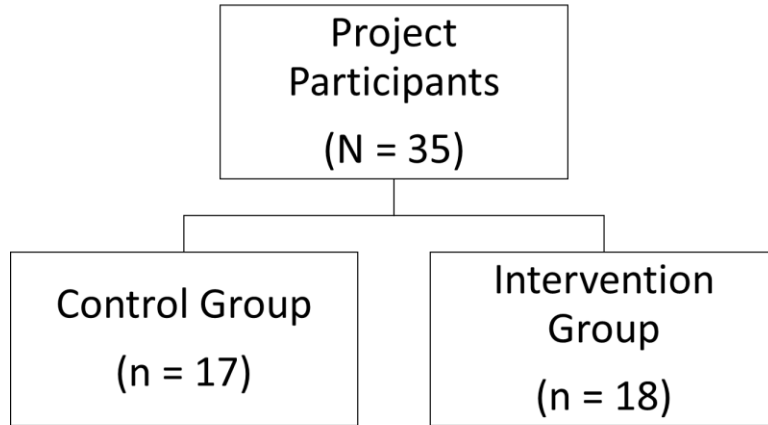


Figure 3.3. Participants, as examined for Objective One

Objective Two

Intervention group participants were divided into two sub-groups for objective two, the people who were the user of the HFHS app in their household and the people who were not the user of the app in their household (See Figure 3.4). The Mann-Whitney U test was used to make comparisons between the pretest and posttest scores of these two groups of participants in self-care maintenance, management, and confidence. The Wilcoxon signed-rank test was used to examine the improvement from pretest to posttest in self-care maintenance, management, and confidence within each group.

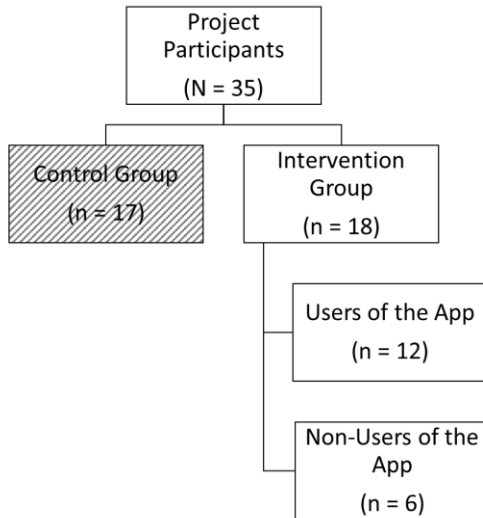


Figure 3.4. Participants, as examined for Objective Two

Objective Three

Intervention group participants were divided into two sub-groups for objective three, the people in households with high-level use of the HFHS app and the people in households with low-level use of the app (See Figure 3.5). The Mann-Whitney U test was used to make comparisons between the pretest and posttest scores of these two groups of participants in self-care maintenance, management, and confidence. The Wilcoxon signed-rank test was used to examine the improvement from pretest to posttest in self-care maintenance, management, and confidence within each group.

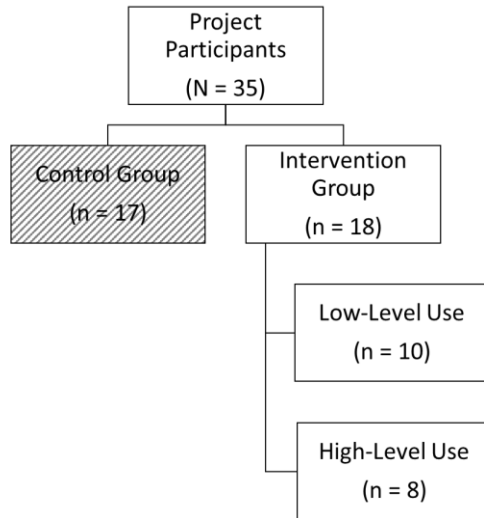


Figure 3.5. Participants, as examined for Objective Three

Objective Four

Intervention group participants were divided into two sub-groups for objective four, people with heart failure who had a support person who participated in the project and people with heart failure who had a non-participating support person (See Figure 3.6). The Mann-Whitney U test was used to make comparisons between the pretest and posttest scores of these two groups of participants in self-care maintenance, management, and confidence. Paired t-tests were used to examine the improvement from pretest to posttest in self-care maintenance and management within each group. The Wilcoxon signed-rank test was used to examine the improvement from pretest to posttest in self-care confidence within each group.

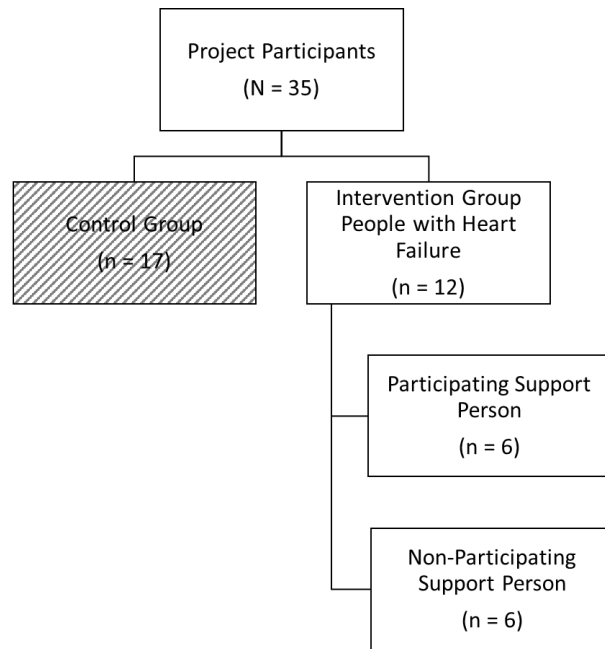


Figure 3.6. Participants, as examined for Objective Four

Summary

The project methodology was multifactorial and complex, yet all of the elements of this project were important to produce meaningful clinical findings. The project intervention goal was to increase performance of basic, daily self-care of heart failure maintenance activities and caregiver contribution to maintenance activities. The purpose of using mobile app technology to achieve this goal was to make the daily task of tracking weight and heart failure symptoms quicker, easier, and more portable and graphically pleasing than a traditional paper log or symptom diary. The aim of the STS calls was to provide ongoing support and encouragement, to build a therapeutic relationship, and promote self-efficacy and confidence, because confidence in performance of self-care leads to better outcomes for people with heart failure.

Excluding the participation and measurement of support people in this project would have simplified the methodology, but no projects were identified in the literature

review that measured self-care of people with heart failure and caregiver contribution to self-care by support people in response to the same intervention in a single project.

Considering the important contribution of support people to self-care of heart failure, it would be remiss to ignore this key factor in measuring the effectiveness of an intervention. The ultimate goal of this DNP project was to produce significant evidence to support implementation of the project intervention on a larger scale, to find a way to inspire more people to actively participate in self-care of heart failure.

CHAPTER 4

RESULTS

The purpose of this project was to determine if using the HFHS app with STS calls was an effective intervention to promote improved self-care of heart failure compared to the standard of care where the intervention was not used. Results will be presented in text, tables, and graphs by project objective. When parametric tests were performed on normally distributed data, results have been reported with mean and standard deviation in text and tables. When nonparametric tests were performed on data that were not normally distributed, results have been reported with median in text and with median and range in tables. All *p*-values were one-tailed. To begin, the project participants will be described by demographics.

Demographics

A total of 35 people participated in this project, 17 (48.6%) in the control group and 18 (51.4%) in the intervention group. No participants had any prior experience using the HFHS app. There were no statistically significant differences in demographics between the intervention and control groups (See Table 4.1). In the intervention group ($n = 18$), only people with heart failure ($n = 12$) used the HFHS app, and they used it on either a smartphone ($n = 11$) or a tablet ($n = 1$).

Participants with heart failure ($n = 22$) shared a similar burden of comorbidities with an average of 2.7 ± 1.1 of the six comorbid conditions specified on the enrollment form. See Figure 4.1 for the distribution of these six comorbid conditions. Additional demographic data for people with heart failure ($n = 22$) are illustrated in Figures 4.2 through 4.5, categorized as control and intervention group participants.

Table 4.1

Comparison of Participants' Demographics by Group

	Control ($n = 17$) f (%)	Intervention ($n = 18$) f (%)	χ^2	p -value
Participant type				
Person with heart failure	10 (58.8)	12 (66.7)	0.230	0.631
Support person	7 (41.2)	6 (33.3)		
Gender				
Male	8 (47.1)	7 (38.9)	0.238	0.625
Female	9 (52.9)	11 (61.1)		
Education				
\leq high school	10 (58.8)	8 (44.4)	0.724	0.395
$>$ high school	7 (41.2)	10 (55.6)		
Currently track symptoms/self-care?				
Yes	12 (70.6)	13 (72.2)	0.011	0.915
No	5 (29.4)	5 (27.8)		
Age (Median, range)	(76, 30)	(68.5, 65)	98.5 ^a	0.072

^a Mann-Whitney U test statistic was performed to compare age between groups.

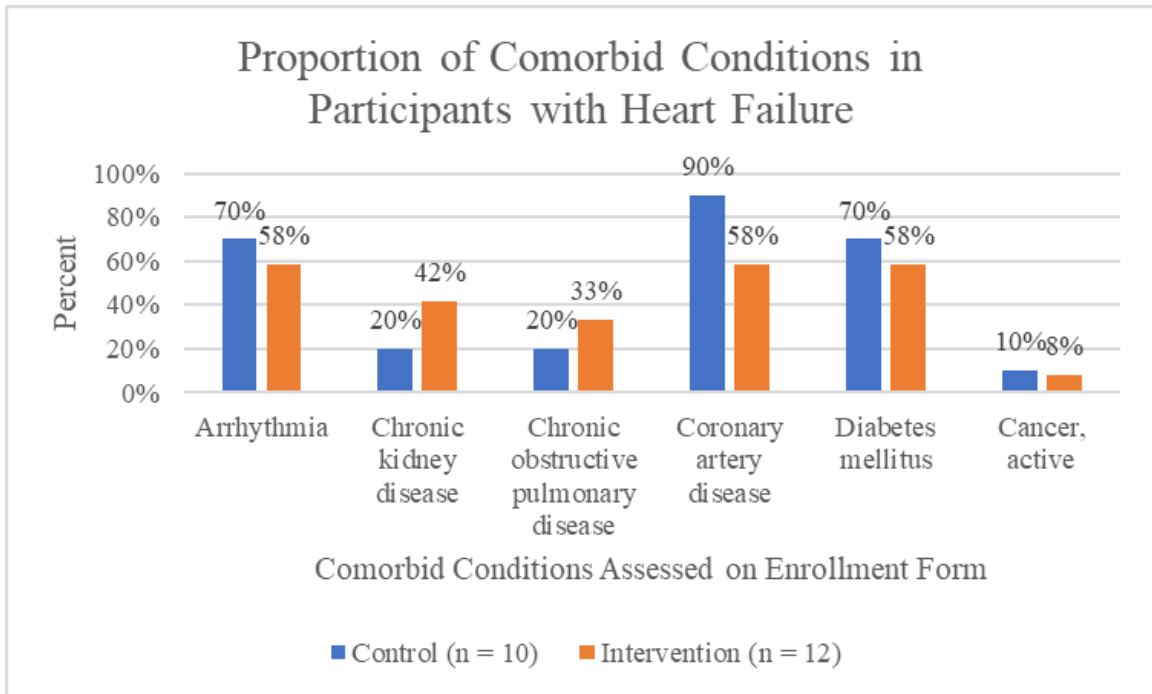


Figure 4.1. Proportion of Comorbid Conditions

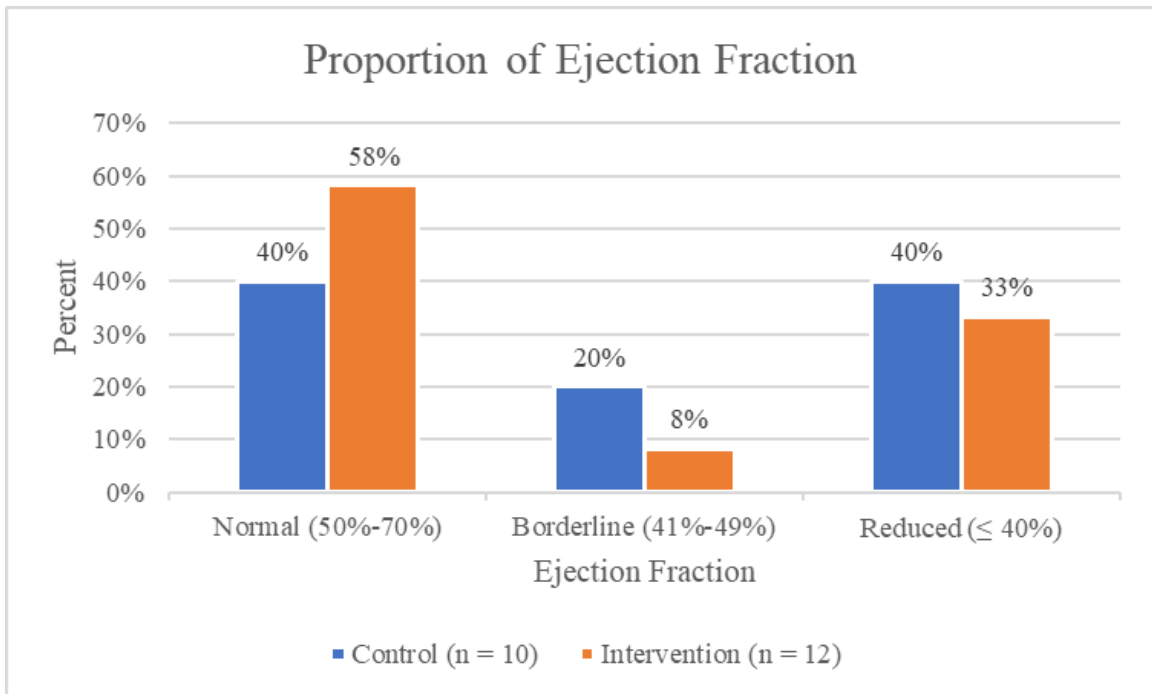


Figure 4.2. Proportion of Ejection Fraction

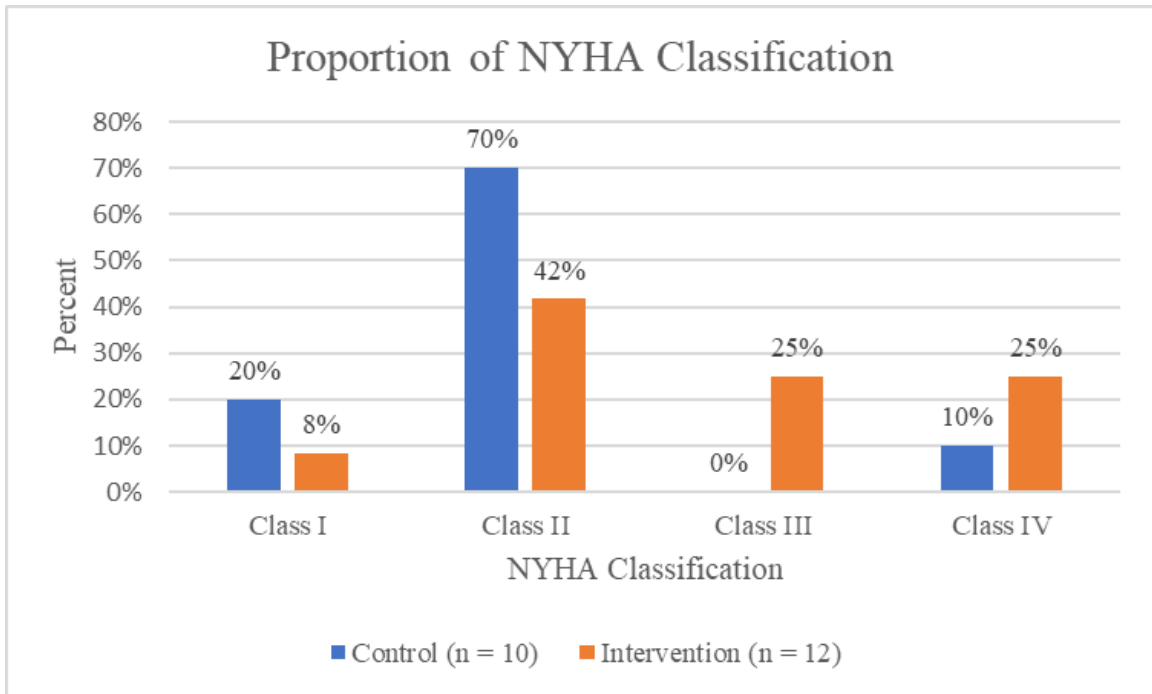


Figure 4.3. Proportion of NYHA Classification

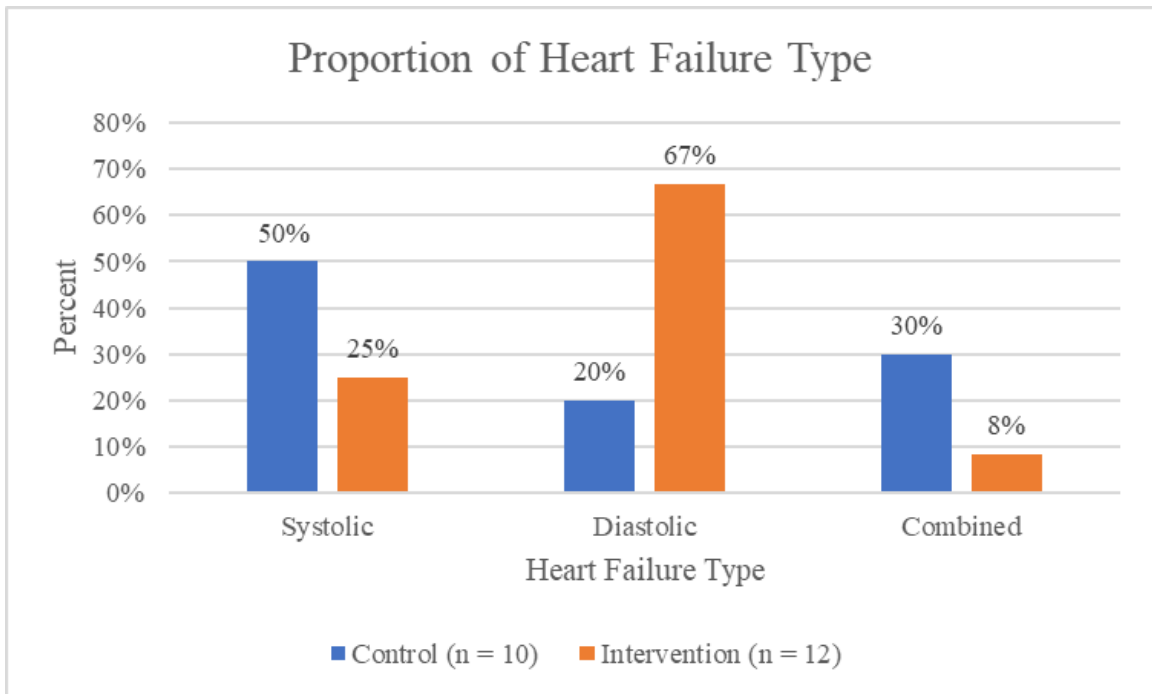


Figure 4.4. Proportion of Heart Failure Type

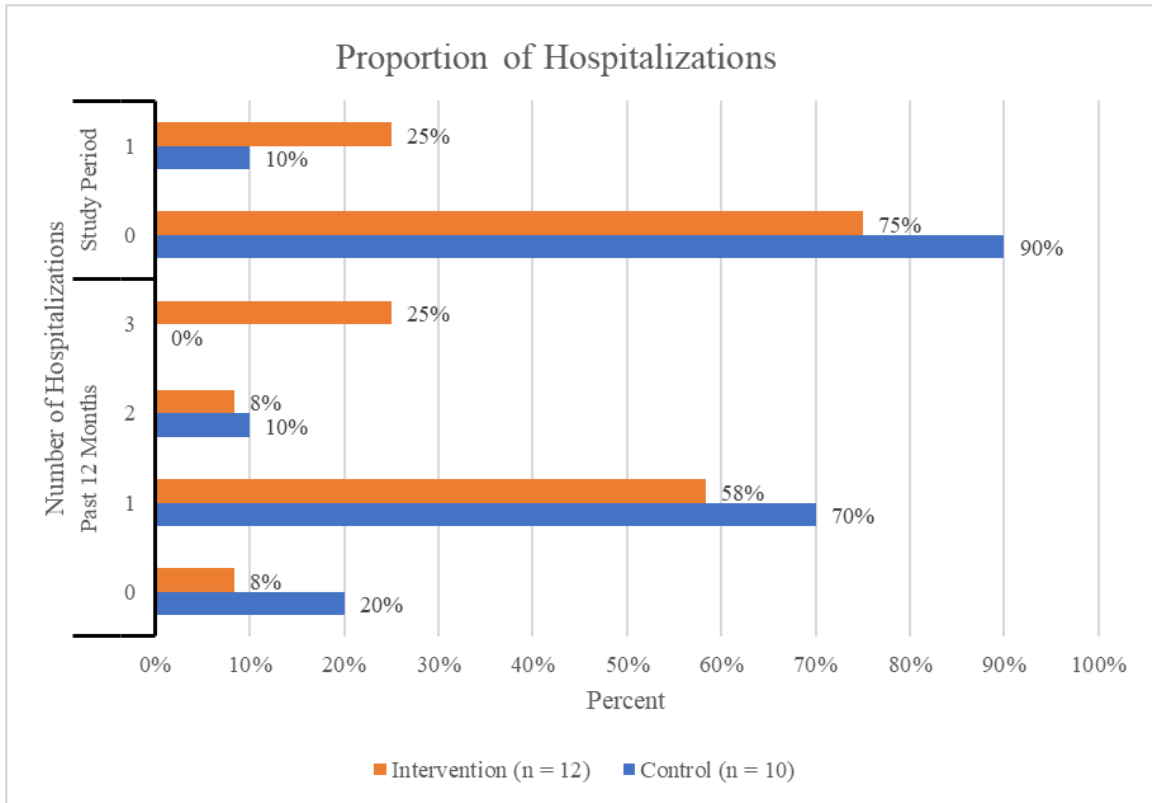


Figure 4.5. Proportion of Hospitalizations

Objective One

The first objective of this project was to determine if a 90-day intervention of the HFHS app with STS calls in a household led to improved self-care of heart failure and caregiver contribution to self-care of heart failure compared to the standard of care. The aim of this objective was to compare the improvement in self-care between the intervention ($n = 18$) and control ($n = 17$) groups. Statistical results for comparisons between groups (See Table 4.2) and within groups (See Table 4.3) have been organized according to the three sections of the SCHFI and CC-SCHFI tools: (a) self-care maintenance; (b) self-care management; and (c) confidence, which were each scored separately.

Self-Care Maintenance Scores

First, the Mann-Whitney U test was used to compare pretest and posttest scores between the two groups. The pretest median score of the intervention group ($Mdn = 68.33$) was not statistically significantly different than the pretest median score of the control group ($Mdn = 69.99$), $U = 121.50$, $p = 0.149$. Likewise, the posttest median score of the intervention group ($Mdn = 68.33$) was not statistically significantly different than the posttest median score of the control group ($Mdn = 73.33$), $U = 138.50$, $p = 0.316$.

Next, the Wilcoxon signed-rank test was used to examine pretest to posttest score improvement within each group. Within the control group, the posttest median score ($Mdn = 73.33$) was not statistically significantly higher than the pretest median score ($Mdn = 69.99$), $z = -1.427$, $p = 0.077$. Within the intervention group, the posttest median score ($Mdn = 68.33$) was not higher than the pretest median score ($Mdn = 68.33$), $z = 0.622$, $p = 0.267$.

Self-Care Management Scores

First, independent t-tests were used to compare pretest and posttest scores between the two groups. The pretest mean score of the intervention group ($M = 52.14$, $SD = 21.90$) was not statistically significantly different than the pretest mean score of the control group ($M = 53.13$, $SD = 29.39$), $t(20) = 0.089$, $p = 0.465$. Likewise, the posttest mean score of the intervention group ($M = 68.46$, $SD = 12.14$) was not statistically significantly different than the posttest mean score of the control group ($M = 50.63$, $SD = 28.84$), $t(8.551) = -1.661$, $p = 0.067$.

Next, paired t-tests were used to examine pretest to posttest score improvement within each group. Within the control group, the posttest mean score ($M = 50.63$, $SD =$

28.84) was not higher than the pretest mean score ($M = 53.13$, $SD = 29.39$), $t(4) = 0.659$, $p = 0.273$. However, within the intervention group, the posttest mean score ($M = 68.46$, $SD = 12.14$) was statistically significantly higher than the pretest mean score ($M = 52.14$, $SD = 21.90$), $t(10) = -2.031$, $p = 0.035$.

Confidence Scores

First, independent t-tests were used to compare pretest and posttest scores between the two groups. The pretest mean score of the intervention group ($M = 59.31$, $SD = 17.27$) was not statistically significantly different than the pretest mean score of the control group ($M = 64.43$, $SD = 23.68$), $t(29.184) = 0.728$, $p = 0.236$. Likewise, the posttest mean score of the intervention group ($M = 69.50$, $SD = 15.40$) was not statistically significantly different than the posttest mean score of the control group ($M = 62.47$, $SD = 22.97$), $t(33) = -1.069$, $p = 0.147$.

Next, paired t-tests were used to examine pretest to posttest score improvement within each group. Within the control group, the posttest mean score ($M = 62.47$, $SD = 22.97$) was not higher than the pretest mean score ($M = 64.43$, $SD = 23.68$), $t(16) = 0.706$, $p = 0.245$. However, within the intervention group, the posttest mean score ($M = 69.50$, $SD = 15.40$) was statistically significantly higher than the pretest mean score ($M = 59.31$, $SD = 17.27$), $t(17)$, $p = 0.001$.

Table 4.2

Between Group Scores: Control & Intervention

	Control (<i>n</i> = 17)	Intervention (<i>n</i> = 18)	Statistics	<i>p</i> -value
Median				
	<i>Mdn</i> (Range)	<i>Mdn</i> (Range)		
Maintenance				
Pretest	69.99 (89.99)	68.33 (79.99)	<i>U</i> = 121.50	0.149
Posttest	73.33 (99.99)	68.33 (30.00)	<i>U</i> = 138.50	0.316
Means				
	<i>M</i> (SD)	<i>M</i> (SD)		
Management				
Pretest	53.13 (29.39)	52.14 (21.90)	<i>t</i> = 0.089, <i>df</i> = 20	0.465
Posttest	50.63 (28.84)	68.46 (12.14)	<i>t</i> = -1.661, <i>df</i> = 8.551	0.067
Confidence				
Pretest	64.43 (23.68)	59.31 (17.27)	<i>t</i> = 0.728, <i>df</i> = 29.184	0.236
Posttest	62.47 (22.97)	69.50 (15.40)	<i>t</i> = -1.069, <i>df</i> = 33	0.147

Table 4.3

Within Group Scores: Control & Intervention

	Pretest	Posttest	Statistics	<i>p</i> -value
Median				
	<i>Mdn</i> (Range)	<i>Mdn</i> (Range)		
Maintenance				
Control	69.99 (89.99)	73.33 (99.99)	<i>z</i> = -1.427	0.077
Intervention	68.33 (79.99)	68.33 (30.00)	<i>z</i> = 0.622	0.267
Means				
	<i>M</i> (SD)	<i>M</i> (SD)		
Management				
Control	53.13 (29.39)	50.63 (28.84)	<i>t</i> = 0.659, <i>df</i> = 4	0.273
Intervention	52.14 (21.90)	68.46 (12.14)	<i>t</i> = -2.031, <i>df</i> = 10	0.035*
Confidence				
Control	64.43 (23.68)	62.47 (22.97)	<i>t</i> = 0.706, <i>df</i> = 16	0.245
Intervention	59.31 (17.27)	69.50 (15.40)	<i>t</i> = -3.766, <i>df</i> = 17	0.001*

* *p* values are significant

Summary of Results for Objective One

Between the intervention and control group participants there were no significant differences in pretest or posttest scores. Although not statistically significant, the posttest scores of the intervention group were higher than the posttest scores of the control group for self-care management and confidence. As expected, within the control group, there were no significant improvements from pretest to posttest in self-care maintenance, management, or confidence. However, intervention group participants did make significant improvements from pretest to posttest in self-care management and confidence.

Objective Two

The second objective of this project was to determine if being the actual user of the HFHS app and receiver of the STS calls in intervention households impacted the effectiveness of the intervention to improve self-care of heart failure and caregiver contribution to self-care of heart failure. The aim of this objective was to compare the improvement in heart failure self-care between people who were users of the app ($n = 12$) and people who were not users of the app ($n = 6$) in intervention households. Due to poor data quality, no analyses were completed for this objective.

Objective Three

The third objective of this project was to determine if the level of use of the HFHS app in intervention households impacted the effectiveness of the intervention to improve self-care of heart failure and caregiver contribution to self-care of heart failure. The aim of this objective was to compare the improvement in heart failure self-care between people in households with high-level use of the app ($n = 8$) and people in

households with low-level use of the app ($n = 10$). Statistical results for comparisons between groups (See Table 4.4) and within groups (See Table 4.5) have been organized according to the three sections of the SCHFI and CC-SCHFI tools: (a) self-care maintenance; (b) self-care management; and (c) confidence, which were each scored separately.

Self-Care Maintenance Scores

First, the Mann-Whitney U test was used to compare pretest and posttest scores between the two groups. The pretest median score of the people in high-level use households ($Mdn = 69.99$) was not statistically significantly different than the pretest median score of the people in low-level use households ($Mdn = 68.33$), $U = 28.00$, $p = 0.141$. Likewise, the posttest median score of the people in high-level use households ($Mdn = 74.99$) was not statistically significantly different than the posttest median score of the people in low-level use households ($Mdn = 66.66$), $U = 26.50$, $p = 0.113$.

Next, the Wilcoxon signed-rank test was used to examine pretest to posttest score improvement within each group. Within the group of people in low-level use households, the posttest median score ($Mdn = 66.66$) was not higher than the pretest median score ($Mdn = 68.33$), $z = -0.713$, $p = 0.238$. Within the group of people in high-level use households, the posttest median score ($Mdn = 74.99$) was not statistically significantly higher than the pretest median score ($Mdn = 69.99$), $z = 0.000$, $p = 0.50$.

Self-Care Management Scores

First, the Mann-Whitney U test was used to compare pretest and posttest scores between the two groups. The pretest median score of the group of people in high-level use households ($Mdn = 52.50$) was not statistically significantly different than the pretest

median score of the group of people in low-level use households ($Mdn = 62.50$), $U = 16.00$, $p = 0.149$. Likewise, the posttest median score of the group of people in high-level use households ($Mdn = 70.00$) was not statistically significantly different than the posttest median score of the group of people in low-level use households ($Mdn = 65.00$), $U = 18.00$, $p = 0.333$.

Next, the Wilcoxon signed-rank test was used to examine pretest to posttest score improvement within each group. Within the group of people in low-level use households, the posttest median score ($Mdn = 65.00$) was not statistically significantly higher than the pretest median score ($Mdn = 62.50$), $z = -0.447$, $p = 0.328$. However, within the group of people in high-level use households, the posttest median score ($Mdn = 70.00$) was statistically significantly higher than the pretest median score ($Mdn = 52.50$), $z = -1.826$, $p = 0.034$.

Confidence Scores

First, the Mann-Whitney U test was used to compare pretest and posttest scores between the two groups. The pretest median score of the people in high-level use households ($Mdn = 58.38$) was not statistically significantly different than the pretest median score of the people in low-level use households ($Mdn = 61.16$), $U = 27.00$, $p = 0.120$. Likewise, the posttest median score of the people in high-level use households ($Mdn = 72.28$) was not statistically significantly different than the posttest median score of the people in low-level use households ($Mdn = 77.84$), $U = 28.50$, $p = 0.149$.

Next, the Wilcoxon signed-rank test was used to examine pretest to posttest score improvement within each group. Within the group of people in low-level use households, the posttest median score ($Mdn = 77.84$) was statistically significantly higher than the

pretest median score ($Mdn = 61.16$), $z = -2.094$, $p = 0.018$. Likewise, within the group of people in high-level use households, the posttest median score ($Mdn = 72.28$) was statistically significantly higher than the pretest median score ($Mdn = 53.38$), $z = -2.214$, $p = 0.014$.

Table 4.4

Between Group Scores: Low-Level & High-Level Use of App

	Low-Level ($n = 10$)	High-Level ($n = 8$)	Statistics	p -value
	Median			
	Mdn (Range)	Mdn (Range)		
Maintenance				
Pretest	68.33 (66.66)	69.99 (30.00)	$U = 28.00$	0.141
Posttest	66.66 (23.33)	74.99 (30.00)	$U = 26.50$	0.113
Management				
Pretest	62.50 (50.00)	52.50 (70.00)	$U = 16.00$	0.149
Posttest	65.00 (35.00)	70.00 (30.00)	$U = 18.00$	0.333
Confidence				
Pretest	61.16 (50.04)	58.38 (66.72)	$U = 27.00$	0.12
Posttest	77.84 (50.04)	72.28 (38.92)	$U = 28.50$	0.149

Table 4.5

Within Group Scores: Low-Level & High-Level Use of App

	Pretest	Posttest	Statistics	p -value
	Median			
	Mdn (Range)	Mdn (Range)		
Maintenance				
Low-Level	68.33 (66.66)	66.66 (23.33)	$z = -0.713$	0.238
High-Level	69.99 (30.00)	74.99 (30.00)	$z = 0.000$	0.50
Management				
Low-Level	62.50 (50.00)	65.00 (35.00)	$z = -0.447$	0.328
High-Level	52.50 (70.00)	70.00 (30.00)	$z = -1.826$	0.034*
Confidence				
Low-Level	61.16 (50.04)	77.84 (50.04)	$z = -2.094$	0.018*
High-Level	58.38 (66.72)	72.28 (38.92)	$z = -2.214$	0.014*

* p values are significant

Summary of Results for Objective Three

Between the low-level and high-level use groups, there was no significant differences in pretest or posttest scores. Although not statistically significant, the posttest scores of the high-level use group were higher than the posttest scores of the low-level use group for self-care maintenance and management. Within the low-level use group, the only significant improvement from pretest to posttest was in self-care confidence. However, within the high-level use group, there was significant improvement from pretest to posttest in self-care management and confidence.

Objective Four

The fourth objective of this project was to determine, for intervention group participants with heart failure ($n = 12$), if having a support person in a household, who participated in the project, impacted the effectiveness of the intervention to improve self-care of heart failure. The aim of this objective was to compare the improvement in heart failure self-care between people with heart failure who had a support person who participated in the project ($n = 6$) and people with heart failure who had a non-participating support person ($n = 6$). Due to poor data quality, no analyses were completed for this objective.

CHAPTER 5

DISCUSSION

Overview

Tracking daily weight and symptoms is a basic maintenance-level activity of heart failure self-care. The main objective of this project was to determine if implementing the use of the HFHS app along with STS calls was a more effective way to promote increased self-care of and caregiver contribution to self-care of heart failure than the standard of care. One ancillary objective was analyzed to determine if the level of use of the app in intervention households impacted the effectiveness of the intervention. Participant demographics and the relationship of the results to the project objectives, theoretical framework, and previous research were summarized and compared to the literature.

Demographics

The lack of statistically significant differences between the intervention and control group participants' demographics supports a low occurrence of confounding variables. Furthermore, the burden of comorbidities for project participants with heart failure, which was similar between the intervention and control groups, was also similar to that of the general population of people with heart failure. All participants with heart failure had at least two comorbid conditions, and their most common comorbid

conditions were arrhythmia, coronary artery disease, and diabetes mellitus. According to the literature, 86% of people with heart failure have at least two comorbid conditions, and over half of heart failure cases are related to conditions that are risk factors for heart failure like coronary artery disease and diabetes, or share common risk factors with heart failure like atrial fibrillation (Benjamin et al., 2019; Manemann et al., 2016; Murad et al., 2015). In summary, participants were demographically similar to each other, and people with heart failure were also similar to the general population of people with heart failure. These factors suggest the generalizability of the project results.

Relationship of Results to Project Objectives

The primary objective of this project was to determine if using the HFHS app with STS calls was an effective intervention to promote improved self-care of heart failure compared to the standard of care. Although, a small sample size and non-normally distributed variables most likely contributed to a lack of significant results comparing the intervention to the standard of care, results within groups were interesting. Within the control group of participants who followed their usual standard of care for 90-days, there were no significant improvements in self-care of heart failure. This group of participants actually had a slight decrease in self-care management and confidence.

On the other hand, results of analyses conducted within the intervention group indicated that use of the HFHS app with STS calls for 90 days had a positive impact on self-care management and confidence. Participants in low-level use households improved in self-care confidence only, but those in high-level use households improved in both self-care management and confidence. Since use of the app involved daily tracking of

self-care maintenance activities, it was disappointing that the intervention group did not make significant improvement in self-care maintenance scores from pretest to posttest.

Despite not making statistically significant improvement in self-care maintenance, high-level users of the app started at a self-care maintenance pretest score of 69.99%, nearly 70%, which is considered adequate, and progressed to a posttest score of 74.99%, nearly 75%, which is associated with direct inpatient cost savings (Riegel et al., 2009). In fact, high-level users of the app made improvement in their posttest scores for all three categories of self-care—maintenance (74.99%), management (70%), and confidence (72.28%)—as a result of the intervention, to reach or surpass the 70% adequate mark. In making statistically significant improvement in self-care confidence, the confidence posttest score of Low-level users of the app (77.84%) also reached an above adequate level. See Figure 5.1 for an illustration of the intervention group’s improvement to adequate levels of self-care as a result of the intervention.

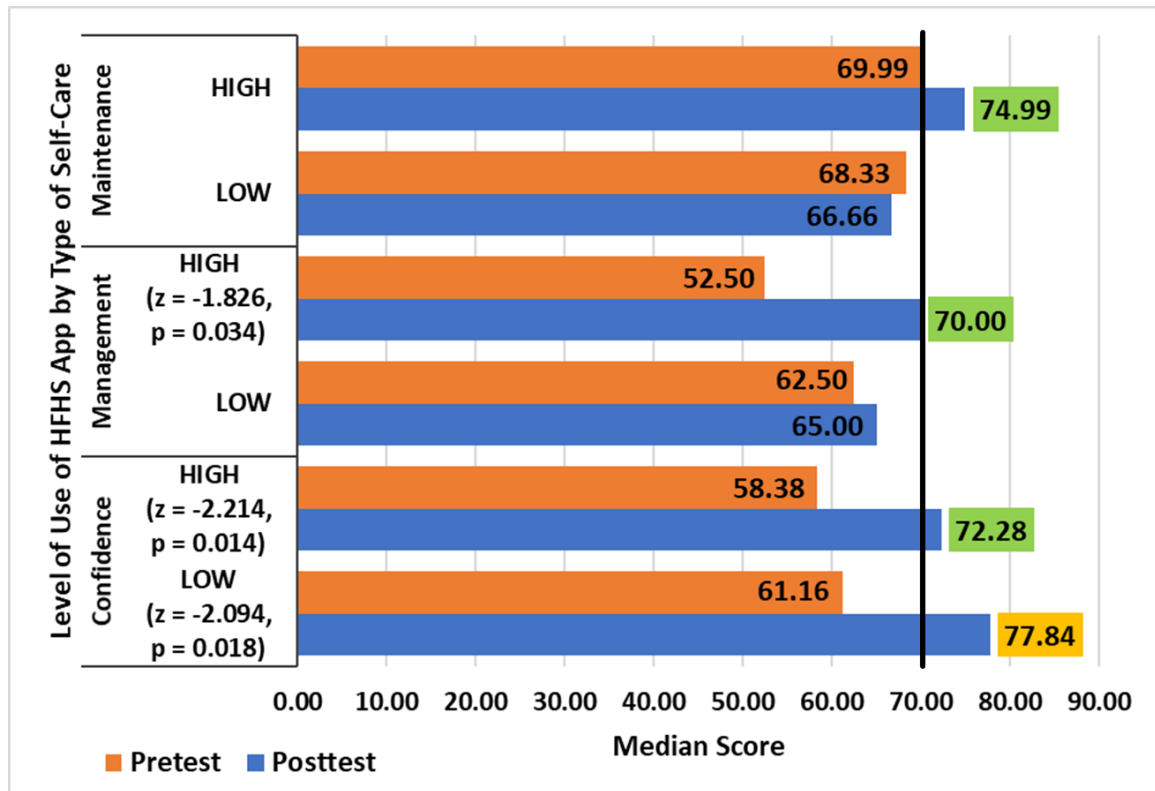


Figure 5.1 Intervention Group’s Improvement to Adequate Levels of Self-Care

On this note, Riegel et al. (2009) observed that people with different levels of engagement in self-care will achieve different levels of self-care, and people can receive benefits from self-care at levels below 70%. With SCHFI scores as low as 15%, people perceived improvements in their health status (Riegel et al., 2009). Scoring above 50% on the SCHFI reduced a person’s odds of hospitalization or death related to a heart failure exacerbation (Riegel et al., 2009). Above adequate scores were associated with even greater outcomes. A score of 75% on the SCHFI was associated with reduced hospitalization costs, and a score of 90% or greater decreased the likelihood of hospitalization at all (Riegel et al., 2009). People who scored above 90% on the SCFHI even rated their health status higher than the average person without a heart failure diagnosis (Riegel et al., 2009). Therefore, the modest increase in self-care maintenance

scores for participants in high-level use households at posttest (*Mdn* = 74.99) was important, because these people nearly reached the 75% mark.

In summary, although the project did not produce significant results comparing the intervention to the standard of care, the intervention group did make significant improvements in self-care management and confidence from pretest to posttest. Additionally, intervention group participants in high-level use households also surpassed the level of adequacy for self-care maintenance, management, and confidence, and participants in low-level use households surpassed the level of adequacy for self-care confidence. The results of this project indicated that the dynamic approach of the intervention, using the HFHS mobile app and STS calls, had a positive impact on self-care of heart failure and caregiver contribution to self-care of heart failure. If implemented on a wider scale, the project intervention has great potential to improve the health and well-being of more people with heart failure by promoting improvements in self-care.

Relationship of Results to Theoretical Framework

This project intervention aimed to promote consistent performance of self-care maintenance activities like adhering to a plan of care, tracking daily weight and symptoms, and taking medications as prescribed, which is the first step to achieving effective self-care management. The project intervention was enhanced by the use of mobile app technology and STS calls, which have been proven to promote adherence to a plan of care, greater awareness of health condition, and confidence. Symptom perception is the second step to achieving effective self-care management (Riegel et al., 2016). Symptom perception, energized by self-care confidence, leads to the third step defined in

the Theory, which is self-care management (Riegel et al., 2016). This project's intervention group participants made statistically significant improvements in self-care management and confidence. While these results are positive, the lack of statistically significant improvement in self-care maintenance was surprising, because the intervention aimed to increase self-care maintenance activities.

According to the Theory, self-care care requires skills to make decisions and to act on those decisions, and it takes experience and time to develop these skills (Riegel et al., 2016). Self-Care confidence can positively influence the progression from self-care maintenance to self-care management (Riegel et al., 2016). However, Dickson et al. (2013) concluded that a moderate level of comorbidity, having two to three comorbid conditions, had a moderating effect on self-care maintenance. Meaning that having more than one comorbid condition in addition to heart failure challenged a person's ability to perform self-care maintenance activities. Self-care management activities were not moderated by comorbidity until a person reached a higher level of comorbidity, having four or more comorbid conditions (Dickson et al., 2013).

Project participants with heart failure had an average of 2.7 ± 1.1 of the six comorbid conditions assessed on the enrollment form, which may account for the lack of significant improvement in self-care maintenance scores. It is also possible that low-level users of the app, who did not improve in self-care management, may have had fewer self-care skills, less self-care experience, or a higher number of comorbid conditions than high-level users of the app. So, despite their improvement in self-care confidence, they did not improve in self-care maintenance or management.

In summary, increased self-care management is the logical outcome of effective self-care maintenance. Self-care confidence positively influences progression from self-care maintenance to self-care management, but a moderate number of comorbid conditions negatively impacts self-care maintenance, and a high number of comorbid conditions negatively impacts self-care management. This explains why participants in this project, who had a moderate number of comorbid conditions, improved in self-care confidence and management, but not self-care maintenance (See Figure 5.2). This project was successful because it utilized theoretical applications.

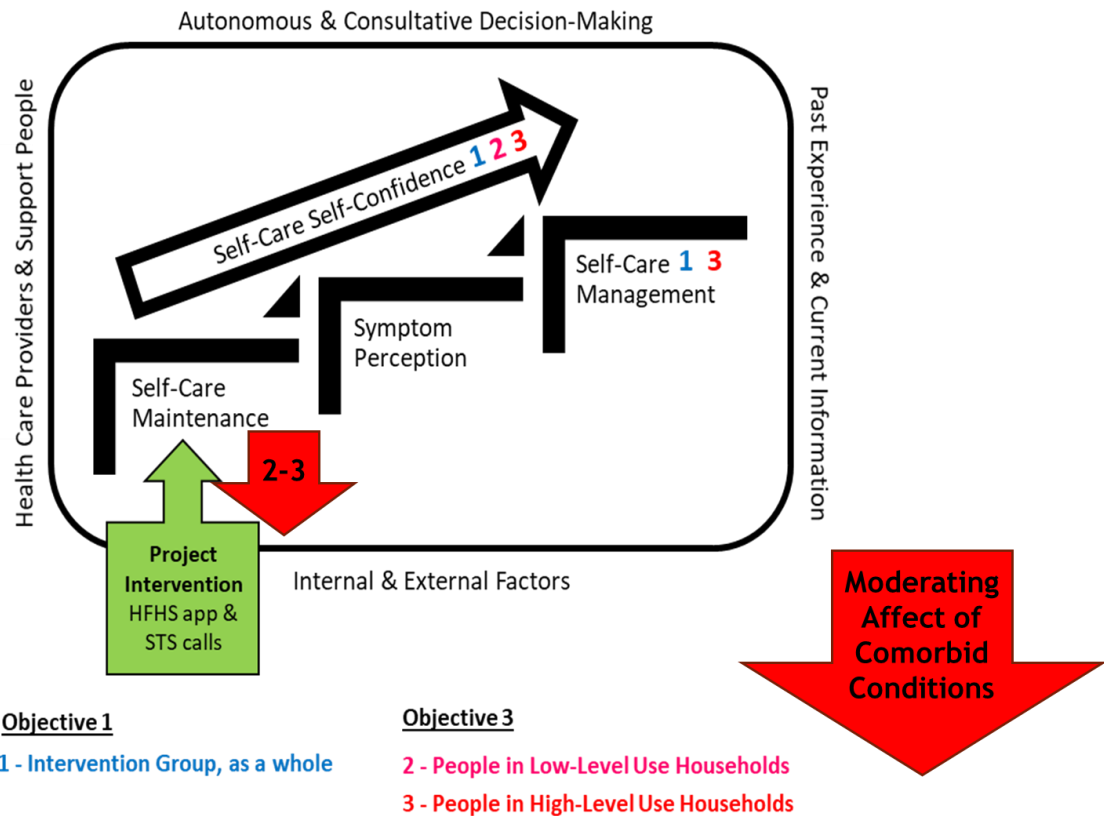


Figure 5.2 Significant Results Within the Intervention Group Related to the Theory

Relationship of Results to Previous Research

The results of this project supported the results of previous research on the use of technology, particularly mHealth, and STS calls in interventions aimed to promote

increased self-care of heart failure and other chronic conditions. The literature has shown that the use technology can enhance interventions aimed to improve self-care of heart failure by improving adherence to a plan of care and greater awareness of health conditions (Athilingam & Jenkins, 2018; Cajita et al., 2016; Morton et al., 2017; Walker et al., 2014). The literature also supported the use of STS calls to promote improved self-care by providing ongoing personal contact for support and encouragement, which can be a particularly important component of interventions involving use of technology (Unverzagt et al., 2016). A distinguishing characteristic of this project was that the impact of the intervention was measured for people with heart failure and support people. No studies were identified in the literature that measured the impact of a single intervention of both of these groups of people.

Use of Technology

A comparison of the results of this project to the results of prior research on the use of mobile phone technology to promote self-care of heart failure resulted in similarities and differences. No other studies were identified in the literature that measured self-care of heart failure for people with heart failure and support people in response to the same intervention. Participants in all of the interventions improved in self-care management (See Table 5.1). Participants in all of the interventions, except Seto et al.'s (2012a) trial of a mobile phone-based intervention, produced significant results in self-care confidence. Participants in two of the interventions, Seto et al.'s and Foster's (2018b), improved in self-care maintenance; whereas, participants in Athilingam et al.'s (2017) study and this DNP project did not.

In summary, while no other studies identified in the literature measured self-care of heart failure and caregiver contribution to self-care of heart failure in response to a single intervention, all of the projects produced significant improvements in self-care management. The reasons for the various differences among these projects were unclear, but there are numerous internal and external factors that can impact heart failure self-care, such as self-care skills, experience, and the number of comorbid conditions (Dickson et al., 2013; Riegel et al., 2009).

Table 5.1

Relationship of Results to Previous Research: Use of Technology

	Participant Types		Improvement in Self-Care		
	Heart Failure	Heart Failure & Support People	Maintenance	Management	Confidence
DNP Project (n = 18)		●		●	●
Seto et al., 2012a (n = 50)	●		●	●	
Foster, 2018b (n = 10)	●		●	●	●
Athilingam et al., 2017 (n = 9)	●			●	●

STS Calls

Again, intervention group participants in this project improved in self-care management and confidence, but the control group made no improvement in self-care. These results were similar to the results of a telephone-based support intervention that resulted in improved self-care for the intervention group and not the control group (Zamanzadeh et al., 2013). Tung et al. (2013) also reported improved heart failure self-care maintenance and management as a result of an educational intervention that included

follow-up calls. Although improved confidence was not reported, participants were reported to have felt more capable of self-care following the intervention (Tung et al., 2013). Finally, although Chen et al. (2016) did not measure heart failure self-care, they did report greater adherence to self-care as a result of their study involving STS calls to encourage adherence to a home exercise program for post-surgical patients. In summary, the outcomes of this project intervention, which included participant support via STS calls, aligned with the results of three interventions described in the literature that were also reinforced by STS calls.

Summary of Relationship of Results to Previous Research

The two main components of the project intervention were the use of technology and STS calls. Technology was used to enhance the basic daily weight and symptom tracking log, which is vital to heart failure self-care, by substituting a mobile app in place of a traditional paper log. Biweekly STS calls were used to support and encourage continued use of the HFHS app. According to the literature, interventions that include use of technology and STS calls can promote improved self-care, and people who were exposed to this project intervention had significant improvements in heart failure self-care management and confidence. In summary, this project was successful because it used an evidence-based intervention.

Project Strengths

Strengths of this project included an evidence-based intervention using an app that was developed using heart failure guidelines and received high ratings for functionality. This project was also guided by a theoretical framework that was specific to self-care of heart failure and validated by research. Valid and reliable tools which

aligned with the Theory were used to measure self-care of and caregiver contribution to self-care of heart failure. The project design was strengthened by the inclusion of a control group. The lack of statistically significant demographical differences between the intervention and control groups indicated strong internal validity for this project, meaning that the main difference between the intervention and control groups was the intervention. Finally, all participants who wanted one were provided with a digital bathroom scale to promote consistent daily weight measurement.

Project Limitations

Significant improvements in heart failure self-care were generated by this project intervention, despite several limitations. Limitations included low enrollment, non-normally distributed variables, and convenience sampling. Low enrollment and non-normally distributed variables limited the analyses that could be performed, particularly for objectives two and four, because some variables of interest were missing or skewed. A convenience sample limited the generalizability of the project results due to bias introduced by enrolling participants from the most readily available people, a single healthcare institution location. Additional convenience sampling bias was created by allowing people to self-select whether or not to participate in the project. Those who chose to participate were also allowed to self-select to either the intervention or control group and whether or not to be the user of the mobile app in intervention group households. Another limitation of the project design was the existence of support people who did not participate in the project, which made it impossible to measure the caregiver contribution to self-care of heart failure by these people. Improving on these deficiencies could produce better results if this project were to be conducted again in the future.

Implications for Future Research

Future research conducted on a larger sample size would produce more data points and possibly more normally distributed data. More data points could produce more robust results from analyses between and within the intervention and control groups. Designing a project with a method of random sampling would eliminate the many biases created by convenience sampling and make the project results more generalizable. Finally, the project could have been improved by eliminating the possibility of non-participating support people by enrolling people with heart failure who either had no support person or had a support person who agreed to participate in the project.

Implications for Practice

This project has several implications for practice. People with heart failure, who are in poorer health with a greater number of comorbid conditions, may not be able to reach an adequate level of self-care management (Brennan et al., 2010; Dickson et al., 2019). For these people, self-care interventions that include the use of technology may simply provide a greater sense of security (Brennan et al., 2010). This intervention resulted in significantly improved self-care confidence for all intervention group participants, low- and high-level users. People with heart failure, who are healthier, have fewer comorbidities, and in earlier stages of heart failure, can benefit from improved self-care confidence and management as a result of using the HFHS app with STS calls. The SCHFI and CC-SCHFI tools can be used in clinical practice to assess baseline and improvements in self-care of heart failure and caregiver contribution to self-care of heart failure (Self-Care Measures, n.d.). Healthcare providers can then use the information

from these tools to customize interventions, like use of the HFHS app with STS calls, to meet individual patient needs (Self-Care Measures, n.d.).

This project addressed a need that was identified in a clinical setting by implementing a more effective way to promote heart failure self-care than use of a traditional paper log, which is what the healthcare institution has been using. By helping people to improve self-care of heart failure, this intervention also addressed a significant population health problem. By helping people to improve heart failure self-care, this intervention can help to reduce hospitalizations associated with heart failure and reduce the risk of mortality for millions of people. In summary, this project intervention and the SCHFI and CC-SCHFI tools can be used in practice to help people with heart failure and support people to improve self-care of heart failure, whether they are in poorer health or better health, and whether they are low- or high-level users of the app. At a minimum, all people who are exposed to the intervention can gain self-care confidence.

Dissemination Plan

The results of this project were presented to the readmission task force at the healthcare institution where the project was completed on February 12, 2020. An educational handout that can be shared with patients and support persons, who may benefit from use of the HFHS app, was developed and shared at this presentation and provided electronically to the organization (Appendix J). A poster presentation will also be created and shared at the Spring 2020 research symposium hosted by Andrews University Eta Zeta chapter of Sigma Theta Tau International.

Project Evaluation

This project was formally evaluated by the project committee at the defense presentation on February 20, 2020. It was also evaluated by stakeholders at the healthcare institution where the project was completed. When the project nurse presented the project results to the healthcare institution's readmission task force, attendees were provided with a written evaluation form to complete at the conclusion of the presentation (Appendix K). Stakeholders were asked to rate their overall impression of the project results, educational handout, and value of implementing the project intervention on a wider scale within the organization. They were also asked to comment on the strengths and limitations of the project, and make suggestions for improvement if the project were to be conducted again in the future.

The evaluation of this project by stakeholders yielded valuable feedback. The evaluation form that was provided to stakeholders asked them to rate the DNP project and the educational handout on a scale of 1 to 10, where 1 was very inadequate and 10 was excellent. Their overall impressions of the DNP project (8/10) and the educational handout (8/10) were positive. They were also asked to give their opinion on the value of implementing the project intervention on a wider scale within the organization, where 1 was no, 2 was maybe, and 3 was yes. Their overall opinion on this was maybe (2/3). The most commonly noted strengths of the project were the use of an evidence-based intervention and the theory-based pretest/posttest instruments. The most commonly noted limitation of the project was the small sample size. One notable suggestion for improvement, should this project be repeated in the future, was to tie the intervention to a

concrete clinical measurement like ejection fraction or adherence to prescribed medications.

As the project nurse, my personal evaluation of the project was that it was a success. All of the people who participated in the project seemed genuinely interested to learn about the project, and intervention group participants were eager to learn how to use the HFHS app to improve their self-care of heart failure. I enjoyed connecting with participants at our meetings and via the STS calls, and my only regret is that I did not have more time and resources to conduct this project on a larger scale.

I will definitely take what have I learned from leading this project to improve my practice as a family nurse practitioner. I will also feel comfortable leading the development, implementation, and evaluation of future projects for practice improvement. In summary, this project benefited intervention group participants by helping them to significantly improve in heart failure self-care management and confidence. The results of this project can be applied to practice to improve outcomes for other people with heart failure and their support people. Finally, I have mastered skills through application of the *Essentials of Doctoral Education for Advanced Nursing Practice* (the *DNP Essentials*) to my project (American Association of Colleges of Nursing [AACN], 2006). I will use these skills in my career as a doctoral-prepared family nurse practitioner.

Mastery of DNP Essentials

The doctor of nursing practice (DNP) is a practice-focused, doctoral degree which prepares advanced practice nurses to deliver innovative and evidence-based care (AACN, 2006). The focus of DNP projects is to apply scholarly knowledge through a practice

experience (AACN, 2006). This project was an evidence- and theory-based intervention implemented in an outpatient clinic setting to promote self-care of heart failure. Through the planning, execution, evaluation, and dissemination of the results of this intervention, the project nurse had an opportunity to apply six of the eight *DNP Essentials, Essentials I, III, IV, VI, VII, and VIII* (AACN, 2006).

Essential I: Scientific Underpinnings for Practice

Essential I: Scientific Underpinnings for Practice is fundamental to any DNP project, because it describes the foundation of doctoral preparation for advanced nursing practice (AACN, 2006; Chism, 2015). It encompasses integration of nursing science and theory with science and theory from other disciplines to transform nursing practice to achieve better outcomes for patients, organizations, and communities (AACN, 2006). The aim of this project was to introduce a dynamic approach to heart failure self-care using mobile app technology as an alternative to a traditional paper log or diary for tracking daily weight and symptoms of heart failure. The intervention was developed using a situation-specific nursing theory, and evidence-based components were identified through a review of the literature. In summary, this project met the AACN (2006) criteria for *Essential I* by developing and evaluating a new, theory- and science-based approach to nursing practice for the healthcare institution where the project was conducted.

Essential III: Clinical Scholarship and Analytical Methods

Clinical nursing experience is an important component of *Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice*, because it is the combination of a base of a clinical knowledge and skills with knowledge of science and theory that prepares DNPs to translate research into evidence-based practice (AACN,

2006; Chism, 2015). Furthermore, the development, implementation, and evaluation of evidence-based practice is conducted for the purpose of resolving gaps identified in clinical nursing practice to improve outcomes (AACN, 2006). In leading or participating in this process to improve clinical practice, DNPs evaluate the scholarly literature and collaborate with colleagues who have research experience to achieve the best results (AACN, 2006; Chism, 2015).

In summary, this project met the AACN (2006) criteria for *Essential III* because it was conceived from the project nurse's clinical experience with people diagnosed with heart failure and supported by her extensive review of scholarly literature. This project could not have been accomplished without the expert guidance that the project nurse sought from advisors who were more experienced in research planning, methodology, and evaluation. Finally, this project was implemented in a clinical setting in an attempt to fill an identified need for a more innovative way to encourage heart failure self-care.

Essential IV: Information Systems/Technology

Mastery of *Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care* ensures that DNPs are prepared to practice and lead change effectively in a world where use of technology is pervasive. Technology and information systems are used for countless purposes to improve the quality of healthcare experiences and outcomes, e.g., communication, patient care and support, organizational management, decision support, remote monitoring and education, and public health surveillance (AACN, 2006; Chism, 2015). DNPs must be able to coordinate with technical experts to plan and evaluate the use of technology with consideration for ethical and legal issues (AACN, 2006; Chism, 2015).

In summary, this project met the AACN (2006) criteria for *Essential IV* because it used mobile app technology to improve a process for patients to record their daily weight and heart failure symptoms, an essential self-care maintenance activity. The project nurse reviewed the scholarly literature to evaluate and select the best mobile app for the project, selecting an app that received the highest rating for usability and adherence to nationally accepted guidelines for heart failure self-care. She initiated the development of custom app modules for the project and coordinated the most effective, ethical, and legal use of this technology with the software developer and the healthcare institution where the project was conducted.

Essential VI: Interprofessional Collaboration

Interprofessional collaboration is an essential skill for everyone working in the complex landscape of healthcare (AACN, 2006; Chism, 2015). DNPs are prepared to lead and participate on interprofessional teams to improve organizational and health outcomes for patients (AACN, 2006; Chism, 2015). The project nurse met the AACN (2006) criteria for *Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes* by applying consultative and leadership skills throughout the project. Initiation of this project required consultation with leaders at the healthcare institution where the project was conducted to identify a need and gain endorsement for the proposed project. The project nurse also consulted and collaborated with the software developer to identify and negotiate the necessary modules and processes involved in the use of the HFHS app for the project intervention. The project nurse also attended unit meetings to educate and collaborate with RNs to recruit

participants. All of this communication and collaboration was for the purpose of improving the patient experience of heart failure self-care to achieve better outcomes.

Essential VII: Clinical Prevention and Population Health

Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health involves identifying population health risks or gaps in health care, and implementing appropriate solutions to reduce risks, improve access to health care, and promote better health outcomes for groups of people (AACN, 2006; Chism, 2015). DNPs are prepared to address population health issues with education and interventions that focus on health promotion and risk reduction, meeting the goals of *HealthyPeople 2020* (AACN, 2006; Chism, 2015). As part of a growing global epidemic of chronic non-communicable disease that has been caused by unhealthy diet and lifestyle choices, heart failure is a significant population health concern (Chan, 2017). Improved heart failure self-care, which includes making healthier lifestyle choices, can reduce hospitalizations associated with exacerbations and improve the risk of mortality for millions of people (Riegel et al., 2017). Therefore, this project met the criteria for *Essential VII* by identifying a risk for the population of people with heart failure at the healthcare institution where the project was conducted and attempting to mitigate that risk with an intervention to promote better self-care.

Essential VIII: Advanced Nursing Practice

Essential VIII: Advanced Nursing Practice is another fundamental of DNP education, which is intended to prepare nurses for the highest level of practice in a specialty area (AACN, 2006; Chism, 2015). This involves making comprehensive

assessments, using critical thinking, and developing evidence-based and effective interventions to improve health outcomes (AACN, 2006; Chism, 2015). An important component of effective interventions is building therapeutic and mentoring relationships (AACN, 2006; Chism, 2015). This DNP project initiative aimed to promote healthier lifestyle practices and avoidance of disease exacerbations, and the project nurse developed therapeutic relationships with many of the intervention participants in the meetings and STS calls. In summary, this project met the criteria for *Essential VIII* because it involved a health promotion intervention that complemented the project nurse's specialty area of family practice nursing.

Finally, the project nurse has been well-prepared by her application of the *DNP Essentials* to function as a doctoral-prepared advanced practice registered nurse. The results of this project can be applied in any outpatient primary care or specialty health care setting to promote heart failure self-care. The methods used to develop, implement, and measure the results of this project can be applied to future interventions to improve practice and health outcomes.

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Appendix A: Self-Care of Heart Failure Index

Participant ID#

Pretest Posttest

Date: _____

SELF-CARE OF HEART FAILURE INDEX

All answers are confidential.

Think about how you have been feeling in the last month or since we last spoke as you complete these items.

SECTION A:

Listed below are common instructions given to persons with heart failure. How routinely do you do the following?

	Never or rarely	Sometimes	Frequently	Always or daily
1. Weigh yourself?	1	2	3	4
2. Check your ankles for swelling?	1	2	3	4
3. Try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. Do some physical activity?	1	2	3	4
5. Keep doctor or nurse appointments?	1	2	3	4
6. Eat a low salt diet?	1	2	3	4
7. Exercise for 30 minutes?	1	2	3	4
8. Forget to take one of your medicines?	1	2	3	4
9. Ask for low salt items when eating out or visiting others?	1	2	3	4
10. Use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

Participant ID#	
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Pretest Posttest

Date: _____

SECTION B:

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past month, have you had trouble breathing or ankle swelling? Circle one.

- 0) No
- 1) Yes

11. If you had trouble breathing or ankle swelling in the past month...

(circle **one** number)

	Have not had these	I did not recognize it	Not Quickly	Somewhat Quickly	Quickly	Very Quickly
How quickly did you recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

Listed below are remedies that people with heart failure use. If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies?

(circle **one** number for each remedy)

	Not Likely	Somewhat Likely	Likely	Very Likely
12. Reduce the salt in your diet	1	2	3	4
13. Reduce your fluid intake	1	2	3	4
14. Take an extra water pill	1	2	3	4
15. Call your doctor or nurse for guidance	1	2	3	4

16. Think of a remedy you tried the last time you had trouble breathing or ankle swelling.

(circle **one** number)

	I did not try anything	Not Sure	Somewhat Sure	Sure	Very Sure
How <u>sure</u> were you that the remedy helped or did not help?	0	1	2	3	4

Participant ID#

Pretest Posttest

Date: _____

SECTION C:

In general, how confident are you that you can:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
17. Keep yourself <u>free of heart failure symptoms?</u>	1	2	3	4
18. <u>Follow the treatment advice</u> you have been given?	1	2	3	4
19. <u>Evaluate the importance</u> of your symptoms?	1	2	3	4
20. <u>Recognize changes</u> in your health if they occur?	1	2	3	4
21. <u>Do something</u> that will relieve your symptoms?	1	2	3	4
22. <u>Evaluate</u> how well a remedy works?	1	2	3	4

Appendix B: Caregiver Contribution to Self-Care of Heart Failure Index

Participant ID#

Pretest Posttest

Date: _____

CAREGIVER CONTRIBUTION TO SELF-CARE OF HEART FAILURE INDEX

All answers are confidential.

We kindly ask you to think about the care you have given to the person with Heart Failure in the past month. There are no right or wrong answers.

How often do you recommend to the person you care for the following things?
(Or, how often do you do these activities because the person you care for is not able to do them).

SECTION A:

	Never or rarely	Sometimes	Frequently	Always or daily
1. To check the weight ?	1	2	3	4
2. To check the ankles for swelling?	1	2	3	4
3. To try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. To do some physical activity?	1	2	3	4
5. To keep doctor or nurse appointments?	1	2	3	4
6. To eat a low salt diet?	1	2	3	4
7. To exercise for 30 minutes?	1	2	3	4
8. To not forget to take medicines?	1	2	3	4
9. To ask for low salt items when eating out or visiting others?	1	2	3	4
10. To use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

Participant ID#	
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Pretest Posttest

Date: _____

SECTION B:

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past month, did **the person you care for** have trouble breathing or ankle swelling? Circle one.

0) No

1) Yes

11. If **the person you care for** had trouble breathing or ankle swelling in the past month...

(circle **one** number)

	Has not had these	I did not recognize it	Not Quickly	Somewhat Quickly	Quickly	Very Quickly
How quickly did you recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

If the **person you care for** has trouble breathing or ankle swelling, how likely are **you** to recommend (or do) one of these remedies?

(circle **one** number for each remedy)

	Not Likely	Somewhat Likely	Likely	Very Likely
12. To reduce the salt in the diet	1	2	3	4
13. To reduce fluid intake	1	2	3	4
14. To take an extra water pill	1	2	3	4
15. To call the doctor or nurse for guidance	1	2	3	4

16. Think of a remedy **you** tried the last time **the person you care for** had trouble breathing or ankle swelling.

(circle **one** number)

	I did not try anything	Not Sure	Somewhat Sure	Sure	Very Sure
How <u>sure</u> were you that the remedy helped or did not help?	0	1	2	3	4

Participant ID#

Pretest Posttest

Date: _____

SECTION C:

In reference to the person you care for, in general, how confident are you that you can:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
17. Keep him/her <u>free of heart failure symptoms?</u>	1	2	3	4
18. <u>Follow the given treatment advice?</u>	1	2	3	4
19. Evaluate the <u>importance of symptoms?</u>	1	2	3	4
20. <u>Recognize changes</u> in him/her health when they occur?	1	2	3	4
21. <u>Do something</u> that will relieve him/her symptoms?	1	2	3	4
22. <u>Evaluate</u> how well a remedy works?	1	2	3	4

Appendix C: Project Committee

Chairperson

Jochebed Bea Ade-Oshifogun, PhD, RN-BC, CNE

Advent Health Endowed Nursing Chair

Andrews University School of Nursing

Phone: 219-471-3363; Cell: 708-769-4259

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Practice Mentor

Jessica Gingerich, MSN, NP-BC, CCRN

Director, Cardiovascular Clinical Services

Elkhart General Hospital

Phone: 574-389-4865

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Appendix D: Institutional Consent Letter



6/23/17

Institutional Review Board
Andrews University
4150 Administrative Drive, Room 322
Berrien Springs, MI 49104-0355

Project Title: Do Self-Care of Heart Failure Index and/or Caregiver Contribution to Self-Care of Heart Failure Index Scores Improve with Use of the HFHS Mobile App?

To Whom It May Concern:

I, Leigh Poepelman, provide institutional consent for April C. Chew, MS, RN, a DNP student at Andrews University and the primary investigator, to implement her DNP project at Elkhart General Hospital under the guidance and supervision of her practice mentor Jessica Gingerich, MSN, BSN, NP-BC, CCRN.

Regards,

A handwritten signature in black ink that reads "Leigh Poepelman".

Leigh Poepelman, MSN, RN, CCRN
Executive Director, Special Care Units

Appendix E: Initial IRB Approvals



December 12, 2017

April C. Chew
Department of Nursing
Andrews University
Berrien Springs, MI 49104

RE: Does Use of a Mobile App and Telephone Support Promote Improved Self-Care of Heart Failure?

Dear Ms. Chew:

This letter is to acknowledge the receipt of the following information for protocol listed above:

- HIPAA Authorization v2

The above referenced protocol has been completed by me, the EGH Chairperson of the IRB on August 30, 2017. The protocol has been approved for 365 days via the expedited review process.

The submitted revised HIPAA Authorization v2 has been Approved on December 12, 2017.

EGH, as a covered entity, upon disclosing protected health information, will be subject to disclosure tracking for accounting purposes. Please use the attached form to record information on all patient medical records included in the chart review. Upon completion, fax the accounting disclosure form to the attention of Michelle Holden, Beacon Medical Records (FAX # 574-523-3474).

This information will be provided to the Institutional Review Board on January 10, 2017.

We look forward to receiving a report of your study findings.

According to IRB hospital policy, you are required to submit the following information:

1. If the study continues beyond one year, a Periodic Report is required to be submitted two weeks prior to the August 1, 2018 IRB meeting regarding progress of the study.
2. Submit a Study Closure Report to the IRB within 30 days of termination of a research.
3. If anything changes regarding use of this information or the scope of the study expands, a request for a protocol amendment is required.
4. If anything changes regarding patient items (i.e. recruitment information), the updated patient items needs to be submitted for IRB review.



The Elkhart General Healthcare System Institutional Review Board complies with the FDA and OHRP requirements for IRBs (OHRP Approved Federalwide Assurance Number: FWA00009238).

Thank you for submitting this information to us. If you have any questions, please call me at (574)523-3447 or Betty McKinney at (574)296-6505.

Respectfully yours,

A handwritten signature in black ink that reads "Darra L. Cover".

Darra Cover, RPh
Chairperson
Institutional Review Board

/bm

Cc: Jessica Gingerich

December 15, 2017

April Chew
Tel. 312-320-1097
Email: chew@andrews.edu

RE: APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS
IRB Protocol #: 17-124 **Application Type:** Original **Dept.:** Nursing (DNP)
Review Category: Expedited **Action Taken:** Approved **Advisor:** Jochebed B. Ade-Oshifogun
Title: Does use of a mobile app and telephone support promote improved self-care of heart failure?

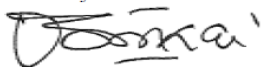
This letter is to advise you that the Institutional Review Board (IRB) has reviewed and approved your IRB application for research involving human subjects entitled: *"Does use of a mobile app and telephone support promote improved self-care of heart failure?"* IRB protocol number 17-124 under Expedited category. This approval is valid until December 14, 2018. If your research is not completed by the end of this period you must apply for an extension at least four weeks prior to the expiration date. We ask that you inform IRB whenever you complete your research. Please reference the protocol number in future correspondence regarding this study.

Any future changes (see IRB Handbook pages 10-11) made to the study design and/or consent form require prior approval from the IRB before such changes can be implemented. Please use the attached report form to request for modifications, extension and completion of your study.

While there appears to be no more than minimum risk with your study, should an incidence occur that results in a research-related adverse reaction and/or physical injury, (see IRB Handbook page 11) this must be reported immediately in writing to the IRB. Any project-related physical injury must also be reported immediately to the University physician, Dr. Katherine, by calling (269) 473-2222. Please feel free to contact our office if you have questions.

Best wishes in your research.

Sincerely



Mordekai Ongo
Research Integrity & Compliance Officer

Institutional Review Board – 8488 E Campus Circle Dr Room 234 - Berrien Springs, MI 49104-0355
Tel: (269) 471-6361 Fax: (269) 471-6543 E-mail: irb@andrews.edu

Appendix F: IRB Approvals for Amended Protocol



March 20, 2018

April Chew, RN
Department of Nursing
Andrews University
Berrien Springs, MI 49104

RE: Does Use of a Mobile App and Telephone Support Promote Improved Self-Care of Heart Failure?

Dear Ms. Chew:

We have received an amended Protocol dated 13Mar2018 and HIPAA Authorization v2 with no changes to the informed consent.

IRB Decision: Approved on Tuesday, March 20, 2018 by myself, Darra Cover, through expedited review

Duration: As set forth at the initial protocol approval
EGH IRB Internal Event # 1137

The Elkhart General Healthcare System Institutional Review Board complies with the FDA and OHRP requirements for IRBs (OHRP Approved Federalwide Assurance Number: FWA00009238).

Thank you for submitting this information to us. If you have any questions, please call me at 523-3437 or Betty McKinney at 296-6505

Respectfully yours,

A handwritten signature in black ink that reads "Darra L. Cover".

Darra Cover, RPh
Chairperson
Institutional Review Board

/bm

March 23, 2018

April Chew
Tel. 312-320-1097
Email: chew@andrews.edu

RE: APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS
IRB Protocol #: 17-124 **Application Type:** Original **Dept.:** Nursing (DNP)
Review Category: Expedited **Action Taken:** Approved **Advisor:** Jochebed B. Ade-Oshifogun
Title: Does use of a mobile app and telephone support promote improved self-care of heart failure?

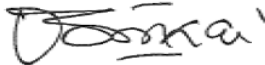
This letter is to advise you that the Institutional Review Board (IRB) has reviewed and approved your IRB **modification** application for research involving human subjects entitled: *“Does use of a mobile app and telephone support promote improved self-care of heart failure?”* IRB protocol number 17-124 under Expedited category. This approval is valid until December 14, 2018. If your research is not completed by the end of this period you must apply for an extension at least four weeks prior to the expiration date. We ask that you inform IRB whenever you complete your research. Please reference the protocol number in future correspondence regarding this study.

Any future changes (see IRB Handbook pages 10-11) made to the study design and/or consent form require prior approval from the IRB before such changes can be implemented. Please use the attached report form to request for modifications, extension and completion of your study.

While there appears to be no more than minimum risk with your study, should an incidence occur that results in a research-related adverse reaction and/or physical injury, (see IRB Handbook page 11) this must be reported immediately in writing to the IRB. Any project-related physical injury must also be reported immediately to the University physician, Dr. Katherine, by calling (269) 473-2222. Please feel free to contact our office if you have questions.

Best wishes in your research.

Sincerely



Mordekai Ongo
Research Integrity & Compliance Officer

Institutional Review Board – 8488 E Campus Circle Dr Room 234 - Berrien Springs, MI 49104-0355
Tel: (269) 471-6361 Fax: (269) 471-6543 E-mail: irb@andrews.edu

Appendix G: IRB Approvals for Project Continuation



July 18, 2019

April Chew, RN
Department of Nursing
Andrews University
Berrien Springs, MI 49104

RE: Does Use of a Mobile App and Telephone Support Promote Improved Self-Care of Heart Failure?

Dear Ms. Chew:

We have received the Continuing Review dated 5/14/19 for the above protocol along with the following items:

- Letter dated June 25, 2019 with explanation why delay in requesting renewal for approval.

The continuation for approval listed above has been reviewed by myself, the IRB Chairperson, is approved by expedited review.

IRB Decision: Expedited Approval on 7/18/2019 by the IRB Chairperson.

Duration: Approved for 365 days until 7/17/2020
EGH IRB Internal Event # 1265

The IRB will expect your next Continuing Review to be submitted four weeks prior to 7/17/2020.

The Elkhart General Healthcare System Institutional Review Board complies with the FDA and OHRP requirements for IRBs (OHRP Approved Federalwide Assurance Number: FWA00009238).

Thank you for submitting this information to us. If you have any questions, please call me at 523-3437 or Betty McKinney at 296-6505

Respectfully yours,

A handwritten signature in black ink that reads "Darra L. Cover".

Darra Cover, RPh
Chairperson
Institutional Review Board

June 26, 2019

April Chew
Tel. 312-320-1097
Email: chew@andrews.edu

RE: APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS
IRB Protocol #: 17-124 **Application Type:** Original **Dept.:** Nursing (DNP)
Review Category: Expedited **Action Taken:** Approved **Advisor:** Jochebed B. Ade-Oshifogun
Title: Does use of a mobile app and telephone support promote improved self-care of heart failure?

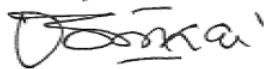
This letter is to advise you that the Institutional Review Board (IRB) has reviewed and approved your IRB **continuation** application for research involving human subjects entitled: *"Does use of a mobile app and telephone support promote improved self-care of heart failure?"* IRB protocol number 17-124 under Expedited category. This approval is valid until June 26, 2020. If your research is not completed by the end of this period you must apply for an extension at least four weeks prior to the expiration date. We ask that you inform IRB whenever you complete your research. Please reference the protocol number in future correspondence regarding this study.

Any future changes made to the study design and/or consent form require prior approval from the IRB before such changes can be implemented. Please use the attached report form to request for modifications, extension and completion of your study.

While there appears to be no more than minimum risk with your study, should an incidence occur that results in a research-related adverse reaction and/or physical injury, this must be reported immediately in writing to the IRB. Any project-related physical injury must also be reported immediately to the University physician, Dr. Katherine, by calling (269) 473-2222. Please feel free to contact our office if you have questions.

Best wishes in your research.

Sincerely



Mordekai Ongo
Research Integrity & Compliance Officer

Appendix H: Informed Consent and Enrollment Forms

Participant ID#

**Andrews University – Department of Nursing
Use of Mobile App and Telephone Support for Self-Care of Heart Failure Project
Informed Consent Form**

Project Investigator: April Chew, MS, RN
Faculty Advisor: Jochebed Ade-Oshifogun, PhD, RN

Project Goal: To determine if use of a mobile app and telephone support can help people with heart failure and their support people to increase symptom monitoring and self-care of heart failure activities.

Participation in this project is completely voluntary.

- There is no penalty if you decide not to participate.
- If you decide to participate, you can drop out at any time with no penalty. You are under no obligation to complete the 90-day project.
- Each participating household will receive a free digital bathroom scales at the beginning of the project, which you are welcome to keep, even if you decide not to finish the 90-day project.

There are two ways to participate in this project. You may select one of the options below.

Option 1: Survey Only

- One meeting when you enroll in the project (30 minutes) to provide information, answer questions, and complete a survey.
- One meeting at the end of the 90-day project period (30 minutes or less) to complete a survey.

Option 2: Survey & Mobile App

- One meeting when you enroll in the project (60-90 minutes) to provide information, answer questions, and complete a survey.
- Use a mobile app on your smartphone or tablet for 90 days to record your self-care activities.
- 6 phone calls from the project investigator over 90 days (one call every 2 weeks to monitor and encourage you).
- One meeting at the end of the 90-day project period (30 minutes or less) to provide feedback and complete a survey.

Risks of participating in this project are minimal. Risks associated with use of the mobile app and answering questions about your self-care of heart failure activities are minimal and not different from your day to day risks.

Potential benefits of participating in this project include:

- Learn to use new technology to track heart failure symptoms and self-care activities.
- Learn to recognize patterns in heart failure symptoms and feel more confident about self-managing heart failure.
- Keep the digital bathroom scales and continue to use the free mobile app for as long as you like even if you do not finish the 90-day project.

Participant ID#

Participants' confidentiality is a priority.

- Your name will be removed from all project data.
- All paper copies of project documents will be stored in a locked filing cabinet in the project investigator's home office.
- Personal health data you enter into the mobile app is stored securely and never shared with anyone by the creator of the mobile app.
- Only aggregated data for all participants will be reported by the creator of the mobile app without reference to individuals.

If you have questions about this project, please contact the project investigator April Chew, MS, RN, Andrews University DNP Student, at (312) 320-1097 or chew@andrews.edu

If you have questions about April Chew, the nursing student project investigator, please contact Dr. Ade-Oshifogun, PhD, RN, Chair of the Andrews University Department of Nursing, at (269) 471-3363 or jochebed@andrews.edu

If you have questions about your rights as a project participant, please contact Darra Cover, RPH at (574) 523-3437, or Charli Mady, a patient representative, who is not involved with this study at (574) 296-6472. You may also contact the Andrews University Institutional Review Board at (269) 471-6361 or irb@andrews.edu.

Conflict of Interest. April C. Chew, the Project Investigator, declares no conflict of interest.

Documentation of Informed Consent. Please sign below only if you agree to the following:

I agree to participate in: **Option 1: Survey Only** or **Option 2: Survey & Mobile App** of this project (select one participation option).

- I understand the goals, benefits, and potential risks of the project.
- I have discussed any questions I have about the project.

Participant Name (Printed):	
Participant Signature:	
Date:	
Home phone#	Preferred <input type="checkbox"/>
Cell phone#	Preferred <input type="checkbox"/>
Address for Project Results Letter to be sent in Fall 2018 (email or US Mail)	

Project Investigator Name:	April C. Chew, MS, RN
Project Investigator Signature:	
Date:	

**Enrollment Form: Descriptive & Demographic Data Collection
(to be completed by PI at enrollment meeting)**

Informed Consent Form must be signed before this form can be filled out.

Type of participant:	Person with HF <input type="checkbox"/> Support Person <input type="checkbox"/>
Participation Option:	Option 1: Survey Only <input type="checkbox"/> Option 2: Survey & Mobile App <input type="checkbox"/>
If you are a person with HF, do you have a support person?	Yes, participating <input type="checkbox"/> Yes, but not participating <input type="checkbox"/> No <input type="checkbox"/>
Participant ID#	HF _____ or SP _____
HFHS app account ID#	
Name:	
Date of birth:	
Gender:	Male <input type="checkbox"/> Female <input type="checkbox"/>
Education Level:	<input type="checkbox"/> No schooling completed <input type="checkbox"/> Preschool to 8 th grade <input type="checkbox"/> Some high school, no diploma <input type="checkbox"/> High school graduate, diploma <input type="checkbox"/> High school equivalent (GED) <input type="checkbox"/> Some college credit, no degree <input type="checkbox"/> Trade/technical/vocational training <input type="checkbox"/> Associate degree <input type="checkbox"/> Bachelor's degree <input type="checkbox"/> Master's degree <input type="checkbox"/> Professional degree <input type="checkbox"/> Doctorate degree
Home phone#	Preferred <input type="checkbox"/>
Cell phone#	Preferred <input type="checkbox"/>
Best time of day to call:	8am–12noon <input type="checkbox"/> 12noon–4pm <input type="checkbox"/> 4pm–8pm <input type="checkbox"/>
Best day (s) of the week to call:	Su <input type="checkbox"/> M <input type="checkbox"/> Tu <input type="checkbox"/> W <input type="checkbox"/> Th <input type="checkbox"/> F <input type="checkbox"/> Sa <input type="checkbox"/>
Do you currently track or help the person with HF to track their symptoms and self-care?	Yes <input type="checkbox"/> No <input type="checkbox"/>

**Enrollment Form: Descriptive & Demographic Data Collection
(to be completed by PI at enrollment meeting)**

If two participants in household, who will enter data into the HFHS app?	Person with HF <input type="checkbox"/> Support Person <input type="checkbox"/> Both <input type="checkbox"/>
What type of device will you use to access the HFHS mobile app?	Smartphone <input type="checkbox"/> Tablet <input type="checkbox"/>
Date of Enrollment:	
Date to start using the HFHS app:	
90 days from start date:	
Date/Time/Location for meeting at conclusion of 90-day study period:	
Date/Time for 6 STS calls:	#1 _____ #2 _____ #3 _____ #4 _____ #5 _____ #6 _____
Person with HF ONLY:	
Date Information Collected from EMR:	
Approximate date of HF diagnosis:	
Number of hospitalizations for HF in the last 12 months:	
Number of hospitalizations for HF during the 90-day study period:	
If hospitalized in the last 12 months for HF, Date of last hospitalization for HF:	
Ejection Fraction:	
NYHA Classification for HF:	
Comorbidities:	Arrhythmia <input type="checkbox"/> Chronic Kidney Disease <input type="checkbox"/> Chronic Obstructive Pulmonary Disease <input type="checkbox"/> Coronary Artery Disease <input type="checkbox"/> Diabetes Mellitus <input type="checkbox"/> Active Cancer <input type="checkbox"/>

Appendix I: HIPAA Consent Form



Institutional Review Board (IRB)

HIPAA Authorization

The United States government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health (HITECH) provisions of the American Recovery and Reinvestment Act of 2009, the Omnibus Final Rule (as applied to 45 CFR Parts 160 and 164 and the regulations promulgated thereunder, as each may be amended from time to time (collectively, "HIPAA"). The Privacy Rule is designed to protect the confidentiality of your protected health information (PHI). The document you are reading, called an "Authorization," explains how your PHI will be used and shared for purposes of this project. This document also describes your rights with respect to the PHI.

Project Information

Project Investigator: April C. Chew, MS, RN

Project Title: *Use of Mobile App and Telephone Support for Self-Care of Heart Failure*

Authorization

You authorize April C. Chew and her project staff to use and disclose your protected health information for the project entitled *Use of Mobile App and Telephone Support for Self-Care of Heart Failure*.

Your protected health information that may be used and disclosed includes:

- Approximate date of heart failure diagnosis
- Number of hospitalizations for heart failure in the last 12 months
- Number of hospitalizations for heart failure during the 90-day study period
- Date of last hospitalization for heart failure (if hospitalized in the last 12 months for heart failure)
- Ejection fraction (or EF)
- NYHA Classification for heart failure
- Presence of the following comorbidities: Arrhythmia, Chronic Kidney Disease, Chronic Obstructive Pulmonary Disease, Coronary Artery Disease, Diabetes Mellitus, and/or Active Cancer
- All information entered into the Heart Failure Health Storylines mobile app during the 90-day project period

Your protected health information will be used to:

Determine if use of a mobile app and telephone support can help people with heart failure and their support people to increase symptom monitoring and self-care of heart failure activities. Your authorization for the Project Investigator to collect your protected health information will allow the Project Investigator to describe the health status of people with heart failure who participate in this project and to ensure that the project meets legal, institutional, or accreditation requirements.

You do not have to sign this Authorization.

If you decide not to sign the Authorization:

- 1. You will not be allowed to participate in the project.

After signing the Authorization

You can change your mind and:

- 1. Withdraw or revoke the Authorization and not let the Project Investigator use or disclose further health information.
- 2. If you revoke the Authorization, you will send a written letter to April C. Chew, Progressive Care Unit, Elkhart General Hospital, 600 East Blvd, Elkhart, IN 46514, to inform her of your decision.
- 3. If you revoke the Authorization, the Project Investigator may only use and disclose the protected health information already collected for this research study.
- 4. If you revoke the Authorization, your protected health information may still be used and disclosed should you have an adverse or unanticipated event.
- 5. If you revoke the Authorization, you will not be allowed to continue to participate in the project.

Your Right to Access PHI and your project data:

Your PHI includes information in your medical record and information entered into the Heart Failure Health Storylines mobile app during the 90-day project period as described in the Authorization section above.

You understand that you have a right to access your own PHI held by the Project Investigator. This can be obtained by sending a written request to April C. Chew, Progressive Care Unit, Elkhart General Hospital, 600 East Blvd, Elkhart, IN 46514.

You understand that your PHI data collected for this project will be de-identified through use of a participant ID# and will be securely maintained in an encrypted storage device by the Project Investigator during and after the conclusion of the project to be used for scholarly presentations and publications about the project findings.

If you have questions or concerns about your privacy rights, please contact the Beacon Privacy Office at (574) 647-7751.

You may also request a copy of the Elkhart General Hospital Notice of Privacy Practices by either contacting the Privacy Office at the telephone number above or on the Elkhart General Hospital website under Privacy.

Signature

As a project participant, you will need to sign this Authorization acknowledging your understanding of what the project will require of you and how your PHI will be used and/or disclosed. A copy of the Agreement will be provided after it has been signed.

This is to acknowledge that I have read the above information or it has been read to me

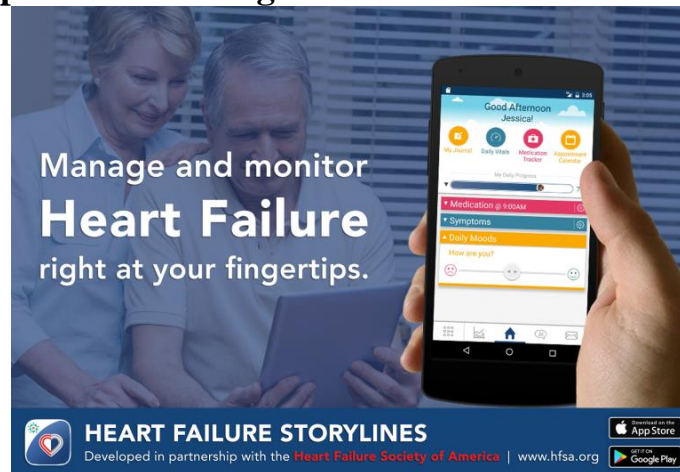
Signature of Project Participant

Date

Printed Name of Above

Appendix J: Educational Handout Provided to Healthcare Institution

Free Mobile & Web App helps make tracking heart failure self-care easier!



<https://www.hfsa.org/patient/patient-tools/patient-app/>

The **Heart Failure Storylines** app was developed in partnership with the Heart Failure Society of America, and is powered by the Health Storylines™ platform from Self Care Catalysts Inc.

It was created with input from people with heart failure so that the right health tools are available to you. Choose what you want to track to build your own summary “Storylines” to learn more about your health and take better care of yourself!

- **DAILY WEIGHT & VITALS:** Keep a record of daily weight and important vitals that you measure regularly, and visualize them graphically over time.
- **SYMPTOM TRACKER:** Track symptoms and side effects to see patterns that you may need to share with your doctor.
- **MEDICATION TRACKER:** Track your medications and get reminders to help you take your medications on time.
- **PHYSICAL ACTIVITY TRACKER:** Keep track of your physical activity levels to maintain a heart healthy lifestyle.
- **LOW SODIUM GUIDELINES:** Learn more about maintaining a low-salt diet and keep a record of meals.
- **SYNC A DEVICE:** Import data from other health and fitness apps that you use.
- **DAILY MOODS AND JOURNAL:** Track and understand your emotions and what might be driving them. Keep a journal as it has been shown to increase well-being.

Heart Failure Storylines: Download Instructions

Sign-up via website

1. Visit <https://heartfailure.healthstorylines.com/app/#/login>
2. If you are a new user, click on Register
3. Click on Get Started
4. You will need to enter in registration information and agree to the Privacy Policy and Terms of Use to begin using the web app.
5. On the left navigation bar, click on my profile to add other information
6. Click on any of the health tools on the main dashboard to start adding information
7. On the left navigation bar, click circle of support to invite your friends and family
8. Start sharing your story!

Download the iPhone or iPad App

1. To install the app, go to the Apple App Store on your iPhone or iPad, and search for “Heart Failure Storylines”
2. Click on the GET button, then click INSTALL.
3. Once installed, click on the Heart Failure Storylines app.
4. Click on “Sign up.” You will need to enter in the registration information and agree to the Privacy Policy and Terms of Use to begin using the mobile app.
5. Now you can start using your iPhone or iPad version of the app!

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Download the Android™ App

1. To install this app, go to the Google Play™ app store on your Android device, and search for “Heart Failure Storylines”
2. Click the INSTALL button.
3. You will see the APP permissions screen, click ACCEPT.
4. Once installed, click on the Heart Failure Storylines app.
5. Click on “Sign up.” You will need to enter in the registration information and agree to the Privacy Policy and Terms of Use to begin using the app.
6. Now you can start using your Android version of the app!

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