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Designing a Health Coach-Augmented mHealth System for the Secondary Prevention of Coronary Heart Disease

Avijit Sengupta

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Designing a Health Coach-Augmented mHealth System for the Secondary Prevention of Coronary Heart Disease

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy
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Keywords: Health Information Technology, Center Based Cardiac Rehabilitation, Design Science Research, Behavior Change Interventions, Chronic Disease Management

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DEDICATION

This dissertation is dedicated to my dearest brother, Amit Kanti Sengupta, with love and respect.
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In completing this dissertation, I have benefited greatly over these years from discussions with Dr. Kaushik Dutta. I would like to acknowledge his support and guidance through my Ph.D. journey and thank him for countless reviews, suggestions, and motivation across these years. Dr. Dutta, a true mentor, has been instrumental in my development as a researcher and teacher.

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ABSTRACT

This dissertation presents research that employs design science research (DSR) methodology to develop and evaluate a high-fidelity prototype of a home-based cardiac rehabilitation (HBCR) system to support self-management of chronic cardiovascular diseases like coronary heart disease (CHD) and to offer secondary prevention against other chronic disease with similar risk factors. While the population of coronary heart disease (CHD) patients requiring cardiac rehabilitation (CR) continues to expand, lack of access and other barriers to center based cardiac rehabilitation (CBCR) presents a huge challenge. A mobile phone and wearable device based technological system can offer a HBCR program for CHD. By following DSR guidelines we have designed a digital health intervention system for use in a HBCR program. The system we propose combines ‘human-expert’ intelligence with machine intelligence to enhance the decision-making capability of a health coach. We initially evaluated the prototype of our system with ten patients with CHD over 13 weeks through a single arm, quasi-experimental study (Sengupta et al. 2020a). The evaluation reveals a significant positive impact of the preprogrammed intervention messages on participants’ step count and walking duration on the same and the next day. Since increased step count and walking duration positively correlates with the improve heart health, we can directly infer that our proposed system is beneficial as a tool for secondary prevention of CHD (Sengupta et al. 2020b).

Mobile health information technology (HIT) interventions (like our HBCR system) offer a new paradigm in chronic disease management by empowering patients with information, tools, and alerts and engaging them in the self-management of their own diseases. However, we know little
about how these technologies work and how we can design features to sustain their use over time. We also explore these issues using the affordance actualization concept to examine two types of affordance actualization offered by these technologies: intended and unintended. We hypothesize the independent and joint effects of these affordance actualizations, by integrating affordance with goal setting theory and nudge theory. The proposed hypotheses are empirically tested using a field trial of our home-based cardiac rehabilitation prototype for patient self-management of coronary heart disease. Panel data from this study, analyzed using multi-level, zero-inflated Poisson, and negative binomial models, provide support for our hypotheses. This study explicates the complex interplay between intended and unintended affordance actualization, draws attention to the actualization of affordances in unexpected ways (Sengupta et al. 2020c), which can potentially explain both effective use and misuse of technologies, elaborates how we can build process oriented models of technology-related behaviors by drawing on conscious and subconscious cognitive processes linked to technological affordance actualization, and demonstrates how HIT design can benefit from considering unintended affordance actualization as a behavioral intervention for chronic care patients.
CHAPTER 1. INTRODUCTION

1.1 Background

Chronic diseases affect six out of ten adults in the United States, cost the nation 90% of its $3.5 trillion annual healthcare costs, and are the leading causes of death and disability (Centers for Disease Control and Prevention 2020). Chronic diseases are generally incurable, but sometimes preventable and often manageable. Key lifestyle risk factors for chronic diseases are tobacco and alcohol use, poor nutrition, obesity, and lack of physical activity (Centers for Disease Control and Prevention 2020). Chronic disease management refers to “an integrated care approach to managing illnesses which includes screenings, check-ups, monitoring and coordinated treatment, and patient education” (Healthcare.gov 2020).

Positive lifestyle changes, such as healthy diet and regular exercise (Moran et al. 2016), are the keys to controlling chronic diseases, reducing their severity, and improving patients’ overall quality of life (Smith et al. 2015). However, patients are often demotivated or lack the discipline to engage in the recommended level of daily physical activity or are otherwise unable to do so because of time constraints, work obligations, or other reasons. While human therapists can work with patients to track their weekly activity levels, customize their intervention programs, and provide them motivational support, such programs are expensive and unrealistic for millions of low-income people or retirees living on fixed income.

Heart diseases, like coronary heart disease, are the most prevalent chronic disease, resulting in one of every four deaths, followed by cancer, lung disease, stroke, diabetes, and
kidney disease. Coronary heart disease (CHD) afflicts 16.5 million American annually and is their leading cause of disability worldwide (Benjamin et al. 2017). The overall prevalence of CHD is expected to increase by more than 40% by 2035. In 2015, the estimated cost of caring for CHD patients was $182 billion in the U.S.; hospitalizations accounted for more than half of the costs (Benjamin et al. 2017). Compared to men, women with CHD or who have undergone coronary revascularization have up to 30% more re-hospitalizations within 30 days and the likelihood of rehospitalization remains the same for up to 1 year (Wasfy et al. 2013, Dreyer et al. 2015, Hess et al. 2017). Effective interventions for improving cardiovascular health among adults with CHD are vital for chronic patient care. In my dissertation, I will discuss the design, deployment, and evaluation of a home-based cardiac rehabilitation (HBCR) system that integrates smartphone-based ecological momentary assessments and behavior change interventions, activity tracking via a smartwatch, and a web-based dashboard for data visualization and patient activity monitoring (Sengupta et al. 2020a, 2020b).

1.2 What is center based cardiac rehabilitation?

Center-based cardiac rehabilitation programs (American Association of Cardiovascular & Pulmonary Rehabilitation 2004) are the gold standard of care (Savage et al. 2011) for the secondary prevention of CHD. Center-based cardiac rehabilitation (CBCR) is a multidisciplinary, comprehensive, evidence-based intervention with proven morbidity and mortality benefits (Forman 2014). CBCR in the U.S. generally takes place in the outpatient setting over 12 weeks after which patients are encouraged to attend ongoing community-based exercise programs (Moran et al. 2016). Inadequate health insurance and co-payments of up to $250/session, low family income, transportation challenges, time constraints, and work obligations deter women from attending CBCR (Beckman et al. 2016, Grace et al. 2009,
Sanderson and Bittner 2005, Beckie and Beckstead 2010). CHD patients struggle with disease self-management without knowledge and skills for effective behavior change to reduce risks for subsequent cardiac events. Limited access to CBCR has led to a call for the design and development of an engaging, personalized, HBCR for patients with CHD (Balady et al. 2011, Lavie et al. 2016).

1.3 Mobile Health Information Technology

To address this issue, mobile health information technology (HIT) interventions have emerged that employ smartphone or smartwatch-based sensors to continually monitor patient activities and provide real-time feedback, automated reminders, and customized recommendations using specially designed smartphone applications. These digital interventions, often used for cardiac and diabetes management, are ushering in a new paradigm of “technology-enabled self-managed care” by empowering patients with data and automated tools they need to manage their own chronic conditions, with limited input from clinical staff. Mobile HIT a system can improve access to CR by offering just-in-time adaptive interventions (JITAI). Such a mobile HIT system, compared to CBCR, overcomes logistical barriers to access, including the limited 3-4 hours weekly in-person contact with staff, and is less costly. It can provide health-related education, real-time feedback, and continuous monitoring through wearable sensors (like smartwatches) and smartphones that are available 24/7. HBCR using mobile health information technologies can provide numerous patient touchpoints for enhanced engagement via wearable sensors, and communication with a health coach when needed.

As smartphone use have grown among chronic disease patients and smartphone-based health apps have become popular, research in mobile HIT interventions is still largely limited to design strategies and generic frameworks for conceptualizing, building, and deploying HIT
artifacts (Chatterjee et al. 2018; Landman et al. 2015; Mirkovic et al. 2014). There has been little academic investigation into whether these interventions can achieve effects similar or comparable to human therapists, if these interventions can motivate desired behavioral changes, or what can we do to maximize and sustain the effects of these interventions (Ashford et al. 2010, Williams and French 2011). One reason for these gaps in the literature is the lack of connection between design and use of mobile HIT interventions and our inattention to theories to link mobile HIT design with patients’ behavioral change. Hence, we occasionally experience underutilization or abandonment of these technologies after their initial acceptance, but cannot explain why such abandonment occurs or how we can remedy it (Krebs and Duncan 2015, Clawson et al. 2015, Carroll et al. 2017).

In this research, we are designing a digital health intervention system for use in an HBCR program that incorporated multiple theory-based behavior change techniques (Michie et al. 2013). We have developed a high-fidelity prototype of the system and evaluated it with ten patients with CHD through a field test over 13 weeks. Unlike most mHealth interventions that deliver text messages that are independent of recent patient behavior (Hutchesson et al. 2015), our system implemented personalized, multiple theory-based interventions in response to the patients’ vulnerable physical and emotional states of patients that were periodically assessed using their own responses to carefully crafted questions, and a smartwatch that recognized their physical activities. This mHealth intervention has significant potential to improve the health behaviors and cardiovascular (CV) risks of patient without access to CBCR. Our research focused on the following questions:

1) What is feasible and required to develop a comprehensive mobile health information technology for cardiac rehabilitation (CR) program for patients with coronary heart disease?
2) What is the impact of a mobile health information technology system for patients with CHD?

Our research can contribute to the current body of knowledge in three possible ways. First, this study describes the process for developing instances of theory-guided, behavior change interventions. Second, the study provides insights regarding the design of a mobile technology-based CR program augmented with a health coach’s involvement by developing and testing a prototype that works as a closed loop system by monitoring outcomes for each of the interventions and then altering the interventions for better outcomes. Third, our study can demonstrate the feasibility and usability of our solution using a quasi-experiment based observational study methodology by analyzing both qualitative and quantitative data collected for the ten participants. The evaluation reveals a significant positive impact of preprogrammed intervention messages on participants’ walk performance on the same day as the message is delivered, as well as on the next day’s performance (Sengupta et al. 2020b). Since increased walking activities directly improve heart health, we can directly infer that the proposed mobile HIT system is beneficial as a tool for secondary prevention among patients with CHD. The designed HBCR system also encourages patients to eat healthy food and manage their stress, both of which are correlated with improved physical activities, hence directly contributing to heart health.
CHAPTER 2. LITERATURE REVIEW

2.1 Literature Review Process

To conduct the literature review we have searched three major databases namely ‘Web of Science’, ‘JSTOR’ and ‘ABI/Inform Global’ by using phrases like ‘mHealth system for home based cardiac rehabilitation’, ‘mHealth interventions for cardiovascular diseases’, ‘system design for cardiac rehabilitation’, etc. Apart from that, we also searched the ACM Digital Library archives using the same phrases. Based on our selection criteria like ‘research design’, ‘availability of details of the mHealth system design artifact’, ‘development of a design artifact’, ‘evaluation of an artifact’ etc. we have finally considered 17 articles for further analysis. We developed four analytical lenses to conduct a thorough review of these 17 research articles. These four analytical lenses are ‘theoretical underpinning’, ‘extent of evaluation’, ‘level of human involvement’ and ‘specificity of the target population’.

These research articles provided a holistic understanding of the current positioning of different research work related to secondary prevention of chronic diseases through mHealth technology systems. We first developed a thorough understanding of the status of extant research by making a comprehensive table that represented all seventeen studies through different important attributes: the purpose of the study, target population, aid type, evaluation method used, features offered by the artifact, use of theory and system components.
2.2 Making Sense of the Extant Literature and Development of Analytical Lenses

Our first two analytical lenses, ‘Theoretical Underpinning’ and ‘Extant of Evaluation’, comprise two axes, which together represent the interaction space of theoretical underpinning and extent of evaluation, as defined in Table 1. We divided this interaction space into four quadrants. While the left-bottom quadrant represents the space where the theoretical underpinning and extent of evaluation are both low, the right-top quadrant represents the space where both of them are high. In a similar manner, the right-bottom quadrant represents the space where the theoretical underpinning is high, while the extent of evaluation is low. The left-top quadrant represents the space where the theoretical underpinning is low, while the extent of evaluation is high.

Table 1: Definition of constructs representing four axes of analytical lens.

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Theoretical Underpinning</td>
<td>We define theoretical underpinning as the extent to which the study uses single or multiple theories in the creation of artifact (construct, method, model and instantiations), sociotechnical system or proposition. For example, we consider a study to have a comparatively higher theoretical underpinning if the study used multiple theories in the development of an artifact than a study that used a single theory in the development of the artifact.</td>
</tr>
</tbody>
</table>
Table 1: (Continued)

<table>
<thead>
<tr>
<th>Extent of Evaluation</th>
<th>We define the extent of evaluation as the development and deployment of rigorous evaluation protocols along with the number of different evaluation methods (both qualitative and quantitative) followed while evaluating a designed artifact. We tag a study with a comparatively higher extent of evaluation if the study used multiple methods to evaluate the designed artifact instead of just one method.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of Human Involvement</td>
<td>We define the level of human involvement as the extent to which the designed artifact involves a human being while performing a specific task assigned to the artifact. As per our definition, we tag a study with a comparatively higher level of human involvement if the designed artifact involves a human being while it is executing a task or making a decision. If a study in which the designed artifact does not involve a human being (i.e., is completely automatic) in executing a task or in the decision-making process, the study is considered to have a low level of human involvement.</td>
</tr>
<tr>
<td>Specificity of Target Population</td>
<td>We define the specificity of the target population as the extent to which the designed solution caters to the needs of a specific population. We assign a comparatively higher level of specificity to a study if the study is trying to address the needs of a population that is quite a niche (e.g., ischemic heart disease patients). If the study is trying to address the needs of a population that is quite broad (healthy people and potential cardiac patients) then it is assigned under a comparatively low level of specificity regarding the target population.</td>
</tr>
</tbody>
</table>
Our third and fourth analytical lens represents the interaction space of the level of human involvement and specificity of the target population, as defined in Table 1. This interaction space has four quadrants. The left-bottom quadrant represents the space related to a low level of human involvement and low specificity of the target population. The right-top quadrant represents the space where both the level of human involvement and the specificity of the target population are high. The right-bottom quadrant represents the space where the level of human involvement is high while the specificity of the target population is low. The left-top quadrant represents the space where the level of human involvement is low while the specificity of the target population is high. After developing a thorough understanding of the individual studies, we plot each of them on the interaction spaces offered by our analytical lens (see Figure 1 and Figure 2).

![Diagram](image)

Figure 1: Plot of all the studies on the interaction space of theoretical underpinning and extent of evaluation
2.3 Identification of Patterns and Generation of Insights

Figure 1 suggests that most of the extant research has a low level of theoretical underpinning, which means most of the studies hardly considered any theories while designing the artifact to address the problem. This may lead to low efficacy of the artifact and early abandonment or underuse of the developed system. This can make the whole prevention program ineffective, as most of the interventions require a certain timespan to become effective. Therefore, designing such an artifact should incorporate relevant theories to ensure the effectiveness of interventions deployed through the artifact or the system. In the current study, we incorporated psychological determinants of behavior suggested by different behavior change theories while developing the artifact (instantiations of behavior change interventions).

![Figure 2: Plot of all the studies on the interaction space of the level of human involvement and specificity of the target population](image-url)
Figure 2 suggests that most of the contemporary studies developed artifacts that are completely automatic in nature and do not involve human expertise while completing a task or making any decision for interventions. This can be a risky proposition as a random or systematic malfunction of the system or artifact can be fatal to the target populations that are more medically sensitive. A completely automated system often fails to predict or prepare alternative intervention strategies to sudden shifts in human behavior. Even though they can detect such events, they fail to assign a meaning to those events or situations which are often obvious to a human expert. Such completely automated systems also produce frequent false alarms, which affects their trustworthiness. Therefore, the presence of a human expert is often essential for the efficient functioning of the complete system. In our home-based cardiac rehabilitation system, we put the health coach in front of the dashboard for making subtle decisions related to the content, time and nature of the interventions. By putting the health coach in the position of decision making, we also close the loop involving proximal and distal outcomes.

Since we want to develop artifacts with a high level of theoretical underpinning and want to evaluate them thoroughly, we mostly focus our discussion on papers that are plotted in the right-top quadrant of interaction space representing a high level of theoretical underpinning and rigorous evaluation of artifacts. As our study is targeted towards a specific patient population (coronary heart disease patients) and we want to keep a human expert in the decision-making process, we also focused on those papers which had considered a specific target population and included human experts in the decision-making process.

We found that there is only one paper (Forman et al. 2014) which is common to both of the quadrants under two different analytical lenses. In their study, Forman and colleagues (2014) examined the feasibility and utility of a mobile smartphone application for non-clinic based
cardiac rehabilitation. They also built a dashboard for the health coach for patient surveillance and used theoretical tenets of reinforced learning and cardiac rehabilitation goals to build the mobile application. Finally, the authors tested the system with 26 patients for 30 days and evaluated the efficacy of the system by analyzing both qualitative and quantitative data. Though the study has established the feasibility of mHealth based CR, it still lacks a strong theoretical underpinning. Apart from that, the trial period of 30 days is often inadequate for a behavior change to occur and be sustained. In our study, we have addressed both of these issues by incorporating multiple behavior change theories and a 13-week field trial period.

While Beatty et al. (2018) used a unified theory of acceptance and use of technology (Venkatesh and Zhang 2010), and theory of planned behavior (Ajzen 1991) as the theoretical base for their study, Sankaran et al. (2016) used the Fogg behavior model (Fogg 2009), a persuasive system design model (Oinas-Kukkonen and Harjumaa 2018) and behavior wizard framework to guide their artifact design. For the extent of evaluation, Beatty et al. (2018) used multiple evaluation methods (individual interviews, survey-based usability testing) to test the efficacy of the system, while Sankaran et al. (2016) only used lab-based usability testing techniques to evaluate the efficacy of their artifact. Despite strong theoretical underpinnings, neither study used long-term field trials to objectively monitor patients’ physical activity to determine the effectiveness of the systems in changing patient behavior. Their evaluation methods were mostly limited to the usability of the systems. Apart from that, neither system explicitly involved human beings in their decision-making processes.

Regarding the use of theory, Moran et al. (2016) used social cognitive theory for the development of a technology-enabled exercise-based system for cardiac rehabilitation, while Ahtinen et al. (2010) used principles of social sharing during the development of their system for
physically fit adults. While Moran et al. (2016) evaluated their system only by providing live interactive demonstrations, Ahtinen et al. (2010) have done both formative and summative evaluations of their system with a small group of people. Ahtinen et al. (2010) used both surveys and personal interview techniques to evaluate their system.

Regarding the evaluation of my study, we adopted a process similar to Ahtinen et al. (2010) along with a 13-week field trial of the system with CHD patients. Systems designed by Moran et al. (2016) and Ahtinen et al. (2010) did not explicitly involve human experts in their decision-making process.

Regarding the level of human involvement along with the specificity of the target population, we will focus on four studies done by Maitland et al. (2016), Geurts et al. (2016), Matheou et al. (2011) and Qudah et al. (2010). While Qudah et al. (2010) and Geurts et al. (2016) both developed a dashboard for continuous monitoring of patients’ attributes, Maitland et al. (2016) developed a collaborative multimedia rehabilitation journal as part of their technological probe. Matheou et al. (2011) developed an integrated web-based system that can regularly monitor several bio-signals of patients like ECG, oxygen saturation, noninvasive blood pressure, and additional parameters like body weight, etc. All these systems involve human experts in monitoring and developing interventions for their target populations. We have followed the same practice in our design science research.

Finally, as we have seen in Figure 2, most of the studies built their systems targeting very specific patient populations. While Micallef et al. (2016) targeted stroke survivors with an arm impairment, Geurts et al. (2016) targeted the patient population suffering from ischemic heart disease. There are a few studies like Vosbergen et al. (2010), Forman et al. (2014), Sankaran et al. (2016), Moran et al. (2016) who have developed their systems for patients suffering from
cardiovascular diseases. Though our primary target population consists of patients who are trying to self-manage their chronic conditions of coronary heart disease, we believe that our proposed system can also be equally beneficial for patients suffering from other cardiovascular diseases.

There are studies in which users have to self-report (by typing inside the app) their physical activity behavior and other physiological biomarkers and their values (Johnston et al. 2016, Varnfield et al. 2014, Widmer et al. 2015, Seo et al. 2015, Layton et al. 2014). Some of these systems even function or intervene based on the information inserted by the patients themselves (Varnfield et al. 2014, Widmer et al. 2015). This can generate various kinds of issues like incorrect data entry and recall bias. Therefore, any intervention which is triggered based on the analysis of such data may fail to make the desired impact. Apart from that, asking patients to enter all the clinical, physiological, psychological, medication and risk-related data on their own can lead to non-use or underuse of the system. This “high data entry burden” issue is not limited to products or prototypes developed to conduct research, but also includes mobile applications for cardiac care which are commercially available and provided by governments or private associations for free. For example, mobile apps like “My Cardiac Coach” and “Love My Heart for Women,” which were developed and offered by American Heart Association and Women’s Heart Center of Columbia University, respectively, also ask patients to enter the health-related data for efficient and meaningful use of the application. The data entry task is often perceived as cumbersome. The United States national level study conducted by Krebs and Duncan (2015) reported that almost half of the app users (45.7%) stop using health related apps due to high data entry burden, loss of interest, and hidden costs. Considering the detrimental effect of ‘high data entry burden’, in our study we have collected patients’ health and physical activity related data as they are using the system rather than asking them to self-report such data.
We developed and evaluated the system prototype by keeping four key requirements in mind. First, our interventions should be based on relevant behavior change theories and model constructs. Second, our evaluation of the system prototype should be thorough and should involve target users in real life settings. Three, the system prototype should cater to the requirements of the specific target population (CHD) and the design should incorporate characteristics of the target population. Finally, the system should not become a standalone system and should keep the health coach at the center of the intervention process, but only as needed. Previous research (Micallef et al. 2016, Consolvo et al. 2006, Ahtinen et al. 2010) in designing self-management systems has not fully realized the benefits of involving a health coach to monitor and facilitate patient behavior change through shared decision making. Augmenting a mHealth system with a health coach can provide expert observation, detection, analysis and deliver effective interventions when and where needed (Dicianno et al. 2015). Involvement of a health coach in the decision-making process can further act as a safeguard against random or systematic malfunction of the system. By doing so we wanted to form a closed loop among the interventions, proximal outcomes, and distal outcomes.
CHAPTER 3. METHODOLOGY

3.1 Design Science Research

We have used design science research (DSR) as the methodology (Hevner et al. 2004) for the development of a high-fidelity prototype of the HBCR system and evaluated the system through a field trial following single arm quasi-experimental design methodology. Over the past decade, DSR has established itself as one of the key research paradigms in information systems (IS) research and encompasses a diverse set of design perspectives on problem-solving (Goes 2014). From a methodological standpoint, DSR offers several succinct frameworks, guidelines for conducting, evaluating, justifying and communicating artifact development. There has also been a rich discussion around the role of theories in DSR (Chatterjee et al. 2018; Vom Brocke et al. 2020). DSR methodology provides a unique opportunity for generating knowledge by following an iterative process of building and evaluating artifacts, which can be constructs, models, methods, and instantiations (Hevner et al. 2004). Starting from the development of instantiation to solve a “wicked problem” (Brooks Jr 1996), DSR methodology can allow us to generate a more abstract forms of knowledge such as models and constructs. These inherent flexibilities of DSR makes it a suitable method for conducting IS research while trying to address a real-life problem (Chatterjee et al. 2018). Table 2 presents how we have followed the seven design science research guidelines suggested by Hevner et al. (2004) to build and evaluate the proposed HBCR system.
3.2 Following Design Science Research Guidelines

Table 2: Adoption of design science research guidelines for the research methodology.

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Description</th>
<th>Adoption of Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline 1: Design Science Research must produce a viable artifact (a construct, a model, a method or an instantiation) (Hevner et al. 2004)</td>
<td>While developing a prototype of an HBCR system for CHD patients, we developed three artifacts that are essential for the efficient and reliable functioning of the system.</td>
<td>Artifact 1 (Instantiation): Customized algorithm for the detection of patient’s activity</td>
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<td></td>
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<td>Artifact 2 (Instantiation): A comprehensive set of graphical representations of different theory-based behavior change interventions</td>
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<tr>
<td></td>
<td></td>
<td>Artifact 3 (Instantiation): A web-based dashboard for monitoring patient’s activity and make necessary interventions</td>
</tr>
<tr>
<td>Guideline 2: The objective of design science research is to develop technology-based solutions to important and</td>
<td>Extensive underuse of center-based cardiac rehabilitation implies that higher mortality, morbidity, re-hospitalizations, and associated costs could theoretically be avoided if cardiac rehabilitation was utilized appropriately on a large scale. We have developed a digital health intervention system for use in a HBCR, which includes a smartwatch, a mobile application and a</td>
<td></td>
</tr>
<tr>
<td>Guideline 3: Design Evaluation</td>
<td>Relevant business problems (Hevner et al. 2004)</td>
<td>web portal at the front end and a HIPAA-compliant, private cloud system at the back end.</td>
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<tr>
<td>-------------------------------</td>
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<tr>
<td>Guideline 4: Research Contribution</td>
<td>Effective design science research must provide clear and verifiable contribution in the area of design artifact, design foundations and/or design</td>
<td>The prototype of a HBCR system along with three different artifacts (components) presents a novel proof of concept solution which positions itself in the upper left quadrant, representing an improvement over other existing solutions in the diagram suggested by Gregor and Hevner (2013, Figure 3). The system differs from other existing efforts in that it places a health coach in a pivotal role in decision making for each of the individual patients. By doing so it combines the advantages of both</td>
</tr>
<tr>
<td>Guideline 5: Research Rigor</td>
<td>Guideline 6: Design is a Search process</td>
<td>Search for an effective artifact requires utilizing available means to reach desired ends</td>
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<tr>
<td><strong>Guideline 5:</strong></td>
<td><strong>Design science research relies upon the application of rigorous methods in both the construction and evaluation of the design artifact (Hevner et al. 2004)</strong></td>
<td>We involved domain experts and tried to incorporate their recommendations while designing the system. Through the NSF I-Corps project, we incorporated 100 interviews of patients with cardiovascular diseases and health-care professionals treating cardiovascular disease patients to help us select appropriate content for theory-based behavior change interventions and their visual representations. This process also served as the required manipulation check for the intervention content we developed. We built multiple prototypes of the system by following an iterative design process suggested by Hevner et al. (2004). We evaluate the HBCR system by recruiting CHD patients and asking them to use the system for 13 weeks.</td>
</tr>
</tbody>
</table>
Table 2: (Continued)

<table>
<thead>
<tr>
<th>Guideline 7: Communication of Research</th>
<th>Design science research must be presented effectively both to technology-oriented as well as management-oriented audiences.</th>
<th>We communicated the implication of our research to both technology-oriented as well as management-oriented audiences by suggesting technology-specific and management-specific takeaways. For the technology-oriented audience, we offer a HBCR system as a novel proof of concept solution and its architecture. For the management-oriented audience, the solution provides opportunities for new levels of customer services and convenience. It offers a scope of altering the current cost structures as well as provides new opportunities for revenue.</th>
</tr>
</thead>
</table>

3.3 **Field Observational Study as Evaluation Method**

As we have mentioned earlier, we used field observational study and quasi-experiment as our evaluation methodology for the HBCR prototype that we have developed. The field observational study method is appropriate for the study for four reasons. First, we cannot study a
patient’s behavior change outside of the patient’s natural setting. Such an attempt would be ineffective as the purpose of the system design is to provide HBCR to CHD patients in their natural settings. Second, the study targets a contemporary event driven by the new advancement of mobile and sensor technologies. Third, in the study, the control or manipulation of subjects is necessary only to the extent to which participants are exposed to pre-designed interventions as per their interactions with the designed artifact. The study did not manipulate an experimental condition regarding the usage or non-usage of designed artifacts and all the behavior change interventions are embedded within the system. The manifestation of interventions completely depends on the patient’s use of the system and we have no particular control over the patient’s use of the system. Four, though the phenomenon of interest uses behavior change theories, none of them specifically offers any prescriptive suggestion based on which such an HBCR system can be designed. As most of the existing behavior change theories are not tailored for the health behavior change using digital technology, their efficacy is still unknown under natural field settings. Therefore, the field observational study method can help us to trace intervention performance over a period of time rather than just frequency of an incidence like relapse, performance, etc. (Benbasat et al.1987, Wynn and Williams 2012). According to Benbasat et al. (1987), the results derived from a field observation study depend heavily on the researchers’ integrative powers, and the “generalizability of the results can only be assessed by observing future similar cases and by applying theory to understand the behavior patterns”. It can easily be argued that the validity of the field observation study cannot be derived from its representativeness since it can never legitimately be claimed to form a representative sample from a larger set. The essence of the selection must rest in the dynamic of the relationship between technology and agent. The selection cannot be tested in typicality. In most field
observation study, the number of observations are small, but they can still provide meaningful insights (Walsham 1995, Walsham 2006).

3.4 System Differentiation

The current study addresses a well-recognized and persistent problem of secondary prevention of CHD through mobile health technology in the context of HBCR. In this study, we propose an alternative to CBCR by developing a system that can be used in the home. The development of these artifacts offers an improved solution to the problem (Gregor and Hevner 2013). In this regard, the system is distinct from the existing solutions in five ways:

1) While many mobile applications target the physical fitness and sedentary behavior of users, most of them are not grounded in the theoretical platform of behavior change. Some of them (Moran et al. 2016, Beatty et al. 2018) suggest a theory-based intervention based on a single or at most two theories. We focus on interventions that are supported by multiple behavior change theories and models.

2) Our design solution is not complete automation, and health coaches are integral for monitoring and timely interventions. The mHealth system complements the health coach in observing, detecting, and analyzing patient’s activity and deploying interventions at the time they are expected to be most effective. The presence of a health coach in the decision-making process facilitates in gaining the trust of patients for utilizing the mHealth system.

3) We designed our solution specifically for patients with CHD. We used graphical user interfaces (GUIs) to create instantiations of behavior change interventions by carefully utilizing psychological determinants of behaviors suggested by multiple different behavior change theories. By being specific and target oriented we have built a solution that is customized to the needs of our target population of cardiovascular patients.
4) Our design solution uses responses from ecological momentary assessments (EMA) to design interventions to target the health behavior of patients. Though EMAs are typically used to examine the mechanisms linking the immediate environment with behaviors, in our design solution we use EMA responses as the basis of behavior interventions.

5) We developed a dashboard to monitor patients’ physical activities, responses to EMA surveys, their activity goals, activity performances and their detailed usage of the system. The dashboard gives the health coach unique opportunities to track both proximal and distal outcomes of the interventions triggered from time to time, for each patient individually (Sengupta et al. 2020b).
CHAPTER 4. SYSTEM DESIGN

4.1 Design of Home-Based Cardiac Rehabilitation System

The primary objective of the HBCR system is to help CHD patients to self-manage their chronic condition by tracking their physical activity in their home or at work, identifying their daily self-reported eating behavior and mood at multiple times during the day, and encouraging them to begin or continue regular physical activity that will improve their heart health. We developed an assistive technology that includes an application for a smartwatch and a smartphone along with a web-based dashboard for monitoring patients’ behavioral data. This provides the research team with a suitable platform for the detection of physical activity behavior and triggering proper behavior change interventions in response to the assessment of the momentary and periodic physical, eating, and emotional states. The system functions in three consecutive stages: 1) sensor (accelerometer and gyroscope in a smartwatch) and ecological momentary assessment (EMA) based data gathering, 2) making sense of data through machine learning and domain expert involvement, and 3) triggering behavior change interventions to encourage patients to improve their health behaviors (Sengupta et al. 2020a, 2020b).

4.2 Key Design Principles

While designing the system, we followed seven design principles throughout the process:

**DP1: Involvement of Health Coach:** The role of the technology is to improve the efficiency of a health coach. The health coach and system together suggest a course of action for patient
behavior. The diagnosis, pattern-matching, and relevance-recognition part are performed by both the health coach and the technology system.

**DP2: Socio-Technological System:** Ours is a healthcare problem, not a technology problem (McGrath 2005; Chatterjee et al. 2018). At the center is the patient, not the technology. This also means that behavior change interventions must adapt to the patient’s requirements and their EMA responses.

**DP3: Simple Interaction:** Patients must comprehend what is being sent as feedback from the technology and the health coach.

**DP4: Interoperability:** The technology needs to be reliable and interoperable (Chatterjee et al. 2018) with a data collection hub placed inside the cloud. All the archived data remains accessible to the health coach for just-in-time adaptive interventions. The data collection should follow HIPAA compliance (Pub 1996, Law 1996).

**DP5: Proximal-outcome based decision rules for behavior change interventions:** The behavior change interventions must be relevant to the patients, and they must be innovative to keep them interested and engaged with the system (Fogg and Adler 2009; Chatterjee et al. 2018). Decision rules for behavior change interventions need to be developed to target proximal outcomes of behavior e.g., healthy eating, increased physical activity, and better stress management. For example, if a patient is continuously reporting eating unhealthy food every day for a certain number of days, the health coach can deploy an intervention suggesting a healthy eating behavior.

**DP6: Multi-modal data collection for accurate interpretation and decision making:** The system must allow the collection of patient data through multiple modes (e.g. sensors, EMA
surveys, etc.) for superior precision, accurate interpretation and decision making. The designed system should allow the use of multiple modes to trigger interventions.

**DP7: Reliability and Trustworthiness:** The system should work efficiently both inside and outside of patients’ home environments for optimal adherence and engagement with the system. This is necessary for a behavior change to occur and the desired behavior to be sustained without any episode of relapse.

In the following sections, we will provide details of the design of the overall architecture of the system and its artifacts. The overall system architecture is depicted in Figure 3.

![Figure 3: System architecture (Sengupta et al. 2020b)](image)

### 4.3 Design of the System Architecture

We use a smartwatch app and a smartphone app to collect data on a patient’s daily physical activity, heart rate, eating episodes and moods. Data from the sensors embedded in the smartwatch are interpreted as step-counts and heart rate and are sent to the smartphone via
Bluetooth and then to a cloud drive via Wi-Fi or 4G. All data uploaded to the cloud is then downloaded immediately and uploaded to a server over a secured VPN connection through the public internet (Sengupta et al. 2020b).

Data in the server is analyzed and projected on the dashboard for the health coach to view. The old data is archived and then refreshed by the most recent data on the dashboard every 10 minutes. Data analysis techniques are applied to make sense of the patient’s activity, heart rate and EMA survey response data. Patients’ physical activities and EMA responses are analyzed through a decision rules based expert system as well as by the health coach. This data is used to send standard preprogrammed intervention messages to the patients by the system and to help the health coach to customize intervention messages to send to patients through the dashboard at the right time to maximize their impact (Sengupta et al. 2020b).

4.4 Theory-Based Behavior Change Techniques (BCTs) and Interventions

According to Alageel et al.’s (2017) theories of the psychological determinants of behavior can be used to develop and evaluate behavior change interventions. Interventions are likely to be more effective when they systematically target psychological determinants of behavior (Alageel et al. 2017, Zhao et al. 2016). We design instantiations of our behavior change interventions based on common determinants of eight behavior change theories. These eight behavior-change theories are Control Theory (CT), Transtheoretical Model (TTM), Social Cognitive Theory (SCogT), Self-Determination Theory (SDT), Theory of Reasoned Action (TRA), Theory of Planned Behavior (TPB), Information Motivation Behavioral Skills (IMB), and Operand Conditioning (OC). They were selected as the most effective from an extensive potential list of 83 behavioral theories (Davis et al. 2015). The underlying assumption is that multiple theoretical frameworks that represent important theoretical constructs (psychological determinants) will
work synergistically when designed thoughtfully, even for complex behavioral interventions (Sengupta et al. 2020b)). Table 3 provides brief details of the eight theories that we have used for the design of instantiations of behavior change interventions.

Table 3: Brief details of the eight theories used for the creation of instantiations of behavior change interventions.

<table>
<thead>
<tr>
<th>Theory / Model</th>
<th>Theoretical Tenants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Theory (CT) (Carver &amp; Scheier 1982)</td>
<td>Control theory specifies action control processes underpinning behavioral regulation. The theory proposes that setting goals, monitoring behavior, receiving feedback, and reviewing relevant goals in the light of feedback are central to self-management and behavioral control.</td>
</tr>
<tr>
<td>Transtheoretical Model (Stages of change) (Prochaska et al. 1992)</td>
<td>The model predicts that interventions tailored to the stage of behavioral readiness to change are more effective. Behavior change occurs in stages from pre-contemplation to action to maintenance. Ten processes of change (e.g. stimulus control, counterconditioning, reward, helping relationships, environmental control) enhance progress through stages. Decision balance, self-efficacy, and situational temptations are key constructs.</td>
</tr>
<tr>
<td>Social Cognitive Theory (SCogT) (Bandura &amp; Wessels 1997)</td>
<td>Perceived self-efficacy, the belief about the capacity to undertake the behavior, influences all aspects of behavior. Behavior change is a function of outcome expectations and efficacy expectations about the target behavior. Key BCTs...</td>
</tr>
</tbody>
</table>
include goal setting, self-monitoring, self-efficacy enhancement, and positive feedback on performance.

<table>
<thead>
<tr>
<th><strong>Table 3: (Continued)</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Self-Determination Theory (Deci &amp; Ryan 1985, Ryan &amp; Deci 2000)</strong></td>
<td>SDT posits that motivation for healthy behaviors is facilitated when basic needs for autonomy (sense of control over behavior), competence (self-efficacy or confidence), and connectedness are met. Perceived competence influences self-regulation, both of which influence the maintenance of behaviors. The premise is that reinforcement and environmental contingencies influence behavior. Motivation can evolve from extrinsic focus to intrinsic with appropriate socio-environmental conditions.</td>
</tr>
<tr>
<td><strong>Theory of Reasoned Action (TRA) (Fishbein &amp; Ajzen 1975)</strong></td>
<td>Individuals evaluating the proposed behavior as positive (attitude), and believing that significant others support the proposed behavior (subjective norm), will have greater intention (motivations) and are more likely to perform the behavior. Behavioral intention (e.g., physical activity) is driven by three constructs: attitudes toward the behavior, subjective norms, and, expanding on the TRA, perceived behavioral control (a combination of self-efficacy and controllability). More favorable attitudes towards the behavior and subjective norms and greater perceived behavioral control will result in stronger intention to perform the behavior.</td>
</tr>
<tr>
<td>Information-Motivation-Behavioral Skills model (IMB) (Fisher et al. 2002)</td>
<td>Information about disease transmission and prevention is a prerequisite of behavioral risk reduction. The second determinant of behavior change is the motivation to engage in behavior change, and having behavioral skills for performing specific behaviors is the third determinant of behavior change. Information and motivation are thought to affect the use of risk reduction behavioral skills that are necessary for initiating and maintaining health behaviors.</td>
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</tr>
<tr>
<td>Operant Conditioning (OC) (Skinner 2014, Skinner 1953)</td>
<td>Operant conditioning assumes that behavioral antecedents and consequences regulate behavior. Constructs include contingencies/consequences, positive and negative reinforcement and antecedents (discriminative stimuli).</td>
</tr>
</tbody>
</table>

**4.5 Designing Graphic User Interfaces for Behavior Change Interventions**

Development of the graphic user interfaces (GUIs) was guided by a thorough review of the body of literature on theoretically based behavior change interventions and personal interviews (as part of NSF I-Corps project) with 30 adults living with heart diseases. Figure 4 and Figure 5 illustrates the instantiations of behavior change strategies, derived from the BCT taxonomy that is incorporated into the behavioral intervention. Note that the GUIs portray patient with more realistic shapes as opposed to a thin body frame. Figure 4a prompts the user to set a daily goal for physical activity that is measurable, achievable and realistic. This behavior change technique, derived from Control Theory, is coded as 1.1 goal-setting (behavior) in the BCT taxonomy.
Self-monitoring (coded as 2.3) and feedback on behavior (coded as 2.2), derived from constructs of Control Theory, are illustrated in Figure 4b and Figure 4c, respectively. Use of BCTs (e.g. self-monitoring with goal setting, providing feedback on performance, review of behavioral goals, etc.) which correspond to Control Theory has been associated with increased intervention effects (Samdal et al. 2017).

Planning for social support has previously been associated with positive effects in behavior change. According to the Transtheoretical Model (TTM) of behavior change, helping relationships is one of 10 processes of change, or activities that individuals use to progress through the continuum of stages of readiness to change behavior. Figure 4d illustrates a GUI that recommends that the individual take a friend with her on the next walk as an illustration of the BCT 3.2 Social Support (practical). This BCT is particularly relevant if the individual is fearful of walking alone after a cardiac event.

According to Social Cognitive Theory, behavior change is a function of, among other things, expectations about one’s ability to engage in and execute the behavior (Bandura et al. 1999). By setting incremental tasks to complete the behavior, the individual is likely to have increased self-confidence in performing and maintaining the behavior. Self-efficacy expectations develop through mastery of experiences such as taking small steps to complete the final behavior. Setting graded tasks was associated with successful behavioral interventions for improving eating and physical activity behaviors (Samdal et al. 2017). My example in Figure 4e illustrates a graded task for gradually increasing walking distance.

Figure 4f shows BCT 2.7, providing feedback on the outcomes of behavior. The GUI conveys positive feedback on accomplishing a distal goal (weight loss) by achieving a proximal goal (sustained exercise program). Interventions that promote monitoring of goal progress lead to
positive changes in behavior. The sex-specific and realistic portrayal of the women in the GUI is likely to be less intimidating to users.

BCT 5.1, providing information on the health consequences of performing a health behavior, is illustrated in Figure 5a. The GUI encourages the individual to “Think about how happy and satisfied you will feel when you have exercised every day this week. Exercise daily for energy!” Providing information and motivation for the performance of healthy behavior is congruent with several behavioral theories depicted in Table 3. In Figure 5b, the GUI represents BCT 7.1, teaching the use of prompts or cues. By prompting the user to identify environmental cues to perform a behavior by placing her shoes at the front door, she is more likely to remember to schedule a time to perform the physical activity. Finally, Figure 5c illustrates BCT 12.3, avoidance or reducing exposure to cues for the behavior. By prompting patients with heart disease to avoid buffet-type restaurants, they are less likely to be exposed to opportunities to overeat or to eat unhealthy food items.
Figure 4a BCT 1.1 Goal setting (behavior)

Figure 4b BCT 2.3 Self-monitoring of behavior

Figure 4c BCT 2.2 Feedback on behavior

Figure 4d BCT 3.2 Social Support

Figure 4e BCT 8.7 Set graded task

Figure 4f BCT 2.7 Feedback on outcomes

Note: All the BCT are adopted from Behavior Change Technique Taxonomy v1.93 Hierarchically Clustered Techniques along with corresponding BCT numbers (Michie et al. 2013)

Figure 4: Graphic user interfaces of some of the behavior change interventions
<table>
<thead>
<tr>
<th>Figure 5a</th>
<th>Figure 5b BCT 7.1</th>
<th>Figure 5c BCT 12.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCT 5.1 Info on health risk</td>
<td>Teach use of prompts/cues</td>
<td>Avoidance of exposure to cues for behavior</td>
</tr>
</tbody>
</table>

Note: All the BCT are adopted from Behavior Change Technique Taxonomy v1: Hierarchically Clustered Techniques along with corresponding BCT numbers (Michie et al. 2013)

**Figure 5**: Graphic user interfaces of some of the behavior change interventions

### 4.6 Behavior Change Theory-based Design Strategy

A behavioral change technique (BCT) is defined as “an observable, and replicable intervention component designed to alter or redirect causal processes that regulate behavior; a technique proposed to be an active ingredient” (Michie et al. 2013). We illustrate how we use four BCTs: “Goals and Planning,” “Feedback and Monitoring,” “Shaping Knowledge” and “Repetition and Substitution” (Michie et al. 2013). All are based on theoretical constructs suggested by behavior change theories. For the BCT “Goals and Planning,” we use sub-techniques of “goal setting” and “review behavior goal” for creating instantiations of intervention. For the BCT “Feedback and Monitoring,” we use sub-techniques like “feedback on behavior,” “self-monitoring of behavior,” “monitoring of outcomes” and “feedback on outcomes” for the creation of instantiations of
intervention. Similarly, for the BCT “Shaping Knowledge,” we use sub-techniques like “instructions on how to perform the behavior” and “information about antecedents” for creating instantiations of intervention. Finally, for the BCT “Repetition and Substitution,” we use sub-techniques like “graded tasks,” “habit formation” and “habit reversal” to create instantiations of interventions. Table 4 shows the process of generating a design strategy regarding the creation of relevant content for a behavior change intervention. It also illustrates the use of eight behavior change theories and corresponding behavior change techniques (Michie et al. 2015) in designing of graphic user interfaces (GUIs) used as instantiations of behavior change interventions for patients with CHD (Sengupta et al. 2020b).

Table 4: Behavior change theory-based design strategy (Sengupta et al. 2020b)

<table>
<thead>
<tr>
<th>Theoretical Framework/Construct</th>
<th>Concept</th>
<th>Behavior Change Technique (BCT)</th>
<th>Description of BCT</th>
<th>Design Strategy/Content Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Theory (CT)</td>
<td>Goals and Planning : a) goal setting b) review behavior goal</td>
<td>BCT1.1 goal-setting (behavior) (Michie et al. 2013)</td>
<td>Create detailed plan of what individual will do including specifying behavioral frequency,</td>
<td>Provide an opportunity to set a daily activity goal: “Set your daily activity goal.”</td>
</tr>
<tr>
<td>Transtheoretical Model (TTM)</td>
<td>Helping Relationships</td>
<td>3.2 Social support (practical)</td>
<td>Advise on social support for the performance of the behavior.</td>
<td>Suggest looking for a social support, “Take a</td>
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</tr>
</tbody>
</table>
### Table 4: (Continued)

<table>
<thead>
<tr>
<th>Theory (SCogT)</th>
<th>Strategy</th>
<th>Level</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social Cognitive Theory (SCogT)</td>
<td>Repetition and Substitution: a) graded tasks</td>
<td>8.7 Set graded tasks</td>
<td>Set easy tasks, and increasing difficulty until target behavior is performed.</td>
<td>Suggest multiple small serial tasks with increasing level of difficulty, “Walk around the block the first week, then 3 blocks a week after that, then 4 blocks after you have successfully achieved that.”</td>
</tr>
<tr>
<td>Self-Determination Theory (SDT); Social Cognitive Theory (SCogT)</td>
<td>Feedback and Monitoring: a) monitoring</td>
<td>2.7 Feedback on outcomes of behavior</td>
<td>Foster intrinsic motivation (autonomous self-regulation) by emphasizing personal feedback: “Congratulations! You have lost 5 pounds since you began your...”</td>
<td>Provide timely feedback: “Congratulations! You have lost 5 pounds since you began your...”</td>
</tr>
<tr>
<td>Theory of Reasoned Action (TRA), Theory of Planned Behavior (TPB), Social Cognitive Theory (SCogT), Information-Motivation-Behavioral Skills (IMB)</td>
<td>Monitoring: self-monitoring of behavior</td>
<td>5.1 Providing information on health consequences (Michie et al. 2013)</td>
<td>Provide information about health consequences of performing the behavior.</td>
<td>Provide relevant information about health consequences, “Think about how happy and satisfied you will feel when you have exercised every day this week. Exercise daily for energy!”</td>
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</tbody>
</table>
| Operant Conditioning (OC) | Shaping Knowledge: a) instructions | 7.1 Teaching to use prompts/cues | Teach individual to identify environmental cues that remind | Teach use of prompts, “Place your shoes near the front door to
Table 4: (Continued)

<table>
<thead>
<tr>
<th>Transtheoretical Model (TTM)</th>
<th>Stimulus control</th>
<th>BCT</th>
<th>Knowledge: a) information about antecedents</th>
<th>Advise on how to avoid exposure to specific social and contextual/physical cues for the behavior (Michie et al. 2013)</th>
<th>To avoid overeating or to eat unhealthy foods. Recommend, “Try to avoid buffet-type restaurants.”</th>
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</thead>
<tbody>
<tr>
<td>Shaping Knowledge:</td>
<td>12.3</td>
<td>Advise on how to avoid exposure to specific social and contextual/physical cues for the behavior (Michie et al. 2013)</td>
<td>To avoid overeating or to eat unhealthy foods. Recommend, “Try to avoid buffet-type restaurants.”</td>
<td></td>
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<tr>
<td>on how to perform the behavior b) information about antecedents</td>
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</table>

BCT, behavior change techniques; CT, Control Theory; GUI, graphic user interface; SDT, Self-Determination Theory; SCogT, Social Cognition Theory; TRA, Theory of Reasoned Action; TPB, Theory of Planned Behavior; TTM, Transtheoretical Model; OC, Operant Conditioning; IMB, Information-Motivation-Behavioral Skills

Note: All the BCT are adopted from Behavior Change Technique Taxonomy v1:93 Hierarchically Clustered Techniques along with corresponding BCT numbers (Michie et al. 2013).

4.7 System Components

4.7.1 Wearable Device (Smartwatch): We used Moto 360 2nd Gen™ smartwatch (Android Wear OS) to collect sensory data captured through the accelerometer and gyroscope embedded in the smartwatch. The data was transferred over Bluetooth to a smartphone and then the data was uploaded to the cloud through secure channels via the Internet (Sengupta et al. 2020b).
4.7.2 Machine Learning Algorithm and Activity Recognition: With the popularity of smartwatches, wrist-worn sensor devices will become an increasingly important tool in personal health monitoring. In this regard different machine learning techniques are used to recognize patient movements as well as activities in real time (Shoeb 2009, Bharti et al. 2018, Fleury et al. 2010, Mortazavi et al. 2014). Smartwatch-based activity recognition can provide unique opportunities for deploying JITAI s to assist patients with disease self-management.

 Accelerometers and gyroscopes embedded in a smartwatch can sense a patient’s movement, which can help the health coach to intervene at a time when the intervention is expected to become most effective. Prior research (Reeder and David 2016), demonstrated that smartwatch-based personal activity detection models perform well when such models are built with training data from representative users (Sengupta et al. 2020b). Therefore, in our study, the activity recognition model that we have built was induced from labeled training data of only elderly patients who are representative of our target population. We developed the model to recognize two activities: walking and sitting (Sengupta et al. 2020b). Figure 6 outlines the process of our model building and activity recognition.
The activity recognition task involves mapping multi-modal time series sensor data from a smartwatch to a single physical activity. In our approach, the time series data is aggregated into examples based on non-overlapping fixed time intervals of data. An activity is recognized correctly if the single activity that occurred during the temporal interval is correctly classified. The data for training and model validation were collected from 15 patients with an average age of 55 years. Each of them was asked to perform two different activities: walking and sitting. Each activity was performed for 5 minutes while the participant wore a Moto 360 2nd Gen™ smartwatch on her dominant hand. All the data was collected using Moto 360 2nd Gen™ smartwatch and the Samsung Galaxy S6 smartphone, both of which were running the Android mobile operating system. From the sensor data recorded from the smartwatch tri-axial accelerometer and tri-axial gyroscope, we extracted 11 features (norm, variance, max, min, entropy, maximum reduced mean, mean crossing rate, spectral energy, maximum frequency, mean absolute deviation and interquartile range). We examined these features’ power to
discriminate among the 2 activities for all the participants. We employed Linear Discriminant Analysis (LDA) where we project sensory data features onto a lower-dimensional space to achieve good discrimination between activity classes for subsequent model/algorithm development. As a result, a total of 5 discriminatory features were extracted and used for model development. The model is based on the notion of Random Forests. Random Forests, similar to decision trees, are popular in machine learning for classification. A decision tree represents a graphical tree where leaf nodes are the classes depicting the final prediction, while non-leaf/internal nodes correspond to a decision that is made based on one of the features. Each internal node generates several branches depending on the condition placed on the corresponding feature. Random Forests (RF) is a decision tree-based ensemble learning technique used for classification and regression, among others. It has the advantage of being extremely fast, efficient on big data and capable of overcoming overfitting (Sengupta et al. 2020b).

Our evaluation strategy is based on leave-one-out strategy, where we take training data from 14 participants, and then evaluate that model on the remaining 15th participant. This is repeated 15 times so that all participants are evaluated. The resultant impersonal model is averaged over the 15 generated models. We achieved accuracies close to 95% percent in classifying activities with good precision and recall. Finally, like many other studies (Årsand et al. 2015, Bang et al. 2015, Thomaz et al. 2015) we also face the issue of running out of limited battery power of the smartwatch due to the continuous transfer of sensor data from the watch to the mobile phone. Power consumption requirements increase along with a greater need for analysis to be performed on smartwatch devices in field settings (Sengupta et al. 2020b). We improved the battery life of the smartwatch considerably by not collecting sensor data when the participant is not physically active. A low power built-in step count sensor in the watch will
immediately indicate if the participant took a step, and only then is our sensor data collection engine triggered. The approach towards developing the machine learning model for activity recognition brings three novel outlooks into the overall system design picture: a) it identifies and classifies both the dynamic and the static physical activity of the participant; b) our design makes use of feature selection in order to reduce the number of required features, thus reducing the model complexity while maintaining classification accuracy; and c) it is fast, energy-aware, accurate, and, most importantly, trained for older patients only (Sengupta et al. 2020b).

4.7.3 Mobile Application: The second component of the system is an application on the smartphone, which can help patients to set their daily physical activity goals and persuade them to accomplish that by providing instant feedback on their activity performance through intervention messages. Below we describe certain key functionalities of the mobile app (Sengupta et al. 2020b).

Goal: The “goal” functionality allows patients to set their daily physical activity goal of walking from 1 to 60 minutes. It also allows patients to report their readiness to begin the physical activity and their current level of energy on a scale of 1 to 10. After setting a physical activity goal, each patient is exposed to a motivational message that encourages her to exercise just for a few seconds. Each patient can set multiple goals of walking on any day (Sengupta et al. 2020b).

Progress: The “progress” functionality allows patients to check their progress towards the achievement of their physical activity goals. It shows the number of minutes the patient has already walked, the number of steps taken and the distance (in miles) covered while walking. This functionality also allows the patient to check the amount of time (in minutes) needed to walk in order to achieve the current activity goal (Sengupta et al. 2020b).
The following section provides the details related to GUI of interventions, content (text messages), decision rules and their tailoring variables.

Intervention Messages: The system deploys two types of behavior change intervention messages: 1) preprogrammed intervention messages sent at a specific time to the patient by the system based on specific decision rules and 2) customized text-based intervention messages sent to the patient based on activity performance and EMA survey responses by the health coach through the dashboard (Sengupta et al. 2020b).

1) **Automatic Preprogrammed Intervention Messages**: Table 5 provides the details of four intervention messages and the decision rules that they follow (Sengupta et al. 2020b).

<table>
<thead>
<tr>
<th>Intervention Screen</th>
<th>Text Message</th>
<th>Decision Rule</th>
<th>Tailoring Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Screen" /></td>
<td>You have achieved your daily activity goal. Congratulations!</td>
<td>Send to the patient as soon as the system recognizes that the patient finished her physical activity goal of walking for a fixed number of minutes.</td>
<td>Continuous tracking of patient’s physical activity performance and her daily activity goal (number of minutes for walking) set by the patient.</td>
</tr>
</tbody>
</table>

1) Activity of Walking: Number of Minutes
| Activity of Walking: Number of Minutes for the activity of walking set as a goal | You have exceeded your daily activity goal. Keep up the good work! | Send to the patient as soon as the system recognizes that the patient has exceeded her physical activity goal of walking by at least 15 percent of the last activity goal. |
| Continuous tracking of patient’s physical activity and her daily activity goal (number of minutes for walking) set by the patient through the application. |

| Time to Exercise | Send to the patient at 3:40 pm if the patient set a physical activity goal for that day but the system did not recognize any activity. |
| Continuous tracking of patient’s physical activity and daily activity goal (number of minutes for walking) set by the patient in a particular day. |
### Table 5: (Continued)

<table>
<thead>
<tr>
<th>1) Activity of Walking:</th>
<th>2) Number of Minutes for the activity of walking set as a goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>physical activity (walking) done by</td>
<td></td>
</tr>
<tr>
<td>the patient by 3:40pm.</td>
<td></td>
</tr>
<tr>
<td>You have just a few more minutes</td>
<td>Send to the patient at 3:40 pm if the patient set a</td>
</tr>
<tr>
<td>to finish. You can do it.</td>
<td>physical activity goal on that day but has not yet fulfilled</td>
</tr>
<tr>
<td></td>
<td>the physical activity goal.</td>
</tr>
<tr>
<td></td>
<td>Continuous tracking of patient’s physical activity and daily</td>
</tr>
<tr>
<td></td>
<td>activity goal (number of minutes for walking) set by the</td>
</tr>
<tr>
<td></td>
<td>patient in a particular day.</td>
</tr>
</tbody>
</table>

1) Activity of walking: Number of Minutes
2) Number of minutes for the activity of walking set as a goal

**Automatic Decision Rule System:** The automatic decision rule implementation system caters to 250 complex decision rules that we have identified through the discussion with health professionals and following standard protocols for the CR process (Sengupta et al. 2020b). These decision rules help us to implement the full spectrum of behavior change technique (BCT)
taxonomy (Michie et al. 2013). The decision rules, which determine the dispatching of appropriate intervention messages, consider the EMA responses that the patient has given over both short and longer periods of time, her activity schedule, as well as her activity performance status. This is because we can expect the patient-related attributes to vary across the patient population and the exact decision rules to also vary across the population. There also exist possibilities in which multiple rules lead to potentially conflicting situations due to contradictory interventions triggered at the same time. To avoid such situations we have created a rule hierarchy structure to manage the deployment of different decision rules without any scope of the potential conflict. The health coach has created all the decision rules along with the rule hierarchy structure, which manages the conditions of deployment of different decision rules. Finally, the system can track the patient’s responses against each of the interventions that he or she received. This provides an opportunity for the health coach for the fine-tuning and alteration of decision rules along with their hierarchical order. Figure 7 shows the process of interaction between the health coach and automatic decision rule system (Sengupta et al. 2020b).

Figure 7: Health coach’s interaction with the automatic decision rule system (Sengupta et al. 2020b)
2) **Customized Text-Based Intervention Messages:** The second type of intervention messages are only text-based. They are developed and customized by the health coach and sent to patients based on their physical activity performance and EMA survey responses through the dashboard (Sengupta et al. 2020b). There are specific antecedents, which initiate the development and dispatch of such intervention messages. These messages are sent to patients at a time that the health coach thinks are the most suitable for making the required impact (Sengupta et al. 2020b). Table 6 provides the details of some of these customized text messages that were sent during the field trial of the HBCR system.

The behavior change techniques are intended to engage patients so they can improve their health behaviors and self-manage their chronic conditions. It is important to ensure that the intervention messages sent to the patient remain fresh and relevant. This can help to alleviate so-called message fatigue (Fogg and Adler 2009) and adherence to our system required for successful behavior change. Each day the patient can possibly receive a maximum of two text messages over her mobile phone. The system sends at least one preprogrammed intervention message and one or no text-based message to the patient based on previous physical activity behavior. Prior research has shown the efficacy of telephone reminders (Dick et al. 2011) and technological cues. During the field trial, the health coach occasionally called the patients to discuss their progress and motivate them to reach their goal (Sengupta et al. 2020b).

**Learning from Customized Intervention Message:** The automated decision rules system learns the context of developing and deploying different customized intervention messages (designed by the health coach) over time. This system consists of a repository and a recommendation system that preserves all the text messages developed by the health coach and makes recommendations to the health coach for further rules and intervention messages that can
Table 6: Customized text based intervention messages and their schedule (Sengupta et al. 2020b)

<table>
<thead>
<tr>
<th>Antecedent/Decision Rule</th>
<th>Text Message</th>
<th>Time for Dispatch</th>
</tr>
</thead>
<tbody>
<tr>
<td>For 3 consecutive days, the patient reported “sitting” as the present activity for all five EMA surveys sent in a day</td>
<td>Dear &lt;Patient Name&gt;, If you believe that exercise is good for your heart then you would want to set a 30 minute walking goal.</td>
<td>4th day morning at 9:00 am</td>
</tr>
<tr>
<td>For 3 consecutive days, the patient reported “Restaurant or eating place” as present location for at least one EMA survey sent in a day</td>
<td>Dear &lt;Patient Name&gt;, Please stick to your healthy eating when at a restaurant.</td>
<td>4th day, as soon as the patient reports restaurant or eating place as the present location</td>
</tr>
<tr>
<td>For 3 consecutive days, the patient reported eating unhealthy food at least three times in a day (captured through EMAs)</td>
<td>Dear &lt;Patient Name&gt;, Eating healthy will lower healthcare costs.</td>
<td>4th day morning at 9:00 am</td>
</tr>
<tr>
<td>For 3 consecutive days, patient’s mood was negative at least three times in a day (captured through EMAs)</td>
<td>Dear &lt;Patient Name&gt;, Schedule time to quiet your mind – record situations that occur before a stressful event – being tired or overwhelmed?</td>
<td>4th day as soon as the patient reports that she was feeling very negative</td>
</tr>
</tbody>
</table>
be deployed. The health coach can alter these rules before preserving them inside the repository (Sengupta et al. 2020b).

EMA Survey: EMA refers to the collection of behavioral, physiological, and environmental self-reported data in real time and a patient’s natural setting so that the procedure of capturing data is less susceptible to recall bias (Brannon et al. 2016). The “Survey” functionality allows the patient to respond to a number of ecological momentary assessment (EMA) survey questions (Sengupta et al. 2020b).

There are three specific reasons for the growing use of EMA surveys (Sengupta et al. 2020b; 2020c). First, the wearable sensors and applications that objectively track patients’ physical activities often fail to capture valuable contextual information such as activity purpose, mood, and the social and physical environment (Barrigón et al. 2017). Second, EMAs help to identify the antecedence of a particular behavior by linking the immediate environment with that behavior. Last, EMAs are often more useful than conventional instruments of retrospective questionnaire-based survey methods because they sample environmental influences on behavior in real time (Dunton 2017).

Patients can respond to all or none of the EMA surveys that are sent at different times of the day (8 am to 8 pm) with an interval of approximately two hours between two consecutive EMAs. EMA surveys ask questions about the patient’s behavior such as physical activity, eating episodes, social and environmental contexts, and current mood. Collecting EMAs for tailoring variables like mood is critical for developing interventions while attending to the patient’s momentary needs (Sengupta et al. 2020c).
Detailed Design of EMA Surveys: Figure 8 showcases the six EMA-related screens that each patient goes through every time he or she is submitting his or her responses to EMA questions.

**Figure 8: EMA Surveys (Sengupta et al. 2020c)**
Video: The video functionality provides access to nine health videos developed by a cardiovascular expert. The videos represent the behavior change technique of “Shaping Knowledge” to encourage the practice of health behaviors (Sengupta et al. 2020b).

4.7.4 Design of the Dashboard: The final component of the system is the web-based dashboard developed for the health coach following a responsive design framework (Tidwell 2010). The dashboard is developed for monitoring the patients’ physical activity performances, access frequency of the videos, EMA survey responses, heart rates, and intervention messages. Through the dashboard the health coach can send text messages to patients. The dashboard is designed by following principles of visual information display (Ward et al. 2015) to effectively represent patients’ data. It is also evaluated iteratively by involving multiple health coaches (Sengupta et al. 2020b).

The dashboard consists of two hierarchical layers of interaction (see Appendix 3). The first layer allows the health coach to select a single patient ID to monitor the behavioral data. Once the health coach selects a particular patient ID, the coach is taken to the second layer of interaction, where the health coach can see all the data related to that particular patient that has been captured that day (see Figure 9, 10 and 11).
Figure 9: Graphic user interface of dashboard - layer 1 landing screen

Figure 10: Graphic user interface of dashboard - layer 1 selection of patient ID
Figure 11: Graphic user interface of dashboard - layer 1 selection of the range of dates

The second layer of interaction consists of three different pages or screens. The first screen displays information related to the patient’s physical activity goals, status of the patient’s physical activities, EMA responses provided by the patient, messages received by the patient each time she has submitted an EMA survey response, maximum, minimum and average values of the heart rate of patient on an hourly basis, and the patient’s information absorption activities in terms of accessing health related videos (see Figure 12, 13, 14, 15, 16 and 17). The second screen displays information related to the preprogrammed intervention messages received by the patient along with time stamps. Apart from that, this screen also displays records related to the failure of Wi-Fi and Bluetooth connections, as well as every time the patient has received a text message that the remaining battery capacity of her smartwatch and/or mobile phone has fallen below 20 percent. The third screen of the dashboard allows the health coach to create a custom text message and send it to a particular patient instantly. The message is delivered through the app residing inside the mobile phone. This screen also keeps a record for each of the custom messages that were sent to the patient through the dashboard (see Figure 18).
The dashboard also allows the health coach to select a date range by selecting the start date and the end date of the required range through the calendar. Once the health coach provides the start and end dates, all the data captured during that period appears on the dashboard. The selection of the data range function is available for each type of patient data that can be displayed on the dashboard; the types are independent of each other. For each type of patient data, the health coach has to specify the date range separately. This particular function allows the health coach to compare data related to different behaviors of the patient over the same or different time.

![Dashboard Design - Layer 2 Patient Specific Visualization of Activities](image1)

**Figure 12:** Dashboard design-layer 2 patient specific visualization of activities

![Timeline Visualization](image2)

**Figure 13:** Dashboard design-layer 2 patient and date specific timeline visualization of activities
Figure 14: Dashboard design - layer 2 bar chart visualization of activities for individual patient

Figure 15: Dashboard design - layer 2 line graph visualization of activities for individual patient
Figure 16: Dashboard design - goal set activities visualization

Figure 17: Dashboard visualization - goal progress check activities and EMA responses
Figure 18: Health coach correspondences with patients through dashboard
CHAPTER 5. EVALUATION

The primary purpose of this field observational study was to determine the feasibility of an HBCR system and gain information required for developing future versions of the system for further testing. The secondary purpose of the field observational study is to evaluate the impact of both preprogrammed intervention messages and customized text-based intervention messages on participants’ physical activity performance. We have done that by conducting a quasi-experiment during the field observational study.

5.1 Participant Recruitment

We obtained approval from the university’s Institutional Review Board (IRB) to conduct the study (see Appendix 1). All the participants were recruited from a cardiology clinic within 2-3 weeks and the study lasted 13 weeks for each participant. The cardiology clinic is part of an academic medical center, which also is one of the leading in the region for cardiovascular sciences. The clinic is quite advanced in terms of adopting new medical technologies, offering the newest services and treatment options. The clinic already has adopted the EHR system and it is currently used by physicians, nurses and other staff to improve access to patient’s medical history and list of medications. For patients the clinic offers services like access to test and lab results, sending and receiving secure messages, scheduling appointments, receiving care reminders, requesting refills and payment of medical bills through a web portal called ‘MyChart’ (name changed). However, the use of these services by the general patients is still quite limited. In terms of technology proficiency, regular visitors (due to their existing chronic conditions) of
the clinic are quite homogeneous (Sengupta et al. 2020b). The primary reason for this homogeneity is due to the urban location of the clinic. Most of the patients are quite savvy in using smartphones. According to our subject screening criteria patients were eligible for the study if they were aged ≥ 50 years, diagnosed with an acute coronary syndrome or coronary revascularization in the last 10 years, able to read, speak and understand English at a Grade 6 reading level, and able to participate in physical activity such as walking without aid. They also were required to have familiarity with smart phones and texting and have a broadband internet connection at home. Finally, their healthcare provider must have issued verbal clearance to participate in the study at the time of the screening (Sengupta et al. 2020b).

Patients were excluded from the study if they resided outside a 50-mile radius of the study site; were diagnosed with a psychiatric condition including dementia, delirium or schizophrenia; or were actively undergoing acute psychiatric treatment or had a prior neurological brain disorder. They were also excluded (per the principal investigator’s discretion) if they currently used illicit drugs and/or had chronic alcohol use or severe comorbid conditions (e.g., liver disease, cancer, chronic kidney disease) (Sengupta et al. 2020a; 2020b; 2020c).

5.2 Evaluation Procedure

We designed a quasi-experimental study trial in which initially ten participants used our HBCR system for a period of 13 weeks (91 days). In our informed consent form, we made it very clear that study participation is voluntary, and participants may withdraw from the study at any time without jeopardizing their health care. Their decision of withdrawal will have no impact on their relationship with their cardiologist. They only need to inform the Principal Investigator of the study that they wish to withdraw, and no further data collected from that time forward (Sengupta et al. 2020b). During the test period, each participant was asked to use the smartwatch and
smartphone apps. Once a week, the health coach telephoned the participant to hear concerns or answer questions. Participants had baseline assessment data collections and 13-week follow-up data collections conducted in the clinic in a face-to-face session. At the follow-up session after the 13-week study period, a semi-structured interview was also conducted.

5.3 Data Collection

Data was collected from the participants through EMA responses, via sensors from the smartwatch and also by monitoring application usage logs. In addition to using smartwatch and mobile applications, we used semi-structured interviews to collect qualitative data regarding the involvement of a health coach in the HBCR system. No participant decided to withdraw herself from the study (Sengupta et al. 2020b). Table 7 summarizes the data collected during the period of thirteen weeks of evaluation for each participant.

<table>
<thead>
<tr>
<th>Goal for daily walking (in minutes)</th>
<th>Number of EMA survey responses submitted per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity readiness</td>
<td>Number of times a particular choice is selected for physical activity per day</td>
</tr>
<tr>
<td>Energy level</td>
<td>Number of times a particular choice is selected for social companion per day</td>
</tr>
<tr>
<td>Daily walking minutes</td>
<td>Number of times a particular choice is selected for current location per day</td>
</tr>
<tr>
<td>Daily step count</td>
<td>Number of times recent eating episode is selected per day</td>
</tr>
<tr>
<td>Daily distance covered by walking (in miles)</td>
<td>Number of times no recent eating episode is selected per day</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>Number of videos accessed per day</td>
<td>Number of times eating healthy food is reported per day</td>
</tr>
<tr>
<td>Number of times a particular video is accessed</td>
<td>Number of times eating unhealthy food is reported per day</td>
</tr>
<tr>
<td>Minimum heart rate per hour</td>
<td>Number of times a choice is selected as a healthy food per day</td>
</tr>
<tr>
<td>Maximum heart rate per hour</td>
<td>Number of times a choice is selected as an unhealthy food per day</td>
</tr>
<tr>
<td>Average heart rate per hour</td>
<td>Current mood</td>
</tr>
<tr>
<td>Number of automated preprogrammed intervention messages received per day</td>
<td></td>
</tr>
</tbody>
</table>

Table 7: (Continued)
CHAPTER 6. ANALYSIS AND FINDINGS

6.1 Participants

Eleven participants initially signed the informed consent, and 10 participants completed data collection. Two participants, both recently experiencing traumatic life events, engaged very little with the HBCR system. Most of the participants were white (n=8, 80%), married or partnered (n=6, 60%) women with a mean age of 64 years (range 53-75; SD=6) (see Table 8). The majority of participants had health insurance and an income of at least $40,000 annually; about half worked full time. All participants had coronary heart disease, with two diagnosed with a myocardial infarction and one with heart failure. Five (50%) participants had undergone a percutaneous coronary intervention and two (20%) had undergone coronary artery bypass graft surgery. None had ever attended a CBCR program (Sengupta et al. 2020a).

The participants have multiple comorbidities including diabetes mellitus (n=3, 30%), osteoarthritis (n=4, 40%), orthopedic disorders (n=2, 20%) and one was being treated for skin cancer (10%) (see Table 9). The participants exhibited traditional cardiovascular disease risk factors including dyslipidemia, hypertension, physical inactivity, familial heart disease, and being overweight. Most participants had never used tobacco; former smokers had a mean of 23.75±19.3 pack years of smoking. Participants were prescribed numerous evidence-based cardiovascular medications to treat their chronic conditions (Sengupta et al. 2020a).
Table 8: Participant socio-demographic data (n = 10) (Sengupta et al. 2020a)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, year</strong> (Mean ± SD) (range: 53-75)</td>
<td>64.4 ± 6.3</td>
</tr>
<tr>
<td><strong>Race or Ethnicity, n, (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>8 (80%)</td>
</tr>
<tr>
<td>Black, African American</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Asian/ Pacific Islander</td>
<td>1 (10%)</td>
</tr>
<tr>
<td><strong>Education, n, (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Community College</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>4-Year college incomplete</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>4-Year Degree</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Doctoral Degree</td>
<td>1 (10%)</td>
</tr>
<tr>
<td><strong>Employment Status, n, (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Employed Full-Time</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>Not Employed or retired</td>
<td>5 (50%)</td>
</tr>
<tr>
<td><strong>Marital Status, n, (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Married/Partnered</td>
<td>6 (60%)</td>
</tr>
<tr>
<td>Divorced</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>2 (20%)</td>
</tr>
<tr>
<td><strong>Primary Insurance Status, n, (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Private Insurance</td>
<td>6 (60%)</td>
</tr>
<tr>
<td>TriCare (Military/Veterans)</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Medicare</td>
<td>1 (10%)</td>
</tr>
<tr>
<td><strong>Annual Household Income, n, (%)</strong></td>
<td></td>
</tr>
<tr>
<td>$20,000 to &lt; $40,000</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>$40,000 to &lt; $80,000</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>$80,000 to &lt; $100,000</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>$100,000 or more</td>
<td>3 (30%)</td>
</tr>
</tbody>
</table>
Table 9: Clinical characteristics of participants (n=10) (Sengupta et al. 2020a)

<table>
<thead>
<tr>
<th>Cardiovascular Disease Diagnosis</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary Heart Disease</td>
<td>8 (80%)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>1 (10%)</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>1 (10%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Co-Morbidities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>4 (40%)</td>
</tr>
<tr>
<td>Orthopedic Disorder</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Cancer (skin)</td>
<td>1 (10%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiovascular Risk Factors</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Overweight: (BMI 25.0-29.9 kg/m(^2)) or Obese (BMI&gt;30 kg/m(^2))</td>
<td>6 (60%)</td>
</tr>
<tr>
<td>Familial Heart Disease (onset before 60 years in Mother; 50 Father)</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>10 (100%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>6 (60%)</td>
</tr>
<tr>
<td>Physical Inactivity (less than 30 minutes 5x weekly)</td>
<td>8 (80%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tobacco Use</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td></td>
</tr>
<tr>
<td>Former</td>
<td>6 (60%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication Classes Prescribed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta Blocker</td>
<td>8 (80%)</td>
</tr>
<tr>
<td>Calcium Channel Blocker</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Angiotensin Converting Enzyme Inhibitor</td>
<td>4 (40%)</td>
</tr>
<tr>
<td>Angiotensin Receptor Blocker</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>Statin</td>
<td>10 (100%)</td>
</tr>
</tbody>
</table>
Table 9: (Continued)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Metformin</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>9 (90%)</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>5 (50%)</td>
</tr>
<tr>
<td>Other Antiplatelet</td>
<td>3 (30%)</td>
</tr>
</tbody>
</table>

Table 10 summarizes baseline and 13-week follow-up physiological and psychosocial participant characteristics. Although I observed no changes in blood pressure, the participants had clinically modest but statistically significant improvements in waist circumference ($p = .048$), weight ($p = .016$) and BMI ($p = .012$). Further, participant depressive symptoms significantly improved from baseline ($p = .038$).

Table 10: Physiological and psychosocial characteristics (n=10) (Sengupta et al. 2020a)

<table>
<thead>
<tr>
<th>Characteristic, Mean ± SD</th>
<th>Baseline</th>
<th>13-weeks</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure, mm Hg</td>
<td>129.2 ± 12.3</td>
<td>141.5 ± 18.9</td>
<td>NS</td>
</tr>
<tr>
<td>Diastolic Blood Pressure, mm Hg</td>
<td>76.7 ± 8.7</td>
<td>73.6 ± 9.2</td>
<td>NS</td>
</tr>
<tr>
<td>Waist (cm)</td>
<td>97.7 ± 14.7</td>
<td>95.4 ± 12.6</td>
<td>.048</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>80.5 ± 19.7</td>
<td>79.1 ± 18.6</td>
<td>.016</td>
</tr>
<tr>
<td>Body Mass Index (BMI, kg/m$^2$)</td>
<td>29.2 ± 6.0</td>
<td>28.7 ± 5.8</td>
<td>.012</td>
</tr>
<tr>
<td>Self-Efficacy Scale for Managing Chronic Disease</td>
<td>45.4 ± 12.5</td>
<td>48.2 ± 7.6</td>
<td>NS</td>
</tr>
<tr>
<td>Self-Efficacy for Exercise Behavior</td>
<td>52.5 ± 7.6</td>
<td>54.4 ± 6.2</td>
<td>NS</td>
</tr>
<tr>
<td>Self-Efficacy for Diet</td>
<td>88.8 ± 6.0</td>
<td>89.6 ± 6.8</td>
<td>NS</td>
</tr>
<tr>
<td>Perceived Stress Scale</td>
<td>13.3 ± 6.7</td>
<td>9.9 ± 6.9</td>
<td>NS</td>
</tr>
<tr>
<td>Patient Health Questionnaire (PHQ)-9</td>
<td>5.5 ± 5.4</td>
<td>2.9 ± 3.8</td>
<td>.038</td>
</tr>
<tr>
<td>REAP-S</td>
<td>32.7 ± 3.5</td>
<td>33.7 ± 2.7</td>
<td>NS</td>
</tr>
</tbody>
</table>
Self-efficacy for exercise, diet, and managing chronic illness were not statistically significantly different from baseline although they trended in the desired direction. Participants also demonstrated nonsignificant improvements in REAP-S scores and perceived stress. The IPAQ-SF scores showed minimal increase in average number of days of moderate-intensity physical activities but an increased number of minutes of activity on those days. There was no change in time spent in sedentary behavior after 13 weeks (Sengupta et al. 2020a).

### 6.2 Usability

The mean score on the System Usability Scale was 83.60 ± 16.4. Participants generally found our application easy to learn and use. They also found the functionalities to be well integrated and they felt confident in using the HBCR system. The participants did not find it unnecessarily complex or cumbersome to use. They also reported not requiring the support of a technical person to use the HBCR system. Only one patient required a home visit to deal with a technical issue. Participant themes derived from field notes involved mostly technical issues. The most frequent complaint was the short battery life of the smartwatch. We rectified this problem after
valuable participant input. Some working participants found it difficult to carry both a personal phone and a study phone and respond to EMA surveys during the day (Sengupta et al. 2020a).

A participant who worked in a library sought permission from her supervisor to carry the study phone and respond to the EMA surveys. One participant requested taking the HBCR system with her to Europe to allow her to track her activity on vacation. Participant feedback also led to the redesign of some of the graphic user interfaces of the EMA survey. For example, participants requested more options for food categories from which to select. While there was minimal contact between the health coach and the participants during the 13 weeks, and participants went on vacation during the study, they voiced reassurance that their progress was being monitored by the health coach via the dashboard. Participants had no adverse events during the study and there were no issues raised about privacy concerns (Sengupta et al. 2020a).

Table 11 provides comprehensive details of various data for all ten participants. Below, we first describe the summary data, then we identify some individual trends in participant data that provided valuable insights regarding the usefulness of the system. Eight participants (out of ten two of the participants never used our system during the test period) collectively set goals for walking that totaled 3335 minutes (416.87 ± 500.2) and we recorded 4933 (616.62 ± 989.5) minutes of activity. Thus, they walked more than they set goals for. They took a total of 799,537 (98,942 ± 158,789) steps while covering a distance of 399.71(49.96 ± 79.39) miles over a period of 13 weeks. Together they submitted 830 EMA survey responses and accessed eight health educational videos 165 times during the test period. These cumulative results suggest a reasonable amount of use of the system by the participants. Considering the current situation where 80% of health-related apps are abandoned after only two weeks of
usage (Baldwin et al. 2017), we think our HBCR system performed fairly well during the field trial, where the usage of the system is completely voluntary (Sengupta et al. 2020b).

Table 11: Descriptive statistics (Sengupta et al. 2020b)

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Average Goal Set (in minutes) (±Standard Dev)</th>
<th>Physical Activity</th>
<th>Average walk (in minutes) (±Standard Dev)</th>
<th>Average Step Count (±Standard Dev)</th>
<th>Average Distance Travelled (in miles) (±Standard Dev)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant1 (P1)</td>
<td>22 (±9.9)</td>
<td>17 (±21.94)</td>
<td>2751 (±3524.2)</td>
<td>1.37 (±1.76)</td>
<td></td>
</tr>
<tr>
<td>Participant2 (P2)</td>
<td>21.25 (±7.80)</td>
<td>3 (±0.81)</td>
<td>449.33 (±124.1)</td>
<td>0.223 (±0.065)</td>
<td></td>
</tr>
<tr>
<td>Participant3 (P3)</td>
<td>23.33 (±9.46)</td>
<td>9 (±15.5)</td>
<td>1449 (±2464.5)</td>
<td>0.72 (±1.2)</td>
<td></td>
</tr>
<tr>
<td>Participant4 (P4)</td>
<td>6.2 (±2.48)</td>
<td>6 (±3.81)</td>
<td>911 (±612.5)</td>
<td>0.45 (±0.3)</td>
<td></td>
</tr>
<tr>
<td>Participant5 (P5)</td>
<td>33.55 (±15.5)</td>
<td>11 (±9.34)</td>
<td>1815 (±1499.5)</td>
<td>0.90 (±0.74)</td>
<td></td>
</tr>
<tr>
<td>Participant6 (P6)</td>
<td>21.33 (±12.12)</td>
<td>1 (±0)</td>
<td>64.5 (±41.5)</td>
<td>0.03 (±0.02)</td>
<td></td>
</tr>
<tr>
<td>Participant7 (P7)</td>
<td>35.6 (±11.93)</td>
<td>45 (±22.68)</td>
<td>7226 (±3628.3)</td>
<td>3.61 (±1.81)</td>
<td></td>
</tr>
<tr>
<td>Participant8 (P8)</td>
<td>12.36 (±3.79)</td>
<td>8 (±6.12)</td>
<td>1293 (±994)</td>
<td>0.65 (±0.49)</td>
<td></td>
</tr>
</tbody>
</table>

As we have mentioned earlier, while setting a walking goal through the android application, a patient has to also report her activity readiness and current energy level on a scale of 1 to 10. For eight patients the average activity readiness score was 5.46 (Std. Dev=±2.05, Max=10, and Min=1) and the average current energy level was 5.02 (Std. Dev=±2.32, Max=9, Min=1). We found that most of the walking goals were set between 9 am and 11 am (45 times) and between 5 pm and 6 pm (12 times). This pattern suggests that patients mostly preferred to set a walking goal in the morning, within a range of 3 hours. During the evening there is a small patch of time (from 5 pm to 6 pm) when patients prefer to set a goal for walking (Sengupta et al. 2020b).

We found that while Participant1 and Participant7 used the system quite regularly during their walking activity, Participant2 and Participant6 hardly used the system to do physical exercise like walking. The other four participants used the prototype system moderately to do the
physical exercise of walking. Through visualization of related data of the participants’ daily step count, walk duration (in minutes) and distance covered (in miles), we found that each of the participants had a different temporal trend of daily walking over the trial period of 91 days.

Figure 19 and 20 shows the temporal trend of daily physical activity of walking for Participant1, Participant3, Participant4, Participant5, Participant7, and Participant8. In this regard, it is important to mention that since Participant2 and Participant6 barely used our system while walking, we are not able to visualize any temporal trend for these two participants (Sengupta et al. 2020b).

Figure 19: Temporal trend of daily physical activity of walking for Participant1, Participant3, Participant4, (Sengupta et al. 2020b)
Regarding participants’ goal setting behavior, only Participant1 and Participant7 set walking goals on a regular basis (52 times and 39 times respectively). Therefore, we visualized their goal-setting activity data and looked for temporal trends. Interestingly, the two have very different temporal trends of setting walking goals. Though for Participant1 the behavior of goal setting gradually decreases during the last leg of the trial, for Participant7 the behavior of goal setting started going upwards. Figure 21 shows the temporal trend of daily goal-setting activity for Participant1 and Participant7 (Sengupta et al. 2020b).
Regarding EMA survey responses, 8 participants together submitted 830 complete responses during their 13 weeks (91 days) of the testing period. Table 12 provides the details of EMA responses submitted by each participant in terms of percentages.

Table 12: Details of EMA responses submitted by participants (Sengupta et al. 2020b)

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Percentage of Complete EMA Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant 1</td>
<td>10.36%</td>
</tr>
<tr>
<td>Participant 2</td>
<td>34.93%</td>
</tr>
<tr>
<td>Participant 3</td>
<td>2.28%</td>
</tr>
<tr>
<td>Participant 4</td>
<td>6.86%</td>
</tr>
<tr>
<td>Participant 5</td>
<td>3.87%</td>
</tr>
<tr>
<td>Participant 6</td>
<td>0.36%</td>
</tr>
<tr>
<td>Participant 7</td>
<td>36.39%</td>
</tr>
<tr>
<td>Participant 8</td>
<td>4.95%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
</tr>
</tbody>
</table>

We found that Participant2, who hardly used the system during any physical activity, submitted more than 33% of the total number of EMA survey responses through the mobile application. During her debriefing session, she told us that she already had a smartwatch which she uses quite regularly and did not feel like wearing two smartwatches at the same time. The main reason she
provided for not using the smartwatch was that it had a comparatively low battery life.

Participant2 also mentioned that she liked to respond to the daily EMA surveys as it provided her a sense of security and compassion (Sengupta et al. 2020b).

To check the effect of preprogrammed intervention messages on participants’ physical activity performance, we compared the step count, walking duration (in minutes) and distance covered (in miles) for those days in which participants received and acknowledged at least one preprogrammed intervention message with the step count, walking duration and distance covered for those days in which participants did not receive any preprogrammed intervention messages. We used the statistical method of analysis of variance (ANOVA) to check for any significant positive impact of preprogrammed intervention messages. We found a significant positive impact (p<0.05) of preprogrammed intervention messages on participants’ step count, walking duration and distance covered while walking. We were also interested in checking the effect of preprogrammed intervention messages on the participants’ physical activity performance on the next day. To check that, we compared step count, walking duration and distance covered for those days in which an intervention was received in the previous day to those days in which the participant did not receive an intervention on the previous day or the current day. Interestingly, the ANOVA analysis suggests a significant positive impact (p<0.05) of previous-day preprogrammed intervention messages on participants’ step count, walking duration and distance covered for the next day.

We applied the same procedure to check the effect of customized text-based intervention messages on participants’ physical activity performance. The ANOVA results suggest no significant impact (P>0.05) of customized text-based intervention messages, on the same day or the next day, on participants’ step count, walking duration and distance covered while walking.
Even though these results are surprising, researchers in the past have also arrived at similar findings. The study conducted by Karhula et al. (2015) also failed to show the beneficial effect of health coaching supported by telemonitoring on a patient’s quality of life. According to Karhula et al. (2015), “An automatic feedback system, based on their self-monitored health parameters, could have kept patients motivated and informed by the delivery of individualized feedback with a coaching perspective.” Surprisingly, the results of my study point us in the same direction (Sengupta et al. 2020b).

However, during our post-test interviews, participants highlighted their increased confidence and trust in the mHealth system due to the involvement of the health coach. Though there was a lack of statistical evidence supporting the role of the health coach improving physical activity performance, its importance for improving participants’ trust and confidence in our system cannot be denied. Interestingly, we observed participants using the mHealth system prototype even after the stipulated field test period. We attribute this particular observation to the increased trust and confidence in the system due to the presence of a health coach (Sengupta et al. 2020b).

There are other possible explanations for such findings. First, such results can be attributed to the inadequacy of data for customized text-based intervention messages sent by the health coach through the dashboard. Such messages were fewer in number in comparison to preprogrammed intervention messages and they disappeared after 6 hours of their dispatch if not checked. Second, there exists a possibility that the impact of customized text-based intervention messages is mediated through preprogrammed intervention messages (Sengupta et al. 2020b). During the testing, all the participants received both types of intervention messages; thus, it is not very unlikely that the customized text-based intervention messages impacted participants’
physical activity behavior through preprogrammed, system-generated intervention messages (Sengupta et al. 2020b).

We were also interested in checking the possible impact of both preprogrammed intervention messages and customized text-based intervention messages on participants’ walking goal-setting activity. To check the effect of preprogrammed intervention messages on participants’ walking goal-setting activity, we compared the participants’ goal-setting amount (in minutes) for those days in which participants received and acknowledged at least one preprogrammed intervention messages, with participants’ goal-setting amount (in minutes) for those days in which participants did not receive any preprogrammed intervention messages. We also checked the possible effect of preprogrammed intervention messages on each participant’s goal-setting amount (in minutes) for the next day. We deployed ANOVA to check these possible impacts. Though we did not find any statistically significant impact of preprogrammed intervention messages on walking goal-setting amount for the same day, we found a significant (alpha = 0.1) positive impact of preprogrammed intervention messages on walking goal-setting amount for the next day. We did not find any statistically significant impact of customized text-based intervention messages on participants’ walking goal-setting amounts for the same as well as the next day.

To check the validity of our result we also run a participant level fixed effect regression model and estimated the parameter for preprogrammed intervention messages as the predictor variable. The parameter estimate was statistically significant at the alpha level of 0.001 (Sengupta et al. 2020b).
Table 13: ANOVA and participant level fixed effect model results (Sengupta et al. 2020b)

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Mean Value</th>
<th>F</th>
<th>df</th>
<th>P-Value</th>
<th>95% Confidence Interval</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step Count</td>
<td>(n=118)</td>
<td>15.158</td>
<td>212</td>
<td>&lt;0.05</td>
<td>Lower Bound: 976.3, Upper Bound: 2978.9</td>
<td>Yes. (at α =0.05)</td>
</tr>
<tr>
<td></td>
<td>Preprogrammed intervention message(s) received on the day (4574.25)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n=96) No preprogrammed intervention message(s) received on the day (2596.55)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk Duration (in Minutes)</td>
<td>(n=118)</td>
<td>15.149</td>
<td>212</td>
<td>&lt;0.05</td>
<td>Lower Bound: 6.08, Upper Bound: 18.57</td>
<td>Yes. (at α =0.05)</td>
</tr>
</tbody>
</table>
Table 13: (Continued)

<table>
<thead>
<tr>
<th></th>
<th>(n=118)</th>
<th>15.169</th>
<th>212</th>
<th>&lt;0.05</th>
<th>Lower Bound</th>
<th>Upper Bound</th>
<th>Yes. (at α =0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance Covered (in Miles)</td>
<td>Preprogrammed intervention message(s) received on the day (2.28), (n=96) No preprogrammed intervention message(s) received on the day (1.29)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step Count</td>
<td>(n=113)</td>
<td>12.404</td>
<td>207</td>
<td>&lt;0.05</td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td>Yes. (at α =0.05)</td>
</tr>
<tr>
<td></td>
<td>Preprogrammed intervention message(s) received on the day (4597.84), (n=96) No preprogrammed intervention message(s) received on the day (2773.93)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk Duration</td>
<td>(n=113)</td>
<td>12.007</td>
<td>207</td>
<td>&lt;0.05</td>
<td>Lower Bound</td>
<td>Upper Bound</td>
<td>Yes. (at α =0.05)</td>
</tr>
<tr>
<td></td>
<td>intervention message(s) received on the day (28.79), (n=96) No preprogrammed intervention message(s) received on the day (17.56)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Distance Covered</strong></td>
<td><em>(n=113)</em> Preprogrammed intervention message(s) received on the day (2.29), (n=96) No preprogrammed intervention message(s) received on the day (1.38)</td>
<td>12.423</td>
<td>207</td>
<td>&lt;0.05</td>
<td>Lower Bound 0.402, Upper Bound 1.423</td>
<td>Yes. (at α =0.05)</td>
<td></td>
</tr>
<tr>
<td><strong>Walking Goal Set</strong></td>
<td><em>(n=66)</em> Preprogrammed intervention</td>
<td>0.001</td>
<td>105</td>
<td>&gt;0.05</td>
<td>Lower Bound -5.35, Upper Bound 5.35</td>
<td>No. (at α =0.05)</td>
<td></td>
</tr>
</tbody>
</table>
Table 13: (Continued)

| Walking Goal Set (in Minutes) | (n=59) Preprogrammed intervention message(s) received on previous day (26.49), (n=46) No preprogrammed intervention message(s) received on previous day (26.56) | 3.28 | 103 | <0.1 Lower Bound, 0.447, Upper Bound 9.9 | Yes. (at α =0.1) |

Participant level Fixed Effect Model

<table>
<thead>
<tr>
<th>Fixed effect</th>
<th>Dependent Variable</th>
<th>Estimate for the regressor:</th>
<th>F-Value</th>
<th>df</th>
<th>Significance level</th>
</tr>
</thead>
</table>
Table 13: (Continued)

<table>
<thead>
<tr>
<th>Level</th>
<th>Step Count</th>
<th>Preprogrammed intervention message(s) received on the day (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eight</td>
<td>1469.408</td>
<td>26.75 206 &lt;0.001</td>
</tr>
</tbody>
</table>

6.3 Health Coach Technology-Symbiosis

While designing the system prototype of our HBCR we followed an approach to effectively combine cardiovascular knowledge of the health coach with the high-level observational (through sensors), analytical (dashboard) and large-scale pattern matching power (machine learning) of a computing system for optimal utility. Through the design of the system, we augmented the observational and decision-making capabilities of the health coach. The system provided unique intervention opportunities for the health coach. For example, Participant3 and Participant4 received phone calls from the health coach due to their comparatively higher heart rate for a small period of time that the coach observed through the web-based dashboard (see Figure 22). Certain values of a heart rate are beyond the safe range (Sengupta et al. 2020b).

In Figure 22, we have circled those values. The health coach observed those values through the dashboard and called individual participants to inquire about their wellbeing.
Participant3 was very surprised but comforted to receive the call but it turned out to be noise in the heart rate monitor. The same was the case for Participant4. Though Participant3 and Participant4 could not provide any additional information to explain the higher heart rate and no major concern was identified by the health coach through discussions over the phone, both of them were very happy as they came to know that the health coach was looking at their heart rate data in order to ensure their safety. According to Participant3, “I am not sure what I was doing that time but I am really glad that you called me. Now I am very relaxed as I know somebody is watching my back.” Both the participants expressed their satisfaction regarding the personalized messages that they received from the health coach during the test period (Sengupta et al. 2020b).

This demonstrates the extended capacity of the health coach due to the presence of the dashboard in the system. The intervention messages from the health coach were particularly well-received, even in the cases of “false alarms,” increasing the confidence of the participants. Future versions of the dashboard will have the capability of informing the health coach instantly (sending messages to her phone) whenever such situations arise (Sengupta et al. 2020b).

![Participant3: Daily Heart Beat Rate](image1) ![Participant4: Daily Heart Beat Rate](image2)

Figure 22: The daily heart rates, trend lines and out of normal range values for heart rate (circled) for Participant3 and Participant4.
CHAPTER 7. DISCUSSION

The primary aim of this study was to determine the usability of the mobile health system with a cohort of patients with CHD before proceeding with development of a comprehensive home-based secondary prevention intervention. Our secondary aim was to evaluate the influence of the mobile health system on various psychosocial and health behaviors of the participants. The main finding of the study was that the system was acceptable and usable in its prototypic form. The level of engagement of participants with the mobile health system was greater than anticipated given the relatively primitive features. We developed the mobile health system to avoid high data entry burden and designed gender-specific graphic user interfaces to foster engagement. Given that 80% of health-related apps are abandoned after only two weeks (Baldwin et al. 2017), the engagement of the participants with the prototype was good particularly when they were given little prodding for using the technology. We viewed this as encouragement to proceed with the expanded version of the mobile health system with heightened involvement with the health coach.

Comparisons of user engagement with mobile applications of participants with characteristics similar to the participants in my study are difficult to make because usability was defined differently in these studies (Forman et al. 2014, Johnston et al. 2016, Widmer et al. 2015, Hagglund et al. 2015). Some described metrics such as app usage frequency, duration, data registration or responsiveness of the user to daily tasks. In addition to often low participant numbers, dropouts and short study duration, conclusions about engagement are difficult to draw.
Completion of tasks within the app, such as completion of an education module, was a typical measure of use in studies with a focus on healthy lifestyle. Forman et. al. (2014) gauged engagement by patient completion of at least one prescribed daily task. In others, emphasis was on logging medication intake or physical measurements (Johnston et al. 2016, Widmer et al. 2015). The authors did not report the acceptability of a data entry requirement. We made the decision early during development, based on numerous interviews with patients, to avoid the requirement of data entry to reduce respondent burden. In an uncontrolled single group, pre-test, post-test design (Bengtsson et al. 2016), participants were required to log daily blood pressure measurements for 55 days; however, it was unclear whether all patients logged blood pressure each of 55 days. Patients in one small study of both heart failure and CHD participants (Layton et al. 2014) appreciated medication reminders and physical activity information. However, they felt daily requirements for data entry or other responses were inconvenient. Clearly, high data-entry burden is a usability issue (Bao et al. 2019).

We did not see evidence of the message fatigue reported by others (Kim 2018). That the participants responded to 830 EMA surveys over 13 weeks was, in my opinion, quite remarkable. While the number of EMA survey responses was greater than expected, the responds indeed declined over time. Educational videos on healthy eating behavior were more often viewed than were videos related to physical activities, presumably because eating a healthy diet is often a daily or hourly struggle between reflex and self-control. Participants may have viewed the videos seeking assist with making healthy eating decisions. Eating and body weight regulation is a complex process that involves both metabolic and hormonal control mechanisms and neurocognitive processes involved with memories, expectations, and evaluation about food and the consequences of eating (Davidson et al. 2019). The decisions about what and when to eat
are a balance between reflexive behavior and higher-level cognitive processes. Eating can be reflexive and automatic by the mere smell of a favored food (Jones et al. 2018). This reflexive eating can be opposed by dietary restraint of choosing a healthy food which involves higher-level cognitive processes to counter the power of tempting environmental stimuli (Appelhans et al. 2009).

Based on the decision rules related to participant responses employed in the mobile health system, some intervention messages were dispatched more frequently than others. Most participants exceeded the walking goals they set. In other words, most of the time participants did not abruptly stop their walk after achieving their physical activity goal but rather exercised beyond the goal. We hypothesize that this may reflect low self-efficacy when setting the goal followed by greater confidence when they surpassed the goal. Although we did not set a target for time spent walking or for step count, participant daily step count was relatively modest. A common goal of 10,000 steps per day has been perpetuated by the lay press and is often used as the default by software programs on wearables and smartphones (Torjesen 2018). In the United States the average number of steps accrued daily (measured by smartphones) is about 4800; Worldwide it is approximately 5000 (Althoff et al. 2017). There is sparse data on how many daily steps are needed for health (Bassett et al. 2017, Kraus et al. 2018) or clinical outcomes and mortality (Dwyer et al. 2015).

Although we did not expect participant health behaviors, self-efficacy, perceived stress or depressive symptoms to improve with a limited functionality prototype, we nonetheless observed significant reductions in waist circumference, weight, body mass index as well as reduced depressive symptoms after study participation. These improvements were unexpected because the research team had minimal contact with the participants during the 13 weeks and we did not
prompt them to set goals for walking. Participants reported minimal positive changes in their self-efficacy for exercise, diet or managing chronic illness but they were nonetheless trending in the expected direction. From baseline to the 13-week follow-up there was a modest increase in the mean minutes of moderate-intensity exercise. There were no reductions in participants’ time spent sitting (Sengupta et al. 2020b).

Though cardiac rehabilitation (CR) has, for many years, been a highly recommended approach to secondary prevention for patients recovering after a cardiac attack or cardiac surgery, the use of CR program delivered through a hospital outpatient center or a cardiac clinic is still quite low (Varnfield and Karunanithi 2015). The major benefit of the remote platform for CR delivery is the ability to deliver interventions without face-to-face contact, which not only overcomes some of the barriers of the traditional CR program but also provides an opportunity to reach a much larger number of people. Such home based mHealth platforms have the potential to deliver long-term follow up, which programs delivered by health professionals cannot afford to do due to the shortage of staff and budget restrictions (Varnfield and Karunanithi 2015). We have developed a comprehensive, multi-component intervention system that is personally tailored, promotes self-monitoring and involves a qualified health coach for rehabilitation and intervention-related decision making. We have evaluated our high-fidelity prototype by conducting a field observational study and a quasi-experiment to find the efficacy and effect of two different types of interventions (Sengupta et al. 2020b).

The interventions provided by our system are both immediate (preprogrammed messages) and personalized (messages sent by the health coach). While the preprogrammed intervention messages offer instant alert and gratification, personalized messages received by the participants are more carefully crafted on the basis of participants’ physical activity trends and other
behavioral patterns observed for a period of time. They covered both the dynamic and static aspects of participants’ behavior change. Instead of providing one uniform intervention for all irrespective of patient condition, it is appropriate to develop a set of choices of possible interventions from which the health coach can select one that best suits the need and circumstances of the patient. Burke et al. (2015) suggested that we know very little about the intervention components or combinations that are best to produce clinically meaningful outcomes. Our study can be considered the first step towards finding the optimal intervention or intervention combination for secondary prevention of coronary heart disease (Sengupta et al. 2020b).

According to a scientific statement published by American Heart Association (Burke et al. 2015), “there is no evidence to suggest that SMSs as a stand-alone intervention are effective (p.1167)”. On the contrary, Yang et al (2019) suggested that for mHealth system increased health coach – patient interaction “should be the rule rather than exception”. Extant research also points us towards the same direction. For example, Martin et al (2015) reported increased physical activity for those patients who have received text messages (intervention) bearing the name of their cardiologist. Chow et al (2015) also reported improvement in cholesterol and other cardiovascular risk factors for those patients who have received intervention text messages bearing the name of the specific hospital from which they are receiving the care. Therefore, we consider the health coach one of the essential parts of our technology based HBCR system. Our system specifically emphasizes the role of the health coach in making decisions related to 1) time of intervention 2) type of intervention and 3) the decision of creating and modifying new decision rules based on patient’s EMA response patterns. From a change management perspective, it is also quite necessary to define the role of nurses and support staffs, as
implementation of the system should align to the current practices of those stakeholders without making any negative impact (Sengupta et al. 2020b).

Our current study also tried to address some of limitations that exists in the extant mHealth system design approach. For example, the study conducted by Gilson et al. (2017) revealed that the financial incentives themselves were not very motivating. Similarly, the study conducted by Vilpp et al. (2017) reported that providing electronic pill bottles, lottery incentives and extra social support did not improve medical adherence. According to Burke et al. (2015), the absence of a “theoretical basis,” “limited application of the best practices in technology design” and “low use of empirically supported behavioral strategies” are preventing existing mHealth systems from making their desired impacts on patients’ behavior change. Burke et al. (2015) also suggested mixed method research to generate a holistic understanding of issues that can hamper the implementation of these interventions outside the controlled trial settings. Our study addressed both of these issues. First, for different behavior change interventions developed and deployed by our prototype, instantiations are based on constructs suggested by multiple behavior change theories. Second, we collected patients’ health related data through multiple modes of interaction and analyzed them by following both qualitative and quantitative procedures. This helped us to develop a more holistic understanding of the barriers and challenges. This understanding is also expected to help us in designing better prototypes and intervention strategies (Sengupta et al. 2020b).

It might be worth mentioning that we collected participants’ health-related data without causing any interference in their daily routines. Participants do not have to enter any text while interacting with our mobile application. Therefore, while interacting with our application, participants experience hardly any data entry burden. This strategy provided our system with two
distinct advantages. First, it relieved our participants of the data entry burden. Second, because of the minimal provision of self-reporting (only for the EMA survey), we were restrained from an overestimation while figuring out the effectiveness of our interventions (Sengupta et al. 2020b).

Another important aspect of our intervention system was the creation of decision rules for intervention messages crafted by the health coach based on the participant’s ecological momentary data. Burke et al. (2015) suggested the utilization of the currently available technologies that permit the collection of data in real time to better learn about behaviors and moods of individuals in their natural settings. They (Burke et al. 2015) also suggested the development of interventions that can be derived in real time and thus provide support when individuals are in need of them (McKee et al. 2014). Our prototype system used this particular approach to motivate participants to walk daily and to eat healthy foods.

Finally, many mHealth technologies have been evaluated with motivated individuals in an ultra-controlled, unrealistic setting. These idealized conditions often lead to exaggerations of the effectiveness of system driven interventions (Burke et al. 2015). Most of the studies were also of short duration, a design which calls into question the sustainability and adherence to the product. There are significant chances that the interventions will work over a short term but fail to support durable behavior change. Our study addressed both these issues as it evaluated the system by randomly selecting individuals from the target population with varied levels of motivation and tested the system for a time period of 13 weeks (91 days). Future research should check the efficacy of these interventions for a much longer period of time (Sengupta et al. 2020b).

Finally, to summarize, our study offers three important contributions. First, we have designed three novel artifacts in order to support a home-based cardiac rehabilitation program.
By evaluating these three artifacts through a case study we showed the usefulness of these artifacts in context of CR. According to Baskerville et al. (2018) if “the artifact is novel and useful, then it necessarily contributed to design knowledge. Based on the previous argument, development of our IT artifacts and introduction of these artifacts into an application context with measurable improvement can be considered as our first DSR contribution (Sengupta et al. 2020b).

While developing the instantiations of behavior change interventions, we delineated the process of creating meaningful instantiations of interventions from seemingly abstract psychological constructs suggested by different behavior change theories. It was a challenging task, and our study was able to illustrate a successful process for the development of these particular categories of instantiations. Though developed in the context of CHD the process can easily be followed for creating instantiations of digital interventions related to other non-communicable chronic diseases like diabetes mellitus (DM), chronic respiratory diseases (CRDs), chronic obstructive pulmonary diseases, etc. Therefore, the creation of this particular reference process (Baskerville et al. 2018) which can impact both design and practice can be considered as the second DSR contribution of our study (Sengupta et al. 2020b).

Third, the development of our novel IT solution for the secondary prevention of CHD also provides the scope of making fine grain observation of patient’s behavior. These micro-level observations can offer support for the identification of new behavior patterns, insights and understanding, based on which new design knowledge in the form of kernel theory can be generated. In this way, our new technology-based solution can be a possible impetus to the new scientific development in the form of required groundwork for new emerging DSR theories.
(Baskerville et al. 2018). This can be considered as the third DSR contribution of our research (Sengupta et al. 2020b).

7.1 Contribution to home-based healthcare

Our proposed solution can easily be generalized to other chronic diseases. A similar architecture using a smartwatch, a mobile application and a web-based dashboard along with an array of other medical devices can work for patients suffering from other non-communicable chronic diseases like diabetes mellitus (DM), chronic respiratory diseases (CRDs), or chronic obstructive pulmonary disease (COPD). While some of the sensors/devices and parameters need to be adapted to the new context, the architecture for the collection of data, interpreting data and triggering the right interventions remains similar. Therefore, we argue that our research contribution is generalizable across a class of health-related problems (Sengupta et al. 2020b).

7.2 Contribution to practice

We designed and developed a prototype for an HBCR system using a smartwatch, a mobile application, and a web-based dashboard with the goal of facilitating behavior change and improving proximal health behaviors. Using a decision rule-based intervention dispatch system, the participants received intervention messages based on their daily activity goals and activities in real time. Our system differs from other existing efforts in that it places a health coach in a pivotal role of decision making for each of the individual patients. By doing so it combines the advantages of a sensor-based automated system with the insights of a human expert. Our high-fidelity prototype of an HBCR system can monitor patient activities 24/7 and interact with patients in real time. Most of the existing health-related fitness applications are stand alone; they mostly rely on users’ own effort in reporting various parameters and rarely involve a health
coach to monitor patients. Our system, through its technological infrastructure and health coach combination, offers a more holistic and efficient prototype of an HBCR with better monitoring in the home environment (Sengupta et al. 2020b).
CHAPTER 8. ECOLOGICAL MOMENTARY ASSESSMENT AS A BEHAVIORAL NUDGE

8.1 Overview

Mobile health information technology (HIT) interventions offer a new paradigm in chronic disease management by empowering patients with information, tools, and alerts and engaging them in the self-management of their own diseases. However, we know little about how these technologies work and how we can design features to sustain their use over time. We explore these issues using the affordance concept to examine two types of affordances offered by these technologies: designed and emergent. We hypothesize the independent and joint effects of these affordances, by integrating affordance with goal setting theory, dual process model of cognition, and nudge theory. The proposed hypotheses are empirically tested using a 91-day field trial of a home-based cardiac rehabilitation prototype for patient self-management of coronary heart disease. Panel data from this study, analyzed using multi-level, zero-inflated Poisson and negative binomial models, provide support for our hypotheses (Sengupta et al. 2020c). This study explicates the complex interplay between designed and emergent affordance, draws attention to the actualization of emergent affordances in unexpected ways, which can potentially explain both effective use and misuse of technologies, elaborates how we can build dual-process models of technology-related behaviors by drawing on conscious and subconscious cognitive processes linked to technological affordances, and demonstrates how HIT design can benefit from considering emergent affordance as a behavioral intervention for chronic care patients.
8.2 Research Questions

In this study, we employ the concept of technological affordance (Gibson 1966; Norman 1999) to explore HIT (specifically, mobile app) features that can motivate the desired behavior change among chronic care patients. In addition to designed affordances intended to motivate desired behaviors, we elaborate the concept of “emergent” affordance as a behavioral change mechanism and explore the interplay between designed and emergent affordances in actualizing the desired behavior change (Sengupta et al. 2020b). Our research questions of interest are:

1. What are the effects of designed (intended) and emergent (unintended) affordances of mobile HIT interventions on chronic disease patients’ daily physical activities?

2. Do designed and emergent affordances of mobile HIT interventions complement or substitute each other in influencing chronic disease patients’ daily physical activities?

To answer the above questions, we start with technological affordance as our theoretical lens and augment this perspective with goal setting theory (Locke and Latham 2002), dual process model of human cognition (Kahneman 2011), and nudge theory (Thaler and Sunstein 2009) as supporting theories, to postulate a set of research hypotheses linking designed and emergent affordance to chronic disease patients’ behavior change. The proposed hypotheses are empirically tested using a 91-day field trial of a smartphone-based prototype for CHD care (Sengupta et al. 2020b). This prototype included a smartwatch, paired with a custom-built smartphone application to continually monitor patients’ step count and other physical activity using embedded sensors, display that data using a mobile dashboard, employ ecological momentary assessment (EMA) surveys to collect data on issues not available from onboard
sensors, and provide continuous feedback and recommendations to patients. We use a field trial of this app to track daily feedback messages and EMA encounters for eight coronary heart disease patients over a period of 91 days. This rich, multi-level, temporal combination of sensor and user-reported data were analyzed using multi-level, zero-inflated Poisson and negative binomial regression models.

Our study makes several broad theoretical contributions. First, it contributes to the technology affordance literature by explicating the complex interplay between designed and emergent affordances, and by extending the impact of technology affordance from use of an artifact to the consequences of such use. In particular, it draws attention to the actualization of emergent affordances in unexpected ways, which has potential for explaining both effective use and misuse of technologies. Second, our study elaborates the potential of building dual-process models of technology-related behaviors by drawing on conscious and subconscious cognitive processes linked to technological affordances. Third, we provide a preliminary example of how to build a “theory of the solution” (Majchrzak et al. 2016) to explain when, how, and why IT artifacts can solve a given problem like self-management of chronic care. Lastly, we contribute to healthcare research by elaborating its potential role of EMA surveys as a behavioral intervention and by demonstrating how it can complement other interventions to achieve synergistic effects on patient behaviors.

8.3 Related Literature

HIT is one of the newer domains of information systems research, tracing back only about fifteen years or so. Research in this domain can be organized into three streams: (1) HIT use, (2) HIT impacts, and (3) HIT design. Early research in this domain focused on adoption, use, assimilation, and adaptation of EHR (and related) systems among physicians and patients, mostly
using behavioral studies such as surveys and experiments. For example, Bhattacherjee and Hikmet (2007) examined physician resistance to computerized physician order entry systems, a component of EHR systems, to explain how loss of power and control engendered by these systems posed a professional threat that hindered their adoption among physicians, despite their expected benefits. Angst and Agarwal (2009) studied the role of privacy concerns in impeding consumer adoption of EHR, and persuasion strategies that could motivate their EHR opt-in adoption. Angst et al. (2010) examined the role of social contagion in explaining the growing adoption of EHR systems using annual survey data from over 4,000 U.S. hospitals from 1975-2005, and observed that hospital size, age, and spatial proximity were positively related to the likelihood of adoption among non-adopters, while a hospital’s “celebrity” status and younger hospitals were associated with greater infectiousness. Using an identity theory lens, Mishra et al. (2012) examined how physicians’ dual identities as care providers and members of a physician community influence their EHR assimilation in physician practices, and how government influence diminishes the former effect. In a recent study of a home-based telemonitoring system, Brohman et al. (2019) examined the cascading effects of two types of alerts (medical and compliance alerts) generated by the system on the provision of three types of care provider feedback (outcome, corrective, and personal), and how such feedback influenced chronic illness patients’ adaptive behaviors. The study found that personal and outcome feedback linked to patients’ medical tests improved patients’ adaptation, but corrective feedback (care providers telling them what to do) attenuated the benefits of outcome feedback.

The second stream of HIT research focused on examining their effects on patient health outcomes, healthcare quality, or costs, mostly using econometric analysis of large-scale data sourced from EHR systems, health information exchanges (HIE), and related systems. For
example, Devaraj and Kohli (2003) analyzed monthly panel data on HIT use and performance from a chain of eight hospitals over three years, to conclude that HIT use has lagged effects on patient mortality and hospital revenues per admission and per day. Das et al. (2010) analyzed 26 years of hospital on HIT investments for patient management, transactional support, communications, and administration and hospital costs and labor productivity, and demonstrated that HIT reduces operating costs and increases labor and administrative productivity but that these effects are realized with different time lags. Bardhan et al. (2015) examined the relationship between HIT use in hospitals and readmission risks for patients with congestive heart failure, using data from 67 hospitals in North Texas over a four-year period. Venkatesh et al. (2016) demonstrated how the implementation of e-health kiosks to disseminate authentic health information helped reduce infant mortality across ten villages in rural India over a period of seven years. Integrating four years of data on EHR use, healthcare information exchange and payer claims database from 45,000 cardio-metabolic disease patients in Vermont, Thompson et al. (2020) showed that technology and analytics that matched care resources with patient health conditions, improved patient ownership of their healthcare and resulted in continuous improvement of population health outcomes. In a quantitative meta-analysis, Kalankesh et al. (2016) found that telehealth interventions significantly reduces all-cause hospitalization in 40% of the studies and length of stay in 36% of the studies. The third and most recent stream of HIT research is the design of mobile HIT interventions, such as healthcare apps designed for home-based use, to assist patients with chronic diseases and the general population at large. For example, Tulu et al. (2017) developed and piloted a mobile app for weight management called SlipBuddy and a web-based provisioning system for clinicians to monitor users’ progress and manage delivery of individually tailored interventions. Banerjee et al. (2016) designed a mobile
ambulatory blood pressure monitoring application, CheckMyVitals, which allows patients to enter data from any offline or online location, and demonstrated the system’s efficacy using a telephone survey of 385 patients. Kheirkhahan et al. (2019) designed and evaluated a smartwatch-based real-time mobility assessment and monitoring tool that collected self-reported data (e.g., pain level) and displayed analytics results. Son et al. (2020) developed a tool to detect abnormal inhaler usage patterns among patients suffering from chronic asthma and to model the impact of environmental asthma triggers by using usage logs data of Bluetooth-enabled inhalers.

Many novel and useful mobile HIT interventions, such as those described above, fail to influence long-term behavior change among the target population, perhaps because their designs are not grounded in theories of behavior change. Among exceptions, Sankaran et al. (2016) incorporated Fogg’s (2009) behavior model of persuasive design with a multidisciplinary user-centered design approach to create a mobile cardiac tele-rehabilitation application. Ahtinen et al. (2010) used the behavioral concepts of social sharing and playfulness to create a mobile phone based wellness app to motivate physical activities among physically fit adults. Moran et al. (2016) used social cognitive theory (Bandura and Wessels 1997) to design a technology-enabled, exercise regimen for cardiac rehabilitation. In an interpretive study of diabetic patients’ self-management of home-based care, Dadgar and Joshi (2018) used value sensitive design (VSD) to identify twelve technology-related values shared by patients, namely accessibility, accountability, autonomy, compliance, dignity, empathy, feedback, hope, joy, privacy, sense-making, and trust, and argued that HIT features that fail to integrate these values can constrain rather than enable patients’ self-management abilities.

Our review of mobile HIT literature reveals several patterns and gaps. First, although there is a growing body of research on the design, use, and impacts of HIT interventions for
chronic care, this research has generally proceeded along independent trajectories, with little consideration to the connections between HIT design, use, and impacts. As Devaraj and Kohli (2003) noted, HIT use mediates the relationship between HIT design and its impacts, and whether or not a given HIT realizes its expected promise at the patient level, hospital level, or at a broader societal level is a function of how it is used by its intended users. Hence, technological features should be designed to motivate use. Furthermore, these design features may be appropriated by users in expected and unexpected ways, to realize (or not) desired HIT outcomes. HIT intervention research that do not explicitly consider the unanticipated effects of these technologies on user behavior cannot explain why well-intentioned technologies are sometimes underutilized or abandoned by their intended users, or are enthusiastically adopted initially only to experience subsequent disinterest and declining use over time. Second, the American Heart Association (Burke et al. 2015) notes the absence of a “theoretical basis” to guide HIT design and rehabilitation practice as a key reason why HIT interventions fail to realize their full potential. For the most part, medical research on chronic diseases generally treats HIT interventions as a “black box” and largely ignores their potential impacts on patient perceptions and experiences (Jiang and Cameron 2020). A parallel stream of research in information systems and computer science on the design of HIT apps examines the technology in detail, but largely ignores the chronic disease context and patients’ specific needs (Ayobi et al. 2017). For example, little is known about the timing, frequency, form, and framing of interventions, or how to reduce alert fatigue, desensitization, and information overload that often negate the benefits of HIT use. Sherer (2014) argues that theory should drive HIT design and serve as the basis for evaluating those designs. There are suggestions that theories of psychological determinants of behavior can help design intervention strategies to motivate behavioral change, and that HIT interventions can
be more effective when they systematically target those psychological determinants, at least until
technology use becomes habitual (Alageel et al. 2017).

Our study addresses the above limitations in the HIT literature by exploring how HIT
design elements influence chronic care patients’ use behaviors in expected and unexpected ways.
In doing so, we bridge the gap between HIT design and use, specifically focusing on the
psychological determinants of such use. We do so using technological affordance as our
theoretical lens, which has been recommended by Jiang and Cameron (2020) as a useful way of
viewing the IT-based self-monitoring component of chronic disease management, and
complementing this perspective with theories of behavior change from the psychology and
behavioral economics literatures.

8.4 Theory and Hypotheses

8.4.1 Technological Affordances

The notion that technologies are not just material artifacts that exist and operate on their own to
accomplish specific tasks predetermined by their designers, but are rather means employed by
human agents to accomplish expected and unexpected tasks has gained widespread recognition
in the IS literature (e.g., Markus and Silver 2008; Leonardi 2011; Karahanna et al. 2018).
Technologies may sometimes constrain our ability to accomplish desired tasks or afford us the
possibility to accomplish new unanticipated tasks, or even misuse them in unintended ways
(Hutchby 2001). This inherent tension between technologies and the tasks they afford is captured
in the concept of “technological affordance” (Gaver 1991). This concept of technological
affordance and how it manifests itself in expected and unexpected ways while using an HIT
application is the central theme of this paper.
Coined by psychologist James Gibson (1979), the term “affordance” refers to possibilities of action provided by the environment (Anderson and Robey 2017). Viewing technological artifacts as part of the environment, information systems scholars have defined technological affordance as the possibility of different tasks that users can perform using new technologies available at their disposal (Hutchby 2001). In the healthcare IT context, such artifacts may refer to EHR systems that allow clinicians to track patient care in real-time, personal health records that allow patients to track their test results and prescriptions and communicate with physicians, smartphone apps that help patients track and manage their everyday physical activities, and so forth – possibilities that were infeasible before the availability of these artifacts. Technological affordances are not attributes of an artifact; users can use the same technology to perform very different tasks or use different technologies to perform the same task (Hutchby 2001). While the human agency perspective suggests that people’s work is not determined by the technologies they use and that they can use a given technology in unanticipated ways (e.g., using a web browser as a calculator or a dictionary or a foreign exchange converter) and material agency refers to non-human entities’ ability to act on their own without human guidance (e.g., a complier translating source code from a high-level programming language to machine language), affordance emerges from the interaction of material and human agencies (Leonardi 2011). Therefore, the affordance perspective offers a useful conceptual bridge to explore the interplay between human and material agencies, while simultaneously permitting a clear separation of these agencies.

Markus and Silver (2008) define functional affordance as “the possibilities for goal-oriented action afforded to specified user groups by technical objects” (p. 622). Such affordances are designed or intended affordances that can be communicated via signals from artifact
designers to its intended users (Norman 2013). However, affordances may also emerge from users’ mental interpretation of an artifact, their unique task requirements, and/or their prior knowledge of or experience with similar artifacts. Unique task-related knowledge or prior experience may help users discover new affordances from an artifact that were not originally envisioned by artifact designers. These unplanned or “emergent” affordances (Gaver 1991) are not purposefully crafted, but emerge during use through the interaction between the artifact and its users (Van Osch and Mendelson 2011). The relational nature of affordances also explains why different users may interact with the same technology in very different ways, leading to dramatically different outcomes, or realize different levels of value from that technology (Leidner et al. 2018). More generally, the concept of “emergence” is concerned with behaviors in dynamic systems that arise from interactions of the parts that cannot be predicted from the properties of those parts (Casti 1997, Hovorka and Germonprez 2013). It shifts the focus from static properties of systems to improvisations and even accidental changes that may depend on the timing of events or specific paths undertaken to perform a task. Emergent affordance may also occur as people reflect upon, restructure, and appropriate new technologies, new technology-enabled processes, and new assemblages of agent, information, and technology (Germonprez et al. 2011).

While most scholars follow Gibson (1979) in viewing affordances as behavioral possibilities or opportunities, few explicitly address the actualization of affordances (Anderson and Robey 2017). Since there may be many potential affordances available at any given time, there is a chance that an actor may not act upon a particular affordance for task performance. At the same time, an actor may actualize emergent affordances in unexpected ways.
The theoretical lens of affordance has received considerable interest in IS research to explain how technologies shape (or constrain) user behavior at an individual level (Mettler and Wulf 2019) and within organizations (Strong et al. 2014; Volkoff and Strong 2013). In the following sections, we investigate how affordances provided by digital technologies can shape chronic disease patients’ physical activity performance in planned (designed) and unplanned (emergent) ways. Our study deviates from the prior literature in two ways: (1) by elaborating the role of emergent affordances, and (2) by focusing on the actualization of affordances.

8.4.2 Intended Affordance Actualization

While HIT can offer different affordances in healthcare settings, one of its primary affordances is providing pertinent information to users in a manner that is understandable and actionable by the user. The growing variety of smartphone-based healthcare apps serve this affordance by recording users’ daily physical activity data using on-board sensors, providing users a real-time graphical display of their daily activities, and using automated reminders to help them follow their desired physical activity regimen. Reminders are typically based on a target level of physical activity (e.g., step count or walking distance) set by users.

Locke and Latham’s (2002) goal setting theory suggests that setting clear, meaningful goals and having a mechanism to receive timely feedback on the progress toward that goal are the key predictors of goal accomplishment. Goals serve an energizing role; they create the motivation to invest effort to achieve that goal. These goals should be clear, measurable, realistic, time-bound, and take into account users’ physical abilities (Latham 2003). If users ownership of the goals by actively participating in goal-setting t, they are likely to invest the time and effort necessary to realize those goals. Accomplishing goals lead to satisfaction and further
motivation, while non-accomplishment of goals may lead to disappointment and cognitive dissonance that users would prefer to avoid.

Organizational research show that goals have a pervasive influence on employee behavior and performance in organizations (Locke and Latham 2002; Lunenburg 2011). Managers widely accept goal setting as a means to improve and sustain performance (DuBrin 2011). Nearly every modern organization use some form of goal setting at strategic, tactical, and individual levels. Programs such as management by objectives, high-performance work practices, technology operations quality control, sales, financial management, outsourcing, customer service, and strategic planning, include the setting of activity-specific goals (Lunenburg 2011).

Timely feedback on progress towards a goal is the second critical driver of goal achievement. Feedback helps in two important ways. First, it helps people assess how well they are doing toward the achievement of their target goals. For example, it tells chronic care patients how much physical activity they have accomplished for the day and how much more activity is needed to accomplish their goal. Second, feedback also helps people determine adjustments needed to improve their performance. For example, just as feedback can help a golfer adjust her swing, it can also help a patient adjust her schedule to best fulfil her daily physical activity goal (e.g., go for a walk or jog early in the morning).

Goal setting theory has been extensively validated across a wide range of behavioral, psychological, educational, and organizational contexts for over 50 years (Locke and Latham 2019). In healthcare contexts, recent research demonstrate the utility of goal setting as an effective health behavior change strategy for overweight and obese adults (Pearson 2012), for increasing fiber consumption, decreasing fat intake, and increasing exercise adherence (Shilts et
al. 2004), for reducing medical and lifestyle health-risks such as high blood sugar, alcohol use, stress, and cigarette smoking (Rohrer et al. 2010), and for chronic disease management by improving adherence to specific dietary, physical activity, and/or medication protocols (Estabrooks et al. 2005; DeWalt et al. 2009; Naik et al. 2011).

Mobile HIT applications, by design, provide tools for patients to set clear and measurable goals in terms of step count, walking distance, and/or walking duration. Using baseline reference data, they can also suggest appropriate goals based on a patient’s age, weight, and medical conditions, which patients can adjust up or down based on their personal preferences or ability. Onboard sensors on a smartphone or a smartwatch record patients’ actual step count, and a mobile app on a smartphone provides a real-time visual dashboard of the patients’ daily progress toward their target goal and a daily activity report of their activities. These systems also generate preprogrammed, rule-based intervention feedback messages such as congratulations when patients reach their daily goal and reminders if a patient made little or no progress toward their goal. These feedback messages, a representation of just-in-time adaptive intervention technique (Pickering et al. 2016), is an example of a designed affordance that are intended to positively influence chronic care patients’ physical activity behavior (Sengupta et al. 2020c). Hence, we hypothesize:

H1. Feedback messages in HIT apps will have a positive effect on participants’ daily physical activities.

8.4.3 Unintended Affordance Actualization

Though most theories of behavior change like goal setting theory focus on the role of conscious, reflective factors in predicting and changing behavior, there is also evidence that we occasionally
behave subconsciously and instinctively (Sheeran et al. 2013), such as reacting instinctively to a speeding vehicle while crossing a road. Such subconscious behavior is sometimes necessary for our physical and psychological survival. Since our overall behavior is a function of both conscious and subconscious processes, simultaneous consideration of both processes can lead to more holistic and comprehensive understanding of human behavior. Furthermore, this will allow us to explore whether the conscious and subconscious processes are additive or multiplicative, whether they complement or substitute for each other, and so forth. It would also help us design more effective behavior change efforts leveraging the advantages and disadvantages of both processes.

The dichotomy of conscious and subconscious behaviors was explained in Kahneman’s (2011) dual process model of human cognition. Kahneman suggests that we process information in two ways: (1) a fast, automatic, subconscious approach based on heuristics and environmental cues (System 1 processing) and (2) a slow, reflective, analytic processing based on reasoning and thinking (System 2 processing). It is not that we can categorize people as System 1 (instinctive) or System 2 (thinking) types, but the same people can respond in either way depending upon the context. For example, a physician who would often invoke System 2 processing in her medical decisions, may employ System 1 processing (e.g., suggestions from a financial planner) in her retirement decisions. When both approaches are available, because System 2 processing is effortful and slow, we often tend to navigate towards System 1 processing, especially when faced with time constraints or other pressures or when the situation overwhelms our cognitive capacity for System 1 processing.

The intended effect of designed affordances on our behavior can be viewed as System 2 processing, while the unintended effect of emergent affordance is an instance of System 1
processing. One such emergent affordance in HIT apps for chronic care is Ecological Momentary Assessment (EMA). EMA is a tool that employs self-reported questionnaires to capture patients’ psychological reactions and environmental conditions that cannot be otherwise captured using onboard sensors (Stone and Shiffman 1994; Shiffman et al. 2008). Examples of psychological reactions thus captured may include patients’ current mood, and environmental conditions may include whether it is raining, the number of parks within short distances of their homes, or whether they have a pet dog, which are presumed to influence their physical activity levels and general well-being (Ekkekakis et al. 2011; Mammen and Faulkner 2013). In EMA, “ecological” implies that the data are captured in subjects’ natural environments, “momentary” means that assessments focus on current feelings and behaviors, rather than on prior behaviors (which may be susceptible to recall bias), and “assessment” implies that multiple measurements are done at different points in time. This data is typically captured at random points in time during the day and is used to create a temporal behavior profile for each patient (Shiffman et al. 2008). EMA surveys can employ event-based sampling, organized around discrete events or episodes in subjects’ lives, such as headaches or drinking episodes, or time-based sampling, such as subjects’ mood, outcome expectancies, or physical activity intentions at different points in time (Shiffman 2007, Shiffman et al. 2008). While EMA surveys were originally administered by human interventionists in chronic care programs, recent technological advancements allow us to collect and record such data online multiple times a day, which is significantly less expensive than any human intervention.

Although EMA surveys were originally intended as a data collection tool, a chronic care app can use EMA as an “unintended intervention” to subtly and subconsciously nudge patients toward desired behaviors. By asking simple questions such “how is the weather today” or
“would you like to take your dog out for a walk” or “do you enjoy outdoors”, EMAs can nudge patients to go outside for a walk, particularly if the weather is nice and they are physically inactive that day. Because EMA is not intended to motivate behaviors, this is an instantiation of an emergent affordance, which could nevertheless have an impact comparable to a designed affordance like automated reminders. While feedback and reminders can motivate patient behavior through System 2 processing, EMA can motivate similar behaviors subconsciously through System 1 processing.

To understand how EMA works as a System 1 intervention, we consider nudge theory (Thaler and Sunstein 2009) in the behavioral economics literature. Thaler and Sunstein (2009) define “nudge” as a choice architecture that alters people’s behaviors in a predicable manner through the appropriate design of the environment in which they live. Nudges are not mandates; nor do they forbid any available options or significantly change users’ economic incentives for desired behaviors. For example, banning junk food is not a nudge, but placing fruits at eye level near the checkout counter at a grocery store is a nudge that can motivate healthy eating. Originating in clinical psychotherapy in the late 1980’s (O’Hanlon and Wilk 1987), nudges have been used successfully to prime and trigger subconscious user behaviors across a wide range of activities from healthy eating to increasing workplace productivity to improving hygiene among health care workers. In one study, Sheeran et al. (2013) asked one group of participants to complete scrambled sentences containing words related to effort and persistence immediately before entering the university gym, while those in three other groups were asked to either complete scrambled sentences containing neutral words, complete a questionnaire about their views of the gym, or were merely observed as they entered and left the gym. Participants in the first group spent more time working out in the gym than those in the other three groups. In
another study (Papies and Hamstra 2010), some customers entering a butcher’s store were primed with a poster with a recipe for a slim figure, while others were not. Participants’ dietary restraint was recorded as the number of free meat snacks each customer ate from the store counter. Findings showed that customers who saw the diet recipe consumed fewer snacks than other customers.

Despite the theoretical reasoning of EMA as a nudge to influence patients’ behavior through System 1 processing, to the best of our knowledge, the extent to this logic actually works has not been previously studied. Furthermore, in today’s digital world, we are continuously bombarded with digital survey requests, and we often tend to ignore or “tune out” many survey requests, and there is the possibility that EMA may not work as a digital nudge. However, based on theoretical expectations, we propose:

H2. EMA in HIT apps will have a positive effect on participants’ daily physical activities.

Recent work on System 1 and System 2 processing suggest that the two systems may not be independent but may rather support and complement each other. For example, Peters et al. (2006) conducted an experiment in which they gave participants tasks that required processing numbers. While participants with high numeracy (System 2 processing) outperformed low numeracy participants, they also found that more numerically able participants’ initial subconscious responses triggered their use of conscious thought needed to complete the task. Also, high numeracy subjects’ consistent and effective use of System 2 reasoning calibrated their System 1 processing to make it more effective, essentially creating a feedback loop. Outside experimental settings, our everyday tasks provide further evidence for complementary nature of Systems 1 and 2 processing. In communicative tasks, we use language deliberately and consciously, but we also use grammatical rules subconsciously, without rehearsing; System 1
processing of grammar helps us improve the speed and efficiency of our System 2 formal communication (New Scientist 2018). Similarly, typing or playing instruments also require a combination of deliberate and automatic action. Likewise, our physical activity and exercise is partly habit-driven, yet also requires conscious oversight to be successfully completed (Gardner and Rebar 2019).

A related question is the primacy of System 1 versus System 2 processing, i.e., whether one type of processing supersedes the other. Kahneman (2011) stated that although most cognitive processes are a mix of both systems, System 2 may be a slave of System 1 in that System 1, as the faster, more efficient process, does most of the mental work and calls on System 2 as needed for more deliberate processing of relevant information. This idea was originally suggested by eighteenth century philosopher David Hume, who recognized the importance of the heart or emotions (System 1) for the head or reason (System 2) to make important decisions. Hume (1740) suggested that reason is merely a cold, mechanical method of calculation, informing us of the consequences of our actions, but lacking the motivation or drive to push us into action; this motivation comes from emotion or the heart. Moreover, when System 1 and 2 conflicts, often times, we tend to go with System 1 (gut feel) rather than System 2 (reason), resulting in inferior choices, such as making poor investment decisions or trusting the wrong people.

In a laboratory experiment, Stajkovic et al. (2006) compared the effects of primed, subconscious, achievement goals (“do your best”) with explicitly assigned, conscious, performance goals, and found both priming and conscious goals to improve task performance, with the conscious goal having a larger effect size, and a positive interaction between the goals. The above logic and evidence suggest functional synergies between designed affordance (feedback messages) and emergent affordance (EMA surveys), as instances of System 2 and
System 1 processing respectively. These two affordances may have distinct effects on patients’ physical activities, and in addition, are expected to have a multiplicative joint effect, where EMA can complement the effect of feedback messages on desired patient behaviors. This expectation leads us to hypothesize:

H3. EMA in HIT apps will positively moderate the effects of feedback messages on participants’ daily physical activities.

Figure 23 shows the overall conceptual framework of our study. In addition to our two affordance-theoretic predictors (feedback messages and EMA), chronic disease patients’ physical activities can also be a function of covariates such as comorbidity (number of diseases), average (baseline) walking capacity, age, obesity, employment status, whether they are arthritic or diabetic, day of week, and whether the particular day in question is a weekday or weekend. Hence, these variables, that represent unobserved heterogeneity due to patient-related or day-related factors, are included in our model as control variables. Empirical data collection to test these hypotheses is discussed in the next section.
8.5 Research Method

8.5.1 Intervention Design

We designed and custom-built our own mobile app for patients with coronary heart disease (CHD) to test our hypotheses. This app was part of a broader field trial of modern digital technology use for a home-based cardiac rehabilitation (HBCR) program led by an outpatient cardiology clinic affiliated with a large urban university in the southeastern United States (Sengupta et al. 2020c).

The HBCR system deployed two types of messages to patients: (1) feedback messages sent at a specific time of day based on specific decision rules, and (2) EMA surveys sent at six random times each day, for the entire duration (91 days) of the field trial. We programmed four types of feedback messages: (1) a congratulatory message when patients reached their physical activity goal for the day, (2) encouragement if patients exceeded 15% of their preset goal, (3) a
reminder at 3:40 pm for patients who were physically inactive that day until that time, and (4) a reminder at 3:40 pm for patient who did some activity but has not yet reached their goal for the day. EMA surveys asked about patients’ current mood, current location, recent physical activity, current companion, and recent eating episodes (Sengupta et al. 2020c).

The distribution of feedback messages and EMA surveys was recorded with timestamps on a central server, along with participants’ responses (or non-responses) to these interventions. This data was used for analysis. Sample screenshots for feedback messages and EMA surveys are shown in Table 5 and 7.

8.5.2 Study Design

We employed a single group, quasi-experimental design with ten CHD patients recruited from the cardiology clinic where this study was being conducted. Our screening criteria included women aged 50 years or higher, diagnosed with acute coronary syndrome or requiring coronary revascularization within the last 10 years, who could read, speak, and understand English, could walk unaided, used smartphones and mobile apps in their daily lives, and were reasonably technology-proficient (e.g., used the clinic’s online portal to schedule appointments, access test and lab results, send and receive secure messages, request refills, and pay medical bills). We also sought verbal clearance from their cardiologist for their study participation. Exclusion criteria included residence outside a 50-mile radius of the study site, psychiatric conditions such as dementia, delirium or schizophrenia or actively undergoing acute psychiatric treatment, prior neurological brain disorders, current use of illicit drugs and/or alcohol, or life-limiting comorbid conditions (e.g., metastatic cancer) (Sengupta et al. 2020c).
Each participant received our HBCR prototype (a smartwatch and an app on their smartphone) as part of this field trial. Their use of the prototype was monitored by a health coach, who telephoned each participant once every week to document their concerns with the study or answer questions. The health coach also collected baseline assessment data (e.g., typical walking duration) for each participant at the start of the study, conducted semi-structured interviews with participants when they visited the cardiology clinic during the course of the study, and did follow-up assessments at the end of the study. Participants’ physical activity was continuously monitored using the app for the 13 week (91 day) duration of the trial. Participants received feedback messages (designed affordance) based on physical activity goals they set and six EMA surveys (emergent affordance) every day, and this data was also recorded on application logs (Sengupta et al. 2020c).

The study was approved by the Institutional Review Board of the university of affiliation of this cardiology clinic and that of the authors. Study participation was voluntary, and participants were free to withdraw from the study at any time without jeopardizing their health care or relationship with their cardiologist. Subjects received no financial incentive for participating in this study (see Appendix 1).

Two of the ten participants experienced traumatic life events during the 91-day period of the study, and therefore engaged very little with our HBCR application. These participants were dropped from the sample. For the remaining eight participants, we had data for 91 days, including some days during when they did not record physical activities or EMA surveys, perhaps because their smartphone was turned off for the day (Sengupta et al. 2020c).
8.5.3 Data Modeling

We had multi-level (participant-level and daily-level) panel data for the 91-day period of the study, with step count and walking duration (in minutes) as our two measures of the dependent variable (physical activity). We analyzed this data using multi-level fixed effects Poisson models, with patients and daily activities as the two levels. A Poisson model was appropriate given the non-negative, discrete, count measures of our dependent variables. The key predictors in these models were the number of times participants responded to EMA surveys per day, the number of feedback messages they received per day, and interaction between EMA responses and feedback messages. Because the number of EMA surveys per day was constant (i.e., six) and patients responded to only 19.2% of the EMA survey requests, we used the number of EMA responses per day as our measure of emergent affordance. Since participants could not respond to an EMA if they missed it (e.g., if their phone was switched off at that time), EMA response by patients was a better indicator of emergent affordance than EMA survey request. Control variables included participants’ age, daily goal set, baseline walking duration (in minutes), previous day step count/walking duration and daily use of the smartwatch (in minutes) as numeric variables, and their obesity, arthritis, diabetes, employment status, and cardiovascular disease diagnosis (e.g., was the patient diagnosed of myocardial infraction or a similar disease) as dummy variables at the patient level, and day of week and whether the specific day was a weekday or weekend as dummy variables at the day level. In addition, to control for unobserved heterogeneity for patient-level effects and week-level effects (e.g., in case patients’ physical activity varied from week to week), we incorporated the fixed effects of these variables. The unit of analysis was patient-day. The model specification is shown in the equation below:
\[
\begin{align*}
\ln(\text{StepCount}_{ijk}) & = \left\{ \alpha + \beta_1 \cdot \text{EMA}_{ijk} + \beta_2 \cdot \text{FeedbackMessage}_{ijk} + \\
\ln(\text{WalkingDuration}_{ijk}) & \right. \\
& \left. + \beta_3 \cdot \text{PreviousDayStepCount} / \text{WalkingDuration} + \\
& + \beta_4 \cdot \text{WalkingDuration} + \\
& + \beta_5 \cdot \text{DailySmartWatchUse} + \lambda_1 \cdot \text{Age} + \\
& + \lambda_2 \cdot \text{BaselineWalkingDuration} + \lambda_3 \cdot \text{Obesity} + \\
& + \lambda_4 \cdot \text{Arthritis} + \lambda_5 \cdot \text{Diabetes} + \lambda_6 \cdot \text{Employed} + \lambda_7 \cdot \text{CVDiseaseDiagnosis} + \\
& + \delta_i \cdot \text{WeekdayOrNot}_{ijk} + \sum_{k=1}^{12} \mu_k \cdot \text{Week}_{ijk} + \sum_{j=1}^{2} \phi_j \cdot \text{Patient}_{ijk} + e_{ijk} \right\}
\end{align*}
\]

Where \(i\) represents an individual patient, \(j\) represents whether a specific day was a weekday or weekend, and \(k\) represents the day of week.

The Poisson regression model specifies the count \(Y\) (measures of physical activity-walking duration / step count) to have a conditional mean of the exponential form:

\[
E\left(Y \mid X\right) = \exp\left(X'\beta\right).
\]

\(X\) is the vector of all the exogenous regressors. This ensures that the conditional mean is positive as that should be the case for any random variable that is restricted to be nonnegative (Cameron and Trivedi 2005). However, the key marginal effect (ME)

\[
\frac{\partial E\left(Y \mid X\right)}{\partial X_j} = \beta_j \exp\left(X'\beta\right)
\]

now depend on both the parameter estimate \(\beta_j\) and the particular value of \(X\) at which the marginal effect is evaluated. The starting point for Poisson regression analysis is the Poisson distribution, with probability mass function

\[
f\left(Y \mid X\right) = e^{-\mu} \mu^Y / Y!
\]

(Cameron and Trivedi 2005). Substituting in \(\mu = \exp\left(X'\beta\right)\) from \(E\left(Y \mid X\right) = \exp\left(X'\beta\right)\) gives the conditional density of the \(i\)th observation. This in turn gives the log-likelihood function

\[
Q(\beta) = \sum_{i=1}^{N} \left\{ -\exp\left(X'_i\beta\right) + Y_i X'_i \beta - \ln Y_i! \right\}
\]

which is maximized by the maximum likelihood estimator (MLE) (Cameron and Trivedi 2005). The Poisson MLE solves the associated first-order conditions that can be shown to be

\[
\sum_{i=1}^{N} \left\{ Y_i - \exp\left(X'_i\beta\right) \right\} X_i = 0.
\]

The Poisson MLE requires
only the much weaker condition that the conditional mean function given by
\[ E(Y|X) = \exp(X'\beta) \]
is correctly specified.

The equidispersion property frequently been violated in applied work as overdispersion is quite common in count data. When the conditional variance exceeds the conditional mean the additional dispersion needs to be accounted in some way (Cameron and Trivedi 2005). One of the most commonly used approach is to look for unobserved heterogeneity. Unobserved heterogeneity, which generates additional variability in the dependent variable \( Y \), can be generated by introducing multiplicative randomness.

We can replace \( \mu \) with \( \mu \nu \), where \( \nu \) is a random variable, hence \( Y \sim\text{Poisson}(Y|\mu \nu) \). If we specify \( \nu \) such that \( E(\nu) = 1 \) and \( Var(\nu) = \sigma^2 \). Then we can show that \( \nu \) preserves the mean but increases the dispersion. Specifically, \( E(Y) = \mu \) and \( Var(Y) = \mu(1 + \mu \sigma^2) > E(Y) = \mu \). The term overdispersion describes the feature \( Var(Y|X) > E(Y|X) \), in a regression model.

In the well-known special case that \( \nu \sim \text{Gamma}(1, \alpha) \) where \( \alpha \) is the variance parameter of the gamma distribution, the marginal distribution of \( Y \) is a Poisson-gamma mixture with a closed form -the negative binomial (NB) distribution denoted by \( \text{NB}(\mu, \alpha) \) -whose probability mass function is
\[
Pr(Y = y|\mu, \alpha) = \frac{\Gamma(\alpha^{-1} + y)}{\Gamma(\alpha^{-1})\Gamma(y+1)}\left(\frac{\alpha^{-1}}{\alpha^{-1} + \mu}\right)^{\alpha^{-1}}\left(\frac{\mu}{\mu + \alpha^{-1}}\right)^y \quad (Cameron and Trivedi 2005).
\]

Where \( \Gamma(\cdot) \) denotes the gamma integral that specializes to a factorial for an integer argument (Cameron and Trivedi 2005). The negative binomial model is more general than the Poisson model, because it accommodates overdispersion and it reduces to the Poisson model as
$\alpha \to 0$. The moments of the negative binomial regression model are $E(y|\mu, \alpha) = \mu$ and $Var(y|\mu, \alpha) = \mu(1 + \alpha\mu)$. Empirically the quadratic variance function is a versatile approximation in a wide variety of cases of overdispersed data. The negative binomial lets $\mu = \exp(X'\beta)$ and leaves $\alpha$ as a constant (Cameron and Trivedi 2005).

Poisson models require two critical assumptions on part of the dependent variable: (1) absence of over-dispersion, and (2) absence of excess zeroes. We found evidence of significant over-dispersion in both step count and walking duration ($p<0.001$). Since negative binomial models are robust to over-dispersion, we fitted negative binomial models to re-estimate our model parameters (Cameron and Trivedi 2005). We also observed an unusually high count of zero values in our dependent variable measures (step count: 50.94% or 649 of 1274 patient-day, walking duration: 51.18% or 652 of 1274 patient-days). During those days, it is possible that our participants forgot to turn on their smartphone or did so intentionally for valid reasons. Because these “excess zeroes” were presumably caused by a different data generating process (forgetfulness or intentional) than the valid, usable observations (feedback messages, EMA, etc.), we also fitted zero-inflated Poisson and zero-inflated negative binomial models. In the two zero-inflated models, excess zeroes in the dependent variable were modeled using a logit function with whether the HBCR app was used at all that day by the patient or not, as the sole predictor. Non-zero values predicted by this logit model were then fitted against the hypothesized predictors in Poisson and negative binomial models (Cameron and Trivedi 2005).

There are two key methodological challenges existed for the study. The first challenge to our model is the endogeneity of the key regressor, the number EMA survey responses per day, given that this variable was not exogenously set by the researchers, but rather self-responded by
patients. We addressed this endogeneity concern using two methods: a structural-model approach and a nonlinear instrumental variable (NLIV) approach (Cameron and Trivedi 2005). In the first approach, we employed a two-stage structural model in which the endogenous regressor was specified as a linear model of an instrumental variable in the first stage, and the residual from this stage was included as an additional predictor in our second-stage Poisson or negative binomial models (Cameron and Trivedi 2005).

In the structural equation method for the count of physical activity measured through walking duration in minutes and step count is either a Poisson model or a negative binomial model with a mean that depends on a possible endogenous regressor, number of daily EMA survey response:

\[ Y_{ii} \sim \text{Poisson or Negative Binomial (} \mu_i \text{)} \]

\[ \mu_i = E(Y_{ii} | X_{i1}, X_{i2}, u_{ii}) = \exp(\beta_i X_{i1} + \beta_2 X_{i2} + u_{ii}) \]  \hspace{1cm} (2)

where \( Y_{ii} \) is the count of physical activity measure (walking duration in minutes or step count), \( X_{i1} \) is the number of daily EMA survey response which can be endogenous and \( X_{i2} \) is the vector of exogenous control variables (Cameron and Trivedi 2005). The term \( u_{i1} \) is an error term that can be interpreted as unobserved heterogeneity correlated with the potentially endogenous regressor \( X_{i1} \) but is uncorrelated with the exogenous regressors, \( X_{i2} \). The error term, \( u_{i1} \), is added to allow for endogeneity (Cameron and Trivedi 2005). This error term also includes overdispersion, so that the Poisson model has been generalized to control for overdispersion as it would be the case if a negative binomial model was used.

Next, to clarify the nature of interdependence between \( X_{i1} \) and \( u_{i1} \), we specify a linear reduced-form equation for \( X_{i1} \). This is
\[ X_{ii} = X_{2i}'\gamma_1 + X_{3i}'\gamma_2 + \varepsilon_i \]  \hspace{1cm} (3)

Where \( X_2 \) is a vector of exogenous variables that affects \( X_1 \) nontrivially but does not directly affect \( Y_i \), and hence is an independent source of variation in \( X_1 \). It is standard to refer to this as an exclusion restriction and to refer to \( X_3 \) as excluded exogenous variable or instrumental variable (\( X_3 \)). By convention, a condition for robust identification of long-term mean count of the dependent variable, as in the case of linear model, is that there is available at least one valid instrument (Cameron and Trivedi 2005).

Assume that the error \( u_i \) and \( \varepsilon \) are related via

\[ u_{ii} = \rho \varepsilon_i + \eta_i \]  \hspace{1cm} (4)

Where \( \eta_i \sim [0, \sigma^2_\eta] \) is independent of \( \varepsilon_i \sim [0, \sigma^2_\varepsilon] \).

This assumption can be interpreted to mean that \( \varepsilon \) is a common latent factor that affects both \( Y_i \) and \( X_1 \) and is the only source of dependence between them, after controlling for the influence of the observable variables \( X_2 \) and \( X_3 \). If \( \rho = 0 \), then \( X_1 \) can be treated as exogenous. Otherwise, \( X_1 \) is endogenous, since it is correlated with \( u_i \) in equation \( X_{ii} = X_{2i}'\gamma_1 + X_{3i}'\gamma_2 + \varepsilon_i \), because both \( X_1 \) and \( u_i \) depend on \( \varepsilon \) (Cameron and Trivedi 2005).

Maximum likelihood of this model is computationally challenging. A two-step estimator is much simpler to implement. For the two-step estimation procedure: first equation 3 is estimated by OLS and generate the residuals \( \hat{\varepsilon}_i \). Second, estimate parameters of the Poisson or negative binomial model provide below (equation 5) after replacing \( \varepsilon_i \) by \( \hat{\varepsilon}_i \).

\[ \mu_i | X_{2i}, X_{ii}, \varepsilon_i = \exp (\beta_i X_{ii} + X_{2i}' + \rho \varepsilon_i) \]  \hspace{1cm} (5)
The first step generates residuals from a linear probability regression of the endogenous variable on exogenous control regressors and instrument. The second step fits a Poisson or Negative binomial on exogenous control regressors which also include the residuals generated in the first step (Cameron and Trivedi 2005).

While applying this two-step procedure we used amount of time spent on app (in minutes) per day as instrumental variable. This variable represents the amount of time each patient spent on our mobile application per day. We found the variable amount of time spent on app per day share a strong correlation \( (r = 0.87) \) with the endogenous regressor- number of daily EMA responses- while uncorrelated with the measures of dependent variable physical activity performance (daily walking duration in minutes and step count). The correlations between amount of time spent on app per day and daily walking duration and step count are quite low \( (r = 0.19 \) and \( r = 0.21 \), respectively). These values of correlation coefficients support the other criteria of amount of time spent on app per day to be a strong instrument as they suggest patient’s physical activity performance cannot be determined by the of amount of time spent on app per day while controlling for other exogenous regressors. Finally, to become a legitimate instrument variable for the endogenous variable, number of EMA responses per day, the instrument variable amount of time spent on app per day should not correlate with the error term, so that the estimates calculated while using the instrument variable remain consistent. However, this condition can only be addressed theoretically as there is no empirical way to address this issue (the error term is not known). As per our understanding theoretically there exist no potential threats to the validity of using amount of time spent on app per day as an instrument as we think it is uncorrelated with the error term.
In the second approach, we employed a nonlinear instrumental variable to generate Generalized Method of Moment (GMM) estimates that are robust to endogeneity, as described by Cameron and Trivedi (2005).

In this method we assume the existence of the instrument $Z_i = (X_{i1}', X_{i2}')'$ that satisfy $E[Z_i \{Y_{ii} - \exp(\beta_1 X_{i1} + X_{i2}' \beta_2)\}] = 0$. This is a less parametric approach and will lead to an estimator that differs from that using the structural approach even in the limit as $N \to \infty$. To apply non-linear IV to our estimation we use one-step generalized method of moment (GMM) estimation (Cameron and Trivedi 2005).

The GMM begins with the population moment conditions $E\{h(w_i, \theta)\} = 0$ where $\theta$ is a $q \times 1$ vector, $h(\cdot)$ is an $r \times 1$ vector function with $r \geq q$, and the vector $w_i$ represents all the observables including the dependent variable, regressors and where relevant the instrumental variable (IV). A leading example of linear instrumental variable (IV), where $h(w_i, \theta) = z_i (Y_i - X_i' \beta)$ (Cameron and Trivedi 2005).

If $r = q$, then the method of moments (MM) estimator $\hat{\theta}_{MM}$ solves the corresponding sample moment condition $N^{-1} \sum_i h(w_i, \theta) = 0$. This is not possible if $r > q$ such as for an overidentified linear IV model, because there are more equation equations than parameters. Since we have only one instrument for one endogenous regressor our model is not susceptible to this particular condition (Cameron and Trivedi 2005).

The GMM estimator $\hat{\theta}_{GMM}$ minimizes a quadratic form in $\sum_i h(w_i, \theta)$, with the objective function $Q(\theta) = \left\{ \sum_{i=1}^N h(w_i, \theta) \right\}' W \left\{ \sum_{i=1}^N h(w_i, \theta) \right\}$ where the $r \times r$ weighting matrix $W$ is
positive-definite symmetric, possibly stochastic with a finite probability limit, and does not depend on \( \theta \). The moment of method estimator, the special case \( r = q \), can be obtained most simply by letting \( W = I \), or any other value, and then \( Q(\theta) = 0 \) at the optimum (Cameron and Trivedi 2005). Provided the condition \( E\{ h(w_i, \theta) \} = 0 \) holds, the GMM estimator is consistent for \( \theta \), and is asymptotically normal with the most robust estimate of VCE (Cameron and Trivedi 2005).

The Poisson regression model specifies that \( E\{ Y - \exp(X'\beta) | X \} = 0 \) because
\[
E(Y | X) = \exp(X'\beta).
\]
Suppose instead that \( E\{ Y - \exp(X'\beta) | X \} \neq 0 \), because of endogeneity of one regressor, but there is an instrument \( Z \) such that \( E[Z_i \{ Y_i - \exp(X'_i\beta) \}] = 0 \) then the GMM estimator maximizes \( Q(\beta) = h(\beta)'Wh(\beta) \) where the \( r \times 1 \) vector \( h(\beta) = \sum_i Z_i \{ Y_i - \exp(X'_i\beta) \} \) (Cameron and Trivedi 2005).

This is a special case of \( Q(\theta) = \left( \sum_{i=1}^{N} h(w_i, \theta) \right)' W \left( \sum_{i=1}^{N} h(w_i, \theta) \right) \) with
\[
h(w_i, \theta) = Z_i \{ Y_i - \exp(X'_i\beta) \}.
\]
We define the \( r \times k \) matrix \( G(\beta) = -\sum_i \exp(X'_i\beta)Z_iX'_i \). Then the \( k \times 1 \) gradient vector \( g(\beta) = G(\beta)'Wh(\beta)' \) and the \( k \times k \) expected Hessian is
\[
H(\beta) = G(\beta)'WG(\beta)' \] where simplification has occurred by using \( E\{ h(\beta) \} = 0 \). The estimate of the VCE is with
\[
\hat{G} = G(\hat{\beta}) \text{ and } \hat{S} = \sum_i \{ Y_i - \exp(X'_i\hat{\beta}) \}^2 Z_iZ'_i.
\]
We let \( W = \left( \sum_i Z_iZ'_i \right)^{-1} \) as for linear two-stage sequences (Cameron and Trivedi 2005).

In both approaches, our instrumental variable was the amount of time spent on app (in minutes) per day, which had a strong correlation (\( r=0.87 \)) with the endogenous regressor
(number of EMA responses per day), but weak correlation with dependent variable measures: daily walking duration (r=0.11) and step count (r=0.12). Results of our analysis are presented next.

8.6 Results

8.6.1 Descriptive Statistics

The eight participants who completed this study were mostly white (80%), married or partnered (60%), and employed (50%), and had health insurance (100%), mean age of 64 years (range 53-75 years), and annual income of over $40,000. All participants were CHD patients, and in addition, two participants had myocardial infarction, one experienced heart failure, four had undergone percutaneous coronary interventions, and two had undergone a coronary artery bypass graft surgery. None of the participants had attended a cardiac rehabilitation program prior to this study.

Our eight participants received a total of 4,368 EMA surveys (6 surveys per day per participant for 91 days) and completed 838 surveys, for an overall response rate of 19.2%. Figure 24 shows the cumulative EMA survey responses for these participants over the 91-day period, showing a declining pattern of EMA responses from the start to the end of the study.
Figure 24: Cumulative EMA survey responses (n=838) for participants over 91 days

Of 728 total observed patient-days (91 days for each of the eight participants), our smart watch recorded walking activity for 395 days (54.2%), during which participants recorded a total of 1,838,056 steps or 919.01 miles. The cumulative walking goal set by all eight participants was 3,335 minutes; however, we recorded 11,491 minutes of total walking activity, showing that participants set conservative goals and exceeded them. The mean walking duration was 29.09 minutes per day (SD=23.70; range=1-132 minutes), the mean step count was 4,653.31 (SD=3,794.24; range=10 to 21,179 steps).

Figure 25 shows the cumulative daily step count and walking duration for the eight participants over the study period of 91 days. Both graphs show periodic ups and downs, but generally depict a decreasing trend over time, indicating a declined interest in walking toward the end of the study, possibly due to the wearing off the novelty of the intervention.
Figure 25: Cumulative step count and walking duration for all participants
8.6.2 Hypotheses Testing

Figure 26 shows histograms of our two measures of dependent variable (physical activity): step count and walking. These histograms depict Poisson distribution with an unusually high count of zero values. A one-sample Kolmogorov-Smirnov test with a reference Poisson distribution confirmed that our data likely followed Poisson distributions.

![Histograms of dependent measures](image)

**Figure 26: Histograms of dependent measures**

Parameter estimates from our four multi-level models (Poisson, negative binomial, zero-inflated Poisson, and zero-inflated negative binomial) for step count and walk duration are shown in Tables 14 and 15 respectively. These estimates are largely consistent between the two zero-inflated models. However, in the presence of both over-dispersion and excess zeroes, the zero-inflated negative binomial model provides the most unbiased estimates, and therefore, we will use this model for interpretation.

Tables 14 and 15 shows that feedback messages and EMA responses have significant positive effects on both step count and walking duration (in minutes) at least 0.01 significance level (in both zero inflated models), providing empirical support for Hypotheses H1 and H2.
respectively. The interaction between feedback messages and EMA responses was also significant and positive for both dependent variable measures, supported Hypothesis H3. From the estimated beta coefficients in the zero-inflated negative binomial model, we find that each feedback message increased average daily step count of patients by 16.3% and average daily walking duration by 18.5%. Likewise, each EMA response increased average daily step count

Table 14: Estimated parameters for step count model

<table>
<thead>
<tr>
<th>Dependent Variable Measure: Step Count</th>
<th>Poisson Model</th>
<th>Negative Binomial Model</th>
<th>Zero Inflated Poisson Model</th>
<th>Zero Inflated Negative Binomial Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback Messages</td>
<td>-0.159***</td>
<td>0.334</td>
<td>0.145***</td>
<td>0.163**</td>
</tr>
<tr>
<td></td>
<td>(0.002)</td>
<td>(0.451)</td>
<td>(&lt;0.000)</td>
<td>(0.041)</td>
</tr>
<tr>
<td>EMA</td>
<td>-0.005***</td>
<td>-0.029</td>
<td>0.057***</td>
<td>0.079**</td>
</tr>
<tr>
<td></td>
<td>(&lt;0.001)</td>
<td>(0.134)</td>
<td>(&lt;0.000)</td>
<td>(0.023)</td>
</tr>
<tr>
<td>EMA * Feedback Messages</td>
<td>0.013**</td>
<td>-0.084</td>
<td>0.019***</td>
<td>0.024***</td>
</tr>
<tr>
<td></td>
<td>(&lt;0.001)</td>
<td>(0.096)</td>
<td>(&lt;0.000)</td>
<td>(0.002)</td>
</tr>
<tr>
<td>Daily Goal Set</td>
<td>-0.002**</td>
<td>-0.024</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>(&lt;0.001)</td>
<td>(0.013)</td>
<td>(&lt;0.000)</td>
<td>(0.004)</td>
</tr>
<tr>
<td>Age</td>
<td>0.232***</td>
<td>0.411***</td>
<td>0.063***</td>
<td>0.066**</td>
</tr>
<tr>
<td></td>
<td>(&lt;0.000)</td>
<td>(0.075)</td>
<td>(&lt;0.000)</td>
<td>(0.026)</td>
</tr>
<tr>
<td>Baseline Walking Capacity</td>
<td>0.020***</td>
<td>0.031***</td>
<td>0.003***</td>
<td>0.005***</td>
</tr>
<tr>
<td></td>
<td>(&lt;0.001)</td>
<td>(0.006)</td>
<td>(&lt;0.001)</td>
<td>(0.002)</td>
</tr>
<tr>
<td>Employed</td>
<td>0.394***</td>
<td>0.473</td>
<td>0.597**</td>
<td>0.552*</td>
</tr>
<tr>
<td></td>
<td>(0.002)</td>
<td>(0.548)</td>
<td>(0.002)</td>
<td>(0.181)</td>
</tr>
<tr>
<td>Obesity</td>
<td>3.966***</td>
<td>6.649***</td>
<td>0.478***</td>
<td>0.766*</td>
</tr>
<tr>
<td></td>
<td>(0.006)</td>
<td>(1.224)</td>
<td>(0.007)</td>
<td>(0.309)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>-0.831***</td>
<td>-2.028**</td>
<td>-0.076***</td>
<td>-0.111***</td>
</tr>
<tr>
<td></td>
<td>(0.003)</td>
<td>(1.682)</td>
<td>(0.003)</td>
<td>(0.014)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>-2.550***</td>
<td>-4.016***</td>
<td>-0.070***</td>
<td>-0.412***</td>
</tr>
<tr>
<td></td>
<td>(0.007)</td>
<td>(1.114)</td>
<td>(0.008)</td>
<td>(0.030)</td>
</tr>
<tr>
<td>Cardiovascular Disease Diagnosis</td>
<td>-7.000***</td>
<td>-11.889***</td>
<td>-1.638***</td>
<td>-1.953***</td>
</tr>
<tr>
<td></td>
<td>(0.010)</td>
<td>(1.689)</td>
<td>(0.011)</td>
<td>(0.535)</td>
</tr>
<tr>
<td>Weekday or Not</td>
<td>-0.118***</td>
<td>0.016</td>
<td>-0.135***</td>
<td>-0.143***</td>
</tr>
<tr>
<td></td>
<td>(0.001)</td>
<td>(0.271)</td>
<td>(0.001)</td>
<td>(0.015)</td>
</tr>
<tr>
<td>Intercept</td>
<td>-9.130</td>
<td>-23.204</td>
<td>4.062</td>
<td>3.914*</td>
</tr>
<tr>
<td></td>
<td>(0.034)</td>
<td>(5.440)</td>
<td>(0.037)</td>
<td>(1.191)</td>
</tr>
</tbody>
</table>

***p<0.001, **p<0.01, *p<0.05
Participant and week dummies excluded from this table to conserve space.
Table 15: Estimated parameters for walking duration model

<table>
<thead>
<tr>
<th>Dependent Variable Measure: Walking Duration (in minutes)</th>
<th>Poisson Model</th>
<th>Negative Binomial Model</th>
<th>Zero Inflated Poisson Model</th>
<th>Zero Inflated Negative Binomial Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback Messages</td>
<td>-0.159***</td>
<td>0.191</td>
<td>0.161***</td>
<td>0.185***</td>
</tr>
<tr>
<td></td>
<td>(0.028)</td>
<td>(0.257)</td>
<td>(0.029)</td>
<td>(0.010)</td>
</tr>
<tr>
<td>EMA</td>
<td>-0.006</td>
<td>-0.021</td>
<td>0.053***</td>
<td>0.069**</td>
</tr>
<tr>
<td></td>
<td>(0.007)</td>
<td>(0.078)</td>
<td>(0.007)</td>
<td>(0.023)</td>
</tr>
<tr>
<td>EMA * Feedback Messages</td>
<td>0.013**</td>
<td>-0.055</td>
<td>0.023***</td>
<td>0.030***</td>
</tr>
<tr>
<td></td>
<td>(0.005)</td>
<td>(0.055)</td>
<td>(0.005)</td>
<td>(0.002)</td>
</tr>
<tr>
<td>Daily Goal Set</td>
<td>-.002**</td>
<td>-0.015</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>(&lt;.001)</td>
<td>(0.008)</td>
<td>(&lt;.001)</td>
<td>(0.003)</td>
</tr>
<tr>
<td>Age</td>
<td>0.232***</td>
<td>0.341***</td>
<td>0.063***</td>
<td>0.066**</td>
</tr>
<tr>
<td></td>
<td>(0.006)</td>
<td>(0.041)</td>
<td>(0.006)</td>
<td>(0.020)</td>
</tr>
<tr>
<td>Baseline Walking Capacity</td>
<td>0.020***</td>
<td>0.027***</td>
<td>0.004***</td>
<td>0.005**</td>
</tr>
<tr>
<td></td>
<td>(&lt;.001)</td>
<td>(0.003)</td>
<td>(&lt;.001)</td>
<td>(0.001)</td>
</tr>
<tr>
<td>Employed</td>
<td>0.390**</td>
<td>0.413</td>
<td>0.564***</td>
<td>0.524***</td>
</tr>
<tr>
<td></td>
<td>(0.034)</td>
<td>(0.328)</td>
<td>(0.036)</td>
<td>(0.142)</td>
</tr>
<tr>
<td>Obesity</td>
<td>3.965***</td>
<td>5.616***</td>
<td>0.513***</td>
<td>0.773*</td>
</tr>
<tr>
<td></td>
<td>(0.085)</td>
<td>(0.660)</td>
<td>(0.092)</td>
<td>(0.323)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>-0.835***</td>
<td>-1.618***</td>
<td>-0.079*</td>
<td>-0.116***</td>
</tr>
<tr>
<td></td>
<td>(0.038)</td>
<td>(0.381)</td>
<td>(0.040)</td>
<td>(0.159)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>-2.529***</td>
<td>-3.369***</td>
<td>-0.081</td>
<td>-0.373</td>
</tr>
<tr>
<td></td>
<td>(0.097)</td>
<td>(0.381)</td>
<td>(0.104)</td>
<td>(0.322)</td>
</tr>
<tr>
<td>Cardiovascular Disease Diagnosis</td>
<td>-6.944***</td>
<td>-9.845***</td>
<td>-1.636***</td>
<td>-1.913***</td>
</tr>
<tr>
<td></td>
<td>(0.136)</td>
<td>(0.877)</td>
<td>(&lt;0.000)</td>
<td>(0.431)</td>
</tr>
<tr>
<td>Weekday or Not</td>
<td>-0.116***</td>
<td>-0.007</td>
<td>-0.146***</td>
<td>-0.157*</td>
</tr>
<tr>
<td></td>
<td>(0.020)</td>
<td>(0.163)</td>
<td>(0.020)</td>
<td>(0.080)</td>
</tr>
<tr>
<td>Intercept</td>
<td>-14.198</td>
<td>-22.939</td>
<td>-1.001</td>
<td>-1.178</td>
</tr>
<tr>
<td></td>
<td>(4.38)</td>
<td>(2.941)</td>
<td>(0.477)</td>
<td>(1.530)</td>
</tr>
</tbody>
</table>

***p<0.001, **p<0.01, *p<0.05
Participant and week dummies excluded from this table to conserve space.

by 7.9% and average daily walking duration by 6.9%. Finally, the interaction between feedback messages and EMA responses increased average daily patient step count by 2.4% and average daily walking by 3.0%, suggesting that the two interventions, as instantiations of designed and emergent affordances respectively, indeed had synergistic effects on patients’ daily physical activity.
Though not of theoretical interest, we also observed that patient’s age, baseline walking capacity, employment status, and obesity were positively related to their physical daily activity performance (for both step counts and walking duration), while arthritis, diabetes, and history of cardiovascular disease were negatively related to their physical activity.

Parameter estimates based on structural-model approach and nonlinear instrumental variables (NLIV) approach for our test for endogeneity are shown in Table 16. In these models, the effect of feedback messages, EMA survey responses, and interaction between EMA and feedback messages were significant and positive for both measures of dependent variable. This is consistent with estimates in our zero-inflated negative binomial models reported in Tables 14 and 15, suggesting that endogeneity did not significantly bias our observed parameter estimates.

Parameter estimates based on structural-model approach and nonlinear instrumental variables (NLIV) approach for our test for endogeneity are shown in Table 16.

8.7 Discussion

This paper started with two research questions: (1) what are the effects of designed and emergent affordances of mobile HIT applications on chronic disease patients’ daily physical activities, and (2) do designed and emergent affordances of mobile HIT applications complement or substitute each other in influencing chronic disease patients’ daily physical activities? To seek answers to these questions, we used technological affordance as our theoretical lens, which we integrated with goal setting theory (Locke and Latham 2002), dual process model of cognition (Kahneman 2011), and nudge theory (Thaler and Sunstein 2009) to postulate the main and interaction effects of designed and emergent affordances of mobile HIT apps on chronic disease patient behaviors. The resulting hypotheses were tested using a 91-day field trial of a home-based cardiac rehabilitation app with a sample of eight participants.
Table 16: Estimated parameters for step count and walking duration

<table>
<thead>
<tr>
<th></th>
<th>Structural-Model Approach (Negative Binomial Model)</th>
<th>Non-linear Instrumental Variable (NLIV)/GMM Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Step Count</td>
<td>Walking Duration</td>
</tr>
<tr>
<td>Feedback Messages</td>
<td>0.351***</td>
<td>0.200***</td>
</tr>
<tr>
<td></td>
<td>(0.025)</td>
<td>(0.018)</td>
</tr>
<tr>
<td>EMA</td>
<td>0.019***</td>
<td>0.017***</td>
</tr>
<tr>
<td></td>
<td>(0.010)</td>
<td>(0.009)</td>
</tr>
<tr>
<td>EMA * Feedback Messages</td>
<td>0.100***</td>
<td>0.067***</td>
</tr>
<tr>
<td></td>
<td>(0.005)</td>
<td>(0.004)</td>
</tr>
<tr>
<td>Daily Goal Set</td>
<td>0.024**</td>
<td>0.016</td>
</tr>
<tr>
<td></td>
<td>(0.005)</td>
<td>(0.015)</td>
</tr>
<tr>
<td>Age</td>
<td>0.399***</td>
<td>0.331**</td>
</tr>
<tr>
<td></td>
<td>(0.062)</td>
<td>(0.041)</td>
</tr>
<tr>
<td>Baseline Walking Capacity</td>
<td>0.031***</td>
<td>0.027***</td>
</tr>
<tr>
<td></td>
<td>(0.004)</td>
<td>(0.003)</td>
</tr>
<tr>
<td>Employed</td>
<td>0.380</td>
<td>0.338</td>
</tr>
<tr>
<td></td>
<td>(0.348)</td>
<td>(0.283)</td>
</tr>
<tr>
<td>Obesity</td>
<td>6.646***</td>
<td>5.613***</td>
</tr>
<tr>
<td></td>
<td>(0.933)</td>
<td>(0.673)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>-1.994***</td>
<td>-1.591***</td>
</tr>
<tr>
<td></td>
<td>(0.460)</td>
<td>(0.291)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>-4.061***</td>
<td>-3.404***</td>
</tr>
<tr>
<td></td>
<td>(0.953)</td>
<td>(0.736)</td>
</tr>
<tr>
<td></td>
<td>(1.380)</td>
<td>(0.875)</td>
</tr>
<tr>
<td>Weekday or Not</td>
<td>-0.008</td>
<td>-0.012</td>
</tr>
<tr>
<td></td>
<td>(0.157)</td>
<td>(0.141)</td>
</tr>
</tbody>
</table>

***p<0.001, **p<0.01, *p<0.05
Participant and week dummies excluded from this table to conserve space.

Our app instantiated designed and emergent affordances as feedback messages and EMA survey responses respectively, which were found to influence coronary heart disease patients’ physical activity behaviors (step count and walking duration), independently and in conjunction, in a synergistic manner, while controlling for covariates and fixed effects of patient-level and
week-level variables. In this section, we discuss the key limitations of this study and its contributions for theory and practice.

8.8 Limitations

Like most empirical studies, our study is not without limitations. First, our experimental design, comprising of two main effects and one interaction effect, may be seen as being overly simplistic. As Rai (2017) noted, the value of a research project can be evaluated in terms of its (1) aesthetic value (arising from “powerful simplicity”), (2) scholarly (theoretical) value, and (3) practical utility. We submit that this research project meets all three criteria. While complex models may have more explanatory power in specific contexts, simple models are more useful because they are more generalizable over a wider range of contexts, by virtue of having fewer theoretical constraints or boundary conditions. The idea that “less is more” is also core to the concept of “model parsimony” that have influenced psychology research at large (Goldstein and Gigerenzer 2011). Indeed, goal setting theory and the concept of digital nudge described in this paper, are powerful in their simplicity and broad applicability. Moreover, the theoretical value of this study is its elaboration and empirical demonstration of the independent and conjugative effects of unintended actualization of technology affordance, which was alluded to but not clearly articulated as such in the previous affordance literature. Our practical value lies in eliciting how affordances can be built into mobile HIT applications to affect positive behavioral change among chronic care patients.

Our second limitation is that we did not thoroughly examine the effect of goals on chronic care patient behaviors. Goal setting theory says that goals that are too high or unrealistic are less likely to be realized. However, the objective of this study was not to test goal setting theory, which has been validated in hundreds of prior studies, but to examine the effect of
affordance actualization, and goal setting theory was a supporting theory to make a theoretical case for intended actualization of affordance. It also turns out that our study participants did not set unrealistic goals; they set fairly conservative goals (cumulative walking goal set by all fourteen participants was 11,277 minutes), which they accomplished very comfortably (they recorded 19,860 minutes of total walking activity). Hence, goal setting was unlikely to play a major role in this study due to ‘ceiling effect’.

Third, it may be that our use of six EMA surveys per day was too overwhelming for our study participants, to the extent that they started tuning it out toward the end of the study like spam electronic mails. Indeed, we saw a declining trend of EMA responses from the beginning to the end of the study (Figure 24). We selected six EMA surveys per days based on suggestions in the EMA literature. But it may be possible that six EMA was not as effective as a digital nudge compared to fewer EMAs, at least in later stages of the study. It is also possible that participants may have responded more enthusiastically to EMA surveys if we surveyed them less frequently. We do not have these answers from this study. Nonetheless, this issue has important design implications and represents a potentially useful opportunity for future research.

8.9 Contributions to Theory

This paper has several important theoretical contributions. First, we contribute to the technology affordance literature in two ways: (1) by explicating the interplay between intended and unintended affordance actualization, within a healthcare context, and (2) by extending the impact of technological affordance from technology use to the impacts of such use. On the first issue, we found that unintended actualization of affordances like EMA responses have substitutive effects with intended actualization of affordances like feedback messages, which to the best of our knowledge, is a novel finding in the technology affordance literature. Affordances
are complex assemblages of technological properties of an artifact, users, and their interrelationships, which is why they can interact with other affordances and produce various outcomes in non-deterministic ways (Leidner et al. 2018; Volkoff and Strong 2017). Such interaction draws together a variety of dualities: designed versus emergent, user versus artifact, intended versus unintended, and so forth. These dualities dissolve within the concept of affordances which we consider both dispositional and relational, revealing a complex dynamic, even within the most mundane of behavior enactments like walking. However, we also know that affordance is a necessary but not sufficient condition for enactment (Lindberg and Lyytinen 2013). The situation within which an affordance emerge, provides the conditions for the actualization of that affordance. Our study unveiled one of such mechanisms through which a technology affordance gets actualized in an unexpected manner in the context of HIT app use by drawing attention to the nudging and priming capability of EMA survey responses independently as well as in conjunction with feedback messages. However, since affordances are actualized in use, and unintended actualization of affordances are unknown in advance, the possibility exists that some affordances may never even be actualized (Volkoff and Strong 2013). Further research on the implicit processes about the actualization of technology affordance are suggested to develop further understanding of emergent mechanisms. On the second issue, the concept of affordances is used to describe how technologies are used (or misused or abused) by their intended users. However, the objective of IT design should not be just to enhance its use, but to achieve useful or effective outcomes from such use. To that end, our study connects affordance actualization with human objectives of technology use and user goals. Future research on technological affordances may extend this linkage between artifact design, use, and impacts and/or use this conceptual framing to study technology use or misuse.
Second, we provide an illustrative example of how to build a “theory of the solution” (Majchrzak et al. 2016) or “design relevant explanatory/predictive theory (DREPT)” (Kuechler and Vaishnavi 2012) that can explain when, how, and why information technologies can solve an organizational, social, or personal problem. Though built from behavioral theories, this theory is rooted in artifact design (design science research theory), and is not simply an application or adaptation of behavioral theories from a referent discipline, as is common in the information systems literature. Majchrzak et al. (2016) note that construction of such theories, focusing on a real problem and an artifact-based solution, is essential if the information systems discipline is to build its own corpus of theories and establish legitimacy as a theory-building discipline. In this paper, the problem in question is the self-management of chronic care patient needs, and mobile HIT applications have emerged as a potentially useful and cost-effective solution to this problem that works by empowering users with the data, tools, and alerts they need to self-manage their own chronic care. We attempted to build and validate a preliminary ‘design relevant explanatory/predictive theory’ (DREPT) of HIT-enabled self-management of chronic diseases, by using technology affordance as a theoretical lens and complementing this perspective with goal-setting theory, cognitive dissonance theory, and nudge theory. Undoubtedly, the preliminary theory presented here can be developed further, for example, along a temporal dimension, to explore why patients’ physical activity decreased over time, and what HIT affordances can help sustain the desired behaviors. Future research can also examine what non-technological conditions may interplay with technology affordances in shaping user behavior.

Lastly, we contribute to a growing body of research on EMA in the healthcare research literature by elaborating its potential role as a behavioral intervention in self-management of chronic diseases. Although prior studies have already demonstrated the efficacy of EMA surveys
in healthcare settings, our analysis suggests that EMA may have broader ramifications as an intervention to influence patients’ physical activities. We also provide theoretical explanations for these effects, which has been missing in much of the prior EMA literature.

8.10 Contributions to Practice

For practice, our study demonstrates the utility of considering theories of behavior change in design considerations of mobile HIT interventions. It demonstrates the relevance of intended and unintended actualization of affordances that may influence patient behaviors in expected and unexpected ways, and the need to proactively and consciously consider such affordances. In our study, we did not design our EMA surveys to nudge the patients to perform physical activity. But now that we are aware of this new potential of EMA surveys, this new affordance can be strategically designed and its content carefully framed in a manner to not only motivate desired health behaviors, but also sustain such behaviors over the long run or prevent patients from performing unwarranted behaviors. Such strategic design of EMA surveys can have higher impacts than surveys not designed with such purpose in mind. This unexpected observation holds the potential of opening a new frontier in EMA survey design.

Lastly, although our study was conducted in the context of coronary heart disease rehabilitation, physical inactivity is a risk factor for many other chronic diseases such as diabetes and other cardiovascular diseases. Digital technologies can not only empower patients with the tools, data, and recommendations for effective self-management of their chronic disease, but also has the potential to reduce the high cost of chronic care by reducing the need for trained disease management professionals. Moreover, we expect that the findings of our research to further generalize to people with high risk for chronic diseases, but not yet diagnosed as such, such as
prediabetic and obese people, who can benefit from technology-managed physical activity regimens.
CHAPTER 9. FUTURE WORK

Based on our previous research described earlier we are trying to test our more feature-oriented advanced prototype through a mini randomized controlled trial (RCT) for three months. Most coronary heart disease patient spends over 5000 hours yearly independent of medical providers (Asch et al. 2012). Arming them with behavior change techniques (BCTs) that can be implemented anytime can have a significant effect on the hearth health as well as access to cardiac rehabilitation. The prototype that was developed has significant potential to improve the health behavior and CV risks of patients unable to attend CBCR. Higher levels of self-monitored and unsupervised exercise inherent in HBCR versus CBCR can aid the transition from active intervention to life-long self-management seamlessly.

9.1 Research Plan: Method and Procedures

Our primary objective is to determine, in a mini randomized control trial, whether our new advanced prototype is more effective than an Educational Usual Care (E-UC) comparison group, for improving the primary outcomes, exercise capacity (EC), as well as other indicators of cardiovascular health among the 80% of patients unable to attend the CBCR. Our central hypothesis is that compared to E-UC, the advanced prototype will provide an effective, scalable, potentially economical (reduced cost and health service utilization) HBCR intervention for cardiovascular patients unable to attend CBCR for improving the primary outcome of exercise capacity (EC), health behavior (e.g. physical activity, healthy eating patterns, stress management) and cardiovascular health. The scientific premise for this study is built on our prior
work and that of others suggesting that a behavioral theory-based mHealth intervention, such as
our advanced prototype, will effectively improve exercise capacity (EC) (six-minute walk test)
and health behaviors such as physical activity, healthy eating patterns, and stress management,
known to reduce cardiovascular risks.

9.2 Specific Aim

In the mini RCT, we would like to evaluate whether our advanced prototype compared to
educational usual care (E-UC) improves the 3-month primary (six-minutes walk test 6MWT)
and secondary outcomes (physical activity, health-related quality of life (HRQoL), depressive
symptoms, body mass index (BMI), waist circumference, blood pressure (BP), anxiety,
perceived stress, engagement and self-efficacy for managing chronic illness.

Hypothesis: Patients randomly assigned to our advanced prototype compared to
educational care (E-UC) will demonstrate greater improvements at 3 months in primary and
secondary outcomes defined earlier.

Research Design: In a two-arm mini RCT, we will randomly assign patients in a 1:1 ratio
to either our HBCR (with advanced prototype) group or educational usual care group.

Randomization: Random assignment to either the HBCR (with advanced prototype)
group or educational usual care group will be performed, after baseline data collection is
completed, in a 1:1 ratio.

Expected Results and Impact: The proposed trial addresses the health disparities of patients
with coronary heart disease and represents a critical step towards providing accessible,
potentially low cost, personalized HBCR for patients that overcomes barriers of CBCR.
9.3 Interventions

Advanced Prototype (Experimental group). The core behaviors targeted by the HBCR system include: physical activity, healthy eating, stress management, medication adherence, and, if relevant, smoking cessation. The core functions of the HBCR system include 1) Goal setting; 2) Ecological Momentary Assessments (EMA); 3) Automated Ecological Momentary Interventions (EMI); 4) Progress review on behavior improvements; 5) Educational videos; 6) Access to health coach via a web portal; and 7) Peer support via a chat function.

1. **Goal Setting:** Participants set daily goals on the smartphone for health behaviors (e.g., physical activity, healthy eating, stress management) and specify their readiness to improve their health behaviors. The goals are recorded in the web portal dashboard.

2. **EMA:** Participants receive brief electronic surveys on the smartphone at five random intervals daily so that, based on the social, affective, and environmental contexts of participant behaviors during daily life that they report, they receive appropriate automatic behavior change screens to their smartphone. Participants are not obligated to respond to all five EMAs – it is their choice.

3. **EMI:** Collecting EMAs on tailoring variables (e.g., mood) is critical for timely tailoring of just-in-time adaptive intervention (JITAI) options to participant’s momentary needs. Tailoring variables used to make intervention decisions for delivering up to 300 behavior change techniques (BCT), incorporated into the gender-specific graphic user interfaces for health behaviors, are constructed from smartwatch data and EMA self-report data. Participants receive approximately 30 behavior change techniques automatically on their phone each day depending on their EMA responses and the health goals they set. Behavior change technique development has been guided by the tenants of the most effective behavior change theories including the Transtheoretical Model, Theory of Planned Behavior, Social Cognitive Theory, Information-
Motivation-Behavioral Skills Model, Self-Determination Theory, and the Health Belief Model. The HBCR system uses standardized BCTs designed from 10 of the most effective behavior change theories. The BCTs for health behaviors are endorsed by the Society of Behavioral Medicine, and grounded in the secondary prevention guidelines from the AHA, American College of Cardiology, and American Association of Cardiovascular and Pulmonary Rehabilitation. Decision points for BCT delivery are both health coach-specified and participant-initiated. Health coach-specified include: a) at given time intervals, b) specific times during the day, or c) in response to EMA data. Participant-initiated decision points reflect times where they either request support or access the intervention on the smartphone. Ecological momentary interventions are delivered anytime they are needed in the participant’s natural setting. For example, consider a JITAI that uses daily accumulated physical activity (PA) distance, inferred from the smartwatch, as the tailoring variable. A decision rule for a PA intervention uses 4 PM as the decision point. the HBCR system then automatically delivers an intervention option to either recommend physical activity or send an encouraging BCT depending on the daily accumulated PA distance achieved. The exercise component of the HBCR system promotes physical conditioning, balance, and flexibility. Baseline 6MWT results will determine individual physical activity levels.

4. Progress on behavior change: Participants can monitor the achievement of their behavioral goals on the smartphone at any time. Physical activity and heart rate data can be viewed continuously from the Moto 360 smartwatch and on the web portal dashboard.

5. Education videos: Twenty 10-minute educational videos on topics related to improving targeted health behaviors have been developed for the HBCR system by the PI and are accessible on the smartphone.
6. **Health Coach**: Participants have contact with the health coach via telephone, the dashboard, and via messages sent to their phone. The health coach who continuously monitors physical activity, goal setting, ecological momentary assessment, and heart rate data via the dashboard, delivers weekly telephone calls to participants who can also call the health coach (Monday-Friday, 8 AM to 5 PM). The health coach will answer questions and provide encouragement for health behavior change including physical activity, healthy eating, and stress management.

7. **Peer support**: the HBCR system participants use the chat function to receive support from their study peers. Participants will choose a user name that does not reveal their identity. The PI will monitor the chat function regularly for any disruptive messages or incorrect information among the participants.

9.4 **Educational Usual Care (E-UC) (Control group)**

Participants in both groups will continue to receive their usual standard of healthcare uninterrupted by study involvement. The standard of care for coronary heart disease patients includes regular visits with their health care providers for management of lipids, blood pressure, blood glucose, and cardio-protective medications. If eligible, and with the receipt of a physician referral and appropriate health insurance coverage, they can attend a center-based cardiac rehabilitation program. Participants in the study will have baseline and 3-month data collection. To supplement usual care and enhance study retention, participants will receive a 208-page workbook and a 90-minute DVD published by the AHA entitled “An Active Partnership for the Health of Your Heart” based on the MULTIFIT program originally developed by DeBusk et al. (1994). This 12-chapter workbook is often used as part of CBCR or can be used by individuals unable to attend CBCR. It covers all topics typically taught in CBCR including risk factor
management, diet, physical activity, weight loss, understanding heart disease, taking medications, and stress management.

9.5 Measurements

*Measurements:* Instruments used in the study are illustrated below (Table 17).

*Biological:* We will collect cardiac history, comorbidities, medications, and cardiovascular risk factors at the baseline visit.

*Psycho-social:* Socio-demographic attributes collected at baseline include age, marital and work status, religious affiliation, education, occupation, living arrangements, insurance status and income. Dietary self-efficacy (SE) is measured using the 20-item Eating Habits Confidence Survey consisting of a 5-point scale ranging from 1 to 5 with higher scores reflecting higher SE (http://sallis.ucsd.edu/measure_selfefficacy.html). This instrument has shown strong internal consistency in overweight postmenopausal women. Exercise Self-Efficacy is measured with the 12-item Exercise Confidence Survey asking participants to rate their confidence in maintaining an exercise routine when facing various barriers. Scores range from 12 to 60; higher scores reflect higher self-efficacy.

*Primary Outcome:* Exercise capacity (EC) is an important therapeutic endpoint because sustained physical activity is one of the most important behaviors needed for long-term health. The six-minute walk test (6MWT) assesses submaximal EC, with significant prognostic value, and has evidence of reliability when performed twice on subsequent days (ICC = 0.90 [95% CI 0.63-0.96]; p<0.0001). The 6MWT is commonly used to estimate EC in CBCR patients, is responsive to clinical change following CBCR, and can be performed safely soon after an ACS and open-heart surgery. The 6MWT was prognostic for hospitalization and mortality in heart failure patients with diverse exercise capacities and largely matched the efficacy of the
cardiopulmonary exercise test (CPX). The six-minute walk distance (6MWD) of 300 meters is discriminant for morbidity and mortality in patients ≥65 years undergoing CBCR. The 6MWD

Table 17: Instruments that is going to be used at the beginning and end of the trial

<table>
<thead>
<tr>
<th>Concept</th>
<th>Measurement</th>
<th>Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL = baseline</td>
<td>BL 3M</td>
</tr>
<tr>
<td><strong>Baseline biological Variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health History</td>
<td>Diagnosis, comorbidities, CV risk factors, medication</td>
<td></td>
</tr>
<tr>
<td><strong>Psycho-Social Variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Socio-demographics</td>
<td>Marital/work status, SES, education, race/ethnicity, income</td>
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</tr>
<tr>
<td>Self-Efficacy Diet</td>
<td>Eating Habits Confidence Survey</td>
<td>x</td>
</tr>
<tr>
<td>Self-Efficacy Exercise</td>
<td>Exercise Confidence Survey</td>
<td>x</td>
</tr>
<tr>
<td><strong>Primary Outcome (3 month follow-up)</strong></td>
<td>Exercise Capacity</td>
<td>Six-Minute Walk Test (6MWT)</td>
</tr>
<tr>
<td><strong>Secondary Outcomes (3 month follow-up)</strong></td>
<td>Health-related quality of life</td>
<td>SF-36,2 Health Survey</td>
</tr>
<tr>
<td>Physical Activity</td>
<td>International Physical Activity Questionnaire-SF; Moto 360 smartwatch (Advanced Prototype group only)</td>
<td>x x</td>
</tr>
<tr>
<td>Physiological characteristics</td>
<td>Body mass index (weight (kg)/height (m²)); waist circumference; blood pressure; heart rate</td>
<td>x x</td>
</tr>
<tr>
<td>Depression</td>
<td>Center for Epidemiological Studies Depression Scale</td>
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</tr>
<tr>
<td>Tobacco Use</td>
<td>Self-report</td>
<td>x</td>
</tr>
<tr>
<td>Medication Adherence</td>
<td>Medication Adherence Questionnaire</td>
<td>x</td>
</tr>
<tr>
<td>Anxiety</td>
<td>State Anxiety Inventory</td>
<td>x</td>
</tr>
<tr>
<td>Perceived Stress</td>
<td>Perceived Stress Scale</td>
<td>x</td>
</tr>
<tr>
<td>Self-Efficacy for Managing Illness</td>
<td>Self-Efficacy for Managing Chronic Disease Scale</td>
<td>x</td>
</tr>
<tr>
<td>Adherence/Engagement</td>
<td>Minutes PA/week. Advanced Prototype: # exercise sessions; click-depth, interaction, recency</td>
<td>x</td>
</tr>
<tr>
<td>Usability</td>
<td>System Usability Scale</td>
<td>x</td>
</tr>
</tbody>
</table>

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correlates with the maximum effort reached on a CPX during CBCR. The 6MWT will be measured at baseline and 3 months using standardized protocols.

*Secondary Outcomes:* HRQoL is measured with the SF-36v2™ Health Survey comprising 36 questions measuring physical and mental health perceptions on 8 subscales. Physical activity (PA) will be assessed with the 7-day recall International Physical Activity Questionnaire (IPAQ) that measures PA in 5 domains (occupational, transportation, domestic, leisure, sedentary) and 4 dimensions (intensity, frequency, duration, energy expenditure). PA will be measured objectively (Advanced Prototype group only) with the Moto 360. It assesses acceleration via a tri-axial accelerometer and rotation via a tri-axial gyroscope with sampling rates set to 100Hz. The smartwatch is worn every day except for bathing, sleeping or swimming. These sensors produce more than 2 GB of data/participant per day. To enable processing efficiency, our system carefully extracts features from the accelerometer and gyroscope data that classify activities at 60-second epochs. Number of steps and distance walked are computed. Time-stamped raw sensor data are transmitted via Bluetooth from the watch to the smartphone, and exported via Wi-Fi to the HIPAA-compliant Microsoft Azure server every 3 minutes. Depressive symptoms will be measured with the Center for Epidemiological studies – Depression (CES-D) scale with scores ranging from 0-60.

*Weight:* With participants in light clothing without shoes, weight is measured to the nearest 0.1 kg using research precision grade, calibrated, digital scales and height is measured to the nearest 0.1 cm using a freestanding stadiometer. Body mass index is calculated as weight (kg)/height (m²). Waist circumference, assessed just above the uppermost lateral border of the right ilium using a Gulick tape measure, model 67020, will be calculated to the nearest 0.1 cm as the mean of the
2nd and 3rd measures.

BP will be obtained with a calibrated automated monitor according to standard protocol.

*Smoking status:* We will rely on self-reported smoking status (including electronic cigarettes) because we previously found a 98% correlation between urinary cotinine levels and self-reported smoking.

The Medication Adherence Questionnaire includes 3 questions regarding medication adherence. If they are nonadherent, there are potentially 24 additional questions about the reasons why State anxiety will be measured using the 20-item State Anxiety Inventory.

*Perceived Stress:* The Perceived Stress Scale consists of 14 items that are measured on a 5-point scale. Adherence/Engagement with the Advanced Prototype and E-UC will be measured indirectly as minutes of physical activity reported per week. Adherence of the Advanced Prototype will be measured directly as the number of exercise sessions recorded in Advanced Prototype. We will evaluate participant’s perceptions of their self-efficacy for managing chronic illness with a 6-item instrument developed by Lorig et al. (2001).

*Usability:* We will administer the System Usability Scale to evaluate the ease of use, usefulness, clarity of presentation and satisfaction with the Advanced Prototype.

### 9.6 Expected Contribution

We expect our research to have several implications for both research and practice. First, to the best of our knowledge, this is one of the first studies that create a completely functional prototype to use of HBCR which keeps the health coach at the center of the cardiac rehabilitation process and merges human-expert intelligence with machine intelligence to augment health coach’s decision-making capabilities. Our work is in response to the call made by Yang and his colleague (2019) where they suggested that the success of a mHealth intervention depends on
how well the system connects patients back to their clinical care, rather than its behavior modification techniques in isolation. Our study has tried to achieve that in the context of secondary prevention of coronary heart disease.

Second, while developing a prototype of an HBCR system for CHD patients, we developed three artifacts that are essential for the efficient and reliable functioning of the system. The first artifact ensures accurate detection of the patient’s physical activity based on the data captured through the accelerometer and the gyroscope embedded in a smartwatch. The second artifact that we have created is a comprehensive set of graphical representations of different theory-based behavior change interventions, which we have deployed in the mobile application. Finally, we have created a web-based dashboard as our third artifact for monitoring patients’ data captured through smart watches and mobile applications. Based on the case study evaluation results we have modified all three of our artifacts and made significant improvements. According to Baskerville et al. (2018) if “the artifact is novel and useful, then it necessarily contributed to design knowledge. Therefore, our advanced prototype for the HBCR system, which we have developed by following the iterative process of artifact development suggested by Hevner et al. (2004) qualify as a significant design science research contribution. In this regard, our advanced prototype along with three different artifacts (components) presents a novel proof of concept solution which positions itself in the upper left quadrant, representing an improvement over other existing solutions in the diagram suggested by Gregor and Hevner (2013, Figure 3).

Finally, from the research perspective in our advanced prototype we have implemented instances of interventions representative of 12 different behavior change techniques namely ‘Goals and Planning’, ‘Feedback and Monitoring’, ‘Social Support’, ‘Shaping Knowledge’, ‘Comparison of Behavior’, ‘Association’, ‘Repetition and Substitution’, ‘Comparison of
Outcomes’, ‘Self-Reward’, ‘Antecedents’, ‘Identity’, ‘Self-belief’. All these behaviors change techniques (BCTs) are developed based on psychological determinants of behaviors (constructs) suggested by eight behavior change theories (See Table 3). These instances of interventions are deployed in a particular order for the treatment group. The proposed mini randomized controlled trial (RCT) will help us to check the efficacy of each of these interventions deployed in a particular order. By doing so it the proposed mini RCT eventually helped us to check the efficacy of twelve different constructs suggested by eight behavior change theories. The proposed RCT can help us to find the boundary conditions of these constructs particularly in the context of secondary prevention of CHD.

Moreover, this research provides a scope of identification of antecedents of certain behavioral patterns related to CHD patient’s exercise, eating and stress management. Such new observations can eventually help is modifying behavior change theories in order to make them or generalizable or context-specific or can provide the groundwork for new behavior change theories.
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APPENDIX 1 INSTITUTIONAL REVIEW BOARD APPROVAL

6/4/2018

Theresa Beckie, Ph.D., R.N.
College of Nursing
12901 Bruce B Downs Blvd
MDC Box 22
Tampa, FL 33612

RE: Expedited Approval of Amendment
IRB#: Ame4_Pro00030109
Title: A Mobile Health Secondary Prevention Program for Women with Heart Disease: A feasibility Study

Dear Dr. Beckie:

On 6/2/2018, the Institutional Review Board (IRB) reviewed and APPROVED your Amendment. The submitted request and all documents contained within have been approved, including those outlined below, as described by the study team.

I have received a small grant award from the USF Women in Leadership and Philanthropy - the 2018 Heart Health Faculty Research Award. Thus I would like to be able to compensate the subjects in this study with a $25 gift card after enrollment, consent, and baseline data collection, and another $25 gift card at study completion. I have added a sentence in the protocol, changed the document to version 2 and added a sentence in the consent form, and changed the footer to version 2. That is the only change I request.

Approved Item(s):
Protocol Document(s):
Consent Document(s)*:
Clean consent form.pdf

*Please use only the official IRB stamped informed consent/assent document(s) found under the "Attachments" tab on the main study's workspace. Please note, these consent/assent document(s) are valid until they are amended and approved.

The IRB does not require that subjects be reconsented.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with USF HRPP policies and procedures and as approved by the USF IRB. Any changes to the approved research must be submitted to the IRB for review and approval via an amendment. Additionally, all unanticipated problems must be reported to the USF IRB within five (5) business days.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

Mark Ruiz, PhD, Vice Chairperson
USF Institutional Review Board
APPROVAL

April 19, 2021

Theresa Beckie
12901 Bruc B Downs
BlvdMDC Box 22
Tampa, FL 33612

Dear Dr. Theresa Beckie:

On 4/16/2021, the IRB reviewed and approved the following protocol:

<table>
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<th>Application Type:</th>
<th>Continuing Review</th>
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<tr>
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<td>Pro00040086_CR000002</td>
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<tr>
<td>Review Type:</td>
<td>Committee Review</td>
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<tr>
<td>Title:</td>
<td>Mini Trial of Technology-Assisted Lifelong Cardiac Rehabilitation for Women (TOTAL CARE)</td>
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| Approved Protocol and Consent(s)/Assent(s): | • Mini Clinical Trial of Total Care Protocol Version 5 Revised 7.7.20 Clean.docx;  
  • TOTAL CARE Consent SB Adult MR_3_4_20 Clean.pdf;  
  Approved study documents can be found under the ‘Documents’ tab in the main study workspace. Use the stamped consent found under the ‘Last Finalized’ column under the ‘Documents’ tab. |

The IRB approved the protocol from 5/17/2021 to 5/17/2022. Within 45 days of 5/17/2022, submit a continuing review/study closure request in BullsIRB by clicking Create Modification/CR.

If continuing review approval is not granted before the expiration date of 5/17/2022, approval of this protocol expires on that date.

The IRB determined that all future reviews can be conducted under Expedited category 9 (Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but theIRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified). The Board determined that a full continuing review is required so the IRB can ensure the research is progressing appropriately.
In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely, Jennifer Walker
IRB Research Compliance Administrator

Institutional Review Boards / Research Integrity & Compliance

FWA No. 00001669
University of South Florida / 3702 Spectrum Blvd., Suite 165 / Tampa, FL 33612 / 813-974-5638
APPENDIX 2 DESIGN CYCLES

We adopted the design cycle view (Figure 25) proposed by Takeda et al. (1990), and followed the proposed methodology to build our design solution. There are six distinct stages in the process, and we showed the corresponding methods and activities in this DSR project catering to every stage (Figure 25). We also indicated the outcomes of each of the stages (Meth et al. 2015). In the following section we briefly discuss the methods and activities pertaining to each of the stages and their outcomes.

Awareness of problem: The genesis of our problem comes from the behavioral medicine literature and surveys that clearly highlight the importance of secondary prevention and self-management of the conditions of chronic disease and coronary heart disease (CHD) in particular.

As a secondary preventive approach, cardiac rehabilitation was developed as a vital means to stabilize CHD patients after severe cardiac events (myocardial infarctions or surgery) that entailed hospitalizations, residual ischemia, increased arrhythmias, and/or severe deconditioning (scientific awareness). While the population of patients eligible for cardiac rehabilitation continues to expand, the lack of use of cardiac rehabilitation presents a huge challenge. Extensive underuse implies that higher mortality, morbidity, re-hospitalizations, and other detrimental outcomes could theoretically be avoided if cardiac rehabilitation was utilized appropriately on a large scale (social awareness). There is growing evidence (Qudah et al. 2010, Forman et al. 2014, Geurts et al. 2016) that suggests that mobile-based platforms can offer HBCR to CHD patients. HBCR can offer opportunities to mitigate the increasing disparity of
access to affordable and even free resources. Such mobile-based platforms can allow personalized interventions in the patient’s own environment and can monitor the patient’s physical activity in real time. A system that caters to the needs of such patients must 1) have the capability to capture the patient’s goals and activity data through multiple channels, 2)
be able to process the data automatically and 3) be able to make decisions for interventions at the right time.

**Suggestion:** The scientific and social awareness of the problem delineates the requirements of the system design and also makes suggestions for the system architecture for HBCR. Our system architecture incorporates a smartwatch (which captures the patient’s physical activity data through an accelerometer and a gyroscope and the patient’s heart rate through an optical heart rate sensor), an android mobile application (which can calculate patient’s progress towards her goal and provide feedback as well as interventions) and a web-based dashboard (which can monitor patient data and build important analytics for planning behavior change interventions). The “Design of Home-Based Cardiac Rehabilitation System” section will provide descriptions of some key design principles that we have followed while developing our home-based CR system.

**Development:** While developing a prototype of an HBCR system for CHD patients, we developed three artifacts that are essential for efficient and reliable functioning of the system. The first artifact ensures accurate detection of the patient’s physical activity based on the data captured through the accelerometer and the gyroscope embedded in a smart watch. The second artifact that we have created is a comprehensive set of graphical representations of different theory-based behavior change interventions, which we have deployed in the mobile application. The “Designing User Interfaces for Behavior Change Interventions” section provides the detailed description of graphic representation of different behavior change interventions suggested by multiple behavior change theories. Finally, we have created a web-based dashboard as our third artifact for monitoring patients’ data captured through smart watches and mobile applications. This dashboard helps the health coach build analytics for sending behavior change interventions at the right moments.
**Demonstration:** We involved domain experts and tried to incorporate their recommendations while designing the system. Through the NSF I-Corps project we incorporated 100 interviews of patients with cardiovascular diseases and health-care professionals treating cardiovascular disease patients in order to help us select appropriate content for theory-based behavior change interventions and their visual representations. This process served as the required manipulation check for the intervention content we developed. We built multiple prototypes of the system by following an iterative design process suggested by Hevner et al. (2004). All these prototypes went through numerous lab-testing events to ensure proper functioning of the features of the designed system.

**Evaluation:** Once we ensured proper functioning of the integrated system under laboratory conditions, we field-tested the HBCR prototype with 6 participants who have a history of CHD. They used the system for 12 weeks, during which time we captured their data. We used the case study and data analysis approach regarding usage of the HBCR system.

**Conclusion:** Finally, we analyzed all the participants’ data captured during the field trial and identified different general and participant-specific usage, which can be useful for the further development and fine-tuning of our designed solution.
The dashboard consists of two hierarchical layers of interaction. The first layer allows the health coach to select a single patient ID in order to monitor the behavioral data. Once the health coach selects a particular patient ID, the coach is taken to the second layer of interaction, where the health coach is able to see all the data related to that particular patient that has been captured that day.

The second layer of interaction consists of three different pages or screens. The first screen displays information related to the patient’s physical activity goals, status of the patient’s physical activities, EMA responses provided by the patient, messages received by the patient each time she has submitted an EMA survey response, maximum, minimum and average values of the heart rate of patient on an hourly basis, and the patient’s information absorption activities in terms of accessing health related videos. The second screen displays information related to the preprogramed intervention messages received by the patient along with time stamps. Apart from that, this screen also displays records related to the failure of Wi-Fi and Bluetooth connections, as well as every time the patient has received a text message that the remaining battery capacity of her smartwatch and/or mobile phone has fallen below 20 percent. The third screen of the dashboard allows the health coach to create a custom text message and send it to a particular patient instantly. The message is delivered through the app residing inside the mobile phone. This screen also keeps a record for each of the custom messages that were sent to the patient through the dashboard.
The dashboard also allows the health coach to select a date range by selecting the start date and the end date of the required range through the calendar. Once the health coach provides the start and end dates, all the data captured during that period of time appears on the dashboard. The selection of the data range function is available for each type of patient data that can be displayed on the dashboard; the types are independent of each other. For each type of patient data, the health coach has to specify the date range separately. This particular function allows the health coach to compare data related to different behaviors of the patient over the same or different periods of time.

Table A2: Functionalities embedded in the two interaction layers of the dashboard.

<table>
<thead>
<tr>
<th>Functionality</th>
<th>Description</th>
<th>Interaction Layer+ Screen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID Dropdown Menu</td>
<td>This is a drop-down menu function, which allows the health coach to select a patient ID for the purpose of observing her recent and old data related to her daily physical activities, eating behavior, etc. This drop-down menu function also resides on the top of all the screens of the second layer.</td>
<td>First layer and Second layer + Dashboard screen, Statistics screen, Sent message screen</td>
</tr>
<tr>
<td>Patient’s Goal(s)</td>
<td>This is a table embedded inside the Dashboard screen, which displays the patient’s physical activity goals for the day. Inside the table each submitted goal occupies a single row. There are five columns in the table, displaying the date, time, patient’s readiness level score (self-reported), patient’s goal of walking (number of minutes) and patient’s energy level score (self-reported). There are previous and next buttons, which allow the health coach to navigate through all the previous records. This table also offers the function for displaying all the physical activity goals submitted by the patient within a date range by selecting start and end dates.</td>
<td>Second layer + Dashboard screen</td>
</tr>
</tbody>
</table>
Table A2: (Continued)

| Patient’s Activity Status | This table displays the patient’s most updated physical activity status for the day. Inside the table, each row displays the most updated activity status of the patient for that day. There are six columns inside the table. They display the date, time, amount of time the patient spent sitting that day, amount of time the patient spent walking for that day, total number of steps the patient has taken so far in that day, and the distance the patient has covered while walking. By default, this table corresponds to a single row, which always shows the most updated data related to patient’s physical activity | Second layer + Dashboard screen |
status. It also supports display of older records through previous and next buttons. Similar to the patient’s goals, this table also offers the functionality for displaying all the end-of-day physical activity performance statuses of the patient within a date range.

| EMA Survey Responses | This table displays all the EMA survey responses submitted by the patient on that particular day. The table also displays all of the motivational messages that the patient has received after submitting each of the EMA survey responses. The table consists of eight columns which represent the date, Second layer + Dashboard screen |
Table A2: (Continued)

| Heart Rate | This joint bar diagram displays the minimum, average and maximum values of heartbeat of the patient on an hourly basis. By default, | Second layer + Dashboard screen |

| time, EMA survey response to patient’s immediate physical activity, current companion, current location, recent eating episode, and current feeling. The last column displays the motivational messages that the patient has received after submitting the EMA survey response. Like all other tables, this table also offers the functionality for displaying all the EMA survey responses submitted by the patient within a range specified between two dates. |  |  |
this diagram displays joint bars corresponding to each hour already passed on that particular day. It is capable of displaying twelve hourly minimum, average, and maximum values of the heartbeat of the patient chronologically. There are previous and next buttons, which allow the health coach to navigate through all the previous records. Similar to other tables, this table also provides the option of viewing all records between a particular range of dates.

<table>
<thead>
<tr>
<th>Video</th>
<th>This table displays the patient’s health information-seeking activity in terms of watching videos by showing</th>
<th>Second layer + Dashboard screen</th>
</tr>
</thead>
</table>

Table A2: (Continued)
Table A2: (Continued)

| Feedback Message | This table is embedded in the Statistics screen, which by default displays all the preprogrammed intervention messages received by the patient on a particular day. The table consists of three columns, which display the date, time and the particular intervention message received by the patient. Like all other tables embedded in the dashboard, this one also | Second layer + Statistics screen |

the name of the video along with the date and time of access. It also allows the health coach to check the patient’s previous video watching activities by selecting a start and an end date.
<p>| Bluetooth Connection Failure | This table embedded in the Statistics screen displays the date and time when the connection between the smart watch and the mobile phone via Bluetooth is severed without any patient action, and the patient receives a text notification. It also offers the provision of displaying previous records through previous and next buttons as well as through selection of a range of dates. | Second layer + Statistics screen |</p>
<table>
<thead>
<tr>
<th>Table A2: (Continued)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WI-FI Connection Failure</strong></td>
</tr>
<tr>
<td><strong>Remaining Battery Left for Mobile Phone</strong></td>
</tr>
<tr>
<td>Sent Message</td>
</tr>
</tbody>
</table>
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Author: Avijit Sengupta
Publication: IEEE Transactions on Engineering Management
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