USABILITY AND EFFECTIVENESS OF A SELF-CARE MOBILE HEALTH APP IN INDIVIDUALS WITH HEART FAILURE

A DISSERTATION

SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

IN THE GRADUATE SCHOOL OF THE

TEXAS WOMAN'S UNIVERSITY

SCHOOL OF PHYSICAL THERAPY

COLLEGE OF HEALTH SCIENCE

BY

ANAS ABABNEH PT, M.Sc.

DENTON, TEXAS

DECEMBER 2021

DEDICATION

To the Almighty God, Allah, for guiding me throughout my life and giving me the strength, patience, and perseverance required to face the challenges that appear in every chapter of our lives.

To my parents, Fathi and Fatima, who dedicated their lives to educating and raising us (my brothers and I) to be strong in our lives and work hard for the things we aspire to achieve.

To my wonderful wife, Sajeda, who has been a constant source of support and encouragement during the PhD and our life journey. She always gave me a reason to be hopeful every day. I am truly grateful for her love, patience, and endless support.

To my children Taim Allah, Salma, and Yousef ... You are my joy ... I love you all to the moon and back.

To my brothers, my sister, and my friends for all their support and for being by my side through this journey.

ACKNOWLEDGEMENTS

I have been very fortunate to have performed my graduate work at a university as collaborative as Texas Woman's University; therefore, there are many people to thank for their part in my success. I would like first to express my sincere thanks to my advisor, Dr. Suh-Jen Lin, for giving me a home in her teaching and research labs and her support over the years, as well as her countless hours of reflecting, reading, encouraging, and most of all, patience throughout the entire journey of my doctoral study. Also, I would like to thank my other dissertation committee members: Dr. Elaine Trudelle-Jackson, Dr. Hui-Ting Goh, and Dr. Mark Weber, for their contributions to this work. Over the years, each of them has given me magnificent scientific guidance, many insightful suggestions, and they demonstrated a sincere interest in my project. This journey was challenging, and I would not have accomplised it without all the support and guidance I have received from all of you.

I would like to acknowledge the generous assistance of Dr. Ann Medley, in particular, and many faculty who helped and encouraged me while I worked as a graduate assistant at the School of Physical Therapy – Dallas Campus. This rich stage of my life was crucial in my doctoral study journey, as I learned a lot about academic and research life, which I think reflected positively on my project and my life.

I would like to express my appreciation to the Texas Woman's University - Center for Student Research for funding this project. In addition, I would like to thank the

hospital of Texas Health Resources – Dallas for referring patients with heart failure from their heart failure clinic in 2018 and 2019.

Last but not least, I would like to express my profound gratitude to all the Doctor of Physical Therapy Students (Leonardo Carranza, Laura Danks, Micah Fisher, Adrian Atos, Kiellor Conn, Ariana Weeks, Carolyn Young, Valeri Lopez, and Patricio Rivalcaba.) for their incredible support and help on this project. They gave a lot of their time and efforts to make this project a success.

ABSTRACT

ANAS ABABNEH

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DECEMBER 2021

Introduction: People with heart failure (HF) often describe HF symptoms as minor deviations in health and delay seeking early medical care, which often leads to hospital readmissions. Mobile health (mHealth) apps with features to actively engage users (e.g., tracking vitals, real-time adjustments, and social interaction functionalities) could become a novel strategy for promoting self-care and improving health outcomes. This study examined the usability and the effectiveness of the Heart Failure Health Storylines (HFHS) app on quality of life (QoL) and physical activity (PA) in HF people. **Methods:** HF individuals were recruited nationwide for a four-week study. Participants were randomly assigned to the intervention group along with daily remote professional monitoring and the control group. Telehealth was used for the initial session for informed consent, gathering baseline data, and training participants. Both groups were trained on utilizing the pedometer for tracking daily step counts. The training on the HFHS app included tracking heart rate, blood pressure, medication schedule, and body weight. The remote professional monitoring included daily monitoring participants' health parameters on the app, sending alert messages on worsening signs, and weekly phone calls for feedback. Descriptive statistics were conducted on demographic data, tracking

frequencies, alert messages, Quality of Experience (QoE) survey, and QoL measures: MLHFQ and SF-36. Two-way mixed ANOVA was conducted on PA and QoL measures with $\alpha = 0.05$. **Results:** 23 participants were randomized, but 18 completed the study (58 ± 15 yrs). The app offered a satisfactory user experience with an average score above 80% for App criteria of QoE: security, ease of use, availability, appearance, and learning. Thirty-three alert messages were sent and prompted four physician visits/calls. The weekly tracking adherence was above 91%. The Minnesota Living with HF Questionnaire (MLHFQ) average score of the App group had a larger favorable reduction trend (pre: 32 ± 26, post: 25 ± 22) than the No-App group (pre: 33 ± 33, post: 31 ± 28). **Conclusion:** Using the app with professional monitoring for self-care seemed feasible in HF people, with excellent adherence to tracking health parameters and a favorable trend toward improved QoL.

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CHAPTER I

INTRODUCTION

Heart failure (HF) is a growing global health challenge. The estimated prevalence of HF is about 6 million cases in the USA and approximately 64.34 million cases globally and is expected to reach 8 and 109 million cases, respectively, by 2030 (Lippi & Sanchis-Gomar, 2020; Virani et al., 2021). The 1-year HF mortality rate is about 29.6% in the USA and about 23.9% across Europe, North Africa, and the Middle East (Chen et al., 2011; Crespo-Leiro et al., 2016). In addition, the health care cost is estimated at about $43.6 billion nationwide and 346.17 billion globally (Heidenreich et al., 2013; Lippi & Sanchis-Gomar, 2020). Besides all these substantial health burdens, the all-cause readmission rate in this population is considered high (Gupta & Fonarow, 2018), where it ranged between 20.2% to 24.4% within 30 days from the initial discharge in the USA (Centers for Medicare & Medicaid Services, 2021; Patil et al., 2019), and about 31.9% among representative centers from 12 European countries (Maggioni et al., 2013). Half of the HF readmissions were for cardiovascular causes, with one-third of readmissions due primarily to HF-related exacerbating factors (Dharmarajan et al., 2013; Manemann et al., 2016; Patil et al., 2019). The exacerbating factors were pneumonia, myocardial ischemia, arrhythmia, uncontrolled hypertension, worsening renal function, and non-adherence to medications and diet (Fonarow et al., 2008; Gheorghiade et al., 2013). These factors usually develop gradually, and their related symptoms begin days to weeks before

hospital readmission (Gheorghiade et al., 2013). Many of these factors could be avoided through adhering to self-care behaviors, such as taking medications as prescribed, awareness of unusual weight changes (e.g., fluid overload), and maintaining a healthy lifestyle (Reeder et al., 2015).

Different guidelines on HF management emphasize the importance of effective self-care to improve HF patient outcomes, including enhanced quality of life (QoL) and reduced mortality and readmission rates (Jaarsma et al., 2021; Riegel et al., 2009). Self-care, in general, entails three main concepts: adhering to self-care behaviors (maintenance), detecting and interpreting signs and symptoms (monitoring), and responding to occurrence or change in symptoms (management; Riegel et al., 2016). However, implementing self-care could be a challenge for people with HF. Some patients with HF perceive signs and symptoms to be unrelated to the heart (Jurgens, 2006). Others may not recognize the gradual somatic changes that lead to HF acute exacerbations (Albert et al., 2010). For instance, about 60.5% of patients with HF could not easily recognize HF-related sudden weight gains (Carlson et al., 2001) because it takes a period of days to weeks between the onset of HF worsening symptoms and hospital admission (Schiff et al., 2003). Adding to these challenges, non-adherence with self-care behaviors in patients with HF has been reported in some other studies. About 50% to 62% of HF patients could not properly adhere to medication therapy (Schiff et al., 2003; Silavanich et al., 2019), and 14%-48% could not adhere to lifestyle changes and other self-care recommendations (Riegel et al., 2019). Hence, it is important to find innovative and

effective strategies to promote implementing the three main concepts of self-care in people with HF.

With the increased popularity of mobile phones in our lives, technology might provide a convenient means for facilitating and promoting self-care for people with chronic conditions like HF (Burke et al., 2015). This type of health-related service and intervention delivered through mobile phone is called Mobile Health (mHealth). The World Health Organization defines mHealth as: "a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" (World Health Organization, 2011, p. 6). One of the most common forms of mHealth systems is a health-related mobile application (mHealth app). Approximately 72% of American adults own a smartphone, and 62% of them use mHealth apps when seeking information about a health condition (Kao & Liebovitz, 2017). According to the report from the IQVIA Institute for Human Data Sciences, there are about 318,000 mHealth apps out of 6 million available apps in different app stores (Aitken et al., 2017). In general, these mHealth apps provide clinical-related functions such as reminding physical check-up appointments, tracking vital signs, and sharing health information with healthcare providers. In addition, they are usually designed to perform sophisticated functionalities such as real-time adjustments for health changes, visual feedback, and prompt social interactions. Therefore, most mHealth apps are designed to drive people to engage in self-care to manage their disease and health outcome. On this basis, mHeath apps could be a potentially effective strategy that promotes self-care in people with HF.

Recent systematic reviews examined the functionalities of over 60 mHealth apps that were designed to promote HF self-care (Athilingam & Jenkins, 2018; Masterson Creber et al., 2016; Mortara et al., 2020; Wali et al., 2019). The reviews utilized different assessment tools to evaluate the functions of these mHealth apps, including the Mobile Application Rating Scale (MARS; Athilingam & Jenkins, 2018; Masterson Creber et al., 2016), the 11-item IMS Institute for Healthcare Informatics functionality scoring system (Masterson Creber et al., 2016; Mortara et al., 2020), and a newly developed 25-list of major functions for promoting HF self-care (Wali et al., 2019). These functionalities typically include, but are not limited to, the apps' integration with other health devices, recording user-entered data, communicating with health care providers, providing reminders to the user, displaying and tracking different health parameters such as medications, vital signs, and weight. In addition, some of these reviews examined the consistency of these mHealth apps with the eight specific self-care behaviors from Heart Failure Society of America (HFSA) guidelines for non-pharmacologic management (Masterson Creber et al., 2016). The eight specific self-care behaviors are daily weighing, checking extremities for swelling, doing PA or exercise, eating a low-salt diet, taking daily medications, attending doctor's appointments, daily monitoring of HF symptoms, and actively responding to symptoms when they change (HFSA, 2010). Among these systematic reviews, it was found that the HFHS app had the highest functionality rating score across different assessment tools, and it was the only app that addressed all eight HF-specific self-care behaviors.

In the literature, the researcher identified several clinical trials that investigated the usability and effectiveness of mHealth apps and different mHealth systems on people with HF. The mHealth systems usually were based on mobile web browsers (Dang et al., 2017; Scherr, et al., 2006; Scherr, et al., 2009; Zan et al., 2015), text messaging (Nundy et al., 2013), smart watch (Evans et al., 2016), or developed pre-installed programs on mobile devices (Bartlett et al., 2014; Hägglund et al., 2015; Koehler et al., 2011; Seto et al., 2012; Suh et al., 2011; Triantafyllidis et al., 2015). In comparison, the mHealth apps were based on the health-related mobile applications that are downloadable from the conventional mobile platforms. However, only a limited number of studies examined the usability and effectiveness of mHealth apps on people with HF. The researcher found eight of these studies in the literature; three of them were randomized control trials (RCTs; Athilingam, et al., 2017; Kitsiou et al., 2021; Vuorinen et al., 2014), four pre-post design studies (Alnosayan et al., 2017; Bakogiannis et al., 2021; Chew, 2020; Heiney et al., 2020), and one survey study (Portz et al., 2018). The sample size for these eight studies ranged from 8 to 94 patients with HF and five of them had a sample size less than 30. In addition, the study duration or follow-up on utilizing the apps ranged from 4 weeks to 6 months. All these apps were designed to be compatible with the common app platforms of smartphones. Still, none of these apps are commercially available, except the HFApp app (available on iPad Apple store only) and the HFHS app. All studies requested their patients utilizing mHealth apps to monitor weight and HF symptoms, four studies requested to track medications and daily vital signs (blood pressure and heart rate) (Athilingam, et al., 2017; Bakogiannis et al., 2021; Kitsiou et al., 2021; Vuorinen et al.,

2014), and only three studies encouraged their patients to track their daily PA (Athilingam, et al., 2017; Chew, 2020; Kitsiou et al., 2021). Additionally, some studies provided professional monitoring through HF nurses to follow patients' measurements remotely and then call or text to guide them for appropriate response when a risk was indicated (Alnosayan et al., 2017; Chew, 2020; Vuorinen et al., 2014). Other studies developed tailored text messages as clinical decision support that were sent automatically to the patients if their measurements exceeded pre-determined thresholds (Athilingam, et al., 2017; Heiney et al., 2020; Kitsiou et al., 2021).

The usability of mHealth apps were indicated by various outcome measures, including adherence to self-care behaviors and patients' experience on utilizing apps via interview or self-report survey such as the System Usability Survey and the Post-Study System Usability Questionnaire. The results on adherence to HF self-care behaviors with different mHealth apps have been positive. The studies that utilized the usability scales reported that their apps were useful for daily self-care (Alnosayan et al., 2017; Bakogiannis et al., 2021). For effectiveness of mHealth apps on people with HF, a few outcome measures were utilized, including QoL outcome measures and self-care outcome scales. Different QoL measures were used in these studies, including the MLHFQ (Alnosayan et al., 2017), the Kansas City Cardiomyopathy Questionnaire (KCCQ; Athilingam, et al., 2017; Bakogiannis et al., 2021; Kitsiou et al., 2021), and the 14-item Center for Disease Control and Prevention Health Related QoL Scale (Heiney et al., 2020). The results have been mixed, with some mHealth app studies reporting a positive impact on QoL for people with HF (Alnosayan et al., 2017; Bakogiannis et al., 2021).

But, other studies demonstrated declined QoL or no changes due to a small-scale study, a short intervention duration, or poorer HF-functioning at baseline in the intervention group compared to controls (Athilingam, et al., 2017; Heiney et al., 2020).

Statement of the Problem

The importance of self-care can be seen in alleviating the substantial health care cost burdens facing societies and people with HF alike. Over the past two decades, with technological advancement, there has been increasing interest in mHealth apps to promote self-care for people with chronic conditions, including HF. This increasing interest is not limited to the scientific communities, but it extends to patient communities. They have shown keen interest in mHealth apps as a more convenient, accessible, and attractive way to monitor and manage daily activities, medications, vital signs, and HF symptoms, as well as share health measurements with their supporting circles (family, nurse, physician). The usability and effectiveness of some mHealth apps on people with HF have been investigated in a few studies, with results suggesting that most of these mHealth apps are feasible and demonstrate positive outcomes for improving adherence to HF self-care behaviors. However, the effectiveness of mHealth apps has only been examined via limited clinical outcome measures, (limited QoL measures, for example), and the results are equivocal. In addition, the previous studies on mHealth apps are limited by the use of non-commercially available apps, small sample sizes, single-group pilot study design, and descriptive study design. Therefore, there is a need for systematic RCTs to investigate the usability and effectiveness of high-rated commercially available mHealth apps on different health outcomes in people with HF.

Purpose of the Study

The study's purposes were to examine the usability and the effectiveness of an mHealth app, the HFHS app, in individuals with HF. The first purpose was to examine the usability of the HFHS app by the frequency of participants' data entry of health parameters on the HFHS app over 4 weeks, participants' perception of their quality of experience, the number of alert messages sent, and the number of physician visits prompted by the alert messages. The second purpose was to examine the effectiveness of the HFHS app on PA and QoL over 4 weeks in individuals with HF as compared to the control group who did not use the app.

Research Questions for the First Purpose of the Study

The following research questions were addressed for the usability of the HFHS app (the first purpose of this study):

1. Would participants in the intervention group (App group) utilize the HFHS app at least four days per week (e.g., at least 57% a week) over the course of 4 weeks?
2. Would participants in the App group report a positive experience after utilizing the HFHS app over 4 weeks?
3. Would the professional monitoring program capture undesired physiological changes in health parameters when using the HFHS application?

Hypotheses for the Second Purpose of the Study

The hypotheses for the effectiveness of the HFHS app were:

1. There would be a significant increase in physical therapy (PA) in the intervention group over 4 weeks.

2. There would be a significant difference in PA between the intervention and the control groups after 4 weeks of HFHS app intervention.
3. There would be a significant improvement in QoL measures (36-item Short Form Survey (SF-36) and MLHFQ after 4 weeks for the intervention group.
4. There would be a significant difference in QoL measures between the intervention and the control groups after four weeks of HFHS app intervention.

Operational Definitions

The following terms were defined for this study:

1. The term self-care was defined as "a naturalistic decision-making process that influences the actions of an individual in maintaining physiologic stability, facilitating the perception of signs and symptoms, and directing the management of those signs and symptoms" (Riegel et al., 2016, p. 226).
2. The app in this study stands for a mobile application, which is a software program designed to run on a mobile device such as a smartphone, tablet, or smartwatch.
3. The mHealth was defined by World Health Organization as "a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" (World Health Organization, 2011, p. 6).
4. In this study, the alert messages refer to pre-prepared text messages that were composed to reflect the guidelines of the American Heart Association (HFSA, 2010). These messages were designed to notify a participant who had undesirable

health parameters as a part of the professional monitoring for data entry on the HFHS app.

Assumptions

The following assumptions were made for this study:

1. Each participant was appropriately diagnosed with HF by a physician
2. All participants truthfully filled out the QoL and Quality of Experience (QoE) surveys.
3. Participants in the App intervention group truthfully entered daily vital signs (blood pressure and heart rate), body weight, medication intake, and daily steps on the HFHS app.
4. Participants in the control group truthfully filled out the PA log: step counts per day (see Appendix A).
5. Each participant had access to internet and a smartphone for sufficient time daily over 4 weeks to enter their logs (vital signs and steps counts), review their daily logs on the HFHS app, and deal with the app reminders.
6. All the devices that the participant received from the researcher is assumed to work appropriately and efficiently during the study period if the participant did not contact the researcher about any problems of use.
7. All participants did not use the HFHS app before their enrollment in this study.
8. All participants in the App intervention group could use the HFHS appropriately and efficiently after receiving the initial training on the app and can use the HFHS

app guidance booklet for trouble shooting if the participant did not contact us about any difficulty in use.

Significance of the Study

Limited efficacy testing of highly rated commercially available mHealth apps with a RCT is one of the most significant barriers for readily adopting mHealth apps in HF population. Therefore, this study contributes to helping professional healthcare providers and patients with HF adopt an appropriate self-care intervention that suit their needs. Additionally, this feasibility study could uncover many of the challenges that researchers could face when designing larger confirmatory study, such as determining recruitment capability, selecting appropriate outcome measures, knowing proper data collection procedure, knowing the acceptability degree of the mHealth app interventions in HF populations, and obtaining pilot data for estimating effect sizes.

CHAPTER II

LITERATURE REVIEW

The purpose of this chapter is to review the following topics:

(1) The needs for promoting self-care in patients with HF.
    i. Medical challenges related to HF prevalence, mortality, and health care cost
    ii. Rate of HF readmission
    iii. Ability to avoid contributing factors to readmission
(2) Self-care: definition, importance, and challenges
(3) Self-care with Mobile Health (mHealth) technologies in HF
    i. Mobile Health: definition and characteristics
    ii. Systematic reviews on mHealth Apps' functionalities
    iii. Clinical Trials with mHealth systems for self-care in HF: usability and effectiveness
    iv. Clinical Trials with mHealth Apps for self-care in HF: usability and effectiveness

The Needs for Promoting Self-Care in Patients with HF

Medical Challenges Related to HF Prevalence, Mortality, and Health Care Cost

HF is a progressive chronic cardiovascular disease associated with substantial morbidity, mortality, and economic burdens (Lippi & Sanchis-Gomar, 2020; Virani et al., 2021). The estimated accumulative prevalence is approximately 64.34 million HF cases in the whole world and 6 million HF cases in the USA. The 1-year HF mortality rate is approximately 29.6% nationwide (Chen et al., 2011), and it is about 23.9% across Europe, North Africa, and the Middle East (Crespo-Leiro et al., 2016). Adding to that, the current total healthcare cost for HF has been estimated at 346.17 billion globally (Lippi & Sanchis-Gomar, 2020) and $43.6 billion nationwide (Heidenreich et al., 2013). As a result of these medical and financial challenges, many studies have focused on interventions that target the causes of HF, the prevention of its onset and worsening, and creative solutions to reduce utilizing health care resources related to hospital readmissions (Heidenreich et al., 2013; Lippi & Sanchis-Gomar, 2020).

Rate of HF Readmission

HF is a leading cause of hospital readmission among older patients (Gupta & Fonarow, 2018). A pilot survey for the European Society of Cardiology–Heart Failure reported the HF readmission rate at 31.9% among representative centers from 12 European countries (Maggioni et al., 2013). In the United States, the all-cause 30-day hospital readmission rate of HF was 24.4% for Medicare beneficiaries of patients with HF in 2018 (Centers for Medicare & Medicaid Services, 2021). About 20.2% readmission rate within the first 30 days was reported in another study that evaluated

more than half-million HF admissions in the United States during 2013 and 2014, based on national estimates from the Healthcare Cost and Utilization Project National Readmission Database (Patil et al., 2019). Half of these readmissions were for cardiovascular causes, with one-third of readmissions due primarily to HF. Similarly, about 35.2% of HF 30-day readmissions among Medicare beneficiaries were due to HF cause (Dharmarajan et al., 2013).

Contributing Factors to HF Readmission

The main reason for HF readmissions is congestion in the chest, which is related to high left ventricular filling pressure (Gheorghiade et al., 2006; Gheorghiade et al., 2013). The congestion usually develops gradually before hospital admission when patients may have elevated ventricle filling pressure and symptoms days or weeks before clinical congestion. The OPTIMIZE-HF study enrolled 48,612 patients hospitalized for HF at 259 hospitals from all regions of the United States and reported that 61.3% of these patients had one or more exacerbating factors contributing to HF hospitalization (Fonarow et al., 2008). These exacerbating factors were pneumonia, myocardial ischemia, arrhythmia, uncontrolled hypertension, worsening renal function, and non-adherence to medications and diet (Fonarow et al., 2008). Most of these factors could be avoided through optimizing HF self-care.

Self-Care

Definition of Self-Care

Self-care was defined as “a naturalistic decision-making process that influences the actions of an individual in maintaining physiologic stability, facilitating the

perception of signs and symptoms, and directing the management of those signs and symptoms" (Riegel et al., 2016). Thus, self-care can be characterized by three main concepts (Riegel et al., 2016). The first is self-care maintenance, which refers to adherence to treatment and health behaviors, such as taking medication, having a low-sodium diet, and exercising regularly. The second is self-care monitoring (symptom perception), which involves monitoring, detecting, and interpreting signs and symptoms, such as body weight, shortness of breath, chest pain, pulse, and blood pressure. The third is self-care management, which means responding to signs and symptoms when these symptoms occur or change (Riegel et al., 2016).

Importance of Self-Care

Different guidelines on HF management emphasize the importance of effective self-care as part of successful treatment (Jaarsma et al., 2021; Riegel et al., 2009). The scientific statement from the American Heart Association in 2009 highlighted the concepts and evidence important to the understanding and promotion of self-care in people with HF (Riegel et al., 2009). Although it concluded that the effects of self-care were equivocal on HF outcomes, it showed some benefits of self-care on hospital readmission, cost of care, and QoL. A position paper in 2021 summarized the recommended practices for facilitating self-care behavior in patients with HF by the Heart Failure Association of the European Society of Cardiology (Jaarsma et al., 2021). In particular, it concluded that self-care was essential to improve HF patient outcomes, including enhanced QoL and reduced mortality and readmission rates.

Challenges of Self-Care in HF

Delays in seeking care and non-adherence to health behaviors often contribute to increased HF readmissions (Krumholz et al., 2002). A descriptive study that examined time course, contributing factors, and patient responses to decompensated HF found days to weeks between the onset of HF worsening symptoms (dyspnea, edema, and weight gain) and hospital admission (Schiff et al., 2003). Decreased awareness of somatic changes, perceiving that signs and symptoms are not related to HF, and the gradual onset of symptoms in HF patients have been suggested as the explanations for the delay in seeking care (Albert et al., 2010; Jurgens, 2006; Schiff et al., 2003). Adding to that, non-adherence with self-care behaviors in patients with HF has been reported in some other studies. A descriptive study reported that more than half of patients (57%) missed or skipped their medications (Schiff et al., 2003). A cross-sectional study on patients with chronic HF reported that 61.7% of patients showed a poor to medium adherence to their medications based on the self-reported questionnaire Morisky Medication Adherence Scale (Silavanich et al., 2019). In the same context, a pilot study examined the adherence patterns of self-care behaviors over 12 weeks in patients following hospitalization for an acute exacerbation of HF, and found that adherence to diet and medication declined rapidly after hospital discharge (Riegel et al., 2019). In addition, another descriptive study reported about 60% of patients with HF could not easily recognize HF-related sudden weight gains (Carlson et al., 2001). Therefore, promoting the ability of people with HF to monitor their signs and symptoms effectively and respond to undesired changes appropriately may improve HF outcomes and reduce hospital readmission.

Self-Care with mHealth Technologies in HF

mHealth Definition and Characteristics

The use of technology can make health-related services and interventions more accessible, convenient, and efficient for both health care providers and patients. Utilizing mHealth gives a good example of technology's role in facilitating and promoting self-care for chronic conditions like HF (Burke et al., 2015). At this point, before proceeding to explain why mHealth may positively affect self-care, it should be referred to the comprehensive and clear definition of mHealth from the World Health Organization. mHealth is “a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” (World Health Organization, 2011, p. 6). The scientific statement from the American Heart Association on consumer use of mHealth for cardiovascular disease prevention explained why mHealth improves self-care engagement and health care delivery (Burke et al., 2015). First, mHealth can convey information in real-time and provides professional support to patients when needed. Second, mHealth can deliver ongoing interventions that target behavior change. Third, the amount of collected data with mHealth technologies exceeds what can be collected in clinical visits and reflects the physiological and behavioral measures in a patient's natural setting.

Recently, mHealth apps have become the most commonly used form of mHealth technologies as about two-third of American adults own a smartphone, and more than half of them use these apps when seeking health-related information. (Kao & Liebovitz, 2017). The IQVIA Institute for Human Data Sciences reported that the apps platforms

have about third million mHealth apps out of 6 million available (Aitken et al., 2017). Most of these mobile health apps were designed to encourage users to manage their health conditions through clinical-related functions such as reminding medical appointments, tracking vital signs, and sharing collected information with healthcare providers. Besides that, these mHealth apps have the ability to perform advanced functionalities such as real-time adjustments, graphical feedback, and prompt social interactions. In the following paragraphs, the review focuses on three groups of mHealth studies: 1) the systematic reviews that studied functionalities of commercially available mHealth apps in people with HF; 2) the clinical trials that evaluated feasibility and efficacy of mHealth systems, which used smartphones as a part of their implemented system, in people with HF; and 3) the clinical trials that assessed feasibility and efficacy of standalone mHealth apps in individuals with HF.

Systematic Reviews on mHealth Apps' Functionalities

The functionalities of over 60 HF mHealth apps were examined in different systematic reviews recently (Athilingam, & Jenkins, 2018; Masterson Creber et al., 2016; Mortara et al., 2020; Wali et al., 2019). Different assessment tools to evaluate the function of HF mHealth apps were used in these reviews: the Mobile Application Rating Scale (MARS; Athilingam, & Jenkins, 2018; Masterson Creber et al., 2016), the 11-item IMS Institute for Healthcare Informatics functionality scoring system (Masterson Creber et al., 2016; Mortara et al., 2020), and a newly developed 25-list of major functions for promoting HF self-care (Wali et al., 2019). Specifically, the MARS rating tool has five indicators, which are engagement, functionality, aesthetics, information quality, and

subjective quality. For functionality, the MARS focuses on performance, ease of use, navigation, and gestural design of an app. The IMS Institute for Healthcare Informatics functionality scoring system focuses on the scope of functions, including informing, instructing, recording, displaying, guiding, reminding, and communicating information. Both MARS and IMS tools are consistent with HFSA guidelines for non-pharmacologic management (HFSA, 2010). These guidelines include eight specific self-care behaviors, including daily weighing, checking extremities for swelling, doing PA or exercise, eating a low-salt diet, taking daily medications, attending doctor's appointments, daily monitoring of HF symptoms, and actively responding to symptoms when they change. These eight aspects of self-care can all easily be accomplished with an mHealth app.

In a 2016 systematic review, 34 commercially available mHealth apps designed to support HF symptoms monitoring and self-care management were evaluated (Masterson Creber et al., 2016). Based on the three assessment tools of the MARS, the IMS Institute for Healthcare Informatics functionality, and the HFSA guideline scores, this 2016 review concluded that the highest performing mHealth apps included the following: HFHS, Symple, Continuous Care Health, WebMD, and AskMD (Masterson Creber et al., 2016). In a 2018 review, 26 commercially available mHealth apps specific for HF were identified and their functionalities were examined using the MARS assessment tool (Athilingam, & Jenkins, 2018), and it was found that the apps with a score of 4 out of 5 or higher were AskMD, HFHS, WebMD, Continuous Care Health App, and HearKeeper, in descending order. A 2019 review identified HF apps and evaluated whether they met the criteria for promoting HF self-care (Wali et al., 2019). This 2019 review also

innovatively developed a list of 25 major functions for promoting HF self-care in older adults based on previous scientific works and the expertise of their clinician authors. Among the 25 major functions, five functions are considered standard disease management features of an mHealth app in HF: (1) diagnosis, (2) weight, (3) behavior tracking, (4) self-care, and (5) notifications. The results of this 2019 review showed that 21 apps were both HF and self-care specific, but none of them had all of these five standard features. However, the mHealth app that had the highest score of 18 out of 25 was the HFHS app. Finally, a recent systematic review on mHealth apps in HF, which was published in 2020 summarized some helpful information for physicians and researchers when assessing the potential benefits of mHealth apps for HF patients (Mortara et al., 2020). This 2020 review assessed 10 mHealth apps using the 11-item IMS Institute for Healthcare Informatics app functionality scoring system and concluded that the two highest-scoring apps were HFHS and HF Path, with a score of 10 out of 11. In summary, the HFHS app was found to be the mHealth app specifically designed for HF self-care that had the highest functionalities rating score across different systematic reviews with various rating assessment tools.

Clinical Trials with mHealth Systems for Self-Care in HF

The usability and effectiveness of mHealth systems on people with HF were examined in different clinical trials, including web browsers (Dang et al., 2017; Scherr, D. et al., 2006; Scherr, Daniel et al., 2009; Zan et al., 2015), text messaging (Nundy et al., 2013), smart watch (Evans et al., 2016), or developed programs that are pre-installed on mobile devices (Bartlett et al., 2014; Hägglund et al., 2015; KOEHLER et al., 2011; Seto

et al., 2012; Suh et al., 2011; Triantafyllidis et al., 2015). For the web-based mHealth systems, the participants were instructed to use the web browsers on their smartphones or tablets to enter their health parameters and receive information and tips related to HF self-care behaviors. For the mHealth systems-based text messaging, they were programmed to provide automated text messages that included self-care reminders and patient education on diet, symptom recognition, and access to health care services. For the pre-installed developed mobile device programs, they were designed to automatically collect health information via Bluetooth or wirelessly from sensor devices (weight scale, blood pressure, and ECG), then send the information to secure servers with very limited active interaction between the patient and the system. Most of these programs are equipped with different functionalities, such as monitoring health parameters, fall detection, and reminder function. For all these mHealth systems, professional monitoring was provided to review transmitted data and then communicate with participants based on their responses.

Different outcome measures and time frames were used to evaluate the usability of these mHealth systems in people with HF. Adherence to utilizing the system was the most frequent outcome measure, which was indicated by the percentage of data transfer or days for using the system (Evans et al., 2016; Scherr, et al., 2006; Seto et al., 2012; Triantafyllidis et al., 2015). Some studies included patients' experiences as an outcome measure for mHealth system usability (Nundy et al., 2013; Triantafyllidis et al., 2015; Zan et al., 2015). Another outcome measure for usability was the number of alert messages that clinicians received for daily vital signs that fell out of acceptable range or

that patients received from the clinician as responses for undesired change in self-care behaviors (Seto et al., 2012). Adding to that, another two studies used the System Usability Scale (Bartlett et al., 2014; Evans et al., 2016). The duration of mHealth intervention in all these studies ranged from 4 weeks to 6 months. In summary, the usability of mHealth systems showed good to high adherence in patients with HF.

Regarding the effectiveness of mHealth systems on individuals with HF, hospital readmission rate and duration, mortality, QoL, and changes in self-care scales were the primary outcomes in HF literature. Results on HF hospital readmission and mortality have been equivocal. Some studies showed a positive effect in reducing the relative risk of mortality and rehospitalization (Hägglund et al., 2015; Scherr, et al., 2009), while others found no effect (Koehler et al., 2011; Seto et al., 2012). Regarding QoL, there were various outcome measures used, including a generic one (e.g., SF-36; Dang et al., 2017; Hägglund et al., 2015; Koehler et al., 2011), and disease-specific one such as the MLHFQ; Dang et al., 2017; Seto et al., 2012; Zan et al., 2015), and the KCCQ (Hägglund et al., 2015). Some of these studies reported significantly improved QoL score (Koehler et al., 2011; Seto et al., 2012), others showed improvement only on disease specific QoL (Hägglund et al., 2015), and few studies showed no improvement (Dang et al., 2017; Zan et al., 2015). The effect of mHealth systems on self-care was also measured with various tools, including the Self-Care of Heart Failure Index (Nundy et al., 2013; Seto et al., 2012), the European Heart Failure Self-Care Behavior Scale (Dang et al., 2017), and the Dutch Heart Failure Knowledge Scale (Dang et al., 2017). The results of these self-care

outcome scales consistently confirmed the positive effect of mHealth systems on self-care among people with HF.

Clinical Trials with mHealth Apps for Self-Care in HF

To the researcher's knowledge, there is a lack of quality studies that examined the usability and effectiveness of mHealth apps on individuals with HF. The researcher identified only eight of such studies in the literature; three of them were RCT (Athilingam, Ponrathi et al., 2017; Kitsiou et al., 2021; Vuorinen et al., 2014), four pre-post design studies (Alnosayan et al., 2017; Bakogiannis et al., 2021; Chew, 2020; Heiney et al., 2020), and one survey study (Portz et al., 2018). These studies' sample sizes ranged between eight to ninety-four patients with HF. Five studies had a sample size of less than 30. The interventional duration of utilizing the apps for these studies ranged from 4 weeks to 6 months.

The studies investigating mHealth apps were limited by apps available for public usage and utility in self-care behaviors. Some studies have investigated certain mHealth apps that can be downloaded from smartphones' common apps' platforms. However, two studies only examined mHealth apps that are commercially available, which are the HFApp app (available on iPad Apple store only; Portz et al., 2018), and the HFHS app (Chew, 2020; Kitsiou et al., 2021). In these studies, participants were requested to use the apps to record their daily weight and symptoms of HF, but few studies directed participants to record their medications and daily vital signs such as pulse and blood pressure (Athilingam, et al., 2017; Bakogiannis et al., 2021; Kitsiou et al., 2021; Vuorinen et al., 2014). Interestingly, only three studies encouraged their participants to

track daily physical activities (Athilingam, et al., 2017; Chew, 2020; Kitsiou et al., 2021). Additionally, some of these studies examined the efficacy of their mHealth apps along with other support components. One study provided the mHealth app to monitor vitals, enter symptoms, and read notifications and messages, where a separate sensor device collected body weight, blood pressure, and blood glucose data and then sent directly to a secure server (Alnosayan et al., 2017). Another study determined if the use of a mHealth app with telephone support calls was an effective intervention to promote improved self-care of HF (Chew, 2020). A third study targeted health beliefs, HF knowledge, PA, and self-care awareness through the mHealth app accompanying tailored text messages (Kitsiou et al., 2021).

Professional monitoring was provided in most of the previous studies, either active or passive monitoring form. Active monitoring requires action by professional caregivers or patients, and passive monitoring is performed automatically by a medical device or a mHealth app. In some of these clinical trials, the HF nurses provided active professional monitoring by following patients' measurements remotely and calling or texting them when undesired changes were indicated (Alnosayan et al., 2017; Chew, 2020; Vuorinen et al., 2014). Other studies used the passive form of professional monitoring through sending tailored text messages as clinical decision guidance automatically to their HF patients if their health measurements exceeded pre-determined normal limits (Athilingam, Ponrathi et al., 2017; Heiney et al., 2020; Kitsiou et al., 2021).

Examining usability was one of the main objectives for all mHealth app studies. Usability can be assessed by various outcome measures, including adherence to self-care

behaviors, patients' experiences on apps via interview or self-report survey such as the System Usability Survey and the Post-Study System Usability Questionnaire (Athilingam, Ponrathi et al., 2017; Bakogiannis et al., 2021; Portz et al., 2018; Vuorinen et al., 2014). The results on adherence to HF self-care behaviors with an mHealth app have been positive. For instance, one study found that more than 85% of participants adhered to tracking their self-care behaviors (such as body weight, blood pressure, and pulse; Vuorinen et al., 2014), and another study found medication adherence has improved as assessed by the 8-item self-administered Morisky Medication Adherence Questionnaire (Athilingam, et al., 2017). Regarding the self-report survey approach, a study utilized a "pen and paper" survey to evaluate the app acceptability and concluded that the app acceptability, in general, was positive, and the app was easy to use, understand, and navigate (Portz et al., 2018). Another study reported that patients found the app useful for their everyday self-care as indicated by the Post-Study System Usability Questionnaire (Bakogiannis et al., 2021), and a different study reported that the usability of app was above average as indicated by the System Usability Survey (e.g., 75%; Alnosayan et al., 2017).

Results on QoL and self-care behavior outcomes of mHealth apps have been inconsistent across studies. For example, one study reported no change with the 14-item Health-Related Quality of Life Scale 14 (HRQOL14) after 4 weeks of app intervention (Heiney et al., 2020). Similarly, another study showed a decline in KCCQ score after 4-week app usage (Athilingam, et al., 2017). On the contrary, two other studies found improvement in QoL as measured by MLHFQ and KCCQ, but it was not statistically

significant (Alnosayan et al., 2017; Bakogiannis et al., 2021). Regarding self-care outcomes, two studies used the European Heart Failure Self-Care Behavior Scale: One reported non-significant improvement in both study groups on self-care, but the improvement in the intervention group was larger than the control group (Vuorinen et al., 2014); whereas the other study showed significant improvement after 3 months of app intervention (Bakogiannis et al., 2021). The Self-Care of Heart Failure Index was reported in three studies: one study showed a clinical improvement in self-care maintenance, management, and confidence (Heiney et al., 2020), and the other two studies reported significant improvement in self-care management and confidence only (Athilingam, et al., 2017; Chew, 2020).

CHAPTER III

METHODOLOGY

The first purpose of this study was to examine the usability of the mHealth app, HFHS, in people with HF over 4 weeks. The second purpose was to examine the effectiveness of the HFHS app on PA and QoL over 4 weeks in individuals with HF while compared to the control group who did not use the app. This chapter describes the research design, participants, instruments, procedures, and data analysis for this study.

Research Design

This study had two parts. The first part was a descriptive study for examining the usability of the HFHS app. The second part of the study, examining the effectiveness of the app intervention, was a mixed design RCT with two independent factors (between-subject factor (group) and within-subject factor (time)). The dependent variables included PA (daily steps counts) and QoL measures (MLHFQ and SF-36 survey). The factor of group had two levels: interventional group (App group) and control group (No-App group). The factor of time had four levels (Week 1, Week 2, Week 3, and Week 4) for the outcome of PA, and two levels (pre and post) for the outcome of QoL measures.

Participants

Participants were recruited from local communities at first, then expanded nationwide over the United States of America. The Institutional Review Board (IRB) of

the Texas Woman's University Dallas approved the study (see Appendix B). The study was registered on the Clinical Trials website (ClinicalTrials.gov) with the registration number NCT03509506. In addition, we had a collaboration with the Texas Health Resources (THR) Dallas (see Appendix C), and participants who came from that site were required to sign another consent form approved by the IRB of the THR (see Appendix D).

The sample size estimation of this study was calculated based on daily step count, one of the primary outcomes for this study. According to a previous study, the means and standard deviations for daily step counts at baseline and after the intervention in individuals with coronary artery disease were 6152 ± 2926 (steps) and 8210 ± 2534 (steps), respectively (Van Wormer et al., 2004). The difference between these two results was significant and yielded an effect size of 0.70. A power analysis was performed using G*power 3.1.9.2 with the significance level of 0.05, the power level at 0.80, and the effect size at 0.70, which yielded a sample size of 26 participants needed per group. With 15% of possible attrition, 30 participants was the estimated sample size needed for each group.

Men and women with HF regardless of race or ethnicity, who were over the age of 18 and walking independently with/without an assistive device, were potential participants. Participants with moderate or severe cognitive impairment (< 22 on Montreal Cognitive Assessment [MoCA; Nasreddine et al., 2005; Athilingam, et al., 2011; Carson et al., 2018), or who were unable to follow verbal and written instructions in English were excluded from the study. Additional exclusion criteria included: (1) a

neurological disorder or orthopedic condition that interfered with functional mobility and control of upper extremities, (2) uncorrected vision, (3) hearing problems, (4) not owning a smartphone with internet access.

Instruments

HFHS Application

The HFHS app is a self-care mHealth application developed in partnership with the HFSA. The HFHS app is powered by the Health Storylines platform from the Self Care Catalysts Inc. (Toronto, Ontario, Canada) and freely available on Google Play and App Store. A web version is accessible on a desktop computer or a mobile device browser. Individuals can choose from the following list of HF management tools: (1) daily vitals, (2) medication tracker, (3) exercise diary, (4) routine builder, (5) symptoms tracker, (6) sync a device, (7) low sodium guidelines, (8) pain rating scale, (9) my journal, (10) daily mood, (11) appointment reminder, and (12) sharing the recorded data (Circle of Support). In the current study, the researcher primarily utilized Function 1 through Function 4 of the HFHS app.

QoE Survey

The QoE survey was used to assess the quality of participants' experience in using the HFHS app (see Appendix E; Martínez-Pérez et al., 2015). The original survey used a Likert scale (1 to 5) for 19 questions. In the present study, two questions were eliminated because they were not relevant to the HFHS app. One question was related to regular updates for the app, which was not part of the user's experience. The second one was related to the precision of the app's calculations, and the HFHS app did not perform

any calculation. Ultimately, the survey adopted for this study has 17 questions covering seven aspects of user's experience in using an mHealth apps. The following were seven aspects of the QoE survey, and the questions included in each aspect: (1) Content quality: questions 1–6, (2) Security: Questions 7 and 8, (3) Ease of use: Questions 9–11, (4) Availability: Question 12, (5) Performance: Questions 13 and 14, (6) Appearance: Questions 15 and 16, and (7) Learning: Question 17. The total scores of the QoE survey ranged from 17 to 85, with the lowest score of 17 being the worst experience and the score of 85 being the best experience.

QoL Measures

QoL was assessed using two questionnaires: the SF-36 Survey (version 1.0) and the MLHFQ. The SF-36 survey is a generic self-reporting measure for patient health status, and it was developed by the Research And Development (RAND) Corporation. The SF-36 survey assessed eight domains of health: (1) physical functioning, (2) role limitation due to physical problems, (3) role limitation due to emotional problems, (4) vitality, (5) mental health, (6) social function, (7) bodily pain, and (8) general perception of health (Ware & Sherbourne, 1992). The SF-36 survey had 36 questions with the total score ranging from 0 to 100, where 0 was the worst health-related QoL, and 100 was the best. The SF-36 survey has shown to have good reliability and internal consistency in the general population (Brazier et al., 1992; Stewart et al., 1988). Its scoring method was published by RAND corporation (RAND Health, 1993).

The MLHFQ assessed how HF affected a person's daily life. The MLHFQ was a self-administered disease-specific questionnaire for patients with HF and consisted of 21

items that reflected QoL in physical, emotional, social, and mental domains (Rector, et al., 1987). The items were rated on a Likert scale ranging from 0 to 5, where 0 represents no limitation, and 5 represents maximum limitation. The total score of MLHFQ ranged from zero to 105 with a higher total score indicating a poorer QoL. The MLHFQ had good test-retest reliability (r = 0.87), good internal consistency (Cronbach's alpha = 0.92), and good construct validity (Rector & Cohn, 1992). The minimal detectable change of the MLHFQ was 5 points (Rector & Cohn, 1992).

PA

PA was assessed with a pedometer (Yamax PW-610 (Yamax Corp, Tokyo, Japan; see Appendix F), a small device worn at the waist to count the number of steps walked per day. It was considered very useful for evaluating PA in individuals with HF (Asakuma et al., 2000), had been well validated for accuracy and reliability, and was frequently used in PA research (Crouter et al., 2003; Schneider et al., 2003).

MoCA

The MoCA was a brief cognitive screening tool that aimed to differentiate normal cognitive aging from mild cognitive impairment (Nasreddine et al., 2005; see Appendix G). This tool included eight cognitive domains: (1) visuospatial and executive, (2) naming, (3) memory, (4) attention, (5) language, (6) abstraction, (7) delayed call, and (8) orientation. The highest possible score of the MoCA tool was 30. A score above 26 represented normal cognitive function; a score of 23 to 26 represented mild cognitive impairment; a score of 17 to 22 represented moderate cognitive impairment; and a score $\leq$16 represented severe cognitive impairment suggesting dementia (Nasreddine et al.,

2005). An alternate cutoff score of 23 was suggested to potentially lower the number of false positive results and to improve overall diagnostic accuracy (Carson et al., 2018). The MoCA test had excellent sensitivity (90% – 100%) for detecting mild cognitive impairment and excellent test specificity (87%; Nasreddine et al., 2005).

Patient Health Questionnaire-9

The Patient Health Questionnaire-9 (PHQ-9; see Appendix H) was a screening tool for depression, where scores of 5, 10, 15, and 20 represented mild, moderate, moderately serve, and severe depression, respectively (Kroenke et al., 2001). The total score for PHQ-9 ranged from 0 to 27 with each item scoring from 0 (*not at all*) to 3 (*nearly every day*). The PHQ-9 was reported to be a reliable and valid measure of depressive symptoms in patients with HF (Cronbach's alpha = 0.83, and ICCs = 0.22 – 0.66; Hammash et al., 2013). This questionnaire was utilized in the present study to know if depression would be a confounding variable between the two study groups.

Procedures

Patient Recruitment

Several strategies were utilized for recruitment. Initially, the researcher had a collaboration with THR-Dallas, which gave the researcher access to the patients with HF at the HF clinic. The research team also distributed the study flyer (see Appendix I) to other clinics and medical communities that treated patients with HF in the Dallas–Fort Worth metropolitan area. After IRB approval to recruit participants nationwide was granted, the researcher designed the study website (https://www.heartfailureappstudy.com/) to enable those interested in participating to access the study details easily anywhere and

anytime. In addition, the website allowed the participants to provide us their contact information securely and to communicate with them remotely at their convenience. Most of the recruitment occurred during the COVID-19 pandemic in 2020. To ensure the safety of the study participants and research staff through the pandemic, telehealth via a Zoom videoconference was used to communicate with the participants, collect their baseline data, screen for cognition and depression, and to instruct participants how to use study devices, including the pedometer and study surveys (for all participants), and the HFHS app, a blood pressure unit, and a bathroom scale (for the App group).

Phone Screening & Random Assignment

Once the research team received contact information for a participant from the HF clinic of THR-Dallas, the study website, or other communications channels (such as phone call or email), the team conducted an initial phone call screening (see Appendix J). During the phone call, the team member provided a brief description of the study, and asked questions to determine participant's eligibility before scheduling the initial evaluation/training session. After phone screening, each participant was randomly assigned to either the App group or the No-App group based on the randomization table generated by the Excel spreadsheet.

Initial Online Evaluation and Training Session

The initial evaluation session was then scheduled to be online (telehealth) or onsite at the early phase of the study based on the participant's preference, then it was conducted online completely later on. The onsite sessions were conducted at the research office on the eighth floor of the Institute of Health Sciences in Dallas, Texas Woman's

University. The initial telehealth video sessions were conducted via the Zoom Meetings application, a high-quality, secured, and end-to-end encryption video call platform. For privacy, we did not record these video calls. Each participant received all study documents and free study devices onsite or shipped to them, according to the group assigned. These study documents included: (1) the informed consent for the study, (2) a gift card receipt form, (3) the Activity Log for daily step counts (see Appendix A), and (4) the Visuospatial and Naming sections of the MoCA form because this section requires the participant to draw on the form. The study tools included: (1) a pedometer (Digi Walker Yamax PW-610), (2) a digital bathroom scale, (3) a wrist type of heart rate & blood pressure monitor, and (4) a 3-meter rolling paper to measure stride length for setting up the pedometer. The length of the rolling paper was determined based on the pedometer user manual, which instructs users to walk at least 3 meters for pedometer calibration.

During the initial evaluation and training session, the research team explained the procedures, and the possible risks and benefits of the study to the participants. Each participant was asked to sign the consent form approved by TWU-IRB after they fully understood the details of the study. If they were recruited from THR-Dallas, they additionally signed the THR-approved consent. Then, the team conducted an interview to gather demographic data and medical history using the medical intake form (see Appendix K). During this initial telehealth video chat interview session, the team also asked further questions for clarification on medical history if needed, and this session allowed the team to build up trust and rapport with the participants remotely. After the

medical intake, each participant filled out three online outcome surveys via Google forms: (1) the SF-36 survey, (2) MLHFQ, and (3) PHQ-9 for depression screening on a cellphone or desktop computer. The last portion of the initial telehealth video session was for training participants on how to do self-care monitoring.

Regarding the training for the No-App group, the participants in this group were trained on using a pedometer (Yamax PW-610) to collect their daily step counts and record their step counts on the Activity Log over 4 weeks. During the study period, the research team conducted weekly follow-up phone calls on the first day of each week to collect the number of steps for the last 7 days. After 4 weeks, the team emailed two QoL surveys via Google Forms (SF-36 survey and MLHFQ) to each participant.

For participants in the App group, they were trained on downloading the HFHS app and navigating different functions of the app besides the training on using a pedometer. The following app functions of the HFHS app were used for this study: (1) Daily Vitals that included heart rate, body weight, and blood pressure, (2) Medication Tracker, (3) Exercise Diary to track the daily step counts, (4) Routine Builder. The Routine Builder was one of the HFHS app features that enabled users to build reliable routines by setting up reminders, planning, and tracking health habits. To create an account on the HFHS app for this study, the team prepared a set of unique Gmail and password for each participant. Each participant practiced entering the following health-related parameters into the HFHS app: (1) heart rate, (2) systolic and diastolic blood pressure (BP), (3) weight, (4) number of steps, and (5) medications. Participants were also instructed to monitor and enter the numbers of these parameters daily to the HFHS

app: (1) heart rate, BP, and weight in the morning when getting up from bed, (2) the daily step count at the end of the day, (3) medications as prescribed. After 4 weeks, each participant of the App group also received online Google Forms (the QoE survey, SF-36 survey, and MLHFQ) to fill out (see Appendix L).

Remote Professional Monitoring for the App Group

The research team continuously monitored the data entry on the HFHS app from the participants in the App group during the 4 weeks of study period. The team used each participant's assigned unique email address and password to log in the HFHS app to monitor their data entry. The remote professional monitoring was to observe each participant's progress in entering data (the five health-related parameters) and any undesired health conditions occurred, such as: (1) sudden weight gain over 5 pounds in 3 days (Maisel et al., 2016), (2) skipped taking any the medications, (3) resting HR more than 100 beats per minute (bpm), (4) resting systolic BP over 140 mmHg, or (5) diastolic BP over 90 mmHg. As a part of this professional monitoring, if any of these undesired health conditions was noted, an alert text message was sent to the participant within 24 hours. The alert text messages (see Appendix M) were consistent with the guidelines of the American Heart Association (Virani, et al., 2020). The following was an example for these text messages: "Based on the data that you had entered on the App, your weight gained more than 5 lbs. in three days. This symptom might indicate a need to contact your doctor or health-service provider." In order to see if these alert messages played a role in helping participants managing their symptoms, the research team followed up with

the participant who received alert message(s) in 3 days and asked the following questions:

[R was one of the research team, and P is the participant]

R: Did you visit your doctor or health-service provider recently?

P: Yes OR No. If the answer was yes, the next question was:

R: Was it a routine visit?

P: Yes OR No, if the answer was no, the following question was:

R: was it because of worsening signs and symptoms?

P: Yes OR No. If the answer was yes, the following question was:

R: How did you know that your signs and symptoms were worsening?

P: [one of the potential answers was the "alerting message(s)"]

The team also collected the data on the number of alert messages sent and physician visits. All the data tracked through professional monitoring was then recorded on the Data Collection Sheet for App group (see Appendix N). In addition, the research team collected participants' feedback and challenges they faced throughout the study. In the present study the research team only texted the participants when health data deviated. In other words, the team did not prompt them to enter the data on the HFHS app.

Data Analysis

Descriptive statistics were analyzed for demographic data and baseline characteristics of all participants. Participants' demographic data were compared at baseline to ensure that there were no significant differences between the two groups. The Manny Whitney test was run for the variables that not meeting the assumption of normal

distribution. The chi-square test was used for the variables of gender and pacemaker because these two variables were dichotomous.

The usability part of data over 4 weeks was analyzed with descriptive statistics on the following outcomes: (1) the percentage of adherence in tracking health parameters, (2) the number of alert messages sent, and (2) the average score for each of the seven domains in the QoE survey. The adherence was determined by calculating the average weekly tracking adherence of the App group over 4 weeks. The number of alert messages and the number of physician/clinic visits promoted by the alert messages were summed up. The average score and standard deviation for the total questions that made up each domain in the QoE survey were calculated.

The data for the effectiveness part of the study was analyzed with the two-way mixed ANOVA (group x time) on the following outcomes: PA (daily step counts) and QoL measures (SF-36 survey and MLHFQ). These analyses were conducted to determine whether there were differences between the two groups (App group and No-App group) at baseline and 4 weeks, and within the groups over 4 weeks (pre & post for QoL measures; Week 1, Week 2, Week 3, and Week 4 for PA). Follow-up post-hoc analysis for the two-way mixed ANOVA was conducted if a significant interaction between group and time existed. The significance level was set at the alpha level of 0.05. In addition, the effect size for MLHFQ in the App intervention group was computed by calculating the mean difference divided by the standard deviation. Lastly, the researcher computed the Number Needed to Treat (NNT) on the results of MLHFQ. The NNT was calculated using the inverse of the absolute risk reduction (ARR). The ARR is the difference

between “interventional event rate” and “control event rate.” In order to find the event rate for each group, the researcher calculated the difference between pre and post on MLHFQ results for each participant. Then, the percentage of participants who had 5-point improvement or more on the MLHFQ was computed, representing the event rate for each group. Microsoft Excel for Microsoft 365 and IBM SPSS version 25.0 for Windows (SPSS, Inc. Chicago, IL) were used for all analyses in this study. Participants’ feedbacks were compiled and summarized (see Appendix O).

CHAPTER IV

RESULTS

The study's first purpose was to examine the usability of the HFHS app among individuals with HF over 4 weeks. The second purpose was to examine the effectiveness of utilizing the HFHS app on PA and QoL when compared to the control group that did not use the HFHS app.

Participants

Thirty-eight individuals with HF were recruited nationwide over two phases. In the first phase, 12 participants were recruited only from the Dallas-Fort Worth metropolitan area. The research team conducted the assessment for their eligibility on the Dallas campus of Texas Woman's University and at the THR hospital. In the second phase, 26 participants were referred to the study to be assessed for eligibility remotely; 21 participants were self-referrals via the study website, and clinicians referred five participants. Seven participants were excluded from phase one due to not being interested in the study, and we lost contact with one of the five enrolled participants after two weeks. During the second phase of the recruitment, we lost contact with four participants and excluded four participants. The exclusion was for the following reasons: one participant did not have a smartphone and access to the internet, one participant had dementia, and two participants declined to participate. The rest of the 23 participants

agreed to participate. Five participants dropped out of the study over 4 weeks because of scheduling conflict or lost contact. In the end, there were a total of 18 participants completed the study. Among them, five participants who were initially assigned to the control group agreed to participate in the intervention group after they finished the 4 weeks of the study. Figure 1 shows the CONSORT diagram of participants' enrollment and randomization for this study.

Participant Characteristics

There were no significant differences in any baseline characteristics between the App group and the No-App group. All comparisons were conducted using the independent *t-test*, except that the MoCA & The PHQ-9 were compare using the Manny Whitney U test due to not meeting the assumption of normal distribution. The mean age of the 18 participants was 58 (SD = 15 years). Majority of the participants were in NYHA functional class II (55%, n = 10), meaning that they were comfortable at rest, but that ordinary PA resulted in mild to moderate symptoms, such as tiredness, palpitation, or dyspnea. Participants' MoCA scores ranged from 23 to 30, indicating that all participants had normal cognitive functions on the cutoff of 23 (Carson et al., 2018). Regarding the PHQ-9 results, 11 participants had no depression (PHQ-9 <5), six participants had mild depression (PHQ-9 = 5–9), and one participant had moderate depression (PHQ-9 = 10–14). Regarding Body Mass Index, two participants were normal, nine participants were overweight, and seven were in the obesity category. The participants also had a range of comorbidities. Please see the details of participants' characteristics in Table 1.

Figure 1

CONSORT Diagram of Participants' Enrollment and Randomization

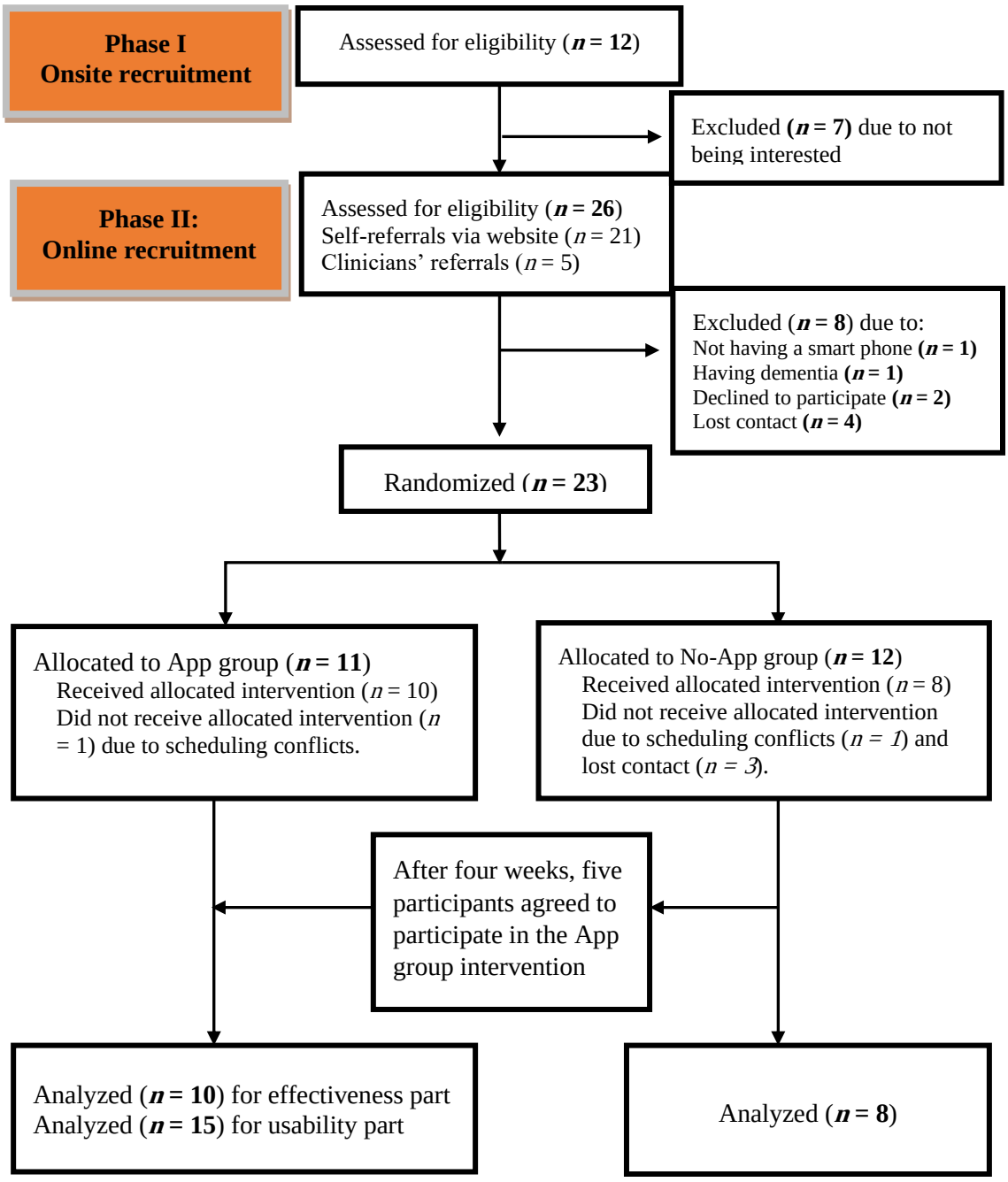


Table 1

Participants' Characteristics of Demographics, Cognition, and Depression

Mean ±SD	All Participants (n = 18)	App Group (n = 10)	No-App Group (n = 8)	p Value
Age (years)	58 ± 15	57 ± 18	60 ± 12	0.80
weight (kg)	93.47 ± 25.49	93.48 ± 20.08	93.16 ± 32.56	0.99
Height (m)	1.69 ± 0.10	1.71 ± 0.11	1.67 ± 0.09	0.35
BMI	32.62 ± 8.23	31.87 ± 6.17	33.55 ± 10.66	0.68
MoCA	27.33 ± 2.66	27.10 ± 3.38	27.63 ± 1.51	0.63
PHQ-9	4.89 ± 4.34	4.50 ± 4.5	5.38 ± 4.34	0.63
Gender (W/M)	10/8	5/5	5/3	
Comorbidity:				
Pacemaker (Yes)	10 (55%)	6	4	
HTN	9 (50%)	4	5	
DM	2 (11%)	2	0	
Dyspnea/ Chest pain	9 (50%)	5	4	
Arrhythmia	5 (28%)	2	3	
Circulation Problem	6 (33%)	3	3	
Pneumonia/respiratory issues (e.g., COPD)	3 (17%)	1	2	
Orthopedic Problems	4 (22%)	1	3	
Overweight	9 (50%)	5	4	
Obesity	7 (39%)	4	3	
NYHA Functional	6 (33%)	5 (50%)	1 (13%)	
Class I	10 (55%)	4 (40%)	6 (75%)	
Class II	1 (0.06%)	1 (10%)	0 (0%)	
Class III	1(0.06%)	0 (0%)	1 (13%)	
Class IV				

Note. kg: kilogram, m: meter, BMI = body mass index, W: Women, M: Men, MoCA: Montreal Cognitive Assessment, HTN: Hypertension, DM: Diabetes mellitus, OA: Osteoarthritis, NYHA: New York Heart Association Functional Classification, , PHQ-9: Patient Health Questionnaire-9 for Depression screening.

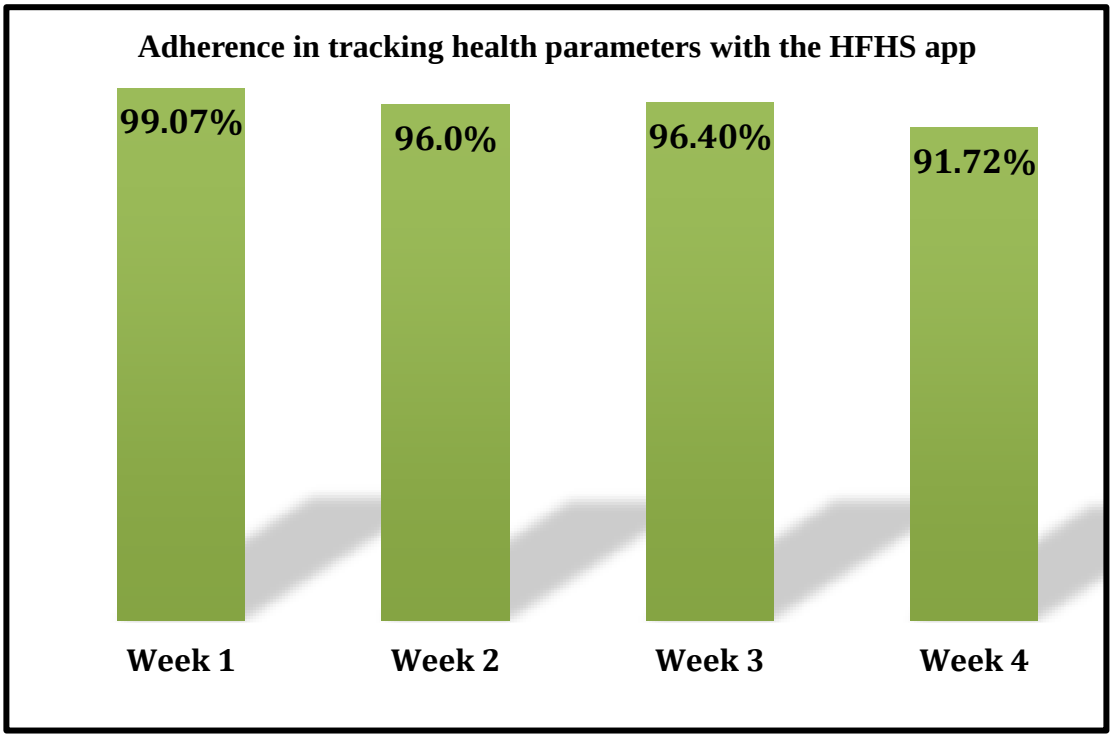
Usability of the HFHS App with Professional Monitoring

The usability of the HFHS application was indicated by the adherence of tracking health parameters, the QoE survey, and the number of physicians/clinic visits that the alert messages prompted. Adherence was determined by measuring the percentage of data entry for each health parameter on the HFHS app for each participant over the 4-week duration. Participants had to enter 112 data points into the HFHS app over the 4 weeks of study period (i.e., 4 health parameters x 28 days) to obtain the full 100% adherence on tracking health parameters with the HFHS app. These tracking data points were distributed over the following four health parameters: (1) heart rate, (2) diastolic & systolic BP, (3) body weight, and (4) medication intake. To determine if the first objective of the study was achieved, the average weekly tracking adherence of the App group over 4 weeks was calculated (see Figure 2). In general, the adherence was excellent, above 91% for each week of the study.

Regarding the results on QoE survey, a total of 15 QoE surveys were collected from the App group. Five aspects of QoE survey had average scores above 4, with the learning aspect having the highest score, and the other two aspects on Performance and Content Quality had the average score of 3.2 and 3.86 respectively (see Figure 3). Appendix D illustrates the seven aspects of the QoE survey, and the number of questions for each aspect. Participants' feedback is summarized in Appendix O.

Figure 2

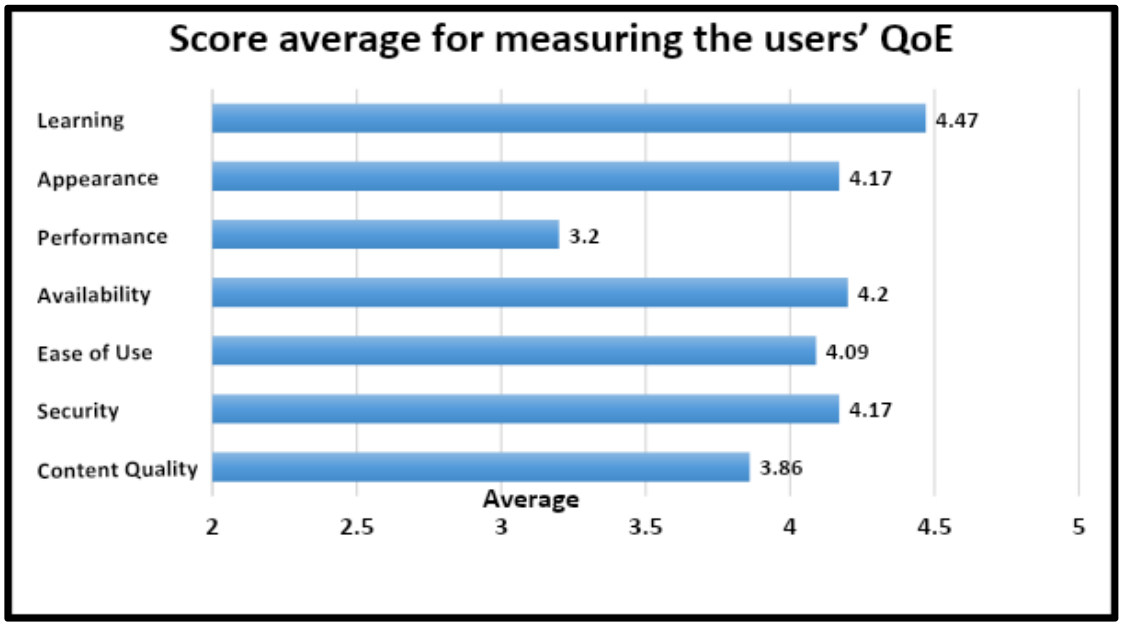
Average Weekly Tracking Adherence of The App Group Over 4 Weeks



As a part of the research team's professional monitoring worsening symptoms from participants' data entry on the HFHS app, the team sent a total of 33 alert messages to the participants who had at least one of the five alert conditions in their recorded health parameters: too high or too low reading of BP (18 times), lower heart rate (once), gaining 5 pounds of body weight in 3 days (2 times), not taking medications (9 times), and missing data (4 times). Overall, the alert messages prompted four physician/clinic visits and calls.

Figure 3

The Average Score on Each Aspect of the Quality of Experience (QoE) Survey



Effectiveness of the HFHS App with Professional Monitoring

For the data analysis on the study's second objective, the number of participants in the app group was reduced from 15 to 10, as five participants who enrolled in the study twice (No-App group first, then the App group) were excluded from this part of data analysis.

The effectiveness of the HFHS app was assessed by determining if there was any significant difference between the App group and the No-App group on PA and QoL measures over 4 weeks. Foremost, the assumptions of outliers, normality, homogeneity of variances, and homogeneity of covariances for the two-way mixed ANOVA on the

outcome measures were tested. The results showed no outliers, as assessed by boxplot and examination of studentized residuals for values greater than ±3. The data were normally distributed, as assessed by Shapiro-Wilk's normality test ($p > .05$). There were homogeneity of variances ($p > .05$) and covariances ($p > .001$), as assessed by Levene's test and Box's M test, respectively.

Daily PA was monitored with a pedometer (Digi Walker Yamax SW-601). The weekly average (Day 1 to Day 7) of PA was calculated for each participant. Table 2 shows the weekly average step counts for all participants in each group. Figure 4 illustrated the weekly PA trend for both groups, which ranged between 4,000 steps and 6,000 steps and showed a slight decline over 4 weeks. Because the assumption of Mauchly's test of sphericity was not met for the two-way interaction, $\chi 2(5) = 21.11$, $p = 0.001$, the Greenhouse-Geisser statistics were reported. The ANOVA results showed no statistically significant interaction group by time on PA, $F(1.738, 27.813) = 1.015$, $p = 0.366$, $r = 0.25$. In addition, there was neither a significant main effect of time on PA ($p = 0.095$, $r = 0.58$), nor the main effect of group ($p = 0.544$, $r = 0.15$).

Table 2

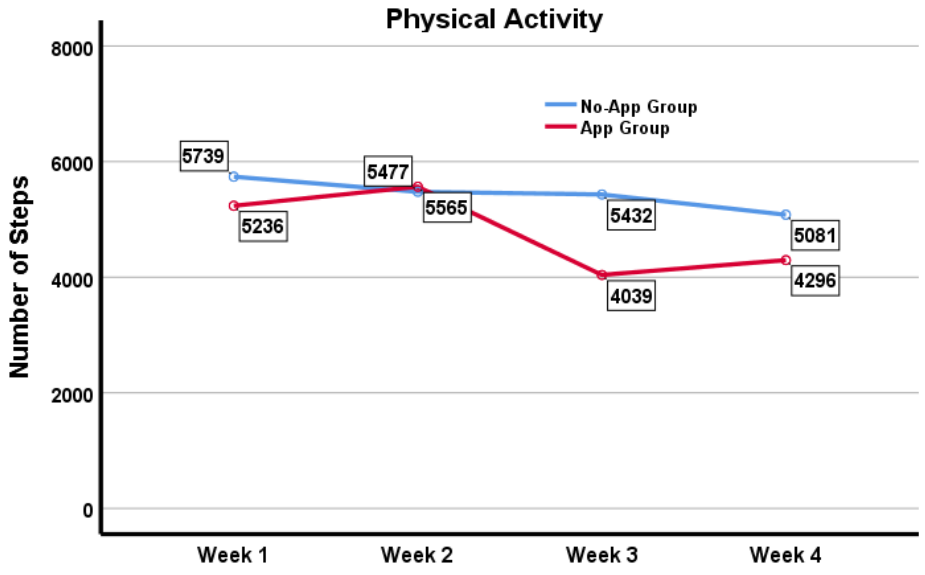
Physical Activity across 4 Weeks (Number of Daily Steps)

(Mean ±SD)	All Participants (n = 18)	App Group (n = 10)	No-App Group (n = 8)
PA in Week 1	5459 ± 2561	5236 ± 2326	5739 ± 2969
PA in Week 2	5526 ± 2490	5565 ± 2404	5477 ± 2759
PA in Week 3	4658 ± 2251	4039 ± 1855	5432 ± 2580
PA in Week 4	4645 ± 2425	4296 ± 2245	5081 ± 2722

Note. SD: Standard Deviation, PA: Physical Activity

Figure 4

Weekly Average PA of the Two Groups over 4 Weeks



The outcome of QoL was indicated by the SF-36 survey and the MLHFQ. These two outcome measures were administered before and after 4 weeks of the study. The average scores for SF-36 survey and MLHFQ of the two groups are shown in Table 3.

Table 3

Results of Average Scores for SF-36 Survey and MLHFQ over 4 Weeks

	App Group (n = 10)		No-App Group (n = 8)	
Mean ± SD	Pre	Post	Pre	Post
SF-36 score	62.00 ± 19.74	62.16 ± 19.37	56.92 ± 21.55	62.93 ± 22.39
MLHFQ score	31.80 ± 26.95	25.80 ± 22.07	32.75 ± 33.11	31.38 ± 28.33

Note. SF-36:36-Item Short-Form Health Survey, MLHFQ: Minnesota Living with Heart Failure questionnaire, Pre: baseline, Post: after 4 weeks of intervention

Figure 5 illustrates the pre and post average scores of SF-36 survey for App group and No-App group. It appears there was no change in the App group and a subtle increase on SF-36 score in the No-App group over 4 weeks. The assumption of sphericity was not tested because the within-subject factor (time) has only two levels (pre and post). For the outcome of SF-36 survey, the ANOVA results showed no statistically significant interaction between group and time, $F(1, 16) = 1.837$, $p = 0.194$, $r = 0.32$. In addition, there was no significant main effect of time ($p = 0.173$, $r = 0.34$) and no significant main effect of group ($p = 0.824$, $r = 0.06$).

Figure 6 illustrates the pre and post average score of MLHFQ for the App group and the No-App group, respectively. It showed a slight improvement in QoL for both groups, and the App group seemed to have slightly more improvement than the No-App

group, as a lower score on the MLHFQ indicates a better QoL. The effect size based on MLHFQ scores was $d = 0.22$.

The assumption of sphericity was not tested because the within-subject factor (time) has only two categories (pre and post). The ANOVA results showed no statistically significant interaction between group and time, $F(1, 16) = 0.609$, $p = 0.447$, $r = 0.19$. In addition, neither was there a significant main effect of time ($p = 0.231$, $r = 0.3$), nor a main effect of group ($p = 0.801$, $r = 0.06$). However, the difference in the average scores of MLHFQ for the App group was clinically meaningful reduction (greater than 5 points; see Table 3). For individual results, the participants who showed a 5-point reduction or more on the MLHFQ were four out of the 10 participants (40%) in the App group and two out of the eight participants (25%) in the No-App group (see Table 4). As a result, the NNT equaled 7, indicating for every seven participants utilizing the HFHS app, one participant would demonstrate a clinically meaningful change (e.g., improvement) on the MLHFQ compared to those who did not use the app.

Figure 5

The Average Score of SF-36 Survey for the Two Groups Pre- to Post-Intervention

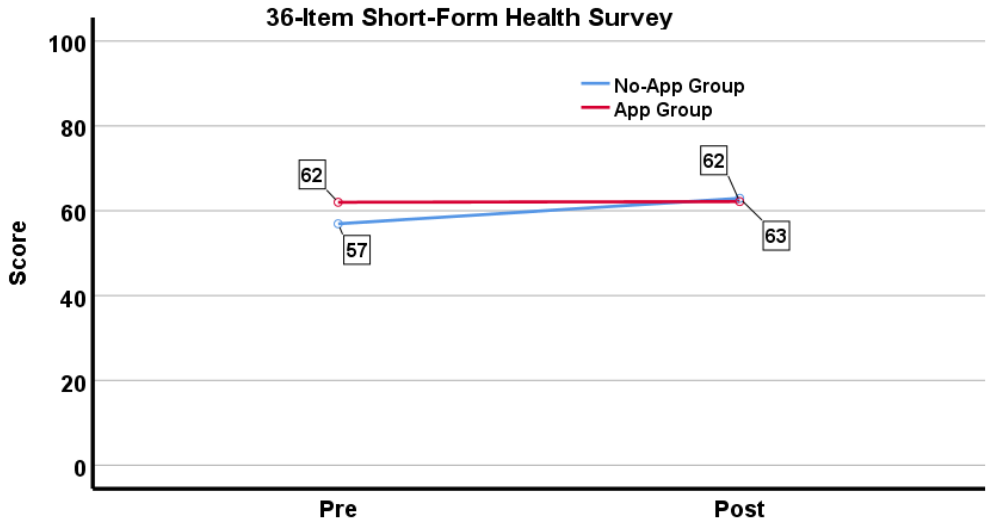


Figure 6

The Average Score of MLHFQ for the Two Groups Pre- to Post-Intervention

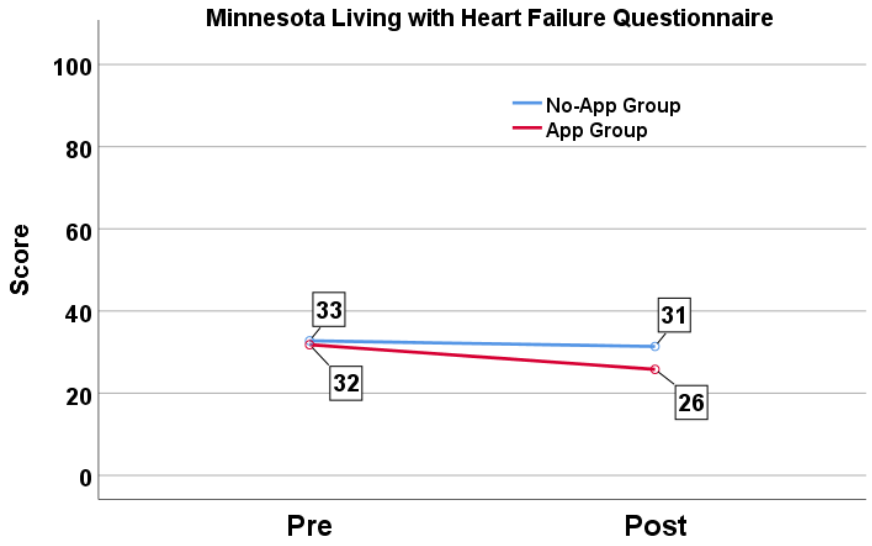


Table 4

Results of MLHFQ Scores for Each Participant

App Group (n = 10)				No-App Group (n = 8)			
Participant #	Pre	Post	Change	*Participant #*	Pre	Post	Change
1	0	0	0	*1*	65	53	-12
2	66	22	-44	*2*	5	7	2
3	81	67	-14	*3*	3	6	3
4	14	15	1	*4*	96	85	-11
5	40	34	-6	*5*	19	17	-2
6	51	53	2	*6*	28	36	8
7	15	25	10	*7*	6	5	-1
8	28	35	7	*8*	40	42	2
9	6	4	-2				
10	17	3	-14				

Note. MLHFQ: Minnesota Living with Heart Failure questionnaire, Pre: before intervention, Post: after 4 weeks of intervention, Change: the difference between post and pre (i.e., post – pre) and the number was bolded if the MLHFQ score reduction after 4 weeks was greater than 5 points.

CHAPTER V

DISCUSSION

Promoting self-care is an essential part of the disease management for people with HF. Self-care entails adhering to treatment and healthy behaviors, monitoring signs and symptoms, and responding appropriately to the changes in signs and symptoms. To achieve self-care as desired, it is crucial to find innovative tools that enable patients with HF to practice self-care effectively and encourage adherence to its practices. With the advancement and accessibility of technology, the scientific and clinical communities have begun utilizing and evaluating mHealth systems as a tool to enhance self-care among people with chronic conditions, in general, and HF in particular. However, one of the most common forms of these systems is the commercially available mHealth applications, which have received limited attention in scientific studies. Thus, this study enriches the scientific literature on the usability and effectiveness of mHealth applications in people with HF. For this purpose, one of the commercially available and highly rated apps based on several systematic reviews, the HFHS app was selected for the current study. The study examined: (1) the usability of the HFHS app over 4 weeks in individuals with HF, and (2) the app's effectiveness on PA and QoL by comparing to the control group who did not use the HFHS app.

The use of the HFHS app among patients with HF, along with the presence of human interaction in this RCT, is feasible and has promising clinical outcomes. The human interaction was represented by the initial intensive 2-hour training on utilizing the app, 4 weeks of remote daily professional monitoring, and weekly follow-up phone calls as needed. About 74% of our participants received their training through online Zoom video conferences. We confirmed that the implementation of telehealth via Zoom video conferencing for training was successful. This remote communication approach mitigated some of the constraints associated with the onsite training, such as travel to the research site and transport availability; and it permitted reaching out to more potential participants than an onsite study. In addition, it was an effective procedure to ensure the safety of our study participants and research staff throughout the COVID-19 pandemic, especially since most of our patient recruitment occurred during the pandemic in 2020. However, remote communication with the participants also imposed some challenges, such as insufficient technology skills and the long waiting time between enrolling and starting the study due to the need for shipping research devices (e.g., a weight scale, a pedometer, a blood pressure unit, and various study forms). This might explain why the team lost contact with six participants during the second phase of the study (online).

Regarding subjects' characteristics, there were no significant differences in the demographics between the App group of participants and those in the No-App group at baseline. Moreover, the frequencies of comorbidities were similar between the App and the No-App group, which was also comparable to the HF population. All participants had at least two comorbid conditions, and their common comorbid conditions were

hypertension, arrhythmia, coronary artery disease, chronic obstructive pulmonary disease, and diabetes mellitus. According to the literature, approximately 90% of people with HF have at least one cardiovascular-related comorbid condition, and 52% of HF cases are related to risk factors for HF like hypertension, diabetes, and obesity (Manemann et al., 2016; Virani, et al., 2021). Therefore, the sample of this study, even though small, was representative of the population of interest. In addition, participants had normal cognition and little depression, which might explain their ability for learning about the HFHS app for tracking health parameters. It is unclear if the findings could be replicated in those with mild cognitive impairment or when a caregiver serves as the proxy to use the HFHS. In summary, the participants in this study were demographically similar between the App group and the No-App group, which support the notion that there were no confounding factors between the two groups.

Part I of the Study: Usability of the HFHS Mobile App

The objective for this part of the study was to determine if the participants in the App group would utilize the HFHS app at least 4 days per week (i.e., at least 57%) over 4 weeks. The results on average weekly tracking adherence were above 91% each week, indicating that most participants understood the importance of self-care in daily monitoring health parameters after the initial training session of the study, and they followed the research team's instructions in using the HFHS app. Over the course of 4 weeks, participants responded positively to the app, as evidenced by their utilization of the app for at least 6 to 7 days each week to enter and track their health parameters. The adherence results were quite encouraging and aligned with a previous study that also

showed 90% adherence rate in utilizing an mHealth app (Vuorinen et al., 2014). The researcher attributed the high adherence of utilization of the HFHS app to the knowledge and care provided by the research team to the participants through the customized initial training session and daily remote professional monitoring. The training, a one-on-one, face-to-face meeting, included activating all app features to suit participants' needs, setting up the app reminders based on medication schedule, setting up appropriate schedules to track the health parameters (e.g., body weight, blood pressure, and daily step counts), and answering any questions a participant might have about using the HFHS app. The daily professional monitoring from the research team during the study period was another route of human interaction with participants besides the training, which might have played a role in increasing the participants' adherence. The team sent alert messages to the participants if their data were out of normal ranges, provided weekly follow-up phone calls after an alert message and helped with troubleshooting when technical challenges existed. In addition to the human interaction, the ease of use of most of the app features could also enhance adherence. For example, tracking medication did not require more than one click on the app to confirm taking the medication, and users could follow their progress on adhering to self-care behaviors by seeing the graphs for most health parameters. In summary, offering an easy-to-use mHealth app with user-tailored training and regular professional monitoring might have contributed to the excellent adherence to the app use in this study, which in turn could promote adherence to self-care behaviors and ultimately enhance general health.

The participants' experience of interacting with the HFHS app was the second indicator in studying its usability. Examining the results of the QoE survey, the high average scores (above 4) were on the following five aspects: Ease of Use, Security, Appearance, Availability, and Learning. This means that the participants found this app, in general, easy to learn, access, and track health parameters. They also found it a secure app and visually attractive. On the other hand, the low average scores (below 4) of QoE survey were on the aspect of Content Quality (3.86) and Performance (3.20). The Content Quality measured the participant's perception of the content quality offered by the app. When looking closely at the average scores for each of the six questions related to Content Quality, the researcher found that two questions with a low average score (3.27 and 3.33) might have contributed to the overall low average score (i.e., below 4) on Content Quality. A number of participants thought that they could do the same function without the app or that there were other traditional methods to do similar functions that the HFHS app provided. In addition, participants could not identify personal health problems with the HFHS app. These results were somewhat expected. Although the HFHS app's features promote users' engagement in self-care behaviors and enable users to self-monitor their vital signs and medications, it does not have the capability of automatically alerting users if their data is outside of normal limits.

Regarding the performance aspect of the HFHS app, some participants believed that the application could have been more efficient, or the app might have some errors that need to be fixed. These results echoed most frequent participants' feedback with the research team during weekly follow-ups (see Appendix O). For example, the application

sometimes took a long time to load or properly save data entries. This was an issue as some participants often thought they kept their data after hitting the “save” button, but in fact, the data was not stored due to a lag time. Additionally, some participants did not like the multistep process of entering their data, particularly daily step counts. Similar to our study, a previous study also reported that patients experienced difficulties in manually entering and sending their daily vital signs, body weight, and medication through an mHealth system (Scherr, et al., 2009). On the other hand, some other participants had positive feedback on utilizing the HFHS app. For instance, several participants stated that the HFHS app successfully kept them tracking their vital signs, body weight, and medication intake schedule. Furthermore, some participants specifically enjoyed the feature of monthly summary data compilation of the HFHS app, which was helpful to show to their doctors during their scheduled clinical visits. Considering the overall participants’ experiences with using the app, the researcher concluded that managing the HFHS app was somewhat of a challenge for the participants over 4 weeks, especially those who were not technology savvy.

As mentioned previously, the study also provided remote professional monitoring on the health data that our participants entered into the HFHS app. Self-care is not parallel to "doing it all by yourself," but rather an integration process between the patient and the care providers, whether nonprofessional caregivers such as friends and family members or professional health care providers such as doctors and nurses (Jaarsma et al., 2021). Without professional monitoring, some changes in self-care behaviors might go beyond autonomous decisions from the patients and need a consultation with a clinician

(Riegel et al., 2016). For example, a patient who noticed a rapid gain in weight might decide to forego eating salty foods (autonomous decision) but taking an extra water pill may necessitate a call to the doctor's office (consultative decision). Self-care is best implemented as joint decision-making process in which both patient's autonomous decisions and care provider's consultative inputs are integrated to guide the actions. Previous mHealth studies employed professional monitoring in their intervention programs by monitoring and analyzing patients' data and directing patients to make an appropriate decision, if necessary, by text messages, emails, or phone calls (Alnosayan et al., 2017; Athilingam, et al., 2017; Bakogiannis et al., 2021; Chew, 2020; Dang et al., 2017; Heiney et al., 2020; Scherr, et al., 2009; Seto et al., 2012; Vuorinen et al., 2014). The professional monitoring led to 30 alert messages sent to the participants due to some undesired changes in symptoms and signs (e.g., systolic BP > 140 mmHg, weight gain by more than 5 lbs. in 3 days, or skipped a medication), and these messages prompted four physician visits/calls. Therefore, the researcher believes that utilizing the HFHS app along with professional monitoring plays a positive role in participants' self-care on health parameters, which in turn enhances adherence to self-care behaviors and promotes positive experiences in using the apps.

Part II of the Study: Effectiveness of the HFHS Mobile App

To the best of the researcher's knowledge, this is the first RCT that examined and reported the effectiveness of utilizing a mHealth app on PA among people with HF. The results showed that the HFHS app did not affect PA in individuals with HF over 4 weeks when compared to the control group who did not use the app. The mean average daily

step count for both groups of participants was between 4,000 and 5,000 steps/day, indicating they were sedentary (<5,000 steps per day; Tudor-Locke et al., 2013). Both study groups were given a free pedometer, which was concluded to be a positive influence to increases PA (Bravata et al., 2007). However, the results did not show any significant changes in PA over 4 weeks for either group, and the effect size for PA was small (r = 0.153). The HF-related comorbidities and symptoms of dyspnea and fatigue could be the primary reasons for non-adherence with recommended exercise in HF population (Evangelista et al., 2001; Pozehl et al., 2018). The PA can be improved with setting weekly goal, support and encouragement, and professional education on exercise intensity with Borg's scale for safety in HF population (Lin et al., 2021). Therefore, PA results in the current study were not surprising because the study only encouraged the participants to self-track their PA without taking into account other recommended behavioral approaches to promote PA, such as a participant-centered goal setting, preventing relapse through using the Borg scale to know when the activity should stop, professional education on planning a walking schedule through the day, providing some resources for motivation (such as receiving verbal positive feedback regarding performance).

Regarding QoL, the results of both outcome measures (SF-36 and MLHFQ) indicated that the HFHS app did not significantly affect the participants who used the HFHS app when compared to those who did not use the app. The lack of significant results could be due to the small sample size. However, the effect size for the MLHF outcome measure was small (d = 0.22), making it unlikely that the lack of significant

results was due to lack of statistical power. The average score of MLHFQ, a disease-specific health related QoL survey, showed a reduction by 5 points after 4 weeks in the App group compared to the No-App control group, indicating a clinically meaningful improvement (Rector, & Cohn, 1992). These results were likely due to both utilizing the HFHS app and professional monitoring, which improved participants' adherence to self-care behaviors and positively affected participants' self-perceived disease burden. However, the results of the SF-36 survey did not point to any specific direction of change, and that might be because the survey is a generic instrument for QoL. Therefore, it may be important to use both generic and disease-specific QoL surveys in future HF research.

Considering the change in MLHFQ score for each participant in both groups, the researcher found that 40% of the intervention group and 25% in the control group had a 5-point clinically meaningful reduction in the total score of MLHFQ. Again, these numbers emphasized that the improved QoL was more prominent for the people who used the HFHS app to track their self-care behaviors. In addition, the existence of favorable results in both groups in this RCT led us to calculate the NNT to help decide whether the intervention might be valuable in clinical practice. For the outcome of MLHFQ, the NNT equals 7, indicating on average, after treating seven patients with HF with the HFHS app to track and monitoring self-care HF behaviors, one patient will demonstrate a clinically meaningful improvement on QoL indicated by MLHFQ when compared to those who did not use the app. Although some authors believe that the NNT score of 3 or less indicates a worthwhile intervention (Mcquay & Moore, 1997), the

researcher still believes that the current intervention might have the potential to improve QoL in HF population. That could be examined with a larger sample size and a longer duration of HFHS app implementation.

Limitations of the Study

The study had several limitations. First, the power analysis performed before starting this study indicated that a minimum of 60 participants was needed to achieve the desired power of 0.8. However, due to difficulty in patient recruitment, only 23 participants were enrolled, and 18 participants completed the study, which limits the generalizability of the study. Second, the study's attrition rate is considered moderate (25%), compared to the attrition rates (i.e., 1% to 50%) in previous HF studies (Athilingam, et al., 2017; Heiney et al., 2020; Lin et al., 2021; Vuorinen et al., 2014). One explanation for the attrition is the challenges related to HF, as its symptom exacerbation could occur suddenly if patients did not comply to good self-care management. Another challenge is related to the COVID-19 pandemic when most of the data collection occurred. Some eligible participants were delayed or cancelled prior to or after enrollment due to sickness or concerns about visiting emergency departments. In addition, the nature of conducting an online study might have contributed to the attrition, such as participant's difficulties in using the online meeting platform. Difficulties in scheduling weekly follow-up due to different time zones between participants and research team might also contribute to the attrition. Third, the study's duration was 4 weeks, which might be too short for favorable changes in participants' behaviors leading to meaningful changes in health outcomes. Fourth, the technology literacy level of the

research participants was not examined, which could have affected the results as participants might have difficulty in understanding the instructions of using the apps. Fifth, participants' prior experiences with other mHealth apps and telemonitoring were not controlled in this study, which could also influence the study's outcomes.

The other aspect of study limitations is related to the HFHS app. Despite the HFHS app having a feature to be synchronized with many electronic devices for collecting health parameters, none of the study devices that were provided had the capability to synchronize with the HFHS app due to limited research funding. Therefore, participants manually entered their health parameters to the HFHS app, which could negatively influence their quality of experience on the app. In addition, participants only utilized four out of 11 self-care behavior features offered by the HFHS app (e.g., tracking medication intake, blood pressure, body weight, PA), which might limit establishing other behavior changes (e.g., low sodium diet) and affect the health outcomes in HF population.

Recommendation for Future Research

The above limitations should be considered in future studies. The researcher recommends future RCTs investigating the impact of self-care management using the HFHS app on a larger sample size for a longer duration. The researcher also highly recommends using sensor devices that can transfer health parameter data automatically to the HFHS app. Lastly, the researcher suggests adding a professional coaching component that would incorporate behavioral intervention for promoting PA in HF population.

Conclusion

The study established the feasibility of using the highly rated commercially available HFHS app along with remote professional monitoring for self-care in HF population, as indicated by high participant's adherence, positive user experience, and the ability to track, monitor, and detect the undesired changes in HF symptoms. Furthermore, the researcher also found that utilizing the mHealth app for 4 weeks had a favorable trend for improving QoL, as indicated by the clinically meaningful improvement in MLHFQ scores. However, the study intervention did not make significant changes in the participants' PA level. Finally, this feasibility study provides a few important directions for future large-scale RCTs on addressing the challenges of utilizing a commercial self-care mHealth app in people with HF.

REFERENCES

Aitken, M., Clancy, B., & Nass, D. (2017). T*he growing value of digital health: Evidence and impact on human health and the healthcare system*. IQVIA Institute for Human Data Science. https://www.iqvia.com/insights/the–iqvia–institute/reports/the–growing–value–of–digital–health

Albert, N., Trochelman, K., Li, J., & Lin, S. (2010). Signs and symptoms of heart failure: Are you asking the right questions? *American Journal of Critical Care*, *19*(5), 443–452. https://doi.org/10.4037/ajcc2009314

Alnosayan, N., Chatterjee, S., Alluhaidan, A., Lee, E., & Houston Feenstra, L. (2017). Design and usability of a heart failure mhealth system: A Pilot Study. *JMIR Human Factors*, *4*(1), e9. https://doi.org/10.2196/humanfactors.6481

Asakuma, S., Ohyanagi, M., & Iwasaki, T. (2000). Simple methods of assessing physical activity in patients with chronic heart failure. *Congestive Heart Failure*, *6*(5), 250–255. https://doi.org/10.1111/j.1527–5299.2000.80163.x

Athilingam, P., King, K. B., Burgin, S. W., Ackerman, M., Cushman, L. A., & Chen, L. (2011). Montreal cognitive assessment and mini–mental status examination compared as cognitive screening tools in heart failure. *Heart & Lung*, *40*(6), 521–529. https://doi.org/10.1016/j.hrtlng.2010.11.002

Athilingam, P., & Jenkins, B. (2018). Mobile phone apps to support heart failure self–care management: Integrative review. *JMIR Cardio*, *2*(1), e10057. https://doi.org/10.2196/10057

Athilingam, P., Jenkins, B., Johansson, M., & Labrador, M. (2017). A mobile health intervention to improve self–care in patients with heart failure: Pilot randomized control trial. *JMIR Cardio*, *1*(2), e3. https://doi.org/10.2196/cardio.7848

Bakogiannis, C., Tsarouchas, A., Mouselimis, D., Lazaridis, C., Theofillogianakos, E. K., Billis, A., Tzikas, S., Fragakis, N., Bamidis, P. D., Papadopoulos, C. E., & Vassilikos, V. P. (2021). A patient–oriented app (ThessHF) to improve self–care quality in heart failure: From evidence–based design to pilot study. *JMIR mHealth and uHealth*, *9*(4), e24271. https://doi.org/10.2196/24271

Bartlett, Y. K., Haywood, A., Bentley, C. L., Parker, J., Hawley, M. S., Mountain, G. A., & Mawson, S. (2014). The SMART personalised self–management system for congestive heart failure: Results of a realist evaluation. *BMC Medical Informatics and Decision Making*, *14*(1), 109. https://doi.org/10.1186/s12911–014–0109–3

Bravata, D. M., Smith–Spangler, C., Sundaram, V., Gienger, A. L., Lin, N., Lewis, R., Stave, C. D., Olkin, I., & Sirard, J. R. (2007). Using Pedometers to increase physical activity and improve health: A systematic review. *JAMA : The Journal of the American Medical Association*, *298*(19), 2296–2304. https://doi.org/10.1001/jama.298.19.2296

Brazier, J. E., Harper, R., Jones, N. M., O'Cathain, A., Thomas, K. J., Usherwood, T., & Westlake, L. (1992). Validating the SF–36 health survey questionnaire: New outcome measure for primary care. *British Medical Journal*, *305*(6846), 160–164. https://doi.org/10.1136/bmj.305.6846.160

Burke, L., Ma, J., Azar, K., Bennett, G., Peterson, E., Zheng, Y., Riley, W., Stephens, J., Shah, S., Suffoletto, B., Turan, T., Spring, B., Steinberger, J., & Quinn, C. (2015). Current science on consumer use of mobile health for cardiovascular disease prevention: A scientific statement

from the American Heart Association. *Circulation (New York, N.Y.)*, *132*(12), 1157–1213. https://doi.org/10.1161/CIR.0000000000000232

Carlson, B., Riegel, B., & Moser, D. K. (2001). Self–care abilities of patients with heart failure. *Heart & Lung*, *30*(5), 351–359. https://doi.org/10.1067/mhl.2001.118611

Carson, N., Leach, L., & Murphy, K. J. (2018). A re-examination of Montreal cognitive assessment (MoCA) cutoff scores. *International Journal of Geriatric Psychiatry*, *33*(2), 379–388. https://doi.org/10.1002/gps.4756

Centers for Medicare & Medicaid Services. (2021). *Chronic conditions.* https://www.cms.gov/Research–Statistics–Data–and–Systems/Statistics–Trends–and–Reports/Chronic–Conditions/CC_Main

Chen, J., Normand, S. T., Wang, Y., & Krumholz, H. M. (2011). National and regional trends in heart failure hospitalization and mortality rates for medicare beneficiaries, 1998–2008. *JAMA*: *The Journal of the American Medical Association*, *306*(15), 1669–1678. https://doi.org/10.1001/jama.2011.1474

Chew, A. C. (2020). *Does Use of a Mobile App and Telephone Support Promote Improved Self–Care of Heart Failure?* (Publication No. 27744797) [Doctoral dissertation, Andrews University]. ProQuest Dissertations. https://search.proquest.com/docview/2388022167

Crespo–Leiro, M. G., Anker, S. D., Maggioni, A. P., Coats, A. J., Filippatos, G., Ruschitzka, F., Ferrari, R., Piepoli, M. F., Delgado, J. F., Metra, M., Fonseca, C., Hradec, J., Amir, O., Logeart, D., Dahlström, U., Merkely, B., Drozdz, J., Goncalvesova, E., Hassanein, M., . . . Mebazaa, A. (2016). European Society of Cardiology heart failure long–term registry (ESC–HF–LT): 1–year follow–up outcomes and differences across regions. *European Journal of Heart Failure*, *18*(6), 613–625. https://doi.org/10.1002/ejhf.566

Crouter, S. E., Schneider, P. L., Karabulut, M., Bassett, J., & David, R. (2003). Validity of 10 electronic pedometers for measuring steps, distance, and energy cost. *Medicine and Science in Sports and Exercise*, *35*(8), 1455–1460. https://doi.org/10.1249/01.MSS.0000078932.61440.A2

Dang, S., Karanam, C., & Gómez–Marín, O. (2017). Outcomes of a mobile phone intervention for heart failure in a minority county hospital population. *Telemedicine Journal and E–Health*, *23*(6), 473–484. https://doi.org/10.1089/tmj.2016.0211

Dharmarajan, K., Hsieh, A. F., Lin, Z., Bueno, H., Ross, J. S., Horwitz, L. I., Barreto–Filho, J. A., Kim, N., Bernheim, S. M., Suter, L. G., Drye, E. E., & Krumholz, H. M. (2013). Diagnoses and timing of 30–day readmissions after hospitalization for heart failure, acute myocardial infarction, or pneumonia. *JAMA: The Journal of the American Medical Association*, *309*(4), 355–363. https://doi.org/10.1001/jama.2012.216476

Evangelista, L. S., Berg, J., & Dracup, K. (2001). Relationship between psychosocial variables and compliance in patients with heart failure. *Heart & Lung*, *30*(4), 294–301. https://doi.org/10.1067/mhl.2001.116011

Evans, J., Papadopoulos, A., Silvers, C. T., Charness, N., Boot, W. R., Schlachta–Fairchild, L., Crump, C., Martinez, M., & Ent, C. B. (2016). remote health monitoring for older adults and those with heart failure: Adherence and system usability. *Telemedicine Journal and E–Health*, *22*(6), 48–488. https://doi.org/10.1089/tmj.2015.0140

Fonarow, G. C., Abraham, W. T., Albert, N. M., Stough, W. G., Gheorghiade, M., Greenberg, B. H., O'Connor, C. M., Pieper, K., Sun, J. L., Yancy, C. W., & Young, J. B. (2008). Factors identified as precipitating hospital admissions for heart failure and clinical outcomes: Findings from OPTIMIZE–HF. *Archives of Internal Medicine (1960)*, *168*(8), 847–854. https://doi.org/10.1001/archinte.168.8.847

Gheorghiade, M., Filippatos, G., De Luca, L., & Burnett, J. (2006). Congestion in acute heart failure syndromes: An essential target of evaluation and treatment. *The American Journal of Medicine*, *119*(12), S3–S10. https://doi.org/10.1016/j.amjmed.2006.09.011

Gheorghiade, M., Vaduganathan, M., Fonarow, G. C., & Bonow, R. O. (2013). Rehospitalization for heart failure: Problems and perspectives. *Journal of the American College of Cardiology*, *61*(4), 391. https://doi.org/10.1016/j.jacc.2012.09.038

Gupta, A., & Fonarow, G. C. (2018). The hospital readmissions reduction program—learning from failure of a healthcare policy. *European Journal of Heart Failure*, *20*(8), 1169–1174. https://doi.org/10.1002/ejhf.1212

Hägglund, E., Lyngå, P., Frie, F., Ullman, B., Persson, H., Melin, M., & Hagerman, I. (2015). Patient–centred home–based management of heart failure: findings from a randomized clinical trial evaluating a tablet computer for self–care, quality of life and effects on knowledge. *Scandinavian Cardiovascular Journal*: *SCJ*, *49*(4), 193–199. https://doi.org/10.3109/14017431.2015.1035319

Hammash, M. H., Hall, L. A., Lennie, T. A., Heo, S., Chung, M. L., Lee, K. S., & Moser, D. K. (2013). Psychometrics of the PHQ–9 as a measure of depressive symptoms in patients with heart failure. *European Journal of Cardiovascular Nursing*: *Journal of the Working Group on Cardiovascular Nursing of the European Society of Cardiology*, *12*(5), 446–453. https://doi.org/10.1177/1474515112468068

Heart Failure Society of America. (2010). HFSA 2010 comprehensive heart failure practice guideline. *Journal of Cardiac Failure*, *16*(6), e1–e2. https://doi.org/10.1016/j.cardfail.2010.04.004

Heidenreich, P. A., Albert, N. M., Allen, L. A., Bluemke, D. A., Butler, J., Fonarow, G. C., Ikonomidis, J. S., Khavjou, O., Konstam, M. A., Maddox, T. M., Nichol, G., Pham, M.,

Piña, I. L., & Trogdon, J. G. (2013). Forecasting the impact of heart failure in the United States: A policy statement from the American Heart Association. *Circulation. Heart Failure*, *6*(3), 606–619. https://doi.org/10.1161/HHF.0b013e318291329a

Heiney, S. P., Donevant, S. B., Arp Adams, S., Parker, P. D., Chen, H., & Levkoff, S. (2020). A Smartphone app for self–management of heart failure in older African Americans: Feasibility and usability study. *JMIR Aging*, *3*(1), e17142. https://doi.org/10.2196/17142

Jaarsma, T., Hill, L., Bayes-Genis, A., La Rocca, H. B., Castiello, T., Čelutkienė, J., Marques-Sule, E., Plymen, C. M., Piper, S. E., Riegel, B., Rutten, F. H., Ben Gal, T., Bauersachs, J., Coats, A. J. S., Chioncel, O., Lopatin, Y., Lund, L. H., Lainscak, M., Moura, B., . . . Strömberg, A. (2021). Self-care of heart failure patients: Practical management recommendations from the Heart Failure Association of the European Society of Cardiology. *European Journal of Heart Failure*, *23*(1), 157–174. https://doi.org/10.1002/ejhf.2008

Jurgens, C. Y. (2006). Somatic awareness, uncertainty, and delay in care-seeking in acute heart failure. *Research in Nursing & Health*, *29*(2), 74–86. https://doi.org/10.1002/nur.20118

Kao, C., & Liebovitz, D. M. (2017). Consumer mobile health apps: Current state, barriers, and future directions. *Pm & R*, *9*(5), S106–S115. https://doi.org/10.1016/j.pmrj.2017.02.018

Kitsiou, S., Gerber, B. S., Kansal, M. M., Buchholz, S. W., Chen, J., Ruppar, T., Arrington, J., Owoyemi, A., Leigh, J., & Pressler, S. J. (2021). Patient–centered mobile health technology intervention to improve self–care in patients with chronic heart failure: Protocol for a feasibility randomized controlled trial. *Contemporary Clinical Trials*, *106*, 106433. https://doi.org/10.1016/j.cct.2021.106433

Koehler, F., Winkler, S., Gelbrich, G., Kirwan, B., Anker, S. D., Schieber, M., Sechtem, U., Stangl, K., Böhm, M., Boll, H., Baumann, G., Honold, M., & Koehler, K. (2011). Impact of

remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: The telemedical interventional monitoring in heart failure study. *Circulation (New York, N.Y.)*, *123*(17), 1873–1880. https://doi.org/10.1161/CIRCULATIONAHA.111.018473

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: Validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*(9), 606–613. https://doi.org/10.1046/j.1525–1497.2001.016009606.x

Krumholz, H. M., Amatruda, J., Smith, G. L., Mattera, J. A., Roumanis, S. A., Radford, M. J., Crombie, P., & Vaccarino, V. (2002). Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. *Journal of the American College of Cardiology*, *39*(1), 83–89. https://doi.org/10.1016/S0735–1097(01)01699–0

Lin, S., Ababneh, A., & Tran, V. (2021). Autonomous walking program and high–intensity inspiratory muscle training in individuals with heart failure—A feasibility study. *Cardiopulmonary Physical Therapy Journal*, *32*(2), 75–83. https://doi.org/10.1097/CPT.0000000000000144

Lippi, G., & Sanchis–Gomar, F. (2020). Global epidemiology and future trends of heart failure. *AME Medical Journal*, *5*(15), 1–6. https://doi.org/10.21037/amj.2020.03.03

Maggioni, A. P., Dahlström, U., Filippatos, G., Chioncel, O., Leiro, M. C., Drozdz, J., Fruhwald, F., Gullestad, L., Logeart, D., Fabbri, G., Urso, R., Metra, M., Parissis, J., Persson, H., Ponikowski, P., Rauchhaus, M., Voors, A. A., Nielsen, O. W., Zannad, F., & Tavazzi, L. (2013). EURObservational Research Programme: Regional differences and 1–year follow–up results of the Heart Failure Pilot Survey (ESC–HF Pilot). *European Journal of Heart Failure*, *15*(7), 808–817. https://doi.org/10.1093/eurjhf/hft050

Maisel, A. S., Shah, K. S., Barnard, D., Jaski, B., Frivold, G., Marais, J., Azer, M., Miyamoto, M. I., Lombardo, D., Kelsay, D., Iqbal, N., Taub, P. R., Kupfer, K., Lee, E., Clopton, P., Zile, M., & Greenberg, B. (2016). How B–type natriuretic peptide (bnp) and body weight changes vary in heart failure with preserved ejection fraction compared with reduced ejection fraction: Secondary results of the HABIT (HF assessment with BNP in the home) trial. *Journal of Cardiac Failure*, *22*(4), 283–293. https://doi.org/10.1016/j.cardfail.2015.09.014

Manemann, S. M., Chamberlain, A. M., Boyd, C. M., Gerber, Y., Dunlay, S. M., Weston, S. A., Jiang, R., & Roger, V. L. (2016). Multimorbidity in heart failure: Effect on outcomes. *Journal of the American Geriatrics Society (JAGS)*, *64*(7), 1469–1474. https://doi.org/10.1111/jgs.14206

Martínez–Pérez, B., de la Torre–Díez, I., & López–Coronado, M. (2015). Experiences and results of applying tools for assessing the quality of a mHealth app named Heartkeeper. *Journal of Medical Systems*, *39*(11), 1–6. https://doi.org/10.1007/s10916–015–0303–6

Masterson Creber, R. M., Maurer, M. S., Reading, M., Hiraldo, G., Hickey, K. T., & Iribarren, S. (2016). Review and analysis of existing mobile phone apps to support heart failure symptom monitoring and self–care management using the Mobile Application Rating Scale (MARS). *JMIR mHealth and uHealth*, *4*(2), e74. https://doi.org/10.2196/mhealth.5882

MCQUAY, H. J., & MOORE, R. A. (1997). Using numerical results from systematic reviews in clinical practice. *Annals of Internal Medicine*, *126*(9), 712–720. https://doi.org/10.7326/0003–4819–126–9–199705010–00007

Mortara, A., Vaira, L., Palmieri, V., Iacoviello, M., Battistoni, I., Iacovoni, A., Macera, F., Pasqualucci, D., Bochicchio, M., & De Maria, R. (2020). Would you prescribe mobile health apps for heart failure self–care? An integrated review of commercially available mobile

technology for heart failure patients. *Cardiac Failure Review*, *6*, e13. https://doi.org/10.15420/cfr.2019.11

Nasreddine, Z. S., Phillips, N. A., Bédirian, V., Charbonneau, S., Whitehead, V., Collin, I., Cummings, J. L., & Chertkow, H. (2005). The Montreal Cognitive Assessment, MoCA: A brief screening tool for mild cognitive impairment. *Journal of the American Geriatrics Society (JAGS)*, *53*(4), 695–699. https://doi.org/10.1111/j.1532–5415.2005.53221.x

Nundy, S., Razi, R. R., Dick, J. J., Smith, B., Mayo, A., O'Connor, A., & Meltzer, D. O. (2013). A text messaging intervention to improve heart failure self–management after hospital discharge in a largely African–American population: Before–after study. *Journal of Medical Internet Research*, *15*(3), e53. https://doi.org/10.2196/jmir.2317

Patil, S., Shah, M., Patel, B., Agarwal, M., Ram, P., & Alla, V. M. (2019). Readmissions among patients admitted with acute decompensated heart failure based on income quartiles. *Mayo Clinic Proceedings*, *94*(10), 1939–1950. https://doi.org/10.1016/j.mayocp.2019.05.027

Portz, J. D., Vehovec, A., Dolansky, M. A., Levin, J. B., Bull, S., & Boxer, R. (2018). The development and acceptability of a mobile application for tracking symptoms of heart failure among older adults. *Telemedicine Journal and E–Health*, *24*(2), 161–165. https://doi.org/10.1089/tmj.2017.0036

Pozehl, B., Mcguire, R., Duncan, K., Hertzog, M., Deka, P., Norman, J., Artinian, N., Saval, M., & Keteyian, S. (2018). Accelerometer–measured daily activity levels and related factors in patients with heart failure. *The Journal of Cardiovascular Nursing*, *33*(4), 329–335. https://doi.org/10.1097/JCN.0000000000000464

RAND Health. (1993). (*36–Item Short Form Survey (SF–36) Scoring Instructions.* https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/scoring.html

Rector, T. S., & Cohn, J. N. (1992). Assessment of patient outcome with the Minnesota Living with Heart Failure questionnaire: Reliability and validity during a randomized, double–blind, placebo–controlled trial of pimobendan. *American Heart Journal*, *124*(4), 1017–1025. https://doi.org/10.1016/0002–8703(92)90986–6

Rector, T. S., Kubo, S. H., & Cohn, J. N. (1987). Patients' self–assessment of their congestive heart failure. Part 2: Content, reliability and validity of a new measure, the Minnesota Living with Heart Failure questionnaire. *Heart Failure*, *3*, 198–209.

Reeder, K., Ercole, P., Peek, G., & Smith, C. (2015). Symptom perceptions and self–care behaviors in patients who self–manage heart failure. *The Journal of Cardiovascular Nursing*, *30*(1), E1–E7. https://doi.org/10.1097/JCN.0000000000000117

Riegel, B., Dickson, V., & Faulkner, K. (2016). The situation–specific theory of heart failure self–care: Revised and updated. *The Journal of Cardiovascular Nursing*, *31*(3), 226–235. https://doi.org/10.1097/JCN.0000000000000244

Riegel, B., Lee, S., Hill, J., Daus, M., Baah, F. O., Wald, J. W., & Knafl, G. J. (2019). Patterns of adherence to diuretics, dietary sodium and fluid intake recommendations in adults with heart failure. *Heart & Lung*, *48*(3), 179–185. https://doi.org/10.1016/j.hrtlng.2018.12.008

Riegel, B., Moser, D. K., Anker, S. D., Appel, L. J., Dunbar, S. B., Grady, K. L., Gurvitz, M. Z., Havranek, E. P., Lee, C. S., Lindenfeld, J., Peterson, P. N., Pressler, S. J., Schocken, D. D., Whellan, D. J., & on behalf of American Heart Association Council on Cardiovascular Nursing, Council on Clinical Cardiology, Council on Nutrition, Physical Activity, and Metabolism, and Interdisciplinary Council on Quality of Care and Outcomes Research. (2009). State of the science: Promoting self–care in persons with heart failure: A scientific statement from the American Heart Association. *Circulation*, *120*(12), 1141–1163. https://doi.org/10.1161/CIRCULATIONAHA.109.192628

Scherr, D., Zweiker, R., Kollmann, A., Kastner, P., Schreier, G., & Fruhwald, F. M. (2006). Mobile phone–based surveillance of cardiac patients at home. *Journal of Telemedicine and Telecare*, *12*(5), 255–261. https://doi.org/10.1258/135763306777889046

Scherr, D., Kastner, P., Kollmann, A., Hallas, A., Auer, J., Krappinger, H., Schuchlenz, H., Stark, G., Grander, W., Jakl, G., Schreier, G., & Fruhwald, F. M. (2009). Effect of home–based telemonitoring using mobile phone technology on the outcome of heart failure patients after an episode of acute decompensation: randomized controlled trial. *Journal of Medical Internet Research*, *11*(3), e34. https://doi.org/10.2196/jmir.1252

Schiff, G. D., Fung, S., Speroff, T., & McNutt, R. A. (2003). Decompensated heart failure: Symptoms, patterns of onset, and contributing factors. *The American Journal of Medicine*, *114*(8), 625–630. https://doi.org/10.1016/S0002–9343(03)00132–3

Schneider, P. L., Crouter, S. E., Lukajic, O., & Bassett, J., David R. (2003). Accuracy and reliability of 10 pedometers for measuring steps over a 400–m walk. *Medicine and Science in Sports and Exercise*, *35*(10), 1779–1784. https://doi.org/10.1249/01.MSS.0000089342.96098.C4

Seto, E., Leonard, K. J., Cafazzo, J. A., Barnsley, J., Masino, C., & Ross, H. J. (2012). Mobile phone–based telemonitoring for heart failure management: a randomized controlled trial. *Journal of Medical Internet Research*, *14*(1), e31. https://doi.org/10.2196/jmir.1909

Silavanich, V., Nathisuwan, S., Phrommintikul, A., & Permsuwan, U. (2019). Relationship of medication adherence and quality of life among heart failure patients. *Heart & Lung*, *48*(2), 105–110. https://doi.org/10.1016/j.hrtlng.2018.09.009

Stewart, A. L., Hays, R. D., & Ware, J. E. (1988). The MOS Short–Form General Health Survey: Reliability and validity in a patient population. *Medical Care*, *26*(7), 724–735. https://doi.org/10.1097/00005650–198807000–00007

Suh, M., Chen, C., Woodbridge, J., Tu, M., Kim, J., Nahapetian, A., Evangelista, L., & Sarrafzadeh, M. (2011). A remote patient monitoring system for congestive heart failure. *Journal of Medical Systems*, *35*(5), 1165–1179. https://doi.org/10.1007/s10916–011–9733–y

Triantafyllidis, A., Velardo, C., Chantler, T., Shah, S. A., Paton, C., Khorshidi, R., Tarassenko, L., & Rahimi, K. (2015). A personalised mobile–based home monitoring system for heart failure: The SUPPORT–HF study. *International Journal of Medical Informatics (Shannon, Ireland)*, *84*(10), 743–753. https://doi.org/10.1016/j.ijmedinf.2015.05.003

Tudor–Locke, C., Craig, C. L., Thyfault, J. P., & Spence, J. C. (2013). A step–defined sedentary lifestyle index. *Applied Physiology, Nutrition, and Metabolism*, *38*(2), 100–114. https://doi.org/10.1139/apnm–2012–0235

Van Wormer, J. J., Boucher, J. L., Pronk, N. P., & Thoennes, J. J. (2004). Lifestyle behavior change and coronary artery disease: effectiveness of a telephone–based counseling program. *Journal of Nutrition Education and Behavior*, *36*(6), 333–334. https://doi.org/10.1016/S1499–4046(06)60406–5

Virani, S. S., Alonso, A., Aparicio, H. J., Benjamin, E. J., Bittencourt, M. S., Callaway, C. W., Carson, A. P., Chamberlain, A. M., Cheng, S., & Delling, F. N. (2021). Heart disease and stroke statistics—2021 update: A report from the American Heart Association. *Circulation*, *143*(8), e254–e743.

Virani, S., Alonso, A., Benjamin, E., Bittencourt, M., Callaway, C., Carson, A., Chamberlain, A., Chang, A., Cheng, S., Delling, F., Djousse, L., Elkind, M., Ferguson, J., Fornage, M., Khan, S., Kissela, B., Knutson, K., Kwan, T., Lackland, D., . . . Tsao, C. (2020). Heart disease and stroke statistics—2020 update: A report from the American Heart Association. *Circulation (New York, N.Y.)*, *141*(9), e139–e151. https://doi.org/10.1161/CIR.0000000000000757

Vuorinen, A., Leppänen, J., Kaijanranta, H., Kulju, M., Heliö, T., van Gils, M., & Lähteenmäki, J. (2014). Use of home telemonitoring to support multidisciplinary care of heart failure patients in Finland: Randomized controlled trial. *Journal of Medical Internet Research*, *16*(12), e282. https://doi.org/10.2196/jmir.3651

Wali, S., Demers, C., Shah, H., Wali, H., Lim, D., Naik, N., Ghany, A., Vispute, A., Wali, M., & Keshavjee, K. (2019). Evaluation of heart failure apps to promote self–care: Systematic app search. *JMIR mHealth and uHealth*, *7*(11), e13173. https://doi.org/10.2196/13173

Ware, J. E. & Sherbourne, C.D. (1992). The MOS 36–item short–form health survey (SF–36): I. Conceptual framework and item selection. *Medical Care*, *30*(6), 473–483. https://www.jstor.org/stable/3765916

World Health Organization. (2011). *mHealth: New horizons for health through mobile technologies*. OMS.

Zan, S., Agboola, S., Moore, S. A., Parks, K. A., Kvedar, J. C., & Jethwani, K. (2015). Patient engagement with a mobile web–based telemonitoring system for heart failure self–management: A pilot study. *JMIR mHealth and uHealth*, *3*(2), e33. https://doi.org/10.2196/mhealth.3789

APPENDIX A

Activity Log for Daily Step Counts

Activity Log – Daily Step Counts

Name:

Starting Date:

End date:

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Notes
Week 1								
Week 2								
Week 3								
Week 4								

APPENDIX B

The IRB of the Texas Woman's University – Dallas

TEXAS WOMAN'S UNIVERSITY CONSENT TO PARTICIPATE IN RESEARCH

Title: Usability and effectiveness of a self-care mobile health app in individuals with heart failure
Investigator: Anas Ababneh, MS .....aababneh@twu.edu (469) 688 3473
Advisor: Suh-Jen Lin PT, Ph.D ..... slin@twu.edu (214) 689-7718

Summary and Key Information about the Study:

You are being asked to take part in this research study conducted by Mr. Anas Ababneh, a Ph.D. doctoral student at Texas Woman's University, as a part of his dissertation. The purpose of this study is to determine the potential benefits that individuals with heart failure (HF) could experience from using the mobile health application, Heart Failure Health Storylines (HFHS), for 4 weeks. You are invited to participate in this study because you have a diagnosis of heart failure, own a smart phone with internet access, could walk independently with or without an assistive device, speak and read English, and do not have a neurological disorder/disease. You will be asked to come for one initial evaluation and training session which will last for one to two hours. You will then be randomly assigned to either the App-intervention group or the No-App group. If you are in the App-intervention group, you will learn to use the HFHS application (App) to track your health by recording your symptoms, vital signs, medications, and more. So, you can build your own "Storyline" to learn about your health. If you are in the No-App group, you will use a pedometer to track your daily step counts. The total time commitment for this study will be 4 weeks and 2 hours. The risks associated with participation in the study include releasing of some confidential information, experiencing sort of fatigue or shortness of breath during your normal daily activities, and experiencing boredom/anxiety from daily recording of your health information in the App. If you are in the No-App group, you will receive a free pedometer. If you are in the App intervention group, you will also receive a free blood pressure monitor, a bathroom scale, and the training on using the HFHS application. Following the completion of the study, every participant will receive a $75 gift card. Your participation in this study is completely voluntary. If you are interested in learning more about this study, please review this consent form carefully and take your time deciding whether or not you want to participate. Please feel free to ask the researcher any questions you have about the study at any time.

Description of the Study Procedures

There is one initial training session and it includes two parts. In the first part, we will ask you to fill out four questionnaires which include information on your age, sex, height, weight, medical history, psychological status and your quality of life.

If you are assigned to the No-App group, you will be asked to track your daily steps with a pedometer and record your data on the "Activity Log" paper form. At each day you need to do two simple actions:

1. You need to zero out the pedometer daily when you get up in the morning.
2. At the end of a day before going to your bed, you need to record the number of steps on the "Activity Log" form, which will need less than 2minutes.

We will call you once per week (mostly the first day of each week) to collect the number of daily steps for the previous week.

If you are assigned to the App group, we will train you to use the mobile application (HFHS) to track your health status, physical activity, manage your medications schedule, and explore the other features that the application has. In this training session, we will ask you to use a set of pre-prepared username and password to log in to the application and track your health parameters. After the training session, we would like you to use the HFHS application each day for 4 weeks. The estimated time that you will need to use the application for the study purpose in each day is 15 minutes approximately. During these 4 weeks, our research team will call you once per week to ask you if you face a problem or challenges while using the app for the previous week. The estimated time for the call will be about 5 minutes. The research team will monitor your health status Via the App during the study duration. As a part of the monitoring, we will text you via the App if one or more of following conditions is noted:

- Your vital signs show undesired readings
- Your records on the App show that you did not take the medications as your schedule say

We will call you after 3 days to follow up regarding your action towards the text message. The estimated time for the call is about 5 minutes.

For both groups, we will send two or three web links (Two links for No-App group and three links for App-group) as a text

Initials_____

message to your phone after 4 weeks of the study. These web links will direct you to electronic questionnaires on an internet browser. We would like you to fill out those questionnaires online. At the end of each questionnaire, there is a button "Submit". Please click it to submit. Your questionnaires will then be received through the principle investigator's secured email address.

Potential Risks The study may include the risk of release of confidential information. However, confidentiality will be protected to the extent that is allowed by law. In this study, a code will be assigned to each participant. The code and participants' names will be saved in a separate file and this file will be stored in a locked cabinet. The principal investigator is the only person who has access to this file. The research team will use just the codes in the data analysis and in the final report. The data that recorded on either on papers or electronic forms will be stored for 3 years, and then will be shredded or deleted permanently.
With a diagnosis of heart failure, you may experience sort of fatigue or shortness of breath during your daily activities. If you have these symptoms or other discomfort feelings, we encourage you to stop the activity and rest until the symptoms disappear. You should take frequent periods of rest during daily activities. If the symptoms do not relieve or you still have discomfort, you should contact your physician as soon as possible.

You may experience boredom or anxiety from 4 weeks of daily recording of the number of steps (if you are assigned to the No-App group) or your health information on the App (if you are assigned to the App group). To reduce the boredom or the anxiety, you will receive a phone call every week from the research team to follow up about your experience with the study (for both groups), and to collect the number of steps (for the No-App group). Also, our research team will be keen to teach you in a good way at the initial orientation session to make sure you are able to perform the tasks required. If you have any questions at home, you can call the primary investigator any time or leave a message.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits Your involvement in this study is completely voluntary and you may withdraw from the study at any time. All your information that identify you will be removed. After such removal, the other collected information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. If you would like to participate in the current study but not allow your de-identified data to be used for future research, please initial here_____.

Through participation in the study, you will receive a free pedometer and a gift card of $75 as incentives. If you are assigned to the App-intervention group, you will also receive a bathroom scale and a wrist blood pressure monitor as part of the study protocol. If you are in the No-App Group initially, you will be given the opportunity to participate in the App-intervention group after 4 weeks or just getting the application training if you do not want to participate. At the end of the study, if you would like to know the results of this study, we will mail or email them to you uponrequest.

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study you should ask the researchers; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940-898-3378 or via e-mail at IRB@twu.edu

Name of Participant _____ Date _____

Signature of Participant: _____

*If you would like to receive a summary of the results of this study, please provide a mailing or email (Preferred) address to which the summary should be sent:_____

APPENDIX C

Collabration Letter from Texas Health Presbyterian Hospital

Texas Health Presbyterian Hospital DALLAS

Nursing Administration

April 11, 2018

Dear Colleagues,

Please accept this letter of support for the doctoral dissertation project entitled *Usability and Effectiveness of a Self Care Mobile Health App in Patients with Heart Failure,* by Anas Ababneh, one of Dr. Lin's doctoral students. Texas Health Presbyterian Dallas has previously collaborated with Dr. Lin on a pilot project related to a breathing and exercise program to prevent readmissions in patients with heart failure since 2013, and we are delighted to be invited to participate in this collaborative study aimed at improving outcomes for individuals living with heart failure. This project provides opportunities for nurses in our clinical settings to work with and learn from interprofessional academic colleagues through involvement in such an important area of research.

Texas Health Presbyterian Dallas (THD) will support the efforts of our advanced practice nurse in the heart failure clinic to serve as the THR principal investigator and our nurse scientist to assist Anas Ababneh and Dr. Lin, and by serving as a local member of this collaborative project team. This randomized clinical trial is designed to test usability and monitor effectiveness of a mobile self-care health app and coaching program over a 4-week period in patients with heart failure as compared to the control group using a pedometer to monitor their step counts. The intervention group will track health parameters over the 4-week period, including: resting heart rate and blood pressure, daily steps, medication, and body weight: the control group will use a pedometer to monitor daily step counts.

We believe this collaborative research endeavor will strengthens and promotes collaborative research with academic partners, such as Texas Woman's University and potentially leads to further interprofessional research involving THD clinical team members. This research also supports fulfillment of our mission, "To improve the lives of the people in the communities we serve." We appreciate the opportunity to work with Dr. Lin and Mr. Anas Ababneh on this collaborative research effort, designed to meet shared goals for the patients we serve.

Sincerely yours,

Dr. Cole Edmonson

Cole Edmonson, DNP, RN, FACHE, NEA-BC, FAAN
Chief Nursing Officer

8200 Walnut Hill Lane, Dallas Texas 75231-4496 | 214.345.6789 | www.TexasHealth.org

APPENDIX D

IRB Consent Form of Texas Health Presbyterian Hospital

ADULT CONSENT FORM TO BE IN RESEARCH
DATA COLLECTION ONLY

Title of the Study: Usability and effectiveness of a self-care mobile health application in individuals with heart failure

You are being asked to participate in a research study. This form describes the study. Research studies include only people who choose to participate. Please read it carefully and discuss it with your friends, family and/or the investigator. If you agree to participate in this study, you can sign the form. Remember that your participation is completely voluntary.

A. Who is conducting this research study?

Main Researcher:
Lindsay Beeker, MSN, BA, RN, ACNP-BC, CHFN
[Heart Failure Coordinator, 214-345-2658]
Heart Failure Clinic - Suite #410, Professional Building #4, THR-Dallas

Co-Researchers:
Suh-Jen Lin, PT, PhD, Texas Woman's University (TWU) -Dallas [214-689-7718]
Anas Ababneh, MS, PhD candidate, TWU
Texas Woman's University, Institute of Health Sciences of Dallas,
School of Physical Therapy – Dallas, Research Suite

B. What is the purpose of this research study?

We would like to learn about the potential benefits that individuals with heart failure (HF) could experience from using a mobile application. The mobile application is the Heart Failure Health Storylines (HFHS). The application is developed in partnership with the Heart Failure Society of America and is powered by the Health Storylines™ platform from Self Care Catalysts Inc.

If you agree to participate in this study, information regarding your medical care may be recorded for research.

This study is considered research because of monitoring health parameters (heart rate, body weight, blood pressure, and physical activity) and measuring its effect on the quality of life, where it is not conducted yet.

C. Why are you invited to take part in this study?

You are being asked to take part in this study because you have been diagnosed with heart failure and fit the inclusion criteria of this study.

D. How many people will take part in the study?

This study plans to recruit a total of 60 participants.

E. <u>What will you be asked to do?</u>

If you agree to be in this study, you will receive the same medical care that you would receive if you were not in the study. By taking part, you agree for the main researcher to collect information regarding your medical care and the status of your health throughout the study.

You will be asked to attend one initial training session. This session will take about 1- 2 hours. The session includes two parts. In the first part, you need to fill out four questionnaires, which include information on your age, sex, height, weight, medical history, psychological status and your quality of life. In the second part, you will be assigned to either No-App group, or App group.

If you are assigned to the No-App group:
You will learn how to track your daily steps with a pedometer. Each day you will need to do two simple actions: 1. Zero out the pedometer when you get up in the morning. 2. Put the pedometer in a pocket of your cloths 2. At the end of a day before going to bed, record the number of steps from the pedometer on the "Activity Log" form. We will call you once per week (mostly the first day of each week) to collect the number of daily steps for the previous week.

If you are assigned to the App group:
You will learn how to use the Heart Failure Health Storyline (HFHS) mobile application. 1. You will log in the app with a set of username and password we prepared for you. 2. You will learn how to track your health status, physical activity, manage your medications schedule, and explore the other features by following the Participant's Guide that we will provide to you. 3. We would like you to use the application every day for 4 weeks. ○ The estimated time to enter your data to the app is about 15 minutes a day. We will call you once a week for follow-up regarding any problems or challenges while using the app. The estimated time for the call will be about 5 minutes. In addition, the research team will monitor your data entry on the App for this 4-week period. We will text you if any of the following conditions is noted: ● Your vital signs show undesired readings ● You skip your medications. We will call you after 3 days to follow up regarding your action towards the text message. The estimated time for the call is about 5 minutes.

After 4 weeks, you need to fill out some questionnaire again. We will send a text message to you. The text message will include two or three web links (Two web links for No-App group and three web links for App-group). Once you receive the web links, you need to do the following three simple steps:

1. Click on the link. It will direct you to the electronic questionnaires.
2. Fill out the questionnaires online.
3. At the end of each questionnaire, click the "Submit" button.

Your questionnaires will be received through the principle investigator's secured email address.

F. How Long Will You Be in This Study

You will be in the study approximately 4 weeks.

G. Can you stop being in this study?

Participating in this study is up to you. You may decide not to be in the study or you may stop being in this study at any time. If you decide not to participate, or you withdraw, you will not have any penalty or loss of benefits to which you are entitled. In addition, your decision will not affect your future medical care.

If you withdraw this consent you will no longer be allowed to participate in the study. However, the information already obtained by the study staff and may be used and disclosed as permitted by this consent form. You will be able to retain the devices that we provided if you decide to withdraw from the study.

The main and/or co-researcher may decide to take you off this research study, even if you would like to continue. Some examples of why the main and/or co-researcher might take you off the study are:

- If funding for the study is stopped
- If the study is canceled;
- If the whole study is stopped or changed for any reason;
- For study management reasons. For example: enough subjects have been enrolled into the study.

H. Will the researchers tell you about new information that may affect your decision to continue in this study?

There should not be any new information that will affect your decision to continue in this study. However, if any new information is discovered, you will be informed of this.

I. What are the possible risks, side effects, or discomforts of being in this study?

There are standard risks of being in a research study. The risks include the loss of privacy and confidentiality. We will use best efforts to be sure that your personal information remains confidential. Section M. tells you who will be allowed to receive and use any of this information, if you give your permission by signing this consent form.

With a diagnosis of heart failure, you may experience some fatigue or shortness of breath during your daily activities. If you have these symptoms or other discomfort feelings, we encourage you to stop the activity and rest until the symptoms disappear. You should take frequent periods of rest during daily activities. If the discomfort symptoms do not relieve after rest, you should contact your physician as soon as possible.

You may experience boredom or anxiety from 4 weeks of daily recording of the number of steps (if you are assigned to the No-App group) or entering your health information on the App (if you

are assigned to the App group). To reduce the boredom or the anxiety, you will receive a phone call every week from the research team to follow up about your experience with the study. Also, our research team will be keen to teach you in a good way at the initial training session to make sure you are able to perform the tasks required.

J. What are the benefits of taking part in this research study?

You will receive a free pedometer and a gift card ($25) as incentives. If you are in the App group, you will also receive a bathroom scale and a blood pressure monitor. These tools are part of the study protocol.

If you are in the No-App group initially, we will offer you the opportunity to participate in the App group after 4 weeks. You can also get the application training without participating in the study.

We will mail or email the study results to you at the end of the study upon your request

The participants in the App group may potentially establish a habit of monitoring their vital signs and body weight regularly. In addition, there is a possibility to improve the quality of life. For participants in the Non-App group, they may, or may not, gain health benefits from improved physical activity with a pedometer.

K. What options are there to being in this study

You do not have to participate in this research study. Your quality medical care will not be changed in any way as a result of this decision.

L. Are there potential conflicts of interest?

A "conflict of interest" is a situation where different interests could influence a person's decisions. The main and/or co-researchers must follow federal government rules for identifying and managing possible conflicts of interest before a research study can be approved. This is to make sure that the design, conduct (actions taken) and reporting of the research will not be influenced by any conflicting interests.

From time to time, the hospital's member company, Texas Health Resources (THR), may invest money in a number of stocks (a share of ownership or an ownership interest in a company) and/or mutual funds (a pool of money managed by an investment company) that might include stocks in the sponsor of the study. Such investments are made by outside investment advisors separately and would be part of THR's investment portfolio (collection of investments held by an institution or a private individual) only and not linked to the study.

The main and/or co-researcher do/does not have any financial interest in the study results. This means that the main and/or co-researcher will not make or lose money due to the results of the study (positive or negative).

Money is not the only thing that can cause a conflict of interest. For example, being invited to participate in research by your nurse practitioner could be a conflict of interest. In such case, your nurse practitioner has an interest in both your care and in the success of this research study. For purposes of the research, the decision the nurse practitioner makes for your care will be directed by the study plan for this Research Study.

Your nurse practitioner is committed to providing quality care, even if you cannot or do not take part in the research. You can choose not to take part in the research or stop taking part in the research study and still receive treatment from your nurse practitioner.

M. What about your privacy? What about confidentiality of your private health information?

This section discusses how we will keep your private information confidential. It will also discuss the limited ways that may not be kept confidential.

Information collected about you will be compared to information collected about other research study participants. Most research study records have some sort of information that may identify you.

The main researcher will continue to have access to the data collected during your participation in the study. We will keep your identity and data confidential at all times. The access to your data will end at the closure of the study. It will also end to the point of study withdrawal by you or your nurse practitioner.
You will be asked to agree to provide requested personal information and to share of such information with Self Care Catalysts, in accordance with their Privacy Policies, for participation in this study. You will also be asked to sign a separate "Authorization to Use or Disclose Protected Health Information for Research". This form will outline with whom your information may be shared for the research purposes. It will also state under what situations it may be shared. You can choose NOT to give your permission for us to use this information. This choice is a very important right that you have. If you do not give us the permission to use this information for this research study, you will not be able to participate in the study. See Section U for more information about your rights as a research subject.
If you have any questions after reading the following sections, please contact the main study researcher or the co-researchers at the number listed in Section A

N. What private information will be collected?

The research study records may include information that could be used by another person to identify you. General examples would be information that shows your name and your phone number. When the information can identify you, we call it "private information". If the information can identify you, it may be used and shared as the law allows and will not affect your privacy.

O. Confidentiality of private information
The collected Information about you for this research will remain confidential unless you give your permission to share it with others, or if we are authorized or required by law to release it.

P. How will your private information be protected?
We will assign a code to each participant. We will save the codes and participants' names in a separate file. This file will be stored in a locked cabinet. The main researcher is the only person who has access to this file. The research team members will use just the codes in the data analysis and in the final report. The data that is recorded on either paper or electronic forms will be stored for 10 years. Then, the data will be shredded or deleted permanently.

Q. How will information about you be used in teaching and publication?

If information about the research study is used for teaching or in publications, private information will not be made public. Your identity will be kept confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, (ID: 19985). It is required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

R. What are the costs of your being in this research study?

No medical treatment is being provided under this study. There will be no charges to you or your insurance company.

S. Will you be paid for being in this study?

You will be provided a $25 gift card for your time and effort for being in this study. You will receive the gift card if you complete the entire 4-week study.

The IRS requires that all income received be reported on your tax return. Your participation in this study does not make you an employee or agent of the study, Texas Health Resources, investigator(s), IRB or any of the companies involved in this study."

T. What if you have an illness or injury related to being in this study?

This study is about data collection and follow-up for your vital signs, medication intake, and physical activity status. Therefore, it is unlikely that you will be injured or harmed from the study activities.

Although we will use our best efforts to see that your personal information remains confidential, neither your researcher, Texas Health Resources, or Texas Woman's University, agrees to give compensation for any injury from being in the study.

By signing this consent, you do not give up any legal rights that you already have.

U. What are your rights as a human research subject?

- You have the right to refuse to participate in a research study without any penalty or loss of benefits to which you are otherwise entitled (have the right to). Taking part in this research is your choice.
- You have the right to drop out of this study at any time without any penalty or loss of benefits to which you are otherwise entitled.
- You have the right to be given important new information that may affect your willingness to stay in this research.
- You have the right to ask questions at any time and have them answered as soon as possible.

Whether or not you take part in this research study or decide to leave the study, it will not affect the care you receive by your nurse practitioner or Texas Health Resources.

V. Whom do you call if you have questions or problems?

If you have questions or concerns about this study, please contact the main researcher or one of the co-researchers listed in Section A of this consent form.

If you have questions, concerns, or comments about your rights as a research subject, please contact the party listed below:

Institutional Review Board (IRB)
Texas Health Resources
Phone: (682) 236-6746
Email: irb@texashealth.org
Website: www.texashealth.org/irb

The IRB includes doctors, scientists, non-scientists, and community members. The IRB reviews, approves, and monitors all human research at Texas Health Resources. The IRB role is to review research studies in order to protect the rights and welfare of subjects taking part in research.

W. Consenting to be in this study

You understand that your participation in this study does not make you an employee or agent of the study, sponsor, investigator(s), IRB or any of the companies involved in this study.

You have read (or someone has read to you) this form, and you are aware that you are being given information about the research study named on page 1 of this form. You have been given the opportunity to ask questions and have had them answered to your satisfaction. You give your informed and voluntary consent to participating in this study. You are not giving up any legal rights by signing this form.

Future Contact: If there is other related research in the future may those persons listed on section A of this informed consent form contact you about the possibility of being in that study?

[ ] Yes [ ] No

You will be given a copy of this signed and dated consent form.

SIGNATURE BY THE SUBJECT OR THE SUBJECT'S LEGAL REPRESENTATIVE:

_____	_____	_
Name of Subject (Print)	**Signature of Subject**	**Date of Signature**

Statement of study personnel obtaining consent:

I have fully explained this study to the subject. As it applies to this study, I have discussed the study's purpose, its experimental and non-experimental procedures and interventions, the possible risks and benefits, the standard of care and research aspects of the study, the alternatives to participation, the voluntary nature of the participation, and the source of funding for the research and conflict of interest on the part of the research staff. I have invited the subject to ask questions and have answered any questions that the subject has asked.

_____	_____
Signature of the main researcher or Co-researchers	Date of Signature

APPENDIX E

Quality of Experience Survey

Quality of Experience (QoE) Survey

		Strongly disagree				Strongly agree
Content Quality						
1	The Heart Failure Health Storylines application has the functions that I expected.	1	2	3	4	5
2	I could do the same without the application.	1	2	3	4	5
3	I think the measurement tools were reliable in collecting data	1	2	3	4	5
4	I was able to identify personal health problems using this application.	1	2	3	4	5
5	It is possible for me to share information about my status with my doctor/Caregiver	1	2	3	4	5
6	I had a better quality of life by using this application	1	2	3	4	5
Security						
7	I think that this application had appropriate security methods to protect the data I entered.	1	2	3	4	5
8	I think that the data obtained with this application was sufficiently protected.	1	2	3	4	5
Ease of Use						
9	I was able to easily find what I needed while using the app.	1	2	3	4	5
10	I think that the traditional method used to track my health is more difficult than using this application	1	2	3	4	5
11	This application was useful for monitoring my vital signs and physical activity.	1	2	3	4	5
Availability						
12	I was able to access the application and its data at any time	1	2	3	4	5
Performance						
13	I think that the application could have been more efficient	1	2	3	4	5
14	This application has some errors or problems that I found while using the application	1	2	3	4	5
Appearance						
15	I found the appearance of this application adequate	1	2	3	4	5
16	I would suggest some changes or add something to this application.	1	2	3	4	5
Learning						
17	I think that the time for learning how to use the application was appropriate	1	2	3	4	5

APPENDIX F

Yamax PW-610 Pedometer


YAMAX
PW-610
10685
STEP
14:55
MODE
/ RESET
POWER WALKING
/ SELECT
/ MEMORY

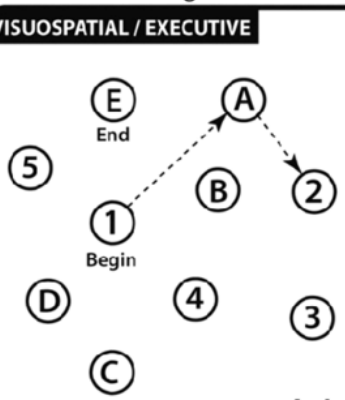
APPENDIX G

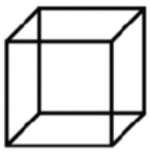
Montreal Cognitive Assessment (MoCA)

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE





Copy cube

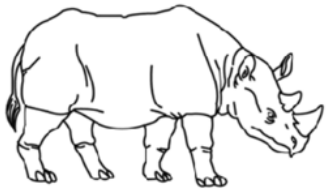
[ ] [ ]

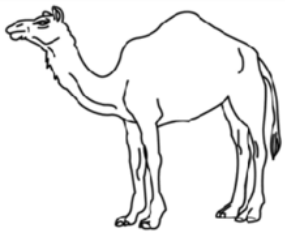
Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

POINTS __/5

NAMING





[ ] [ ] [ ]

__/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

__/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	Has to recall words **WITH NO CUE**	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

www.mocatest.org

Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

APPENDIX H

Patient Health Questionnaire – 9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

APPENDIX I

Study Flyer

YOU KNOW ...

.... that your participation in the support of scientific research is appreciated for its great impact in the development of treatment methods and improving the level of health in society, in general, and individuals with heart failure, in particular.

If you are interested to participate in our study ...
Please call us
214-689-7724
469-688-3473

Or email us:
aababneh@twu.edu

Our Address
School of Physical Therapy
5500 Southwestern Medical Ave.
Dallas, TX 75235-7299

TEXAS WOMAN'S UNIVERSITY

Self-Care Mobile Health App for Individuals with Heart Failure

TEXAS WOMAN'S UNIVERSITY
SCHOOL OF PHYSICAL THERAPY

For individuals with heart failure ..

Are you interested in using your smart phone to do the following:

- Tracking your daily vital signs
- Tracking your physical activity progress
- Managing your medications schedule

If your answer is **YES**, our study provides a free training session on how to use a mobile application for these purposes.

PURPOSE OF THE STUDY

The purpose of this study is to determine the potential benefits that individuals with heart failure (HF) could experience from using a free mobile application. The mobile application is called the **Heart Failure Health Storylines (HFHS).** This application was developed in partnership with the Heart Failure Society of America and is powered by the Health Storylines™ platform from Self Care Catalysts Inc.

STUDY REQUIREMENTS

- Attend **ONE** in-person training session for 1-2 hours at TWU-Dallas.
- 4 week commitment to complete study.
- Use HF application for approximately 15 minutes per day.
- 1-2 follow-up phone calls per week— 5 minutes each

ELIGIBILITY REQUIREMENTS

- Diagnosed with heart failure
- Own smart phone with internet access
- Able to walk independently with or without an assistive device
- ☐ Not have a neurological disorder/ disease
- ☐ Able to speak and read English

BENEFITS

Each participant in our study will:

- ☐ Receive a $75 gift card at the end of 4 weeks
- ☐ Receive a pedometer (an instrument for recording the number of steps taken per day)
- ☐ Be able to track and share health data with your healthcare provider.
- ☐ Be offered the opportunity to receive the results of the study upon completing the study

APPENDIX J

Calls Script for HF screening

HFHS Project - Calling Script for Screening

Greetings	**If no answer:** leave a voicemail as the introduction and purpose of the call. Please return our call and leave a message including a convenient time we can reach you. Our phone number is___. Thank you and have a nice day. **OR:** Good morning/Good evening.
Introduction	My name is ___, and I am from the Texas Woman's University. This call is about the heart failure study. May I Speak with Mr. /Ms. _____? If the prospective participant is not available: Is there a better time for me to call back and talk to Mr./Mrs._____?
Purpose of calling	Thank you, I understand that you expressed an interest in participating in our study. First, I would like to know whether you have a question(s) about the study or you would like to hear a brief description about the study. Then, we will ask you a few questions to see if you qualify for the study.
Getting initial approval	If you don't mind, do you have about five minutes to answer some questions? If no: Is there a better time that I can call you again?
Screening	**Do you have a smart phone with internet access?** If yes: Is it an Android or iPhone? If no: Thank you for your time however you do not qualify for our study at this time. **I'm going to read a list of 5 words, can you repeat them back to me?** ***Face, velvet, church, daisy, red.*** **Do you experience shortness of breath while resting in a sitting or lying position?** If yes: RED Message. **Are you able to walk without someone helping you?** If no: RED Message. **Do you have any uncorrected vision or hearing problems?** If yes: RED Message. **Do you have a heart condition called ventricular arrhythmia? If yes, is it controlled?** If uncontrolled: RED Message. **Are you able to read and write in English?** If no: RED Message. **Have you previously been diagnosed with a neurological condition such as stroke, Parkinson, multiple Sclerosis?** If yes: RED Message. **Can you tell me today's date including month and year?** If no: RED Message. **Can you recall the list of 5 words I said earlier?** If no: RED Message.
Schedule	Thank you for answering our questions. Based on this screening, we would like to schedule the initial evaluation and education session with you. The session will be at Texas Woman's University – Dallas Campus. During the next two weeks, this is our availability: _____. Does any of these times work for you? I will text you the address of our Dallas campus and the specific direction to our campus. The campus has an 8-floor building, a parking garage, and a free visitor parking lot next to the building. The distance from the parking lot to the main entrance of our building is about 2 to 3 minutes of walking. Most of the distance is covered.

APPENDIX K

Medical Intake form

Medical Intake Form

Basic information:

ID:		Date:	
Last Name:		First Name:	
DOB:		Age:	
Gender:		Ethnicity:	
Weight (lb.):		Height (in):	
HR Rest:		BP:	
Level of education:		Date of Diagnosis	

Medical History:

- ☐ Osteoporosis
- ☐ High/low blood pressure
- ☐ Chest pain/ palpitation
- ☐ Shortness of breath
- ☐ Gout
- ☐ Rheumatoid arthritis
- ☐ Anemia
- ☐ Tuberculosis
- ☐ Thyroid problems
- ☐ Kidney problems
- ☐ Asthma / bronchitis / pneumonia
- ☐ Latex allergy
- ☐ Stroke
- ☐ Other neurological disorder
- ☐ Cancer
- ☐ Joint replacement/ repair
- ☐ Severe headaches
- ☐ Poor balance / recent falls
- ☐ Dizziness / vertigo / blackouts
- ☐ Seizers
- ☐ Circulation problems in lower legs
- ☐ Liver problems
- ☐ Fever
- ☐ Night pain
- ☐ Sudden Weight loss
- ☐ Other _____

Do you have a pacemaker or other cardiac device? Yes No

Do you work? Yes No Retired If yes, what do you do? _____

Do you currently use or have previously used (smoke or chew) tobacco? Yes No If no, Date stopped _____

Exercise? Yes No

- Duration _____ Frequency _____ Type_____
- How many blocks can you walk at regular pace without stopping? _____
- What makes you stop? _____
- How many flights of stairs can you got up without stopping? _____

What time of the day do you prefer to call you? _____

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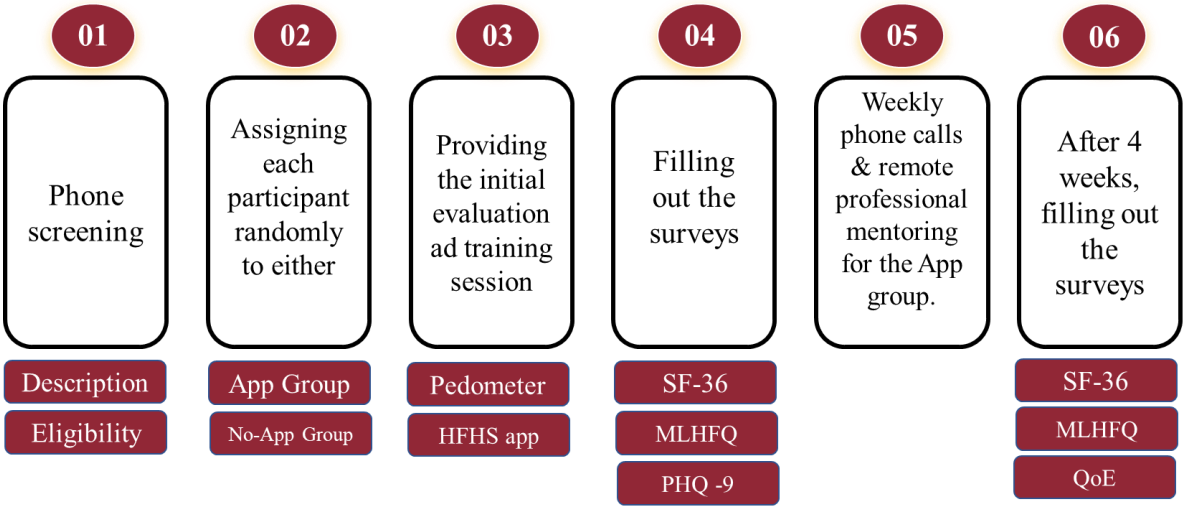
Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

APPENDIX L

Study Procedure


01
Phone screening
Description
Eligibility
02
Assigning each participant randomly to either
App Group
No-App Group
03
Providing the initial evaluation ad training session
Pedometer
HFHS app
04
Filling out the surveys
SF-36
MLHFQ
PHQ -9
05
Weekly phone calls & remote professional mentoring for the App group.
06
After 4 weeks, filling out the surveys
SF-36
MLHFQ
QoE

APPENDIX M

Calling and Texting script for follow-ups

HFHS Project - Calling & Texting Script for Follow-up

The research team will text the participant from the app to follow up 2 days later and ask the following questions:

Did you visit your doctor or health-service provider recently?
If you went to your doctor or health-service provider:

- *Was it a routine visit?*
- *Was it because of your worsening signs and symptoms?*
- *How did you know that your signs and symptoms were worsening?*

If no response to the text, the research team will call the participant to follow up 3 days after original alert message and ask the following questions:

Hi my name is _____ from Texas Woman's University's heart failure study. May I ask who I am speaking with?
• If prospective participant is not available: Is there a better time to reach __?
• If no answer leave voicemail: Hi my name is _____ from Texas Woman's University's heart failure study. I am calling in regard to the alert message sent 3 days ago. I have a few questions for you. Please call back or text at ___-___-___.
I am calling in regard to the alert message sent 3 days ago. I have a few questions for you:
[R is one of the research team, and P is the participant]
R: Did you visit your doctor or health-service provider recently?
P: Yes OR No. If the answer is yes, the next question is:
R: Is it a routine visit?
P: Yes OR No, if the answer is no, the following question is:
R: Is it because of your worsening signs and symptoms?
P: Yes OR No. If the answer is yes, the following question is:
R: How did you know that your signs and symptoms are worsening?
P: [one of the potential answers is the "alerting messages"]
Thank you, have a great day.

For Control group:

Weekly calling for data collection (# of steps)

Hi my name is _____ from Texas Woman's University's heart failure study. May I ask who I am speaking with?
If prospective participant is not available: Is there a better time to reach __?
If no answer leave voicemail: Hi my name is _____ from Texas Woman's University's heart failure study. Please call back or text at ___-___-___.
I am calling to collect your number of steps for each day of the previous week.

Last phone call: Weekly calling plus the following

Over the past four weeks, have you been admitted to the hospital? If yes, what was the reason for this admission?
Over the past four weeks, have you been to the doctor? If yes, how many times have you been to the doctor? What is the reason for these visits?

APPENDIX N

Data Collection Sheet for the interventional group.

Data Collection Sheet for App Intervention Group

Participant ID: _____ **Starting Date _____**

A. Daily Step Counts

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Notes
Week 1								
Week 2								
Week 3								
Week 4								

B. Frequency of Data Entry on HFHS App.

(√) indicates the data has been entered, (χ) indicates the data has **NOT** been entered.

	Parameter	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Week 1	HR							
	BP							
	Weight							
	Meds							
Week 2	HR							
	BP							
	Weight							
	Meds							
Week 3	HR							
	BP							
	Weight							
	Meds							
Week 4	HR							
	BP							
	Weight							
	Meds							

C. Number of the alert messages

Week 1: _____ Week 2: _____ Week3: _____ Week 4: _____

D. Number of Physician Visits

Prompted by the Alert Messages _____

Regular Physician Visits _____

APPENDIX O

Participants' feedback on using the HFHS app

Participants' feedback on using the HFHS app

Things the participants liked about using the HFHS app in this study

- Many participants were pleased to have all their health information in one place (the HFHS app) to take with them to doctor's appointments
- Some participants appreciated the monthly summary data compilation that the HFHA app offers.
- Many participants appreciated the detailed user manual that the team provided describing the HFHS app's widgets.
- Some participants wanted to keep using their accounts to continue tracking their health parameters after the study's conclusion.
- Several participants expressed the influential role of the initial individual training the team provided in facilitating their use of the HFHS app, especially for those who were not tech-savvy.
- Some participants felt that knowing they had a pedometer, it motivated them to walk more throughout the day

Challenges and suggestions from our research participants

- Some participants often thought they saved their data after hitting the save button on the HFHS app, but in fact, the data wasn't stored due to lag times.
- Some participants did not like the multistep process of logging their information on the HFHS app, especially the daily steps count.
- Some participants complained of difficulty in keeping the pedometer with them when they were wearing pocketless clothes.
- Many participants were looking forward to having exercise prescription and aerobic goals for their daily walking from the research team but stated they would have enjoyed it if the study incorporated it.
- Some participants suggested using sensor devices (body weight scale, BP monitor, …etc.) synchronizing with the HFHS app to avoid the multistep process of logging their data. One participant shared her experience using a different application to track vital signs and weight, which was more user-friendly.