Cardiac Rehabilitation Adherence Rates in Elderly Patients Using a Mobile Application

Amanda Wilson
Yale Physician Associate Program, amanda.wilson@yale.edu

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CARDIAC REHABILITATION ADHERENCE RATES IN ELDERLY PATIENTS USING A MOBILE APPLICATION

A Thesis Presented to
The Faculty of the School of Medicine
Yale University

In Candidacy for the degree of
Master of Medical Science

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Amanda Wilson, PA-SII
Class of 2022
Yale Physician Associate Program

Robert L. McNamara, MD, MHS
Professor of Medicine
Department of Medicine
Yale University
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ABSTRACT

Adherence to cardiac rehabilitation reduces cardiovascular disease mortality. Despite this, adherence rates remain suboptimal especially among older patients. Mobile applications are increasingly utilized to deliver virtual healthcare with similar health outcomes. However, no studies have determined whether cardiac rehabilitation delivered via mobile applications can increase adherence rates in elderly patients who may be limited by logistical barriers, such as difficulties with transportation. **The aim of this study is to examine whether cardiac rehabilitation conducted via mobile application can increase adherence rates to cardiac rehabilitation in patients over 65 years old compared with traditional cardiac rehabilitation.** We will conduct a randomized, controlled trial to evaluate the number of mobile application-based cardiac rehabilitation sessions patients attend in the intervention group versus facility-based sessions in the control group. This study will provide insight into the value of virtual cardiac rehabilitation, specifically for geriatric patients.
CHAPTER 1: INTRODUCTION

1.1 Background

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality globally.\textsuperscript{1-4} CVD, which includes coronary heart disease, cerebrovascular disease, and peripheral vascular disease, disproportionately affects the older population, causing approximately one-fourth of deaths in patients over the age of 65 years.\textsuperscript{5} Elderly patients are generally more physically inactive than younger patients and, once diagnosed with a CVD, physically decline at a faster rate than their younger counterparts. This makes them more vulnerable to falls, disability and complications.\textsuperscript{6} The burden of cardiovascular disease impacts the lives of millions of elderly Americans each year, resulting in an increased likelihood of rehospitalizations and a large financial burden on geriatric patients and their families.\textsuperscript{7} Even more concerning is the rate of rehospitalization following an initial cardiac event, such as a myocardial infarction, as up to half of patients will be hospitalized again within the first year.\textsuperscript{7,8} Therefore, there has been increased clinical emphasis placed on secondary prevention measures.\textsuperscript{9}

Secondary prevention measures, intensive risk-reduction therapies for patients with established coronary and atherosclerotic diseases, are aimed at reducing recurrent CVD disease burden and preventing cardiovascular disease related deaths and rehospitalizations.\textsuperscript{8,10} They improve survival, reduce recurrent cardiac events and improve quality of life in patients with cardiovascular disease.\textsuperscript{8,10} This is done by managing risk factors such as blood pressure, lipid levels, weight, smoking frequency, and depression while encouraging a consistent exercise routine.\textsuperscript{9,10}
Cardiac rehabilitation (CR) is a systematic, multi-disciplinary approach to providing secondary cardiovascular prevention measures.\textsuperscript{8,11,12} It promotes strategies to optimize cardiovascular risk reduction, foster positive psychosocial behaviors and encourage healthy lifestyles for patients as they recover from a cardiac event.\textsuperscript{8} CR is a longitudinal rehabilitation program that is divided into 3 phases. Phase 1 occurs while the patient is recovering in the hospital.\textsuperscript{13} Phase 2 typically begins within 1-2 weeks following hospital discharge and, in the United States traditionally occurs over the course of 36 sessions within 12 weeks.\textsuperscript{14} Phase 3 is considered maintenance cardiac rehabilitation and continues indefinitely and independently upon conclusion of Phase 2.\textsuperscript{14}

CR focuses on low intensity physical activity to help patients recover from recent hospital admission for various cardiac events such as myocardial infarction, coronary artery bypass graft (CABG) surgery, or percutaneous coronary intervention (PCI).\textsuperscript{11,12} While primarily focusing on increasing cardiovascular fitness through exercise, cardiac rehabilitation programs also utilize patient assessments and counseling strategies to manage other cardiovascular risk factors such as hypertension, smoking cessation, optimization of psychosocial health, medication adjustments/adherence, and weight management.\textsuperscript{11}

Cardiac rehabilitation is highly recommended following many kinds of cardiac injury. According to the American College of Cardiology (ACC) and American College of Cardiology Foundation (ACCF), cardiac rehabilitation is a Class Ia recommendation after myocardial infarction, indicating it should be administered following recent MI or acute coronary syndrome, post-CABG or post-PCI procedure.\textsuperscript{8} It is also indicated in patients with stable angina or Class 1 or 2 heart failure, according to the New York Heart
Association (NYHA) heart failure classification system. Cardiac rehabilitation reduces cardiovascular events, increases patient’s functional capacity and improves psychosocial health. Additionally, it has been shown to have a significant morbidity and mortality benefit with a 13-24% reduction in total mortality over 1 to 3 years and a 31% decrease in rehospitalization within 1 year. However, most studies regarding cardiac rehabilitation have been performed in a population composed of predominantly middle-aged, low-moderate risk, white men. There is a significant disparity in data about the elderly population; however, the limited data that do exist suggests poor adherence due to increased numbers of barriers to CR adherence.

Despite the proven mortality benefit, adherence rates in cardiac rehabilitation programs remain dismal, especially in patients over age 65. A 2016 observational study of Medicare beneficiaries aged 65 or older, found that only 24.4% of eligible patients participated in the cardiac rehabilitation program and only 26.9% of those who did participate actually completed >36 sessions; the standard number of sessions covered by insurance companies in the United States. Incomplete adherence is significant as those beneficiaries over age 65 who attended >25 sessions were relatively 19% less likely to die over 5 years than matched CR users who attended <24 sessions (p<0.001). Only 56.7% of participants utilized >25 sessions, with an average of 24.8 of 36 sessions utilized; demonstrating a significant drop-off in adherence about two-thirds of the way through the program. However, it was shown that patients who attend 36 sessions have a 14% lower risk of death and a 12% lower risk of myocardial infarction than patients who attended 24 sessions. Due to the dose-dependent effect seen, it is imperative to investigate strategies to increase adherence to CR programs.
There are a multitude of factors that have been evaluated as reasons for lack of adherence to cardiac rehabilitation such as cost burden of co-pays, transportation to programs, return to work expectations and time limitations. In the geriatric population, there are unique barriers to adherence such as difficulties driving, increased comorbidity burden, and already established home exercise routines. Of note, older age was significantly related to a higher number of CR barriers (<65y: 2.4 +/-1.0. vs >65 2.6 +/- 1.0, p<0.001). As patients age, they face more barriers to attending in-person cardiac rehabilitation, due to both patient-centered and system-centered factors. Nonetheless, these barriers need to be addressed to improve adherence to CR.

To increase adherence to cardiac rehabilitation programs and subsequently decrease CVD mortality, it is important to assess these reasons for dropout and make sustainable changes to the program that address some of the barriers to adherence. One method that has been shown to increase adherence rates is home-based cardiac rehabilitation (HBCR), which decreases transportation burden and increases scheduling flexibility. The core components of HBCR are similar to those that have been recommended for facility-based cardiac rehabilitation: patient assessment, exercise training, dietary counseling, and risk factor control through optimal adherence to medication, behavioral activation and psychosocial interventions. The primary difference between the two programs is that facility-based CR programs require direct face-to-face observation of patients, whereas HBCR programs do not. A more recent development in home-based cardiac rehabilitation has been the utilization of mobile technology as a tool for patients to perform cardiac rehabilitation without direct supervision from a medical professional.
Mobile health technology has become a useful method for delivering home-based healthcare, particularly during the COVID-19 pandemic when many healthcare facilities transitioned to virtual healthcare. Mobile health (m-Health) is defined as the medical and public health practice supported by mobile devices such as mobile phones, patient monitoring devices, and personal digital assistants. It has the potential to help overcome some of the barriers that patients face with adhering to traditional cardiac rehabilitation such as difficulty with transportation, time flexibility and established home exercise routine.

In the United States in 2020, it was estimated that 61% of adults over age 65 years owned a cell phone, with this age demographic being the fastest growing market for smartphone use. Recently, there has been a dramatic increase in the number of mHealth related applications available to users, as over 250,000 applications are available for download on the Apple iTunes app store, many of which are tailored for CVD management. This influx of health information and availability that patients have makes mHealth a feasible and patient-centered option for delivering cardiac rehabilitation services to patients who may otherwise have barriers to in-person attendance.

In October 2020, the Center for Medicare and Medicaid service (CMS) temporarily approved video-based cardiac rehabilitation under a COVID-19 Public Health Emergency order that is eligible until December 2023, ensuring that cardiac telerehabilitation is covered under insurance for patients. The wide utility of mobile technology may play a beneficial role in increasing adherence rates in cardiac rehabilitation programs by transitioning programs to a home-based method. New technological advancements, such as app-based models, are being trialed and have shown
similar efficacy in major cardiac rehabilitation outcome measures, thus providing a potential CR option for elderly patients with barriers to traditional CR. \(^{30}\)

1.2 Statement of Problem

Cardiac rehabilitation has been shown to be an effective secondary prevention method to help patients achieve these goals following a cardiac event; however, patient adherence is sub-optimal, with an average completion rate of 66.7\% of sessions. \(^{14,20,31}\) In the geriatric population, adherence rates are even lower, with only 56.7\% of patients completing two-thirds of the sessions. \(^{21}\)

Mobile health applications have been widely developed for use in the cardiology specialty and have shown promise in feasibility studies as effective and safe methods for providing cardiac telerehabilitation. This is in an effort to increase adherence to CR and provide an alternative option for patients utilizing cardiac rehabilitation. \(^{32-34}\) As the general population continues to age and smartphones become more prevalent in the geriatric population, the value of mHealth applications for delivering virtual healthcare will continue to grow, especially in cardiac rehabilitation.

While there have been studies evaluating the use of mobile applications as the primary tool to provide home-based cardiac rehabilitation, most of these studies were conducted in a younger population, averaging 55-64 years old. \(^{35-37}\) However, mobile applications may have the potential to narrow the gap between adherence in the middle-aged and elderly populations. No studies have evaluated the utilization of a mobile application for cardiac rehabilitation in an elderly population. Therefore, more research is needed to determine whether cardiac rehabilitation conducted via mobile application would facilitate increased adherence rates in this population.
1.3 Study Goals and Objectives

The primary objective of this study is to assess program adherence rates by evaluating the number of sessions completed out of a 36-session program within 6 months in elderly patients that are randomized to either a mobile application-based cardiac rehabilitation program or a standard, facility-based program. Secondary outcomes of this study will measure functional capacity via peak VO2 and health-related quality of life via SF-36 questionnaire.

The primary goal of this study is to determine if cardiac rehabilitation via a mobile application can increase cardiac rehabilitation adherence rates in a population of elderly patients, age 65 and older by eliminating barriers to traditional CR attendance such as transportation and accessibility.

1.4 Hypothesis

In elderly patients, age 65 and older, with a myocardial infarction within the past 12 months, history of coronary artery bypass graft surgery, percutaneous coronary intervention, stable angina, or stable heart failure there will be a statistically significant absolute difference in proportion of cardiac rehabilitation (CR) sessions completed out of a total of 36 sessions within a maximum time of 6 months in patients who utilize a mobile application based cardiac rehabilitation program versus patients who attend facility-based CR.

1.5 Definitions

Stable heart failure: New York Heart Association Functional Class I (no limitation of physical activity) or II (slight limitation of physical activity).\textsuperscript{38}
**Stable angina:** Chest pain that occurs upon exertion, mental stress, and/or exposure to cold and usually subsides within 20 minutes of rest or after administration of nitroglycerin.\(^{38}\)

**Myocardial infarction:** Damage or death of an area of the heart muscle resulting from a blocked blood supply to that area.\(^{38}\)

**Coronary artery bypass graft:** A surgical procedure that treats blocked arteries by creating new passages for flow to the heart muscle.\(^{38}\)

**Percutaneous Coronary Intervention:** A procedure that utilizes tubing with an attached, deflated balloon threaded up to the coronary arteries. It is then widened to blocked areas where blood flow to heart muscle has been reduced or cut-off and often implanted with stent to keep artery open.\(^{38}\)

**Adherence:** Completing a number of sessions over the period of assessment.
1.6 References


29. Ravi Choxi DJK, MD; Mahmoud Al Rifai, MD, MPH; Jaideep Patel, MD, FACC; Michael D. Shapiro, DO, FACC. Cardiac Rehabilitation and Implications During the COVID-19 Era. *American College of Cardiology.* 2021.


CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

A systematic review of the literature was performed between May 2021 and June 2022 using PubMed, Scopus, Cochrane, and Ovid databases. Primary searches were conducted using the MeSH terms “cardiac rehabilitation”, “cardiac telerehabilitation”, “patient participation”, “patient compliance”, “telemedicine”, “treatment adherence and compliance”, “ehealth”, “mhealth”, “digital divide”, “elderly”, and “geriatric.” See Appendix A for further detail on search terms. Relevant articles were primarily published in the English language between 2001 and 2022, with one outlier study published in 1957, defining cardiac rehabilitation. Preference was given to clinical studies, meta-analyses, systematic reviews, and studies written in the last 10 years.

2.2 Review of Empirical Studies

2.2.1 Dose-dependent Relationship Between Adherence to CR and Health Outcomes

Traditional cardiac rehabilitation has been shown to be safe and effective in multiple randomized controlled trials and systematic reviews. However, adherence rates have been suboptimal, averaging a 66.7% participation rate in the general population and an even lower participation rate of 56.7% in the geriatric population. To date, there have been six studies that analyzed the relationship between number of cardiac rehabilitation sessions attended and all-cause mortality and associated morbidity. These six studies cohesively demonstrate the dose-dependent relationship between attendance at cardiac rehabilitation sessions and all-cause mortality, rehospitalizations and major adverse cardiac events (MACE) in long term outcomes among patients, demonstrating a 13-34% reduction in risk of mortality overall.
Two studies, a prospective cohort study by Whellan et al.\textsuperscript{11} and a retrospective cohort study by Kuo et al.\textsuperscript{7} reported lower all-cause mortality with only 6 sessions. This was a significantly lower number of sessions needed to see a result compared with other studies analyzing a similar outcome. However, a propensity matched study of 70,040 Medicare beneficiaries performed by Suaya et al. reported a 5 year all-cause mortality relative reduction of 34% with >24 sessions completed as compared with nonusers.\textsuperscript{10}

Another study performed by Doll and others concluded that for every 5 sessions attended, there was a 13% lower mortality (adjusted hazard ratio [HR] 0.87, 95% CI 0.83-0.92), 31% lower overall risk of major adverse cardiac event (adjusted HR 0.69, 95% CI 0.65-0.73) and 21% less risk of death/readmission (adjusted HR 0.79, 95% CI 0.76-0.83).\textsuperscript{8} This study showed a significant dose-dependent relationship between number of sessions attended and morbidity and mortality outcomes.

Most recently, a population based cohort study of 2,507 patients with an average age of 64.3 years showed a statistically significant decreased risk of MACE in patients who attended >20 sessions out of a total of 36 prescribed sessions.\textsuperscript{6} Those who attended an average of 2 sessions per week (approximately 24 of 36 prescribed sessions) were at a 26% decreased risk of a MACE (HR: 0.74 [95% CI, 0.58-0.94]; p=0.010).\textsuperscript{5} While these studies demonstrate the significant importance of attending cardiac rehabilitation, there is still a persistent lack of adherence to these traditional programs for various reasons.\textsuperscript{12} There is a need to address the barriers to CR adherence in order to help limit the long-term morbidity and mortality effects that poor adherence to cardiac rehabilitation can have.
2.2.2 Barriers to Traditional CR Adherence in the Geriatric Population

Studies conducted in the United States and abroad have primarily assessed barriers to adherence to cardiac rehabilitation in the general population, with one study specifically focusing on the geriatric population.\textsuperscript{12-15} The studies obtained within the scope of this review demonstrated that increasing patient age was associated with an increased total number of CR barriers.\textsuperscript{12,13,15} Primary barriers to CR adherence for the geriatric population were transportation difficulties and increased number of comorbidities.\textsuperscript{5,12} Both of these barriers to CR adherence may be addressed by mobile application-based CR as it provides a mobile and flexible option for patients unable to drive or who may be limited by other health conditions.

A cross-sectional study by Grace and others concluded that the geriatric population has an increased number of barriers to cardiac rehabilitation adherence as compared with a younger population.\textsuperscript{12} Barriers to adherence for older patients included increased number of comorbidities and the understanding that patients were already exercising at home. This study utilized a standardized survey in a population of 535 participants to quantitatively investigate barriers to CR participation by age and analyzed specific barriers in the geriatric population. The survey assessed 18 CR barriers that patients may face using a 5-point Likert scale from “strongly disagree” to “strongly agree” with higher scores indicating that item was a barrier. Total number of CR barriers were significantly related to age, as older patients endorsed more barriers to attendance than younger patients (<65y: 2.4 +/- 1.0. vs >65 2.6 +/- 1.0, p<0.001) Utilizing Pearson correlations, barriers that older patients strongly endorsed included: already exercising at home (P=0.001) and other health problems that prevent them from attending (P<0.001).\textsuperscript{12} This study demonstrates that the geriatric population has more barriers to adherence to CR, some of
which could be modifiable through the implementation of a home-based, mobile application program.

Two hundred seventy nine patients with an average age 64.8 years old participated in a cross-sectional study by Dunlay et al. that measured the association between program adherence and reasons for lack of adherence to CR using logistic regression analysis. Clinical characteristics associated with increased CR participation included younger age (OR 0.95 per 1 year increase), male sex (OR 1.93) and the ability to drive (OR 6.25), among other factors. This study demonstrated the association between increased CR adherence and younger age, consistent with prior studies. Additionally, it demonstrated that transportation difficulties may be a limiting factor for patients. This is a key barrier that virtual cardiac rehabilitation can address.

As discussed, common reasons for lack of adherence in the geriatric population includes restricted mobility due to increased number of comorbidities, transportation difficulties, and patients reporting they already exercise at home. These factors specifically may be better addressed via mobile application, home-based cardiac rehabilitation and provides an opportunity for patients to overcome some of the challenges inherently associated with traditional ambulatory CR facilities by completing CR from home.

2.2.3 mHealth Applications and Adherence in Other Medical Conditions

Mobile health applications are being used more frequently to manage various medical conditions. They have been shown to increase adherence rates without sacrificing beneficial health outcomes in many different chronic medical conditions.

In a systematic literature review of 10 studies evaluating the effects of mobile health applications and various telehealth strategies on medication adherence in patients with a prior cerebrovascular accident, there was a statistically significant difference in medication adherence.
between the mHealth technology group and the usual care group (mean difference 0.67, 95% CI [0.49-0.85], p<0.001).\textsuperscript{20} Additionally, in a sub-group analysis, the medication adherence ratio was statistically significant in the mHealth technology group (odds ratio 4.05, 95% CI [2.10, 7.80], p<0.001). However, no significant difference was found in medication adherence ratios between the two groups whose intervention was a telephone call (odds ratio 1.97, 95% CI [0.55, 7.06], p=0.30).

A randomized controlled trial by Kim et al. studied the effects of utilizing a blood pressure monitoring device and mobile application for monitoring and education on medication adherence, smoking cessation, and blood pressure control in a population of 95 patients with mean age 58 years.\textsuperscript{21} Improvement in cigarette smoking (baseline 16.5 +/- 9.3 cigarettes per day vs at 6 months 2.6 +/- 7.3 cigarettes per day, p<0.001) and blood pressure control were observed at 6 months. However, there was no significant difference in medication adherence (baseline 6.6+/-.1.4 on Morisky Medication Adherence Scale vs at 6 months 6.7 +/- 1.4, p=0.79). This was the only study that demonstrated no significant difference in medication adherence with the use of a mobile application. However, in this study, the population had a high level of health literacy at baseline, as they were hospital employees and families, and the median Morisky Medication Adherence Scale (MMAS) score was of 7.0 out of 8.0. This indicated a relatively medium to high adherence at baseline for both the control and the intervention groups which limited the ability to show statistical differences.

A large randomized controlled trial (RCT) of 412 patients of mean age 52 by Morawski et al., aimed to determine if the Medisafe application improves self-reported medication adherence and blood pressure control. The smartphone application was designed to send medication reminder alerts, adherence reports and provide optional peer support for patients in the
intervention group. After 12 weeks, the mean (SD) score on the MMAS increased by 0.4 (1.5) among intervention participants with no change observed within the control group (between group difference: 0.4; 95% CI, 0.1-0.7; p=0.01). Additionally, after 12 weeks, the mean MMAS (SD) systolic blood pressure decreased by 10.6 (16.0) mmHg among intervention participants and 10.1 (15.4) mmHg among controls (between group difference: -0.5; 95% CI, -3.7 to 2.7; p=0.78). This study demonstrated that smartphone utilization may improve self-reported medication adherence. However, intervention participants did not demonstrate a significant change in systolic blood pressure compared with controls despite reporting higher adherence.\textsuperscript{19} The lack of BP increase in the intervention despite improvement in medication adherence could have been due to fluctuations in home BP machines that patients were using to monitor their BP. Overall, these studies demonstrate a modest improvement in medication adherence with the use of a mobile application. This supports the notion that healthcare delivered via mobile applications may increase adherence and possibly improve health outcomes.

In addition to improvements in medication adherence, mobile applications have shown promising results in adherence to other types of rehabilitation programs. A pilot study by Hoaas et al. assessed adherence rates to long-term telerehabilitation in a population of patients with chronic obstructive pulmonary disease and demonstrated increased adherence for the first three months of the study. However, there was decreased adherence in the subsequent 1.75 years.\textsuperscript{23} On average, participants had 2.1 training sessions per week (69.1\%) in the first year and 1.2 sessions per week (40.5\%) in the second year. This may demonstrate the initial motivation and excitement patients exhibits in rehabilitation which wanes over time.\textsuperscript{23}

In a parallel design RCT, 50 patients with obesity were randomized to a telerehabilitation group or standard metabolic rehabilitation group to assess whether a telerehabilitation program
can improve adherence to the rehabilitation program and impact body composition, exercise capacity, and quality of life.\textsuperscript{24} This study by Bughin et al. demonstrated that the use of a comprehensive mobile application for telerehabilitation can have a significant effect on quality of life in patients with obesity. Physical and psychosocial components of EQVOD QOL questionnaire were statistically significantly improved by +9.4 (SD=14.1, p=0.005) and +6.4 (SD 11.7, p=0.02), respectively. Sufficient adherence (95\%) was maintained throughout the study.\textsuperscript{24} Mobile health applications are being utilized with increased frequency as tools to help increase adherence to various medication regimens and rehabilitation programs.\textsuperscript{20,23,24} They have been shown to be useful resources for patients as feasible and safe options to help patients participate in their own medical care. Mobile applications have shown promising results in their ability to increase adherence rates both in medication adherence as well as rehabilitation programs and should be considered for further use in cardiac rehabilitation.

2.2.4 mHealth Applications and Adherence in Cardiac Rehabilitation

Recently, mHealth has been utilized more frequently as an alternative method for delivering cardiac rehabilitation. When examining adherence rates in patients attending mHealth application-based versus facility-based cardiac rehabilitation, studies have consistently shown increased adherence rates in the mobile application groups as compared to facility-based control groups. A meta-analysis published in 2019 showed that, while the use of mobile technology for cardiac rehabilitation is in the initial stage of development, it may be a useful way for improving adherence rates to CR while maintaining efficacy.\textsuperscript{25}

By analyzing eight studies, Xu et al. evaluated the effect of a mobile intervention in cardiac rehabilitation to increase adherence rates as compared with standard cardiac rehabilitation. This meta-analysis demonstrated that CR completion was 38\% higher in mobile
application-based CR than in traditional CR (RR=1.38, CI 1.16-1.65; p=0.0003). However, there were mixed results in the four quasi-experimental groups. Three studies demonstrated that mobile applications had a positive impact on CR adherence while a single outlier study demonstrated no difference between intervention and control groups in number of CR sessions attended (29.0 +/- 3.8 vs 30.7 +/- 4.1, p=0.77). Of note, these studies were not randomized, and patients participating may be inherently motivated to adhere to both interventions. Overall, this review demonstrated a significant increase in adherence in CR among patients with CVD, those ages 55-66 years old, when utilizing a mobile application for CR delivery. While there are no studies that examine adherence rates specifically in the geriatric population, these studies show increased adherence rates in other age groups which shows promise that geriatric populations may benefit from using mobile applications as well. Considering the geriatric population is at a greater mortality risk and has higher incidence of CVD, this population should be examined further.

There are three additional studies that have impacted the future utility of mobile applications in cardiac rehabilitation. Varnfield et al. was one of the first to utilize a RCT to study the effects of a text-based cardiac rehabilitation program on post-myocardial infarction patients. Adherence was dichotomized by defining adherence by participation for at least 4 weeks. This study determined a 26% absolute rate difference between the texting-based intervention group (94% adherence) and the traditional cardiac rehabilitation group (68% adherence). Additionally, CR completion was 33% higher in the text-based intervention group than in facility-based (RR 1.71, 95% CI 1.30 to 2.27, p<0.05). While the study was not large enough to display statistical significance for the functional outcomes, it revealed that patients using a smartphone-based texting and website platform for cardiac rehabilitation had similar
improvements in functional capacity, healthy dietary habits, lipid control, and psychological health both at 6 weeks and at 6 months.\textsuperscript{4} A limitation of this study was that the study population was limited to patients who had recently experienced an MI.\textsuperscript{4}

A single center, prospective RCT of 100 patients who underwent catheter ablation for atrial fibrillation compared adherence rates for patients assigned to a tele-monitored cardiac rehabilitation program with those in a standard program. Adherence was measured as mean number of weeks completed out of a total of 12. Adherence was significantly different between groups (9.6+/−3.1 of 12 weeks= 80.4% +/-26.1%) vs control (5.0+/−3.8/12wks=42%+/−31.6%). While this study demonstrated a significant improvement in adherence between the mobile application CR and control, it was limited by a small sample size and narrow inclusion criteria as patients were required to have been treated for atrial fibrillation.\textsuperscript{26}

In a recent propensity score-matched study of 401 patients by Imran et al., patients were assigned to either a mobile application plus cardiac rehabilitation or cardiac rehabilitation alone. Patients in the mobile technology CR group attended a higher number of prescribed sessions (mean 28/33 vs 22/32, RR=1.17, 95% CI, 1.05-1.31, P=0.009). Patients attending cardiac rehabilitation alone attended 66% of sessions while patients utilizing the mobile application plus traditional rehabilitation had an 85% adherence rate.\textsuperscript{27} While this study was effective at assessing the adherence rates in a mobile application-based cardiac rehabilitation group, the average age was younger than our intended population (average age 59 years old) and the intervention utilized mobile application-based CR as an adjunct to CR rather than a solitary intervention. These three studies are at the forefront of mobile application-based cardiac rehabilitation and demonstrate an increased adherence to a mobile application-based intervention method, making this approach a feasible option to continue to expand into a study with an older population.
2.3 Review of Possible Confounding Variables

Despite utilizing randomization to minimize differences between groups, there is still a chance that unknown confounding may occur. The main confounding variables that this study will account for are electronic health (eHealth) literacy, education status, gender, race/ethnicity, number of comorbidities, and average transportation time. Our proposed RCT will assess any imbalance between two randomized groups using multivariate analysis, if necessary.

Ehealth Literacy

Between 2000 and 2016, internet use among the elderly increased 67% in the United States and currently 61% of Americans aged 65 and older own a smartphone. Based on a systematic review by Neubeck et al., the fastest growing demographic to be utilizing smartphones is that comprised of people 65 and older, most likely due to enhanced usability and increased availability. Despite this recent exponential growth of internet and smartphone use in elderly adults, a digital divide remains among the elderly. Studies have examined this divide by characterizing eHealth literacy. EHealth literacy, or the ability to seek out, assess, and use health-related information on the internet to find a solution to a health problem, is considered an important factor for preserving health status and thus an important aspect to preserve a healthy lifestyle in seniors.

A 2022 systematic review of 24 studies by Xie et al. found that eHealth literacy was relatively lower in older adults and that higher eHealth literacy was associated with better health knowledge and better outcomes. Twenty of 24 studies used an 8 item, clinically validated survey, eHEALS (eHealth Literacy Scale) to assess eHealth literacy which analyzed six core components required to fully engage with eHealth promotion and care: computer, information,
media, traditional, scientific and health literacy. Low e-Health literacy was considered a score of 26/40 or lower. Limitations to this study include the study designs, as most were cross-sectional and therefore only assessed patients at a point in time. This systematic analysis provides insight into the design of our study, demonstrating the importance of considering a patient’s eHealth literacy prior to initiating the study in order best set the patient up for success. This is why we will assess patient’s eHealth literacy utilizing the eHEALS survey at baseline (Appendix B).

The eHEALS was clinically validated by Norman et al. and shown to have modest stability over a period of 6 months (intra-class correlation of 0.49). It was designed to provide a general estimate of consumer related eHealth literacy skills that can be used to inform clinical decision making. To ensure safe and active engagement with the CR program, participants with an eHEALS score of 26 or lower will be excluded from the study.

**Education status**

Education status has also been shown to correlate with lower eHealth literacy, subsequently impacting patient’s ability to participate in mobile-application rehabilitation. A cross-sectional study by Berkowsky et al. assessed eHealth literacy in patients average age 73 years by utilizing an amended version of the eHEALS. They demonstrated a significant positive association between education level and eHealth literacy, indicating that a higher education level was more likely to score higher on eHEALS. This study showed that education was one of the most frequent predictors of low eHealth literacy and patients with lower education levels may benefit from increased interventions and online teaching. While this is an important factor to be aware of in the geriatric population participating in mobile application-based CR, our study will address this by including a 1-hour teaching session prior to initiating the study and requiring a baseline eHEALS score of 26/40 for inclusion in this study.
Gender

Women have notability been found to have lower adherence rates to cardiac rehabilitation once enrolled. In a large Medicare study, female gender negatively predicted adherence to CR. In a systematic review by Oosenbrug et al., average CR adherence rate was 66.5%+/−18.2% while men adhered to 68.6% and women 64.2% of prescribed sessions (mean difference= -3.6, 95% CI -6.9 to -0.3), demonstrating a significant difference in adherence between men and women. Another mHealth specific systematic review looked at the effects of mobile health applications in cardiac rehabilitation, and found a significant gender disparity as, of the 506 total participants, only 18% were female. Women face well-established barriers to adherence that are more prevalent than men such as increased transportation difficulties, family responsibilities, and musculoskeletal issues. In this study, if gender is not equally distributed after randomization, we will assess its impact on the results in post hoc analysis.

Race/Ethnicity

Race and ethnicity also impact adherence rates to cardiac rehabilitation. A systematic review by Castellanos et al. demonstrated that most studies evaluated race and ethnicity using white, African American and non-white groups with Hispanic and Asian Americans being limited in data. Overall, there was a consistently lower CR participation rate for non-white participants compared with white participants. Suaya et al. demonstrated significantly greater participation rates in whites compared with nonwhites (19.6% vs 7.8%) and Thomas et al. found similar results in a survey of 500 CR programs that included patients who underwent MI, PCI or CABG. The established impact of race and ethnicity on adherence to CR is a potential confounder. Similarly to gender, if participants of various races and ethnicities are not
equally distributed through randomization, we will utilize post hoc analysis to assess its impact.

**Comorbidities**

Having greater than five comorbidities has also been associated with lower adherence rates to mobile application-based cardiac rehabilitation. According to the most recent Heart Disease and Stroke Statistics by the AHA, patients with greater than 5 comorbidities have a statistically significant decrease in adherence rates to cardiac rehabilitation. This is likely due to increased transportation burden, likelihood for adverse events and concurrent management of multiple illnesses. Therefore, our study will consider it a potential confounder and account for it through post hoc analysis in the case of imbalance during randomization.

**Transportation Time to CR Center**

Finally, transportation time to cardiac rehabilitation center may limit a patient’s ability to attend CR and lead to increased adherence to mobile-application CR. Past studies have shown that increased transportation time leads to decreased CR attendance. If there is still imbalance between groups after randomization, we will account for it through post hoc analysis.

### 2.4 Review of Relevant Methodology

#### 2.4.1 Study Design and Setting:

The proposed study will be a multi-center, randomized, controlled trial. Based upon the literature review conducted to assess study designs utilizing mobile applications as an intervention for cardiac rehabilitation, there was a clear preference for randomized controlled trials. However, because mobile applications are being utilizing with increasing frequency over recent years, many studies investigating the feasibility and usability of mobile applications are currently still in the pilot phase, which used quasi-experimental studies without control groups. For our proposed intervention, a single arm, feasibility study has already been
performed by Hazard et al. using the same mobile application.\textsuperscript{52, 53} This study demonstrated that the mobile application was shown to be an effective and safe intervention, justifying a randomized, controlled trial to investigate whether this intervention can positively impact adherence rates to cardiac rehabilitation.\textsuperscript{53}

In the geriatric population specifically, there have been three studies measuring adherence rates to cardiac rehabilitation, all three of which utilized a randomized controlled trial.\textsuperscript{54-56} However, none of the interventions utilized a mobile application as an intervention. Therefore, it is reasonable to use a randomized, controlled trial to fill the gap in the literature within this population specifically.

Previous randomized controlled trials examining adherence rates in various populations have taken place at single-centers, limiting their generalizability.\textsuperscript{26, 27} Our proposed study will take place at six Yale New Haven Health-affiliated cardiac rehabilitation centers that are located in diverse neighborhoods, according to the Neighborhood Deprivation Index.\textsuperscript{57} This will increase the generalizability of our study while also accounting for confounding variables that affect cardiac rehabilitation adherence.

2.4.2 Selection Criteria

Participants included in this study will be over age 65 years who qualify for cardiac rehabilitation based off of the American Heart Association Class Ia recommendation for cardiac rehabilitation.\textsuperscript{58} Previous studies utilizing mobile applications as an intervention included participants age 18 and older, with an average age of 55-63 years.\textsuperscript{27, 48, 59} However, our study will focus on the geriatric population specifically since adults over age 65 have not been well represented in cardiac rehabilitation research yet and have a significant amount of CVD burden.
A combination of literature from traditional cardiac rehabilitation in older adults and mobile application-specific cardiac rehabilitation in a broad population were analyzed to assemble an inclusion and exclusion criteria for this study. Inclusion criteria was fairly homogenous within this review, as most studies followed cardiac rehabilitation qualification guidelines according to the American Heart Association (AHA) and Centers for Medicare and Medicaid Services (CMS).\textsuperscript{2,30,32,48,52,53,60} The inclusion criteria for our study was based off of the AHA and CMS guidelines as well, and closely followed the feasibility study performed by Harzand et al. which utilized the same mobile application.\textsuperscript{53} Participants will be included if they have had an acute myocardial infarction within 12 months\textsuperscript{4}, a coronary artery bypass graft, percutaneous coronary intervention, stable angina, or NYHA I or II heart failure.\textsuperscript{61} Additionally, patients will be required to score a 26/40 on the eHEALS questionnaire to establish a baseline technologic health literacy prior to enrolling.\textsuperscript{42}

Exclusion criteria was similarly homogenous throughout this literature review as criteria were aimed to create a safe population of patients participating in the study. Most studies excluded patients with uncontrolled hypertension (resting SBP>200mmHg or DBP>110mmHg), moderate to severe aortic stenosis, uncontrolled atrial or ventricular arrhythmias, symptomatic heart failure (NYHA III or IV), acute systemic illness or fever, active pericarditis or myocarditis or 3\textsuperscript{rd} degree heart block without pacemaker.\textsuperscript{53} Additionally, patients were excluded in many studies if they were unable to participate due to orthopedic problems or peripheral vascular disease that prohibits exercise.\textsuperscript{26,32} Due to the advanced age of our population, our study will also exclude patients with mild cognitive impairment as defined by the inability to complete intake questionnaires independently.\textsuperscript{26}
To decrease potential for adverse events, patients will need to meet these enrollment criteria prior to random allocation.

2.4.3 Randomization Technique and Blinding

For our proposed study, we will utilize a computer-generated simple randomization method that is consistent with other similar studies. Among the trials in this review that explicitly randomized their subjects, most used computer-generated random assignment.\textsuperscript{4,62} Although a majority of trials randomized their subjects, one study allowed patients to switch interventions if they desired.\textsuperscript{32} While this increases acceptability of the intervention for participants, it decreases the internal validity of the study. Thus, our proposed study will randomize patients without option for re-allocation.

Our proposed study will only be single blinded to the outcome assessors analyzing data. This is due to the inability to double blind subjects and study staff to the intervention. The intervention is clearly in different locations and thus both the patient and healthcare providers participating in the study are aware of their placement. This is consistent with prior studies utilizing mobile applications as they were only single blinded to investigators and data analysts.\textsuperscript{26,32,61,63}

2.4.4 Intervention

The mobile application intervention is a commercially available Apple or Android compatible mobile application created by Movn Analytics that patients will access via their own mobile phone or iPad or an iPad that the study lends the participant. The clinical protocol for the cardiac rehabilitation program was developed based off the MULTIFIT guidelines by DeBusk et al., which is a case-management system for home-based secondary prevention techniques in patients with coronary artery disease that meet all American Association of Cardiovascular and
Pulmonary Rehabilitation (AACVPR) and American College of Cardiology (ACC) guidelines for cardiac rehabilitation.\textsuperscript{64,65} This intervention will primarily be based off a feasibility study by Harzand et al. that utilized the same mobile application, determining that its use in cardiac rehabilitation increased enrollment, patient satisfaction and functional capacity.\textsuperscript{53} This mobile application includes daily reminders to exercise, a virtual space to document exercise sessions (including exercise type, length, and peak heart rate achieved), a 2-way chat feature to communicate with a health-care coach, and educational videos.\textsuperscript{53} A detailed image of the mobile application can be seen in Appendix C. Additionally, the healthcare provider working with the patient will have access to a dashboard in each cardiac rehabilitation office to monitor all patient-entered data, review messages from patient and any symptom alerts patients send (Appendix C).

The exercise prescription for our proposed study will be based off two prior studies that safely derived an exercise plan for home-based cardiac rehabilitation by calculating heart rate (HR) from a target range obtained during baseline functional testing.\textsuperscript{53,66} Target heart rate range will correspond to 70-85\% of peak HR (220-age) and patients will be encouraged to participate in at least 2-3 days per week of intense exercise up to target HR. Fitbit watch will be provided upon enrollment into study. More detailed study methods can be found in section 3.5.

For our proposed study, attendance to one session will be considered as logging 30 or more minutes of exercise into the mobile application in one day. Prior studies that have utilized mobile applications as interventions have counted adherence as just opening up the mobile application.\textsuperscript{30} However, this does not encourage accountability to the cardiac rehabilitation program. To encourage a more meaningful exercise routine and attempt to improve quantity and quality of exercise, our proposed study will only consider a session as 30 or more minutes.
2.4.5 Primary and Secondary Outcome Measures

The primary outcome measure in this proposed study will be program adherence rate as defined by the completed number of cardiac rehabilitation sessions out of a possible 36 sessions within a time frame of 6 months. This variable has been selected to remain consistent with current review of literature. We will evaluate this outcome in a niche population, patients over age 65. Based on a comprehensive literature review, adherence in other studies was measured primarily utilizing a proportion of number of sessions completed out of a predetermined, prescribed number.\textsuperscript{4,25,53,63,66} Two outlier studies utilized mean +/- standard deviation of number of minutes of exercise completed per week to operationalize adherence.\textsuperscript{26,67} However, this outcome was not as generalizable as adherence in traditional CR is measured based on number of sessions attended as opposed to number of minutes exercising. We will be utilizing proportion of number of sessions completed out of a total of 36 for our proposed study because it has been shown to be most frequently utilized in prior studies. Our study will calculate adherence rate out of a total of 36 sessions because that is the standard number of sessions prescribed to patients and covered under Medicare insurance.\textsuperscript{58}

While it is recommended that patients complete three exercise sessions per week, thus completing cardiac rehabilitation within a 12-week period, it is understood that this may not be feasible for all participants. Therefore, patients will have 6 months to complete 36 sessions of cardiac rehabilitation. This is consistent with other studies which utilize mobile applications as an intervention and allow for a longer follow-up time to evaluate adherence as well as functional outcomes.\textsuperscript{4,67}

For secondary outcomes, most studies evaluated a combination of functional exercise capacity and health related quality of life (HRQOL) scores to measure the efficacy of a mobile
application for CR. The secondary outcomes of this proposed study include measuring change in peak VO2 (mL/min x kg) to assess functional exercise capacity and administering the SF-36 questionnaire to assess health-related quality of life (HRQOL).

Peak VO2 is an established, reliable measure of exercise capacity in adults with cardiovascular disease.68 Additionally, elderly populations have demonstrated a significant improvement in peak VO2 following cardiac rehabilitation, in the same magnitude as younger patients.69 Based on the comprehensive literature review, it was the most common method of assessing patient’s exercise capacity throughout cardiac rehabilitation.26,30,62,70,71 Two studies utilizing a mobile application as an intervention demonstrated a statistically significant improvement in change in peak VO2. 26,70

A single center, randomized controlled trial in a population of patients with atrial fibrillation demonstrated a statistically significant improvement in change in peak VO2 (control vs intervention; 4.9 +/- 6.6 mL/(min x kg) vs 9.3 +/- 8.0 mL/(min x kg); p=0.003) in the intervention group, a mobile-app guided, telemonitored CR plus EKG monitoring as compared with the control group.26 While this study showed significant improvement in exercise capacity, it was limited to patients with a diagnosis of atrial fibrillation, which is not typically an indication for cardiac rehabilitation.

A single center, prospective RCT in Czech Republic demonstrated similar change in peak VO2 in both the intervention, a wrist heart rate monitor as a telerehabilitation device, and control group.70 However there was statistical significance noted between baseline and 12 weeks in the intervention group (baseline 23.4 +/- 3.3 mL/(min x kg), 12wk 25.9 +/- 4.1 (mL/min x kg); p=0.02). This shows that the mobile intervention was as effective as the control group and still provided improvement in functional capacity throughout the rehabilitation. Because peak VO2 has been
demonstrated to be a valid and effective method of measuring exercise capacity in elderly populations, it will be utilized as a secondary outcome.

In our proposed study, we will also be measuring health-related quality of life (HRQOL) as a secondary outcome to assess whether the mobile application effects patient’s quality of life. Based on our literature review, HRQOL in patients participating in CR is most frequently assessed using the clinically validated Short Form 36 questionnaire (SF-36). SF-36 questionnaire (Appendix D) is a clinically validated health-related quality of life survey composed of 36 items, measuring 8 dimensions of health status including functional status, wellbeing, and overall evaluation of health. More recently it was validated for use in community-dwelling adults over 65 years. While this is a generic measure to assess HRQOL, a systematic review by Brown determined that it is a sensitive, valid tool for cardiac rehabilitation especially considering the lack of a disease-specific QOL tool. This survey will be used to assess patients’ HRQOL at baseline and again upon completion of the 36 session CR program or at 6 months. A study by Batalik et al. demonstrated a statistically significant difference in the cardiac telerehabilitation intervention group between baseline and 12 weeks using SF-36 score (baseline 50.0+-8.8, 12 weeks 61.5+-7.1, p=0.01). Because cardiac rehabilitation is a comprehensive treatment program, it will be important to assess HRQOL in the setting of mobile application-based CR. The SF-36 will provide a reliable measure to obtain this information.

In order to gain understanding about patient-specific barriers to cardiac rehabilitation, each study utilized various questionnaires; However, the most common utilized survey was the cardiac rehabilitation barriers survey (CRBS). The CRBS is a clinically and psychometrically validated survey that asks patients to rate 21 barriers on a Likert scale 1-5 on degree of barrier. It is broken down into a four-factor solution: perceived need of healthcare
factors, logistical factors, work/time conflicts, or comorbidities/functional status. For our proposed study, we will administer this survey at baseline to assess potential reasons for nonadherence. This will help us gain an understanding of potential barriers that patients may face to attending in person cardiac rehabilitation. See Appendix E for further details.

2.4.6 Statistical Analysis and Power

We will use a significance level of 5% and power of 80% as was used in a majority of randomized controlled trials targeting adherence in cardiac rehabilitation delivered via mobile application. For statistical analyses, Cai et al. compared baseline group characteristics utilizing standardized t-tests for continuous variables and Wilcoxon rank-sum test for skewed data. Varnfield et al. compared categorical variables utilizing the Chi-squared test. Within group differences were examined using a paired t-test for symmetric data and Wilcoxon signed-rank test for skewed data. A multivariate analysis was performed to analyze for association between baseline characteristics and outcomes.

Primary outcome will be measured as a proportion and statistical significance will be calculated utilizing a Chi-square analysis. Prior studies with smaller sample sizes utilized Fisher’s exact test; However, for our sample size a Chi-square analysis is appropriate.

To measure secondary outcomes, we will utilize a paired t-test to analyze changes from baseline to follow-up of peak VO2 and SF-36 survey scores (Table 2) and a student t-test to measure changes between control and intervention of both functional capacity outcomes (Table 3), as was similar to a study performed by Cai et al. For our proposed study, we will utilize similar methods of statistical analysis to analyze baseline characteristics as well as primary and secondary outcomes. More detail about how this will be operationalized can be found in Section 3.6.8.
2.4.7 Sample Size

Sample size was calculated after analyzing three studies, specifically their population and effect size. A sample size of 35 subjects per arm, for a total of 70 subjects, utilizing a dichotomous, two-sample proportion was determined necessary to achieve statistical significance. A study by Varnfield et al., studied the adherence rates of a texting driven, smartphone-based cardiac rehabilitation program versus standard cardiac rehabilitation on post-MI patients. They found a 26% absolute rate difference between the intervention group (94% adherence) and the standard cardiac rehabilitation group (68% adherence). This study had the most similar intervention, however the population was more narrow and younger with an average age of 55 years old.4 A study by Imran et al. utilized a similar intervention, a mobile application plus standard cardiac rehabilitation, to study adherence rates in cardiac rehabilitation in a large sample of a racially and socioeconomically diverse patient population. This study showed a 19% rate difference with 85% adherence in the intervention group and 66% adherence in the control group.27 However, this study differed from our proposed study in that it utilized a mobile application as an adjunct to cardiac rehabilitation rather than the primary method of delivery. Finally, a study by Cai et al. demonstrated a 38% mean difference utilizing a continuous outcome variable of 150 minutes of exercise per week in a patient population with atrial fibrillation. While the intervention group utilized a mobile application plus EKG leads as compared to standard cardiac rehabilitation, adherence was measured as a continuous secondary outcome variable.26 Overall, these studies demonstrated an average rate difference of 27.8%. However, the study by Varnfield et al. had the most similar design to the currently proposed study and the rate difference was closest to the average rate difference between all three studies. These studies support a difference in 26% between groups in the sample size calculation.
2.4.8 Safety of Mobile Application-based Cardiac Rehabilitation

It is important to establish safety measures prior to having patients with cardiovascular diseases exercise at home. While patients with significant CVD and serious risk factors will be excluded prior to starting the study (Table 1), it is important to note that overall, cardiac rehabilitation has very low incidence of adverse effects.\textsuperscript{77-79} Van Camp et al. sought to determine the incidence of major CV complications in outpatient cardiac rehabilitation and exercise training (CRET) settings. Out of 167 randomly selected CRET programs including 51,303 patients who had exercised 2,351,916 hours from January 1980 through December 1984, they observed 21 cardiac arrests (18 of which the patient was successfully resuscitated and three fatal) and 8 non-fatal MI's. Incidence rates per 1,000,000 patient hours of exercise were 8.9 for cardiac arrests, 3.4 for MI's, and 1.3 for fatalities.\textsuperscript{77} This showed that the risk of CV complications during cardiac rehabilitation is very low. However, supervision should occur and still does, despite low the risk.

Additionally, the HF-ACTION trial, the largest RCT that assessed safety of exercise training in home-based cardiac rehabilitation was performed in a population of 2,331 patients with stable, chronic heart failure and NYHA class II to IV symptoms.\textsuperscript{79} Patients were monitored with a heart rate monitor and daily exercise plan to guide exercise intensity at home. No significant difference was found between the exercise and control groups for cardiovascular hospitalization or mortality (55% vs 58%, respectively. Hazard ratio [HR], 0.92 [95% CI, 0.83-1.03]; p=0.14) or death (16% vs 17%, respectively. [HR], 0.96 [95% CI, 0.79-1.17, p=0.70) over 3 years.\textsuperscript{79} Cardiac rehabilitation has been shown to have few adverse events upon careful enrollment screening and is a safe model in home-based programs as well.
2.5 Conclusion

The literature demonstrates a need for this study. There is clear evidence that adherence rates to traditional cardiac rehabilitation in the elderly population are poor, especially compared with the general population.\textsuperscript{5,45} It is also clear that the geriatric population faces barriers to cardiac rehabilitation adherence that are different than the general population.\textsuperscript{12,15-17} It has been shown that mobile applications may be a potential solution to help geriatric patients overcome these barriers to adherence.\textsuperscript{20,23,24,80} There have not been any studies looking at the utilization of mobile applications for cardiac rehabilitation in a geriatric specific population and thus more studies need to be performed to elucidate whether this intervention may increase adherence rates.
2.6 References


CHAPTER 3: STUDY METHODS

3.1 Study Design

We will conduct a single-blinded, parallel design, fixed randomized controlled trial among patients aged 65 and older that have been referred and deemed eligible for cardiac rehabilitation at one of six cardiac rehabilitation centers in the Yale New Haven Health System. Patients randomized to the mobile application-based cardiac rehabilitation group will be given access to a commercially available smartphone application called Movn Rehab (by Moving Analytics, Los Angeles, CA), a cardiac rehabilitation-specific mobile application that will independently guide patients through smartphone-based, at-home cardiac rehabilitation exercises. Patients randomized to the facility-based cardiac rehabilitation group will attend facility-based rehabilitation 2-3 times per week, as instructed.

3.2 Study Population and Sampling

Sampling

Patients will be sampled utilizing simple random sampling following referral to any of the six cardiac rehabilitation centers within the YNHH system. These centers include Lawrence and Memorial, Westerly, Branford, Greenwich, New Haven, and Bridgeport Cardiac Rehabilitation Centers. Patients will be contacted by a research associate regarding enrollment in the study upon referral receipt by any of the included centers.

Study Population

The study population will include all patients over age 65 years that have been referred to cardiac rehabilitation within the YNHH system by their provider. Study participation will be voluntary, and patients will be enrolled upon meeting inclusion and exclusion criteria (Table 1) which will be assessed prior to the first session. They will meet with the research associate
following CR referral to determine if they are eligible. They will be expected to meet eligibility criteria for cardiac rehabilitation as defined by Centers for Medicare and Medicaid Services (CMS). Eligibility criteria for cardiac rehabilitation includes a diagnosis of one of the following: acute MI within 12 months, prior CABG, current stable angina, heart valve repair or replacement, prior PCI with or without stenting, or stable heart failure (NYHA Class I or II). Informed consent will be obtained from patients that met screening criteria prior to initiating study.

Table 1. Study Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<tr>
<td>Adults over age 65 years</td>
<td>Unstable angina</td>
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<tr>
<td>Ability to provide informed consent</td>
<td>Uncontrolled hypertension</td>
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<tr>
<td>Baseline eHEALS score: 26/40</td>
<td>Moderate to severe aortic stenosis</td>
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<tr>
<td>Internet access at home</td>
<td>Active pericarditis or myocarditis</td>
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<tr>
<td>Meet CMS eligibility criteria for CR with one of the following:</td>
<td>Uncontrolled atrial or ventricular arrhythmias</td>
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<tr>
<td>- Acute MI within 12 months</td>
<td>Symptomatic heart failure (NYHA Class III or IV)</td>
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<tr>
<td>- Prior CABG</td>
<td>3rd degree heart block without pacemaker</td>
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<tr>
<td>- Prior PCI w/ or w/o stenting</td>
<td>Acute systemic illness or fever</td>
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<tr>
<td>- Heart valve repair or replacement</td>
<td>Orthopedic problems or peripheral vascular disease that would prohibit exercise</td>
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<tr>
<td>- Stable angina</td>
<td>Cognitive impairment</td>
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<tr>
<td>- Stable heart failure (NYHA Class I or II)</td>
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3.3 Subject Protection and Confidentiality

The proposed trial will require Institutional Review Board (IRB) approval via the Human Investigation Committee of Yale University School of Medicine and Yale New Haven Health System. All study staff will be required to complete Health Insurance Portability and Accountability Act (HIPAA) training prior to study initiation. All patients will complete an informed consent form (Appendix F) prior to study initiation. This will include a detailed explanation of risks and benefits of this study. Consent will be provided in both written and verbal form. Patients will be able to revoke consent at any point in time. Signed consent forms will be kept for a minimum of three years.
The Moving Analytics company ensures HIPAA protection via mobile phone encryption and storage on a HIPAA secure cloud-based system. Protected health information will be stored on a secure, data-encrypted server, only accessible via password that has been provided to research team members.

3.4 Recruitment

To make this study more generalizable, study participants will be recruited from six different cardiac rehabilitation sites within the YNHH system. The centers are in neighborhoods of varying socioeconomic status and will provide a socioeconomically diverse sample. A simple random sample will be performed.

3.5 Study Variables and Measure

The independent variable will compare a 36-session mobile application-based, at-home cardiac rehabilitation program with a traditional 36-session facility-based cardiac rehabilitation program. Both rehabilitation programs will incorporate the core components of cardiac rehabilitation which include dynamic aerobic and strength training exercises, educational counseling regarding medication, nutrition, smoking cessation (if necessary) and psychological discussions as necessary. Patients will undergo baseline functional testing to develop an exercise prescription which corresponds to 70-85% of peak HR achieved. Patients will be loaned a Fitbit watch for the duration of the study to monitor heart rate and step count. They will be instructed to wear it during exercise sessions. Exercise sessions for the mobile application-based cardiac rehabilitation will consist of a 5-10 minute warm up and then 20-30 minutes of individual endurance training, depending on equipment available. Patients may walk on a flat surface, walk up and down the stairs, perform chair exercises (with video available), or perform
exercises as provided by the mobile application. Patients will then watch videos and follow strength exercises for 15-20 minutes. These exercise sessions will be performed 2-3 times per week. All data will be logged in Movn Rehabilitation application upon completion of activity. A 1-hour training session about how to utilize the mobile phone application will be offered at the baseline assessment to establish understanding of the app and encourage eHealth literacy in this population. See Appendix G for further detail of mobile application-based cardiac rehabilitation plan.

Weekly phone calls with a healthcare provider trained in cardiac rehabilitation delivery (exercise physiologist, cardiologist, physician assistant, or nurse) will be performed to document patient progress, modify exercises, discuss questions, and monitor adverse events. Patients will have the ability to chat as needed with their healthcare provider via the mobile phone application during the week as questions arise regarding nutritional advice, exercise inquiries or safety questions. Educational videos will be provided to patients in the intervention group to watch on their own time via the mobile application. Exercise videos are provided via YNHH Cardiac Rehabilitation Program. The videos demonstrate home-based exercises and use minimal equipment such as a chair or steps.

Exercise sessions at the facility-based session will consist of a 5-10 minute warm-up, 20-30 minute stationary bike or treadmill walk, and 15-20 minutes of resistance band or lightweight strength training. Educational sessions occur while patients are performing exercises. A nurse will discuss various educational topics with patient during workout and a nutritionist will be available one day per week for discussions about nutritional habits. Participation in one session will be counted as attendance at the facility-based rehabilitation site or documentation of 30 minutes of exercise into application.
The primary outcome will be the number of sessions of cardiac rehabilitation completed out of a possible 36 sessions within a time frame of 6 months. Secondary outcomes of the study will include peak VO2 (mL/mg x kg) and Short Form-36 questionnaire.

To measure secondary outcomes, each group will complete a cardiopulmonary exercise test (CPET) to assess peak VO2 (mL/min x kg) at baseline. This will be done on a cycle ergometer or treadmill and will measure the oxygen consumption during exercise. They will also complete a SF-36 survey at baseline. Peak VO2 via CPET and SF-36 will be assessed again upon completion of cardiac rehabilitation or at 6 months, whichever event occurs first. More information about both outcomes can be found in Section 2.4.5.

3.6 Methodology and Considerations

3.6.1 Blinding of Intervention and Outcome

Our proposed study will be single blinded with blinding of the outcome assessor. Upon receiving data, the outcome assessor will be unaware which patient received mobile application-based cardiac rehabilitation versus facility-based cardiac rehabilitation. However, patients and treating providers will be unable to be blinded to the intervention due to the location of each treatment group (home versus facility).

3.6.2 Assignment of Intervention

Upon consenting to participate in the study, patients will be randomly assigned to each group by utilizing a computer sequence generator. This will randomly allocate patients to 36 sessions of mobile application-based cardiac rehabilitation or 36 sessions of facility-based cardiac rehabilitation. Patients will be notified of their assigned treatment group at the time of their baseline assessment via a sealed, opaque envelope which will contain a computer-generated
code with the assigned group to reduce risk of allocation bias and balance known and unknown factors.

3.6.3 Adherence

Attendance will be taken at each facility-based session. If a patient misses a session, they will be contacted by a research assistant to determine the reason for missing the session. Alternatively, they may be approached at their next session to determine their reason for absence. Attendance at the mobile application-based cardiac rehabilitation will be monitored by documentation of exercise sessions into the mobile application. Patients will speak weekly to the healthcare provider managing their cardiac rehabilitation and discuss any reason for missing an exercise session at that time. Cardiac rehabilitation barriers survey will be conducted at baseline to address reasons for potential difficulties in attendance.

3.6.4 Monitoring for Adverse Events

Most of the safety screening will occur during the enrollment process, as patients who are deemed a high risk of having a repeat coronary event will be excluded from the study. Patients will be monitored in a safe, controlled environment at facility-based CR by wearing a 3-lead ECG throughout the duration of their exercise session. At home, patients will wear a Fitbit watch that will monitor heart rate and transmit any irregularly fast heart rate to the cardiac rehabilitation facility in real time. Outside of business hours, providers participating in the study will have rotating on-call shifts on weekdays from 6am-8am, 5pm-10pm and weekends from 7am-5pm to respond to any patient emergencies that arise while exercising at home. Patients will be instructed to avoid exercising at home outside of the hours of 6am-10pm Monday through Friday and 7am-5pm Saturday and Sunday. This will reduce the risk of missing an adverse event and ensure consistent supervision in the case that patients do develop any adverse event during
exercise. If they feel cardiac related symptoms while exercising such as chest pain or pressure, they can message their provider via the mobile application for further instructions. Adverse events are generally infrequent during cardiac rehabilitation, however if an adverse event does occur, patients will be brought or advised to go to the Emergency Department for further evaluation. Appropriate documentation will be submitted according to the IRB Policy 420 Data and Safety Monitoring.

3.6.5 Data Collection

Adherence will be measured by attendance at facility-based rehabilitation or documentation of the exercise session on mobile-application. Secondary outcomes including peak VO2 and SF-36 questionnaire results will be measured at baseline and at the end of 12-week rehabilitation, or at 6 months, whichever occurs sooner.

Baseline demographic and clinical data including age, gender, education level, self-described ethnicity, average transportation time to clinic, CVD risk factors (hypertension, diabetes, hyperlipidemia, smoking status), number of comorbidities, precluding CR diagnosis, NYHA classification (if applicable), eHEALS score, and Cardiac rehabilitation barriers survey (CRBS) score (Table 2) will be collected by research assistants at each site upon enrollment into study.

<table>
<thead>
<tr>
<th>Table 2 – Descriptive Characteristics</th>
<th>Mobile App CR</th>
<th>Facility-Based CR</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
<td>t-test</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>(%)</td>
<td>(%)</td>
<td>Chi-square</td>
</tr>
<tr>
<td>Highest completed education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Highschool or less</td>
<td>(%)</td>
<td>(%)</td>
<td>Chi-square</td>
</tr>
<tr>
<td>Some college</td>
<td>(%)</td>
<td>(%)</td>
<td>Chi-square</td>
</tr>
<tr>
<td>College/graduate/professional</td>
<td>(%)</td>
<td>(%)</td>
<td>Chi-square</td>
</tr>
</tbody>
</table>
3.6.6 Timeline and Resources

The timeline for our randomized controlled trial, which includes participant recruitment and data collection will be 24 months. 15 months will be allocated for participant recruitment and to perform baseline assessments. Enrollment will begin in July 2022 and the last participant will be enrolled by October 2023. Following enrollment, patients will complete a 12-week cardiac rehabilitation program where data will be collected throughout, and a final assessment...
will be collected during the last week. The final participant will conclude cardiac rehabilitation by March 2024. Data analysis will take place during the final four months of the 24-month time frame.

The principal investigator for this study will be Robert McNamara, MD and the co-principal investigator will be Amanda Wilson, PA-SII. A designated primary investigator at each of the six sites will be assigned prior to patient enrollment. Their job will be to oversee the trial and ensure that criteria is being followed ethically and safely. There will be 6 research assistants total, 1 assigned to each rehabilitation site. Their job will be to obtain written informed consent from each patient enrolling in the study and to collect baseline demographic data as well as perform CPET to obtain peak VO2 upon enrollment. Additionally, they are responsible for delivering the sealed, opaque envelope containing the patient’s assigned intervention group. A statistician will be consulted for a final analysis of collected data.

At each enrollment site, the cardiac rehabilitation team will consist of a cardiologist or cardiology PA, an exercise physiologist, a registered nurse, and a dietician. The cardiologist or cardiology PA will oversee the program and be aware of any adverse events both in facility-based rehabilitation and via mobile app-based cardiac rehabilitation. The exercise physiologist will oversee optimizing each patient’s individual workout routine to match their exercise tolerance. They will adjust patient’s exercise regimen as needed. A registered nurse will oversee patients as they exercise in the facility and be available during business hours to answer questions via chat over Movn Rehab application. Registered nurses and dieticians will also offer educational support and counseling throughout the 12 weeks. They will do this both in person and be available over chat to answer questions for the mobile app-based intervention arm.
3.6.7 Sample Size Calculation

The sample size was calculated by Power and Precision V4 Software and can be found in Appendix H. Our study design utilizes a two-sided hypothesis with 80% power at \( \alpha = 0.05 \) to detect a 26% absolute difference in effect, assuming a baseline cardiac rehabilitation adherence rate of 68%. A sample size of 35 participants per study arm results in an 80% likelihood that the study will yield statistically significant results showing that there will be an absolute difference in adherence rates between mobile-application based cardiac rehabilitation and facility-based cardiac rehabilitation.

3.6.8 Statistical Analysis

Intention to treat analysis will be utilized to analyze the primary outcome data. Baseline demographics and clinical data will be collected at baseline and compared between both study arms. Baseline characteristics presented as categorical variables include gender, education level, self-described race/ethnicity, CVD risk factors, number of comorbidities, CR diagnosis, eHEALS score and NYHF classification. Continuous baseline characteristics include age and transportation time and will be measured using mean +/- SD and median, IQR respectively.

The primary outcome variable will be reported as a percentage since it is a dichotomous variable. Secondary outcomes will be reported as mean +/- standard deviation because they are continuous outcome variables and will be operationalized as mean change from baseline. Bivariate analysis will utilize Chi-Square analysis for the primary outcome. Paired t-test will be utilized to measure secondary outcomes pre and post intervention (Table 3). T-test will be utilized to measure changes between secondary outcomes following intervention (Table 4). We will utilize multiple logistic regression for multivariate analysis to adjust for potential, though
unlikely, confounding including gender, race/ethnicity, education level, and number of comorbidities.

Table 3: Functional Outcome Measures Pre and Post Intervention

<table>
<thead>
<tr>
<th>Secondary Outcome Measure</th>
<th>Mobile application-based CR</th>
<th>Facility-based CR</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
</tr>
<tr>
<td>Peak VO2 [mL/(min x kg)]</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
</tr>
<tr>
<td>SF-36 Questionnaire</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
</tr>
</tbody>
</table>

Table 4: Changes in Functional Outcome Measures

<table>
<thead>
<tr>
<th></th>
<th>Mobile application-based CR</th>
<th>Facility-based CR</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peak VO2 [mL/(min x kg)]</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
<td>t-test</td>
</tr>
<tr>
<td>SF-36 Questionnaire</td>
<td>Mean, SD</td>
<td>Mean, SD</td>
<td>t-test</td>
</tr>
</tbody>
</table>
3.7 References


CHAPTER 4: CONCLUSION

4.1 Advantages and Disadvantages

4.1.1 Advantages

This will be the first randomized, controlled trial to date that investigates adherence rates with a mobile application for cardiac rehabilitation in an elderly population. Advantages of a randomized controlled trial include reduced selection bias, specifically allocation bias, through randomization. While nonparticipation in the study due to a baseline level of technological literacy required to participated in the intervention arm could affect the external validity of the study, the internal validity of this study will not be impacted. Another advantage of our study is the clearly defined and objective primary outcome variable that will reduce information bias throughout this study. Additionally, a comprehensive review of baseline characteristics through multivariate analysis, if necessary, will be performed to minimize confounders.¹

This is the first study to examine the effect of mobile applications on adherence rates in a geriatric population, therefore there will be more specific and applicable information available for this novel population. Unlike many other studies which focused on low-risk CR candidates, this study has a broad inclusion criterion and will be generalizable to a larger population of geriatric patients eligible for CR. Additionally, this study will be performed at multiple cardiac rehabilitation centers with a diverse racial, ethnic, and socioeconomic catchment area, increasing generalizability to a broad population.

4.1.2 Disadvantages

Blinding will not be possible due to the nature of the intervention, though study investigators will be blinded to information received at time of data analysis to reduce bias. This may lead to increased information bias as patients may participate more or less depending on
which group they were randomized to. Additionally, there will be insufficient power to measure statistical significance of secondary outcomes. However, the results may still suggest relationships between functional capacity and the intervention.

Another disadvantage is regarding the safety of home-based CR as it is difficult to monitor patient safety when performing CR at home. Despite multiple safety measures put in place including real-time heart rate monitoring, available chat-based communication, and extended provider monitoring in addition to reduced risk through pre-screening eligibility criteria, safety is of utmost priority and cannot be completely controlled for when CR is performed at home.

Finally, despite providing an exercise prescription and heart rate monitoring devices, exercise quality cannot be monitored directly from mobile application-based CR and therefore may be subject to poorer functional outcomes.

4.2 Clinical and Public Health Significance

Despite the prevalence of cardiovascular disease in geriatric patients and the proven benefit of cardiac rehabilitation to prevent morbidity and mortality in patients with CVD, there is still a significant disparity in adherence rates to CR in this population due to various barriers.\textsuperscript{2-5} This study will address whether the utilization of a mobile application may improve adherence rates to CR in the geriatric population, while remaining a safe and effective option. This mobile application may help to overcome barriers to CR adherence including transportation burden, financial burden, and schedule availability. The results of this study could provide an option for an accessible CR program for the geriatric population following referral to cardiac rehabilitation.
4.3 References


APPENDICES

Appendix A: Controlled Vocabulary Search Terms and Key Phrases

<table>
<thead>
<tr>
<th>Controlled Vocabulary Terms</th>
<th>Key Words</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disease</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td></td>
<td>Percutaneous coronary intervention</td>
</tr>
<tr>
<td></td>
<td>Angina</td>
</tr>
<tr>
<td></td>
<td>Coronary Artery Bypass Graft</td>
</tr>
<tr>
<td></td>
<td>Heart Failure</td>
</tr>
<tr>
<td>Home-based CR</td>
<td>Telehealth</td>
</tr>
<tr>
<td></td>
<td>Smart-phone based e-health</td>
</tr>
<tr>
<td></td>
<td>App-based e-health</td>
</tr>
<tr>
<td></td>
<td>Home-based CR?</td>
</tr>
<tr>
<td>Cardiac Rehabilitation</td>
<td>Cardiac rehabilitation</td>
</tr>
<tr>
<td></td>
<td>Cardiovascular rehabilitation</td>
</tr>
<tr>
<td>Adherence</td>
<td>Enrollment</td>
</tr>
<tr>
<td></td>
<td>Efficacy</td>
</tr>
<tr>
<td></td>
<td>Utilization</td>
</tr>
<tr>
<td></td>
<td>Participation</td>
</tr>
<tr>
<td></td>
<td>Patient Compliance</td>
</tr>
<tr>
<td>Patient Participation</td>
<td>Patient participation</td>
</tr>
<tr>
<td></td>
<td>Patient utilization</td>
</tr>
<tr>
<td>Geriatric</td>
<td>Geriatric</td>
</tr>
<tr>
<td></td>
<td>Elderly</td>
</tr>
</tbody>
</table>
Appendix B: Ehealth Literacy Scale

eHealth Literacy Scale

I would like to ask you for your opinion and about your experience using the Internet for health information. For each statement, tell me which response best reflects your opinion and experience right now.

1. I know what health resources are available on the Internet
   1) □ Strongly Disagree
   2) □ Disagree
   3) □ Undecided
   4) □ Agree
   5) □ Strongly Agree

2. I know where to find helpful health resources on the Internet
   1) □ Strongly Disagree
   2) □ Disagree
   3) □ Undecided
   4) □ Agree
   5) □ Strongly Agree

3. I know how to find helpful health resources on the Internet
   1) □ Strongly Disagree
   2) □ Disagree
   3) □ Undecided
   4) □ Agree
   5) □ Strongly Agree

4. I know how to use the Internet to answer my questions about health
   1) □ Strongly Disagree
   2) □ Disagree
   3) □ Undecided
   4) □ Agree
   5) □ Strongly Agree

5. I know how to use the health information I find on the Internet to help me
1. □ Strongly Disagree
2. □ Disagree
3. □ Undecided
4. □ Agree
5. □ Strongly Agree

6. I have the skills I need to evaluate the health resources I find on the Internet

1. □ Strongly Disagree
2. □ Disagree
3. □ Undecided
4. □ Agree
5. □ Strongly Agree

7. I can tell high quality health resources from low quality health resources on the Internet

1. □ Strongly Disagree
2. □ Disagree
3. □ Undecided
4. □ Agree
5. □ Strongly Agree

8. I feel confident in using information from the Internet to make health decisions

1. □ Strongly Disagree
2. □ Disagree
3. □ Undecided
4. □ Agree
5. □ Strongly Agree

Thank you!
Appendix C: Mobile Application for Cardiac Rehabilitation
Appendix D: Short Form-36 Questionnaire

36-Item Short Form Survey Instrument (SF-36)

RAND 36-Item Health Survey 1.0 Questionnaire Items

Choose one option for each questionnaire item.

1. In general, would you say your health is:
   - 1 - Excellent
   - 2 - Very good
   - 3 - Good
   - 4 - Fair
   - 5 - Poor

2. Compared to one year ago, how would you rate your health in general now?
   - 1 - Much better now than one year ago
   - 2 - Somewhat better now than one year ago
   - 3 - About the same
   - 4 - Somewhat worse now than one year ago
   - 5 - Much worse now than one year ago
The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all
   - ○ 1  ○ 2  ○ 3

4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf
   - ○ 1  ○ 2  ○ 3

5. Lifting or carrying groceries
   - ○ 1  ○ 2  ○ 3

6. Climbing several flights of stairs
   - ○ 1  ○ 2  ○ 3

7. Climbing one flight of stairs
   - ○ 1  ○ 2  ○ 3

8. Bending, kneeling, or stooping
   - ○ 1  ○ 2  ○ 3

9. Walking more than a mile
   - ○ 1  ○ 2  ○ 3

10. Walking several blocks
    - ○ 1  ○ 2  ○ 3

11. Walking one block
    - ○ 1  ○ 2  ○ 3

12. Bathing or dressing yourself
    - ○ 1  ○ 2  ○ 3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

13. Cut down the amount of time you spent on work or other activities
    - ○ 1  ○ 2

14. Accomplished less than you would like
    - ○ 1  ○ 2

15. Were limited in the kind of work or other activities
    - ○ 1  ○ 2

16. Had difficulty performing the work or other activities (for example, it took extra effort)
    - ○ 1  ○ 2
During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>17. Cut down the <strong>amount of time</strong> you spent on work or other activities</td>
<td>0 1</td>
<td>2</td>
</tr>
<tr>
<td>18. <strong>Accomplished less</strong> than you would like</td>
<td>0 1</td>
<td>2</td>
</tr>
<tr>
<td>19. Didn't do work or other activities as <strong>carefully</strong> as usual</td>
<td>0 1</td>
<td>2</td>
</tr>
</tbody>
</table>

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- 1 - Not at all
- 2 - Slightly
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

21. How much **bodily** pain have you had during the **past 4 weeks**?

- 1 - None
- 2 - Very mild
- 3 - Mild
- 4 - Moderate
- 5 - Severe
- 6 - Very severe
22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- 1 - Not at all
- 2 - A little bit
- 3 - Moderately
- 4 - Quite a bit
- 5 - Extremely

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks**...

<table>
<thead>
<tr>
<th></th>
<th>All of the time</th>
<th>Most of the time</th>
<th>A good bit of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>23. Did you feel full of pep?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>24. Have you been a very nervous person?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>25. Have you felt so down in the dumps that nothing could cheer you up?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>26. Have you felt calm and peaceful?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>27. Did you have a lot of energy?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>28. Have you felt downhearted and blue?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>29. Did you feel worn out?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>30. Have you been a happy person?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
<tr>
<td>31. Did you feel tired?</td>
<td>○ 1</td>
<td>○ 2</td>
<td>○ 3</td>
<td>○ 4</td>
<td>○ 5</td>
<td>○ 6</td>
</tr>
</tbody>
</table>

https://www.rand.org/health-care/surveys_tools/ Mos/36-item-short-form/survey-instrument.html
32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- 1 - All of the time
- 2 - Most of the time
- 3 - Some of the time
- 4 - A little of the time
- 5 - None of the time

How **TRUE** or **FALSE** is each of the following statements for you.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Definitely True</th>
<th>Mostly True</th>
<th>Don't Know</th>
<th>Mostly False</th>
<th>Definitely False</th>
</tr>
</thead>
<tbody>
<tr>
<td>33. I seem to get sick a little easier than other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>34. I am as healthy as anybody I know</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>35. I expect my health to get worse</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>36. My health is excellent</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix E: Cardiac Rehabilitation Barriers Survey

Please rate how much each of the following 21 factors affect your ability to attend cardiac rehab. At the end there is a space where you can add any other barriers that are an issue for you that we may have missed.

1. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... distance (e.g., not located in your area, too far to travel)
   - Strongly Disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

2. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... cost (e.g., parking, sessions)
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

3. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... transportation problems (e.g., access to car, public transportation)
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

4. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... family responsibilities (e.g., caregiving)
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

5. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I didn’t know about cardiac rehab (e.g., doctor didn’t tell me about it)
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

6. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I don’t need cardiac rehab (e.g., feel well, heart problem treated, not serious)
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
7. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I already exercise at home, or in my community
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

8. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... severe weather
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

9. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I find exercise tiring or painful
   - Strongly disagree
   - Disagree
   - Neither agree nor disagree
   - Agree
   - Strongly agree

10. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... travel (e.g., holidays, business, cottage)
    - Strongly disagree
    - Disagree
    - Neither agree nor disagree
    - Agree
    - Strongly agree

11. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... time constraints (e.g., too busy, inconvenient class time)
    - Strongly disagree
    - Disagree
    - Neither agree nor disagree
    - Agree
    - Strongly agree

12. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... work responsibilities
    - Strongly disagree
    - Disagree
    - Neither agree nor disagree
    - Agree
    - Strongly agree

13. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I don’t have the energy
    - Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

14. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because of... other health problems prevent me from going
• Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

If applicable, Please specify other health condition:

15. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I am too old
• Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

16. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... my doctor did not feel it was necessary
• Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

17. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... many people with heart problems don’t go, and they are fine
• Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

18. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I can manage my heart problem on my own
• Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

19. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I think I was referred, but the rehab program didn’t contact me
• Strongly disagree
• Disagree
• Neither agree nor disagree
• Agree
• Strongly agree

20. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... it took too long to get referred and into the program
  • Strongly disagree
  • Disagree
  • Neither agree nor disagree
  • Agree
  • Strongly agree

21. I did not attend a cardiac rehabilitation program, or if I do attend, I missed or may miss some sessions because... I prefer to take care of my health alone, not in a group
  • Strongly disagree
  • Disagree
  • Neither agree nor disagree
  • Agree
  • Strongly agree

Other reason(s) for not attending a cardiac rehabilitation program
Appendix F: Informed Consent

CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE NEW HAVEN HOSPITAL

Study Title: CARDIAC REHABILITATION ADHERENCE RATES IN ELDERLY PATIENTS USING A MOBILE APPLICATION
Principal Investigator: Robert McNamara, MD, MHS
Co-investigator: Amanda Wilson, PA-SII

Research Study Summary:
- We are asking you to join a research study.
- The purpose of this research study is to examine adherence rates of a mobile application-based cardiac rehabilitation program.
- Study activities will include: Using a mobile application-based cardiac rehabilitation program or standard cardiac rehabilitation program for 36 sessions, documenting your exercise routine in mobile application, participating in cardiopulmonary exercise testing to calculate peak VO2 at baseline and upon completion of cardiac rehabilitation program.
- Your involvement will require 40 hours.
- There may be some minimal risks from participating in this study including exercising at home without supervision.
- The study may have benefits to you. This may give an alternate option to complete cardiac rehabilitation and provide further insight into the benefit of mobile application-based cardiac rehabilitation.
- There are other choices available to you outside of this research. You may complete cardiac rehabilitation in the facility.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale New Haven Hospital.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you have qualified for cardiac rehabilitation based on a previous cardiac diagnosis and you are 65 years old or above. We are looking for 70 participants to be part of this research study.

What is the study about?
The purpose of this study is to assess program adherence by evaluating number of sessions of cardiac rehabilitation completed out of a 36-session program within 6 months in patients over 65 years old that are randomized to either a mobile application-based cardiac rehabilitation program or a standard, facility-based program. Additionally, this study will assess secondary outcomes such as peak VO2, health-related quality of life and barriers to attendance at cardiac rehabilitation.
What are you asking me to do and how long will it take?
If you agree to take part, your participation in this study will involve random assignment to either the traditional, facility-based cardiac rehabilitation or mobile-application, home-based cardiac rehabilitation.

- Following enrollment in the study, you will undergo baseline testing. This includes collection of baseline demographic and clinical information. Additionally, you will undergo a baseline cardiopulmonary exercise test to determine your peak VO2.
- If assigned to the mobile-application group you will undergo a teaching session on how to use the mobile application. This will include information on how to download the commercially available mobile application on a smartphone or tablet and time to answer any questions you may have. This will take up to 1 hr.
- Both treatment and control groups will complete at 12-week, 36 session cardiac rehabilitation program. This will include specifically designed exercise sessions based off heart rate, educational nutritional videos, and pharmacologic counseling. If assigned to the mobile application group, you will have weekly phone calls with a medical provider to check in on progress.
- Upon completion of 36 sessions or a 6-month time period, you will repeat baseline testing and cardiopulmonary exercise testing.
- Your participation in the study will then be completed.

We think that the study will take 40 hours of your time.

Are there any risks from participating in this research?

We do not expect any risks from taking part in this study. Any contraindications to participating in cardiac rehabilitation will be identified prior to study initiation and will exclude you from the study. Heart rate monitoring will be performed throughout the exercise sessions to monitor for any irregular heart rhythms.

Theoretical risks of exercise in patients with cardiovascular disease do exist within literature. However, as stated above, the risk will be minimized by screening prior to enrollment in the study to maximize safety. Additionally, patients will have weekly phone calls with a medical provider to discuss challenges they faced and any safety concerns. The medical team will also have real-time access to patient exercise and heart rate data to screen for any concerning findings.

The main inconvenience from this study will be the time that it takes to participate in cardiac rehabilitation. If assigned to the facility-based cardiac rehabilitation, patients will be responsible for their own transportation.

There is the possible risk of loss of confidentiality. All data will be stored on the mobile application’s HIPAA secure cloud. Every effort will be made to keep this information secure.

How can the study possibly benefit me or others?

You may benefit from taking part in this study. We hope that our results will add to the knowledge about new technology to further access to cardiac rehabilitation.
Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs may include transportation and your time coming to the study visits.

Will I be paid for participation?
You will not be paid for taking part in this study. However, you will be receiving free cardiac rehabilitation with no copay required as well as potential access to a mobile application that provides educational videos, exercise routines and a communication platform with your provider.

How will you keep my data safe and private?
All your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we must do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission. We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

What if I want to refuse or end participation before the study is over?
Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with Yale New Haven Hospital.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at (203) 785-4127

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

If you have questions about the Psychology Subject Pool, you may contact the coordinator at (203) 432-4518, or psychsubject.pool@yale.edu

Documentation of Informed Consent
Your signature below indicates that you read and understand this consent form and the information presented and that you agree to be in this study.
We will give you a copy of this consent form.

<table>
<thead>
<tr>
<th>Participant Printed Name</th>
<th>Participant Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Person Obtaining Consent Printed Name</th>
<th>Person Obtaining Consent Signature</th>
<th>Date</th>
</tr>
</thead>
</table>
## Appendix G: Mobile Application-Based Intervention Details

<table>
<thead>
<tr>
<th><strong>Baseline – Intake Session</strong></th>
<th><strong>Details</strong></th>
</tr>
</thead>
</table>
| Obtain Patient characteristics: | Demographics  
Medical History  
Comorbidities  
Indication for CR |
| Perform baseline testing | 12-lead EKG  
Maximal ergometer test (determine peak VO2)  
Determine exercise prescription based off 70-85% of peak HR |
| Physical Examination | Vital Signs  
Weight  
Height  
Blood pressure |
| Mobile Application Training | 1 hour training session on mobile application characteristics and use |
| Questionnaires | SF-36  
CRBS  
eHEALS |

### During Cardiac Rehabilitation

<table>
<thead>
<tr>
<th><strong>Details</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform exercise sessions 2-3 times per week, 30 minutes per session</td>
</tr>
</tbody>
</table>
| -Wear Fitbit watch during workouts  
-Document workouts in mobile app upon completion  
-Attempt target HR based on personalized exercise prescription |
| Watch nutritional education videos 1x/wk |
| Phone call with medical provider 1x/wk |
| Chat with medical provider through mobile application as needed |

### 12-week follow-up or upon completion of 36 sessions (within 6 months)

<table>
<thead>
<tr>
<th><strong>Details</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional capacity testing</td>
</tr>
</tbody>
</table>
| Physical Examination | Repeat:  
Vital Signs  
Weight  
Height  
Blood pressure |
| Questionnaires | Repeat SF-36 |
Appendix H: Sample Size Calculation

<table>
<thead>
<tr>
<th>Group</th>
<th>Proportion Positive</th>
<th>N Per Group</th>
<th>Standard Error</th>
<th>95% Lower</th>
<th>95% Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility-based CR</td>
<td>0.68</td>
<td>35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobile app-based CR</td>
<td>0.34</td>
<td>35</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rate Difference: -0.26

Alpha= 0.050, Tails= 2

Power = 0.805
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