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DIL - A CONVERSATIONAL AGENT FOR HEART FAILURE PATIENTS

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APPROVAL OF THE DISSERTATION COMMITTEE

This dissertation has been duly read, reviewed, and critiqued by the Committee listed below, which hereby approves the manuscript of Sanjoy Moulik as fulfilling the scope and quality requirements for meriting the degree of Doctor of Philosophy (Ph.D.) in Information Systems and Technology.

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ABSTRACT

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There is an exceptionally high rate of readmissions and rehospitalizations for patients suffering from chronic diseases especially Heart Failure. Best efforts to address this alarming problem from the Care giver community have fallen short due to a number of factors most notably resource constraints like shortage of trained clinical staff, and money. Using a Design Science Research framework, this work designed and evaluated "DIL", a Conversational Agent that complements the work of clinicians in achieving the desired behavioral and clinical outcomes. The aim is to provide the hospital with an information system that could bridge the current gap in care that occurs when the patient transitions from the hospital environment to the home environment.

The expected contribution is to produce a novel artifact and demonstrate the efficacy and utility of the tool to assist patients with heart failure in improving their self-care. The study conclusions were extremely positive. DIL scored high on User engagement and satisfaction. Every patient felt significantly more positive after their interaction with DIL during the trial period, and had a positive outlook on their quality of life going forward. The patients in the trial found DIL to be helpful in keeping them motivated to follow a healthy lifestyle by controlling their diet, and adhering to clinical guidelines of regular exercise, and taking medications on a timely manner. Given the extremely positive experience of the patients, there is definitely room for such an IT artifact in supporting patients as they make the transition from hospital to the home setting.

Dedication

To my Parents (Bejoy & Chhanda Moulik)

To my wife (Bhaswati Moulik)

To my son (Aarya Moulik)

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I want to thank Dr. Samir Chatterjee for his valuable guidance throughout my PhD journey, and teaching me important lessons especially in the classes I took with him - Persuasive Technology and Design Science Research. He continues to be a source of inspiration in both professional and personal life.

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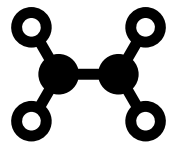


CHAPTER 1: INTRODUCTION

1.1 MOTIVATION

Chronic conditions are increasingly impacting life expectancy and the cost of healthcare all over the world. Among these conditions, Cardiovascular Disease (CVD) stands out because its prevalence continues to rise. According to American Heart Association, Heart Disease and Stroke Statistics 2018 [1], the numbers are alarming:

- Cardiovascular disease, listed as the underlying cause of death, accounts for nearly 836,546 deaths in the US. That's about 1 of every 3 deaths in the US. About 2,300 Americans die of cardiovascular disease each day, an average of 1 death every 38 seconds. Cardiovascular diseases claim more lives each year than all forms of cancer and Chronic Lower Respiratory Disease combined. Coronary Heart Disease is the leading cause (43.8 percent) of deaths attributable to cardiovascular disease in the US, followed by Stroke (16.8 percent), Heart Failure (9.0 percent), High Blood Pressure (9.4 percent), diseases of the arteries (3.1 percent), and other cardiovascular diseases (17.9 percent).
- Heart Disease (including Coronary Heart Disease, Hypertension, and Stroke) remains the No. 1 cause of death in the US. Coronary heart disease accounts for 1 in 7 deaths in the US, killing over 366,800 people a year. The overall prevalence for MI in the US is about 7.9 million, or 3 percent, in US adults. In 2015, heart attacks claimed 114,023 lives in the US.
- Cardiovascular disease is the leading global cause of death, accounting for more than 17.9 million deaths per year in 2015, a number that is expected to grow to more than 23.6 million by 2030.
- Nearly half of all NH black adults have some form of cardiovascular disease, 47.7 percent of females and 46.0 percent of males.
- The estimated annual incidence of heart attack in the US is 720,000 new attacks and 335,000 recurrent attacks. Average age at the first heart attack is 65.6 years for males and 72.0 years for females. Approximately every 40 seconds, an American will have a heart attack.
- From 2005 to 2015, the annual death rate attributable to coronary heart disease declined 34.4 percent and the actual number of deaths declined 17.7% – but the burden and risk factors remain alarmingly high.
- About 92.1 million American adults are living with some form of cardiovascular disease or the after-effects of stroke. Direct and indirect costs of total cardiovascular diseases and stroke are estimated to total more than $329.7 billion; that includes both

health expenditures and lost productivity. CVD and stroke accounted for 14% of total health expenditures in 2013-2014. This is more than any major diagnostic group. Total direct medical costs of CVD are projected to increase to $749 billion in 2035.

- The estimated direct and indirect cost of heart disease in 2013 to 2014 (average annual) was $204.8 billion. Heart attacks ($12.1 billion) and Coronary Heart Disease ($9.0 billion) were 2 of the 10 most expensive conditions treated in US hospitals in 2013. Between 2013 and 2030, medical costs of Coronary Heart Disease are projected to increase by about 100 percent.

In 2012, the American Heart Association reported that 1 out of 5 of individuals with heart failure dies within a year of diagnosis [2]. Although CVD is not curable, evidence shows that the quality of life and life expectancy of individuals with heart failure could be improved if the condition is managed by adhering to medications, monitoring symptoms, and salt intake, etc. [3]. Hospital readmissions remain a continued challenge in the care of the heart failure patient. Although small gains have been made over the past 5 years, still more than 20% of patients are readmitted within 30 days and up to 50% by 6 months [57]. The cost of these readmissions exceeded $15 billion per year for Congestive Heart Failure (CHF) patients (MedCAP) [1]. As readmissions continued, the Center for Medicare and Medicaid Services (CMS) decided to penalize hospitals with high heart failure readmission rates by not reimbursing them for the services they provide since prior studies show that heart failure hospital readmissions could be reduced with quality outpatient services and adherence to care.

CHF is common in the elderly population. As such, the increasing number of cases could be correlated with the aging population. About 10 in 1000 individuals over the age of 65 have CHF and 80% of CHF related hospitalizations are for patients over 65 [4].

Yet, the high readmission rates for heart failure cases have also been attributed to the lack of effective strategies to support the transition in care from the hospital to the home environment. Individuals with heart failure are discharged with the need to manage their comorbidities, physical limitations, personal struggles, lack of information, difficulties adapting with treatments, and debilitating symptoms [5,6]. With proper disease management, early symptoms of disease exacerbation could be detected and treatments could be initiated to prevent them [3], lowering the risk of deteriorating quality of life, death, or readmission to the hospital. Therefore, the American Heart Association recommends patient education and close monitoring to improve treatment adherence [6].

Hospitals vary in the strategies they implement to reduce readmissions. Studies have shown that employing heart failure programs and nurse-directed interventions help [7]. Yet, more evidence is needed for effective strategies to reduce readmissions because the limited number of clinicians can not address the growing needs of patients.

HOME MONITORING SYSTEM

Nagla Alnosayan of the IDEA Lab at the Claremont Graduate University - Center for Information Systems and Technology (CISAT), developed a "Home Telemonitoring System" to support self-care in the context of Congestive Heart Failure Patients, as part of her PhD dissertation [32]. The system was designed, developed and evaluated for the heart failure rehabilitation center at Loma Linda University Medical Center. The project tried to address the current gap in care that occurs when the patient transitions from the hospital environment to the home environment. The research project had lots of interesting findings, but what really stood out and is relevant to this study is the fact that Human support cannot scale, and is constrained by a number of factors, and the patients continue to remain socially isolated especially in the poorer sections of the society. Even though data was remotely collected from homes, and the system could automatically classify the risks of patients, human health workers were needed to intervene and talk to patients for guidance.

This expert rule-based Home monitoring system provides the background, and motivation for the current research to develop an automated intervention system that can be triggered based on patient's risk profile; a software artifact we call DIL that will aim to address the two specific findings of interest – scalability of Human support, and social isolation.

1.2 PROBLEM STATEMENT

Data shows that there is an extremely high number of readmissions (rehospitalizations) for Heart Failure patients particularly CHF cases [8,9]. The costs incurred to treat these cases is skyrocketing. So, there is a tremendous need for effective approaches to manage CHF in such a way that deteriorating cases could be detected and treated before they require hospitalization and more specifically rehospitalization. Different strategies like nurse interventions have been tried out, and met with some success, but in practice their implementation remains low, and many patients do not receive self-care support once they are discharged.

More specifically, the following problems come to the fore when we take a deeper look at these patients:

- They Forget — There is a need to send them reminders to take their prescribed medications, and adhere to the recommended behavior changes like exercise and diet.
- They Need Assistance — In many cases they need help and guidance to follow the recommended behavior changes.
- Social Connection — Many of these patients especially in the under privileged sections of the society are socially isolated.
- Social Motivation — Many have simply given up on the fight and lack the motivation to get better.
- Human support and Scale — In an extremely constrained environment, human support cannot scale.

This was evident at an interview with the director of cardiovascular wellness at Loma Linda University. The challenge with implementing such interventions could be related to the limited number of clinicians and the growing number of patients. Therefore, there is a need to identify strategies that have the potential to identify patients at risk and target clinical resources towards them; in particular some novel ICT-enabled strategies could be very beneficial.

It will also be interesting to find out why the patients fail to adhere to clinical guidelines, what factors prevent them from doing the needful, so that the nurses, doctors and other Health workers can create tailored treatment plans to achieve the desired health outcomes.

Existing health literature articulates the need for research pertaining to CHF self-care promotion. This creates a gap in the literature that this research intends to fill.

1.3 PURPOSE OF THE STUDY

As mentioned in previous sections, the cost of managing chronic conditions like heart failure is significant, and is a tremendous burden to the society at large. Hospitals are often penalized when patients are readmitted within a short duration but despite best efforts, the caregiver community routinely struggle to meet the needs of a huge and diverse patient population. Health professionals have limited resources and are not able to personally monitor and support patients in their everyday life. Human support simply cannot scale to cope with an ever-growing aging population suffering from CVDs. There also seems to be a lack of effective strategies to support the transition in care from the hospital to the home environment.

In this scenario, self care and self management of these conditions becomes even more critical. A technology solution that can aid in the process of self monitoring of vital health data, and provide timely interventions like reminders and motivations for the patients to follow clinical guidelines can go a long way to ease the caregiver burden. Previous studies with Conversational Agents or Chatbots have shown positive outcomes in self-efficacy and attitude change [24].

The purpose of this study is to evaluate the artifact, DIL, a conversational agent for heart-failure patients. Can DIL elicit behavior change, and better adherence to clinical guidelines for the patients in the study group will be a driving question for this research because if it can, then we can safely say that there is definitely room for an IT artifact to address the gap in continuing care as patients transition to home setting as human support can scale. The researcher seeks to compare the patients' behavior and health outcomes, before and during intervention by employing quantitative and qualitative instruments.

CHAPTER 2: LITERATURE REVIEW

2.1 BACKGROUND

CONGESTIVE HEART FAILURE

Congestive Heart Failure (CHF) is a condition that occurs when the heart fails to pump enough blood and oxygen to other organs. Common causes for heart failure include coronary artery disease, high blood pressure, and diabetes [2]. The severity of the disease is often classified into four categories as per the New York Heart Association (NYHA) functional classification These categories are based on the individual's limitations during physical activity and are described in the following table.

Table 1: NYHA Functional Classification

NYHA CLASS	SYMPTOMS
I	Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs, etc.
II	Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
III	Marked limitation in activity due to symptoms, even during less than ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.
IV	Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Table 1: NYHA Functional Classification

As a chronic condition, CHF could be managed with adhering to medications, following a low salt diet, exercising and measuring, recording, and observing vitals and symptoms such as:

- Weight
- Abnormal blood pressure
- Blood glucose levels out of target range if the individual has diabetes
- Shortness of breath
- Swelling
- Chest pain, etc.

Depending on the severity of symptoms, heart failure patients may need to get support or immediate evaluation from the clinical care team to adjust medications (e.g., diuretics) and/or change diet (e.g., restrict sodium intake) to control symptoms.

The process of monitoring symptoms to evaluate treatment is modeled as a 5-stage process that goes from monitoring to recognizing symptoms (e.g., new swelling) and from implementing treatment (e.g., take an extra diuretic dose) to evaluating it as shown in Figure 1 [6].

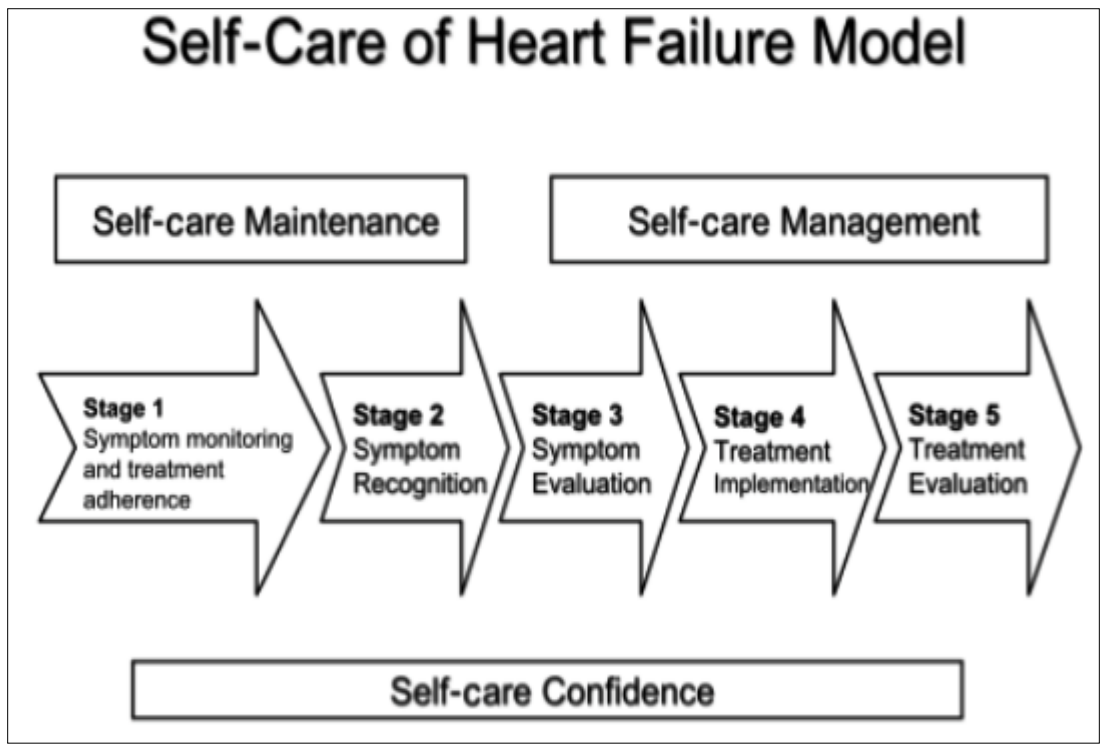


Figure 1: Self-Care of Heart Failure Model (Source: Reigel et al., 2008)

When patients are discharged, they often receive written and verbal instructions to promote self-care but they typically do not understand them since self-care is dependent on the individual's educational level, age, gender, social support, self confidence, self-perceived health, and self-efficacy [6]. In addition, several barriers to self-care exist such as: physical limitations, debilitating symptoms, difficulties coping with treatment, lack of knowledge, distressed emotions, multiple comorbidities, and personal struggles [5].

Supervising patients after discharge provides an opportunity to identify cases at risk. Therefore, the American Heart Association recommends patient education and close supervision [1]. Education topics include symptoms, weight, dietary (i.e., a sodium restricted diet), medications, and exercise [11,12]. When CHF disease management programs are implemented, functional status and quality of life improve while hospital readmissions due to exacerbations decrease (7,10].

With the rapidly increasing number of CHF cases and the scarcity of clinical resources services, risk stratification is key in CHF management in order to target healthcare services at individuals who need them the most and are likely to benefit from them. While risk stratification models such as the Seattle Heart Failure Model [13] exist, they require laboratory parameters and are not

suitable for patients at home. As such, there is a need to develop a risk stratification model for patients at home to predict worsening conditions and alert clinicians accordingly.

A Technology Driven Solution

As mentioned in the previous sections, patients when they are discharged after treatment for CHF, are often given written and verbal instructions to promote self-care. There are many problems with this approach as is evident with the very high readmissions rate [8,9]. When investigated further regarding the root cause of this problem, two broad factors [6] immediately stand out:

Lack of understanding – These patients often do not understand the instructions because of a host of factors like lack of education, literacy level, age, poor economic conditions, self confidence, self perceived health and self efficacy.

Lack of Motivation – The patient's willingness to change and get better is low because of low social support and social isolation, physical limitations, distressed emotions resulting in difficulties dealing with treatment.

Many care giving facilities acknowledge this problem, and make an effort to assign nurses or other care-givers to help these patients adhere to prescribed medications and behavior change like diet and exercise. But despite best efforts, the hospitals and the patients fail to achieve the desired outcomes. Lack of resources, money and trained personnel are often cited as primary reasons for this failure.

Given this situation, the obvious solution is a technology based intervention, and if inspiration can be drawn from pioneering work done by B.J. Fogg in the field of Persuasive Technology, especially his eight step design process [14] on how to design and create Persuasive Technologies, both the problems stated above can be addressed.

Persuasive Technology

B.J. Fogg talks about the best practices for designing Persuasive Technology based intervention, and outlines eight steps [14,16]. The steps as illustrated in Figure 2 are as follows:

1. Choose a simple adherence behavior to target: The first step in designing a successful persuasive technology is to select an appropriate behavior to target for change. We should select the smallest, simplest behavior that matters. Often this requires us to reduce the big goal to a small, seemingly tiny, objective.
2. Choose a receptive audience: Step 2 in the persuasive design process involves choosing the right audience for the intervention, if at all possible, an audience that has a need and hopefully has the motivation for change.

3. Find what prevents the target behavior: Once the appropriate behavior and audience to target is selected, it's time to move on to Step 3. In this step we must determine what is preventing the audience from performing the target behavior. The answers to such questions always fall into some combination of the following three categories:

   I. lack of motivation

   II. lack of ability

   III. lack of a well-timed trigger to perform the behavior

4. Choose a familiar technology channel: Once it is identified what is preventing people from adopting the target behavior, we can move on to Step 4: choosing the best channel for the technology intervention. Which channel is "best" usually depends on three factors:

   I. the target behavior

   II. the audience

   III. what is preventing the audience from adopting the behavior— i.e., the first three steps in the design process.

5. Find relevant examples of persuasive technology: In Step 5 of the design process, we should search for examples of successful persuasive technologies that are relevant to the intervention.

6. Imitate successful examples: The next step in the persuasive design process is to imitate what's working in the successful examples gathered in Step 5.

7. Test and iterate quickly: After we have found ways to imitate successful examples of persuasive technology, the next step is to test various persuasive experiences quickly and repeatedly. A series of small, rapid tests will teach more than one big test. Each test should take only a few hours, start to finish. These are not scientific experiments but quick trials that allow us to prototype the experience and see how people react. We should assess the response, ideally by measuring behavior.

8. Expand on success: Creating a persuasive technology that changes a behavior, no matter how small or simple, is a milestone. In Step 8, we can expand on this success. Now is the time to scale up.

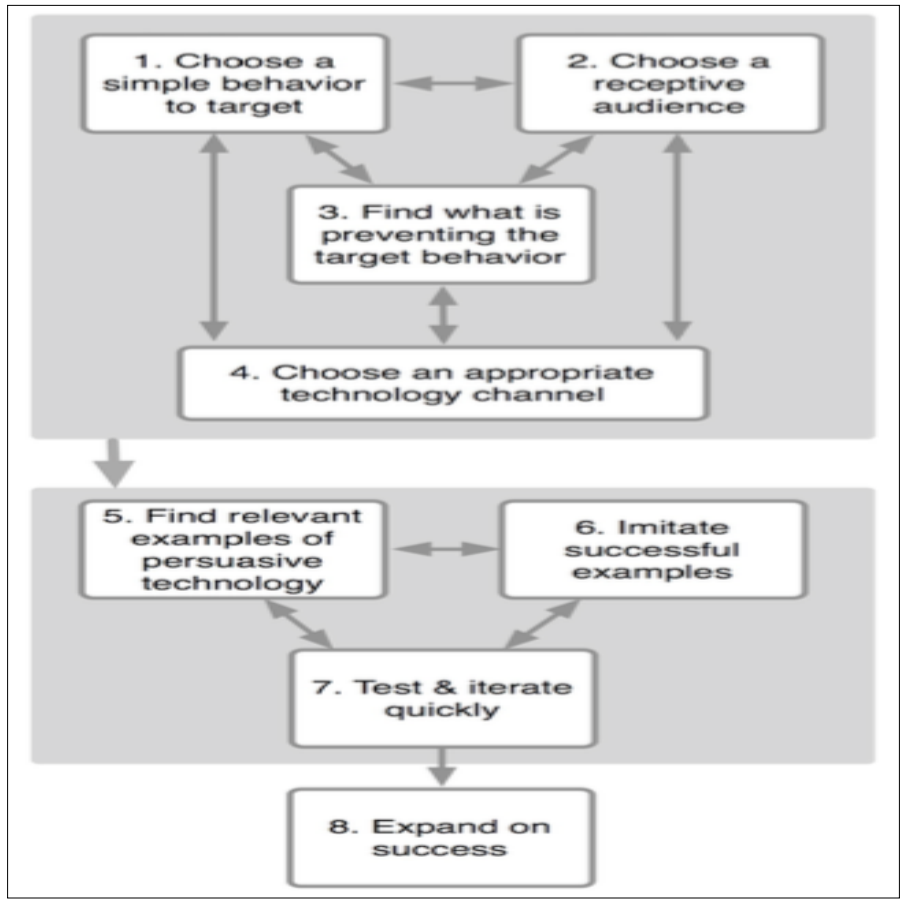


Figure 2: Eight Steps in Early Stage Persuasive Design (Source: B.J. Fogg Paper [14])

It is also important to understand what causes a person to change his behavior, and B.J. Fogg's "Behavior Change Model" [15] can provide deep insight in this regard.

The Model, B=MAT has fundamentally changed how people approached and designed Persuasive Technology interventions. He argued that three elements must converge at the same moment for a behavior to occur: Motivation, Ability, and Trigger. When a behavior does not occur, at least one of those three elements is missing.

1. Motivation – three core motivators with two sides exists
    I. Sensation – pleasure/pain
    II. Anticipation – hope/fear
    III. Social cohesion – acceptance/rejection
2. Ability – make behavior simpler to do
3. Triggers – we are surrounded by triggers (cue, prompt, call to action, request)

Figure 3 illustrates the model

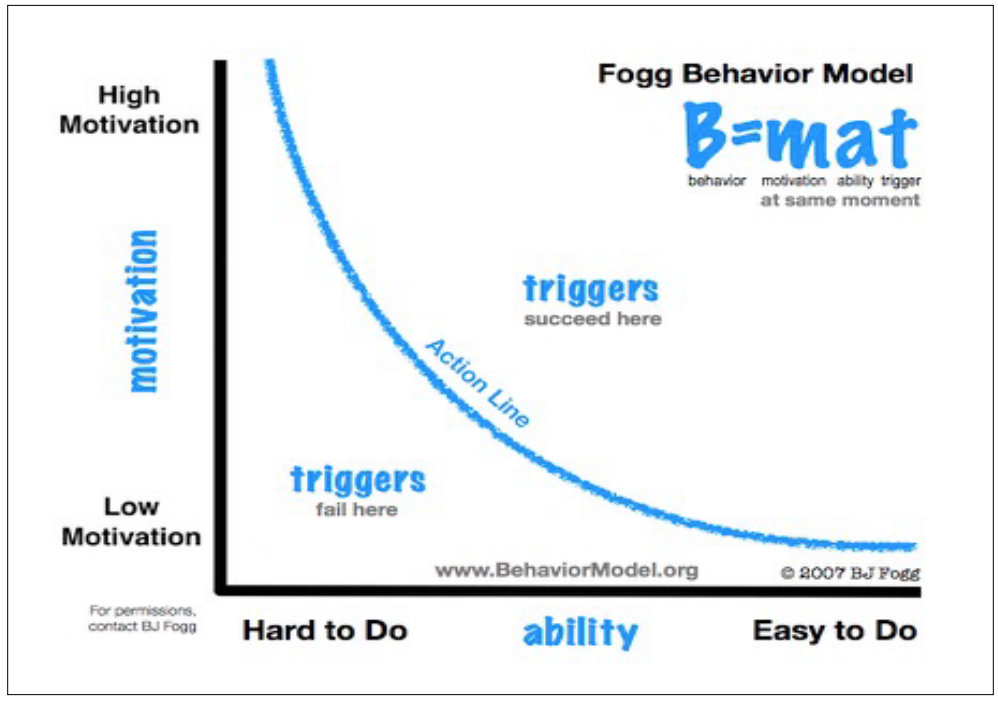


Figure 3: Behavior Change Model (source www.behaviormodel.org [15])

Nir Eyal in an article on Chatbots Magazine, titled "Bots and A.I. In Behavioral Concept" [65] says, triggers and habits are psychological concepts that must be understood first. Triggers for the users can be loneliness, eagerness, satisfaction, uncertainty, or curiosity. Also habits comes from the repeating actions from the mental experiences. "It's about the feelings in the end", says Nir. Therefore, bot makers or A.I. system designers should think where the feelings should be put into the system and extract data from the people's behaviors. Observation and empathy are the most needed skills for designing the system of the bot, basically.

A Conversational Agent - DIL

A conversational agent is a software program which interprets and responds to statements made by users in ordinary natural language. It integrates computational linguistics techniques with communication over the internet. The term Conversational Agent is primarily used in an academic context by scientists and engineers working on these systems to ensure satisfactory and relevant interaction with the user. They focus on developing interactive embodied conversational agents (ECA) and improving verbal and nonverbal human-computer interaction [58]. A conversational agent (CA) can also be considered a dialogue system. It is in essence a computer system intended to converse with a human with a coherent structure. Dialogue systems have employed text, speech, graphics, haptics, gestures, and other modes for communication on both the input and output channel [59].

The idea of a Conversational Agent based intervention for chronic disease management is not new. Research has shown large success in achieving behavioral change with this kind of approach. Chatbots also represent opportunities for positive social impact. Chatbots can make needed services more accessible, available, and affordable. They can strengthen users' autonomy, competence, and (possibly counter-intuitively) social relatedness [64]. Conversational agents can serve as powerful technological mediators to impact motivational outcomes such as self-efficacy and attitude change [24]. The Conversational Agent based intervention has been tried in a variety of settings from Alcohol consumption [25], promoting health behavior change in heart

attacks [26], psychosocial intervention deployed on hand-held computers [27], hospital discharge nurse that explains written hospital discharge instructions to patients with low health literacy [23], psychotherapy [28], and as health dialog systems [29]. Ferguson et. al. proposed CARDIAC: An Intelligent Conversational Assistant for Chronic Heart Failure Patient Heath Monitoring, that can conduct regular “checkup” interviews with patients to collect information relevant to their condition [39]. Lisetti et. al. proposed an architecture for building an On-Demand Avatar-Based Health Intervention for Behavior Change [34].

Behavior change is a multi-step process. It begins with raising awareness by inspiring the curiosity, engaging the interest, and identifying the motivations of a target audience [63] . Through nudges like timed reminders, prompts, and challenges, chatbots can potentially inspire patients to adopt a more positive outlook towards and behavior.

Preliminary Results of a Randomized Controlled Trial on Childhood Obesity using a Text-based Healthcare Chatbot (THCB) [66] with 15 patients indicate promising results with respect to intervention adherence (13.000 conversational turns over the course of 4 months or 8 per day and patient), scalability of the THCB approach (99.5% of all conversational turns were THCB-driven) and over-average scores on perceived enjoyment and attachment bond between patient and THCB.

According to a survey of 100 practicing physicians all across the United States [60], many physicians believed in both costs and benefits associated with chatbots, depending on the logistics and specific roles of the technology. Chatbots may have a beneficial role to play in health care to support, motivate, and coach patients as well as for streamlining organizational tasks; in essence, chatbots could become a surrogate for non-medical caregivers. However, a lot of skepticism remain among the physicians on the efficacy of using Chatbots in self care management. Based on the findings of the survey results [60], many physicians believed that chatbots cannot effectively care for all of the patients’ needs (76%, 76/100), cannot display human emotion (72%, 72/100), and cannot provide detailed diagnosis and treatment because of not knowing all of the personal factors associated with the patient (71%, 71/100). Many physicians also stated that health care chatbots could be a risk to patients if they self-diagnose too often (74%, 74/100) and do not accurately understand the diagnoses (74%, 74/100) [60].

Previous studies and literature especially in chronic disease management have clearly outlined a tremendous need for technological interventions especially in the areas of self care and self management of chronic diseases to ease the caregiver burden since human support cannot scale with the growing population living with CVDs. A recent study showed ninety million Americans have inadequate health literacy, resulting in a reduced ability to read and follow directions in the healthcare environment [23]. A large section of these patients fall through the crack, cannot follow through the behavioral guidelines as prescribed because of a lack of understanding, education, social isolation, or simply motivation to do better, and resource constraints of the hospitals and clinics. It is this gap that a Conversational Agent can address.

In this research, the researcher takes inspiration and ideas from the work in various fields as mentioned above and in subsequent sections, and design and implement DIL – a Conversational Agent, in the specific domain of Heart Failure Patients to address the problems and issues discussed above. In particular, this is an agent that works in conjunction with the 'Home Monitoring' system [32]. DIL would review Home monitoring dashboard results, and have conversations with patients. Techniques like Motivational Interviewing (MI) to persuade patients to adhere to clinical guidelines and better behavioral outcomes by using a combination of persuasive messages and pictures, inspirational videos, and healthcare articles.

2.2 THEORETICAL UNDERPINNINGS

Consolvo et. al. [17] used concepts from behavioral and social psychological theories to shape an understanding of how to design technology to support behavior change while supporting fundamental social needs. In this paper, four distinct theories provide inspiration and form the foundation for designing technologies that motivate behavior change in everyday life. The four theories are:

1. Reinforcement Theory [18,19]
2. Social Cognitive Theory [36, 37, 38]
3. Adherence and Health Outcomes: How much does Adherence Matter [20]
4. Cognitive Dissonance Theory [22]

REINFORCEMENT THEORY

Reinforcement theory [18] of motivation was proposed by BF Skinner and his associates. It states that individual's behavior is a function of its consequences. It is based on "law of effect", i.e, individual's behavior with positive consequences tends to be repeated, but individual's behavior with negative consequences tends not to be repeated.

Reinforcement theory of motivation overlooks the internal state of individual, i.e., the inner feelings and drives of individuals are ignored by Skinner. This theory focuses totally on what happens to an individual when he takes some action. Thus, according to Skinner, the external environment of the organization must be designed effectively and positively so as to motivate the employee. This theory is a strong tool for analyzing controlling mechanism for individual's behavior. However, it does not focus on the causes of individual's behavior.

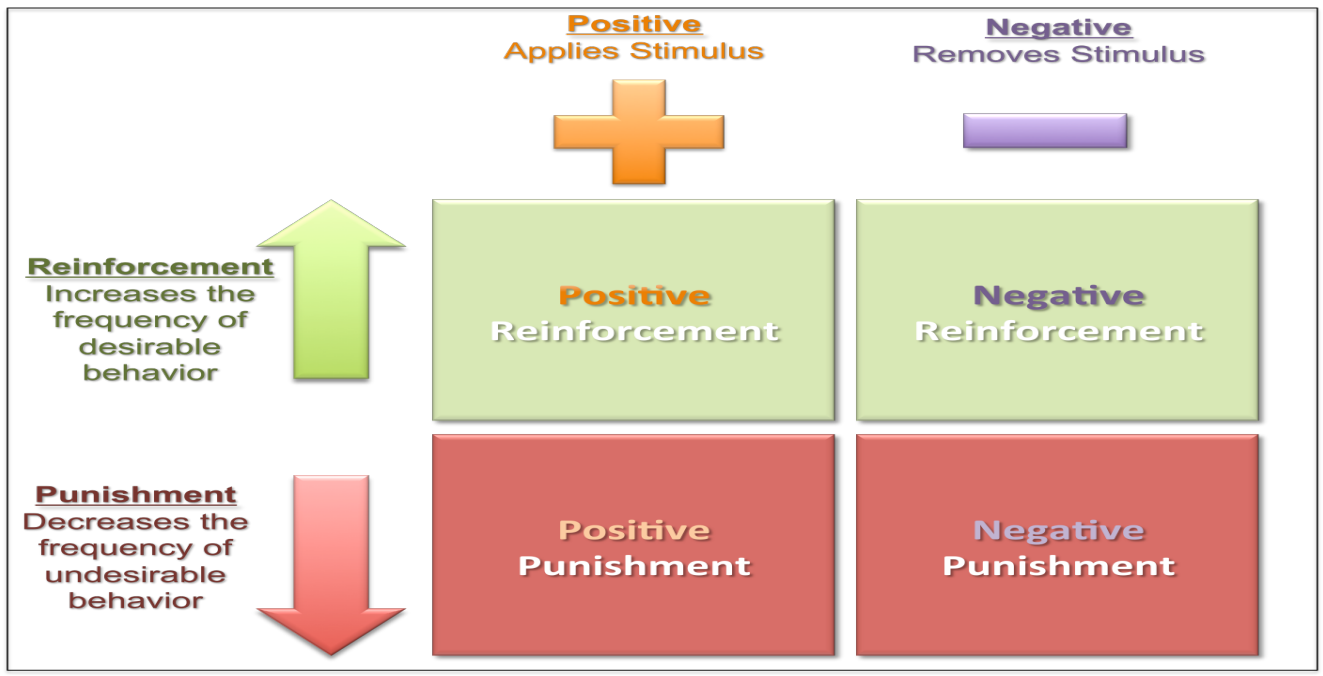


Figure 4: Reinforcement Theory - Operant Conditioning, (Source -B.F. Skinner [18])

Social Cognitive Theory

Social cognitive theory (SCT) refers to a psychological model of behavior that emerged primarily from the work of Albert Bandura [36, 37]. Initially developed with an emphasis on the acquisition of social behaviors, SCT continues to emphasize that learning occurs in a social context and that much of what is learned is gained through observation.

SCT rests on several basic assumptions about learning and behavior. One assumption concerns triadic reciprocality, or the view that personal, behavioral, and environmental factors influence one another in a bidirectional, reciprocal fashion. That is, a person's ongoing functioning is a product of a continuous interaction between cognitive, behavioral, and contextual factors. For instance, classroom learning is shaped by factors within the academic environment, especially the reinforcements experienced by oneself and by others. At the same time, learning is affected by students' own thoughts and self-beliefs and their interpretation of the classroom context.

A closely related assumption within SCT is that people have an agency or ability to influence their own behavior and the environment in a purposeful, goal-directed fashion [38]. This belief conflicts with earlier forms of behaviorism that advocated a more rigorous form of environmental determinism. SCT does not deny the importance of the environment in determining behavior, but it does argue that people can also, through forethought, self-reflection, and self-regulatory processes, exert substantial influence over their own outcomes and the environment more broadly.

A third assumption within SCT is that learning can occur without an immediate change in behavior or more broadly that learning and the demonstration of what has been learned are distinct processes. One reason for this separation is that SCT also assumes that learning involves not just the acquisition of new behaviors, but also of knowledge, cognitive skills, concepts, abstract rules, values, and other cognitive constructs. This division of learning and behavior is a shift from the position advocated by behavioral

theories that defined learning stridently as a change in the form or frequency of behavior. It also means that students can learn but not demonstrate that learning until motivated to do so.

Adherence and Health Outcomes: How much does Adherence Matter?

Patient adherence (also known as patient compliance) involves the degree to which patients follow their medical provider's recommendations for varied health regimens, including taking medications, making changes to diet, exercising, attending follow-up appointments, completing screenings, and attending to a host of lifestyle changes and treatment activities. Rates of non-adherence vary widely across diseases conditions and treatment requirements, but on average, at least a quarter of patients are non-adherent [44].

The relationship between patient adherence and treatment outcomes is critically important to examine in a range of disease realms, where the requirements of adherence and the potential for its benefit vary widely. Studies of Heart disease and myocardial infarction (MI), for example point to a strong relationship between adherence and mortality risk. Specifically, patients whose adherence to the medication clofibrate was at least 80% had a lower risk of death over ensuing 5 years [20].

Medication non-adherence among heart transplant patients has been found to predict adverse outcomes. This serious medical procedure requires complex follow-up care that can mean the difference between transplant success and failure. [20].

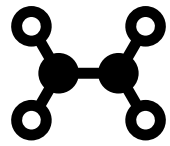
Factors leading to better adherence may include positive provider-patient interactions and communication and greater confidence in one's ability to adhere. As observed in many clinical cases, it is rational to predict that effective and positive provider-patient communication is associated with better adherence and ultimately with improved treatment outcomes.

Many quantitative reviews have been conducted to assess the relationship between adherence and health outcomes. One of the earliest reviews of this relationship included six studies and demonstrated that adherence was related to positive health outcomes in five out of six investigations [46]. A meta-analysis of the relationship between adherence and outcomes across diseases indicated that the odds of a good health outcome are 2.88 times higher if a person is adherent and that there is a 26% greater risk of poor health outcomes in the context of non-adherence [47]. Additional quantitative review has shown a relationship between adherence and the ultimate outcome, lower mortality risk. A meta-analysis of 21 studies of adherence to drug therapy showed significantly lower probability of death among good adherers than among those who were "poor" adherers [48].

Cognitive Dissonance Theory

Cognitive Dissonance Theory [22,17] explains what happens when an individual realizes that her attitudes and behaviors are inconsistent. When that happens, the individual will experience psychological discomfort (or dissonance). Because this dissonance is psychologically uncomfortable, the individual will be motivated to reduce or eliminate the dissonance. Her motivation depends on how important the beliefs or behaviors are to her. That is, the more important they are to the individual, the more likely she will try to reduce or eliminate the dissonance.

When an individual is motivated to reduce or eliminate dissonance, she can change her behavior or knowledge. She may also reduce the importance of the dissonance by actively learning about other things that are more harmful than whatever is causing the dissonance or by actively avoiding information or situations that may produce (or reinforce) the dissonance. Cognitive Dissonance Theory suggests that a persuasive technology to encourage lifestyle behavior change should address whichever factors may prevent the individual from incorporating the change into her everyday life (i.e., by helping her change her behavior to match her attitudes). For example, the technology should help the individual remain focused on her commitment to change and her relevant patterns of behavior. The awareness provided by the technology should be persistently available and easy to access, yet subtle enough so as to support occasional needs for information/situation avoidance.



CHAPTER 3: METHODOLOGY

3.1 GOALS, OBJECTIVES AND RESEARCH QUESTIONS

GOALS

As mentioned above, patients routinely fail to follow the guidelines given to them at the time of discharge, and despite best intentions, the nurses cannot follow up with every patient because of resource problems. So, the goal of this research is to explore:

1. The reasons why patients fail to adhere to clinical and behavioral guidelines.
2. If a Conversational Agent can alleviate the resource problem?

OBJECTIVES

The objectives of the proposed research is to design a Conversational Agent based health-worker that can chat multiple times a week and can perform the following:

1. Carry on a conversation with patients in an empathetic way.
2. Find out and document the reasons patients fail to adhere to clinical and behavioral guidelines.
3. Provide reminders to patients when they forget to perform their prescribed routine tasks.
4. Provide continuous encouragement and motivation to reach desired health goals by sticking to behavioral guidelines prescribed by the clinician.
5. Evaluate the efficacy and utility of such a Conversational Agent; specifically on the quality of life, which will be measured by using the "Minnesota Quality of Life" questionnaire (Appendix C).

RESEARCH QUESTIONS

The research questions that will guide this study can be broadly classified under three different areas of interest:

1. Human Computer Interaction:
    1. *Research Question 1*: How much engagement can DIL elicit? – The proposed system will track and measure the following:

I. How many times the patients responded to chat messages from DIL?

II. What was the typical duration of a chat session?

III. A post survey to get qualitative feedback from the patients.

2. Complimenting Human Nurses and Case Workers

I. *Research Question 2*: Can DIL be a persuasive communication tool? It will be extremely interesting to find out if the patients will be as receptive chatting with DIL as they will be talking with humans – The research will compare results from before and after the implementation of the proposed system, and measure improvements in compliance score, if any, to determine the effectiveness of the DIL as an effective tool for persuasion, and elicit compliance to clinical and behavioral guidelines.

II. *Research Question 3*: Can an Assistive Technology like DIL lower the Caregiver burden in scaling with a large population? – An exit-survey of the patients to determine the Perceived Helpfulness of DIL will be used to gauge how the users felt interacting with DIL

3.2 RESEARCH APPROACH

This study used a design science research approach to address the research questions. Hevner and Chatterjee (2010) [30], explain that the DSR approach is an iterative process that includes three cycles as follows:

1. Relevance Cycle is where the contextual environment of the research project impacts the design science activities.

2. Rigor Cycle is where the knowledge base of scientific foundations, experience, and expertise influence the design science activities.

3. Design Cycle is where building and evaluating the design artifacts happens. Starting from the application context, the relevance cycle starts when the research requirements (opportunity and problem) and the acceptance criteria for evaluation are identified. These requirements and criteria continuously changed as the artifact "DIL" was being built and evaluated.

Figure 5 [31] illustrates the three cycles:

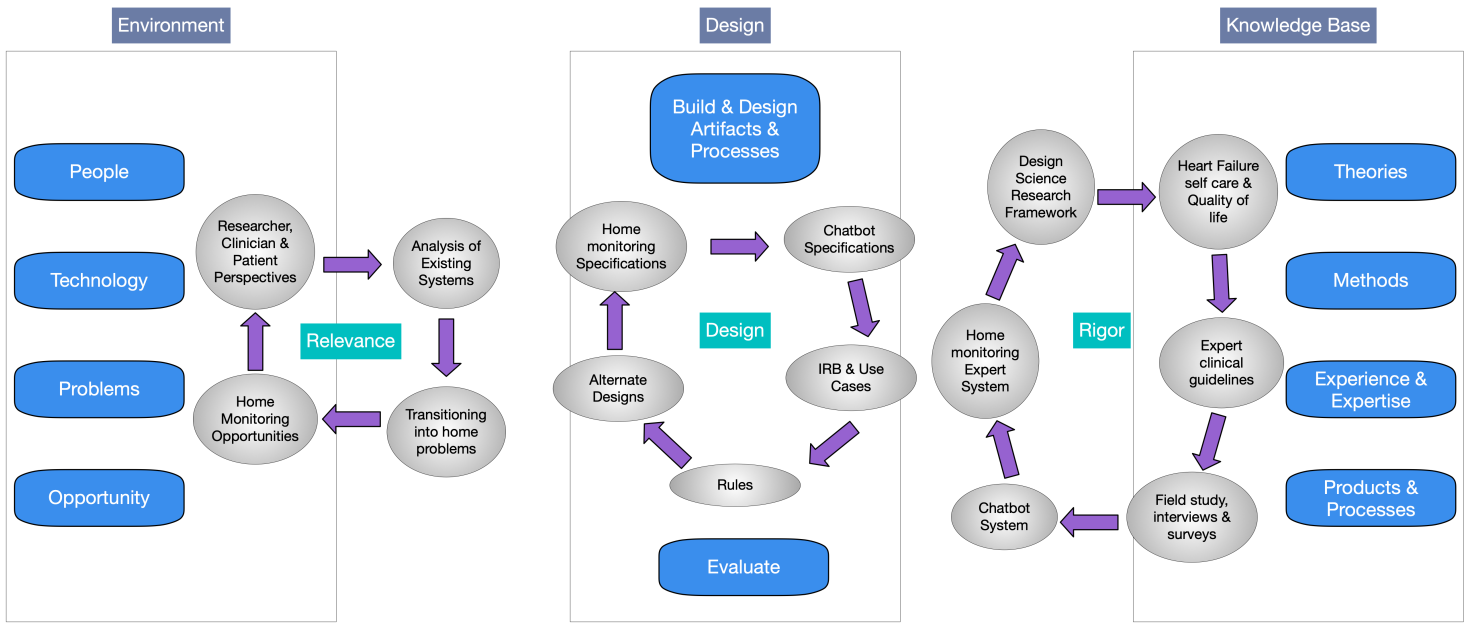


Figure 5: Design Science Research Framework (Source: [31])

The Design Science Research (DSR) Checklist proposed by Hevner and Chatterjee [30] was used to evaluate the research. The questions in Table 2 provide such a checklist that was used to assess progress, and to ensure that the research addressed the key aspects of design science research.

Table 2: DSR Checklist

#	Questions	Answers
1	What is the Research Question (design requirements)?	Stated on Page 25 & 26.
2	What is the Artifact? How is the artifact represented?	A DIL/Conversational Agent – Page 19-21 and 28-34
3	What Design Processes (search heuristics) will be used to build the artifact?	Design and Build – Pages 28-34
4	How are the Artifact and the Design Processes grounded by the knowledge base? What, if any, theories support the artifact design and the design process?	Theoretical Underpinnings – Pages 21-24
5	What Evaluations are performed during the internal design cycles? What design improvements are identified during each design cycle?	Evaluations – Pages 39-59
6	How is the Artifact introduced into the application environment and how is it Field Tested? What Metrics are used to demonstrate artifact utility and improvement over previous artifacts?	Evaluations – Pages 39-59
7	What new Knowledge is added to the knowledge base and in what form (e.g. peer- reviewed literature, meta-artifacts, new theory, new method)?	Conclusions for Research Questions, Practice Implications, Future Research - Pages 61-68
8	Has the Research Question been satisfactorily addressed?	Conclusions for Research Questions - Pages 61-64

Table 2: DSR Checklist

To demonstrate the relationship of these questions with the three research cycles discussed in the previous section, Figure 6 [30] maps the eight questions to the appropriate research cycle.

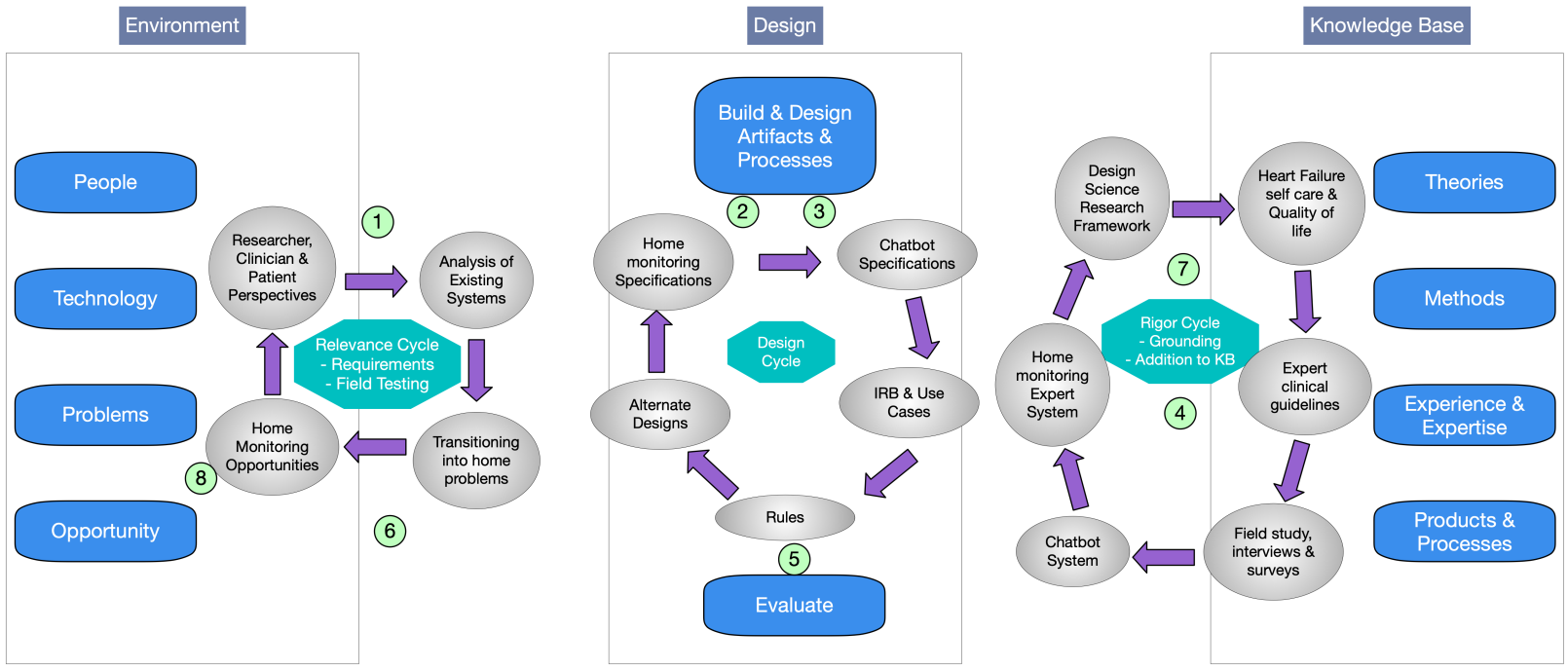


Figure 6 - DSR Checklist mapped to DSR Cycles

DESIGN & BUILD

The Design Artifact, DIL is designed to specifically target Heart Failure patients. It builds on the "MyHeart" system, a collaboration between the IDEA Lab at CGU, and Loma Linda University Hospital.

The MyHeart Home Monitoring system [32] was geared towards Home Monitoring to promote self-care adherence. Every CHF patient participating in trial when discharged from Loma Linda Hospital were given a set of instructions that may include specific guidelines on diet, exercise and medications, as they transition from Hospital care to Home care. The Home monitoring system deployed a set of tools and took advantage of an Expert System that monitored remotely the patients adherence to the prescribed instructions. This tele-monitoring system captured various vital data, and updated on a patient dashboard that was then used by the hospital staff, clinicians and nurses to follow up on the progress of these discharged patients.

DIL employs this MyHeart system to collect patient health data on a regular basis. The patients were all given a set of home-monitoring devices like a Bluetooth enabled weigh scale and a blood pressure monitor. The conversational agent DIL will then evaluate the dashboard of patient health data, and use that data for conversation with patients.

Figure 7 shows the Home-Monitoring Dashboard:

Patient Information

Patient	Age	Gender	Weight	Systolic	Diastolic	BG	HR	Chest Pain	SOB at Night	Short Breath	Feet Swollen	Fatigue	Risk
	56	M	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Low
	61	F	145.80	102	74	Missing	46	0	No	0	0	0	High
	56	F	144.20	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Missing	Low
	71	M	187.40	105	67	142	72	0	No	3	3	2	High
	62	M	Missing	95	58	Missing	68	Missing	Missing	Missing	Missing	Missing	Medium
	79	F	Missing	Missing	Missing	334	Missing	Missing	Missing	Missing	Missing	Missing	High
	57	M	292.20	114	76	227	72	0	No	0	0	2	High
	50	M	167.40	98	74	0	92	0	No	0	0	0	High

Figure 7: Home Monitoring Dashboard

A review of this dashboard data shows that a majority of the patients fail to live up to the required guidelines for a variety of factors outlined in the Problem Statement section. The hospital staff want to know the reasons for non-adherence, but struggle to routinely follow up with these large group of patients, for a number of reasons, more specifically lack of resources and money. It is this gap, that DIL hope to fill.

Figure 8 demonstrates DIL Conversation and Process Flow:

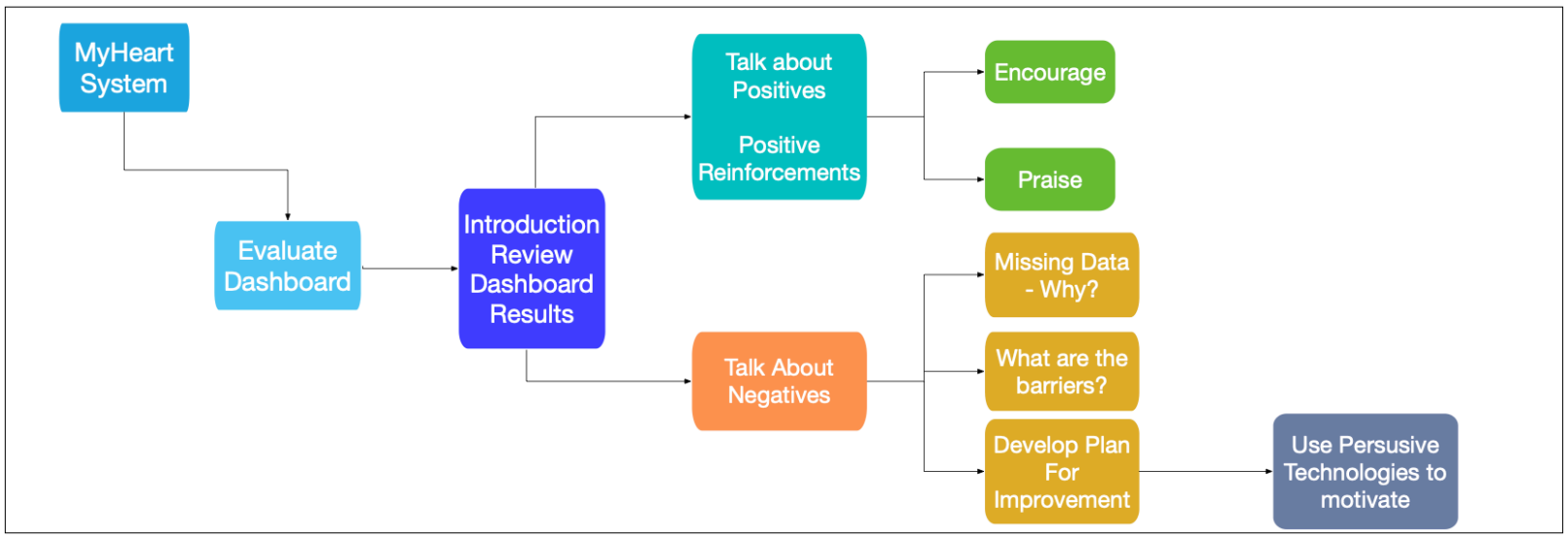


Figure 8: DIL Conversation and Process Flow

A conversation between DIL and the patients happens multiple times a week. DIL has the intelligence to carry on a conversation that is tailored to each patient's specific needs. A typical conversation starts with a "Welcome" message and a review of the Dashboard results. The conversation will then transition to the positive aspects of the dashboard results, congratulate the patient on a job well done with positive reinforcements. The next step will be to review the negatives, find out why the patient is unable

to fulfill the requirements, and enquire about the barriers. At every step, lessons learned from previous research on Persuasive Technology, and Conversational Agents were used to motivate the patient to do better, and achieve the desired outcome of full compliance to the prescribed instructions at the time of discharge.

Here are some screenshots that show a typical Patient - DIL conversation:

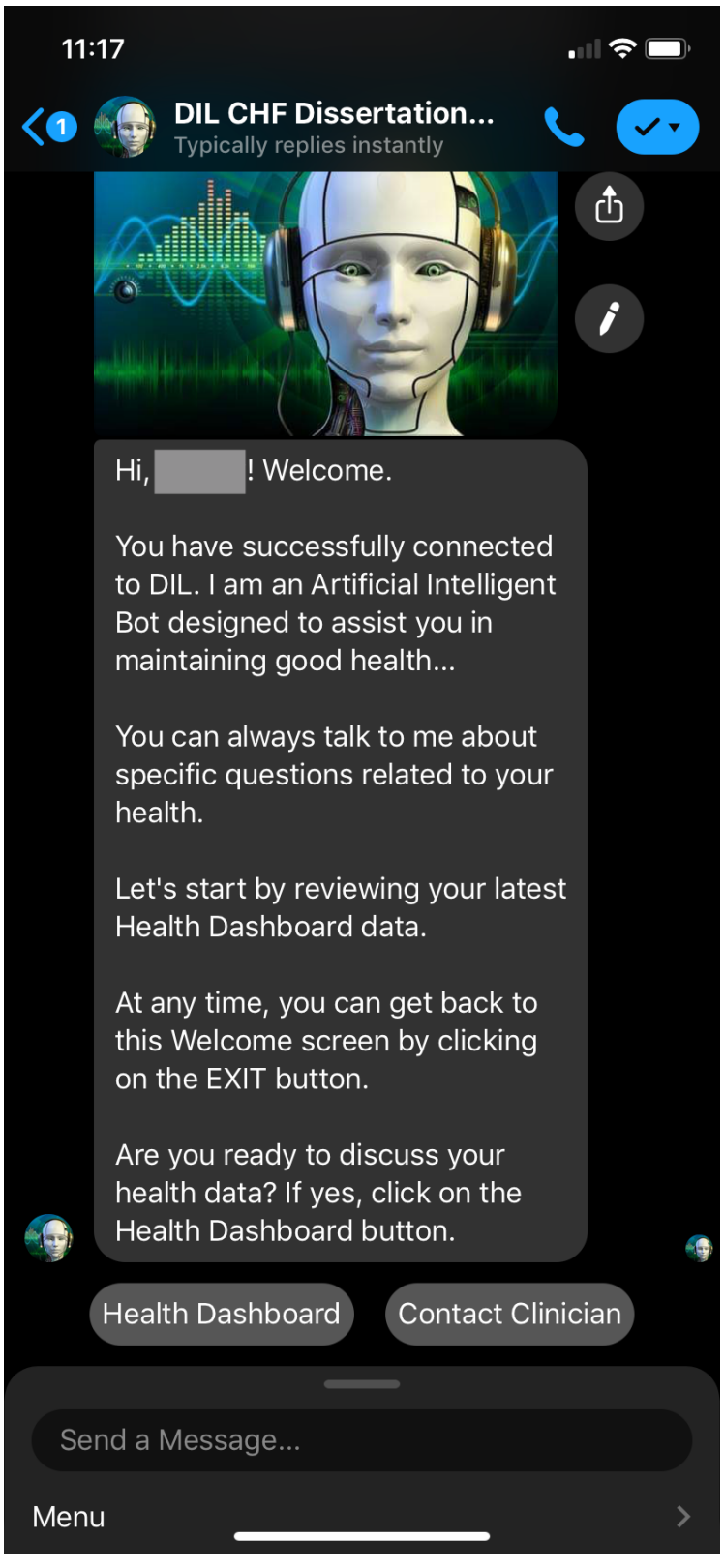


Figure 9: DIL Welcome Screen

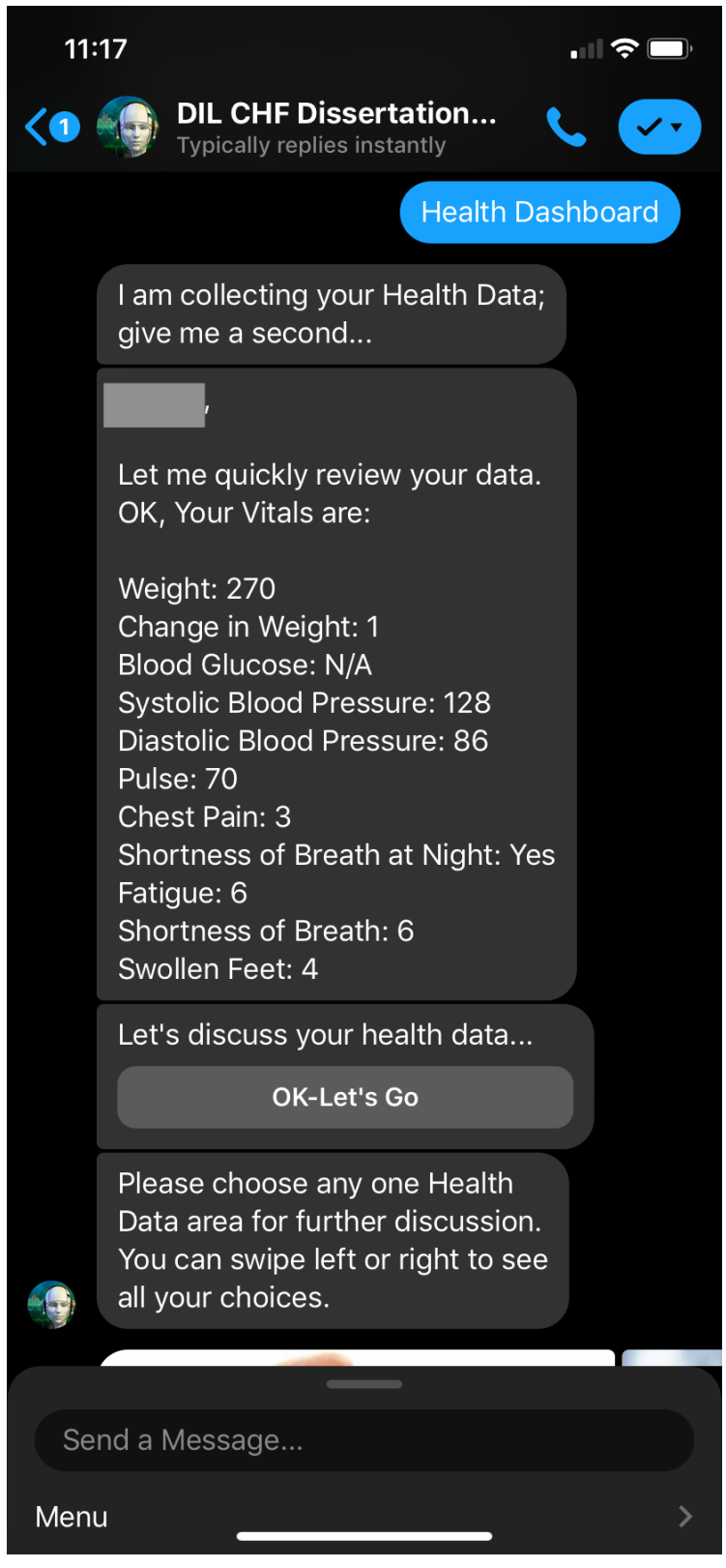


Figure 10: DIL Review Dashboard Data

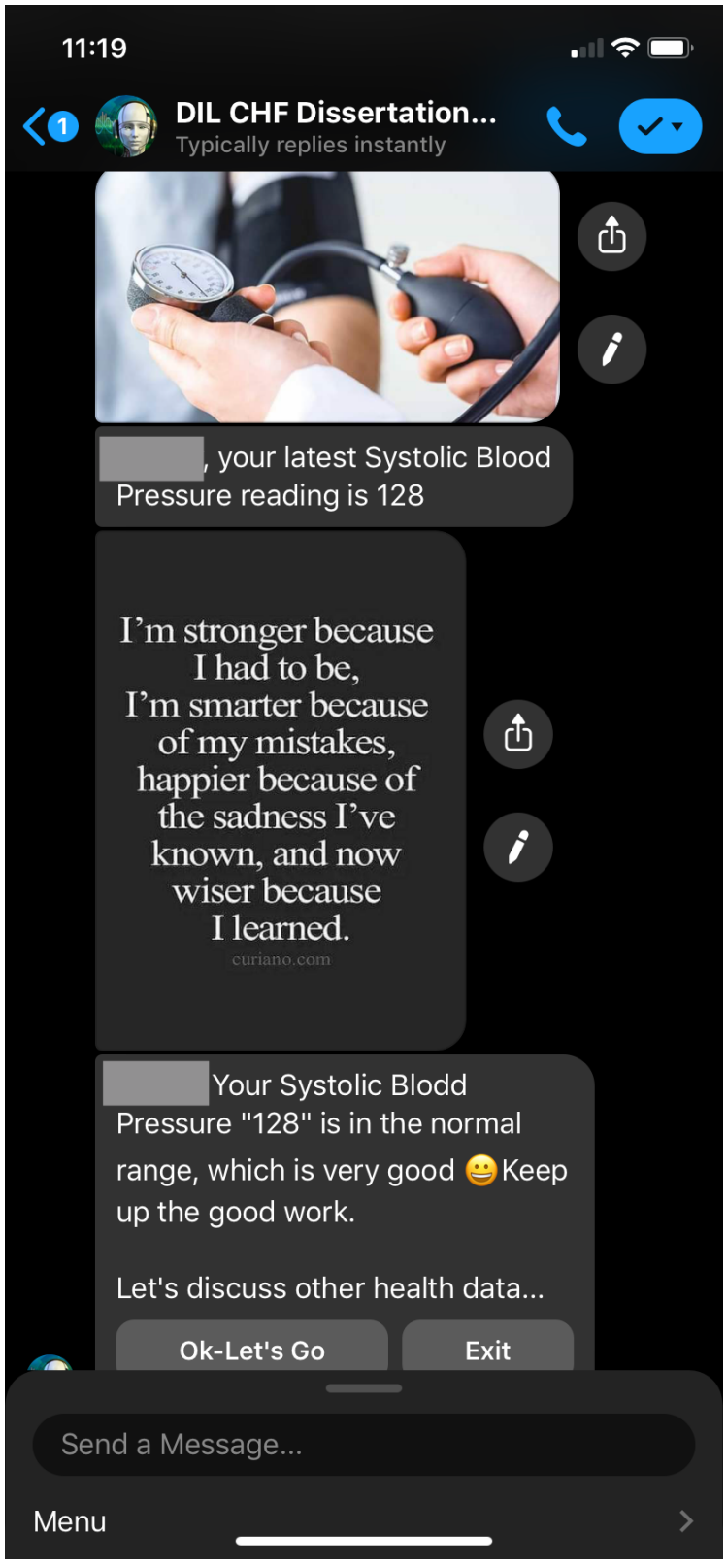


Figure 11: Discuss Systolic BP

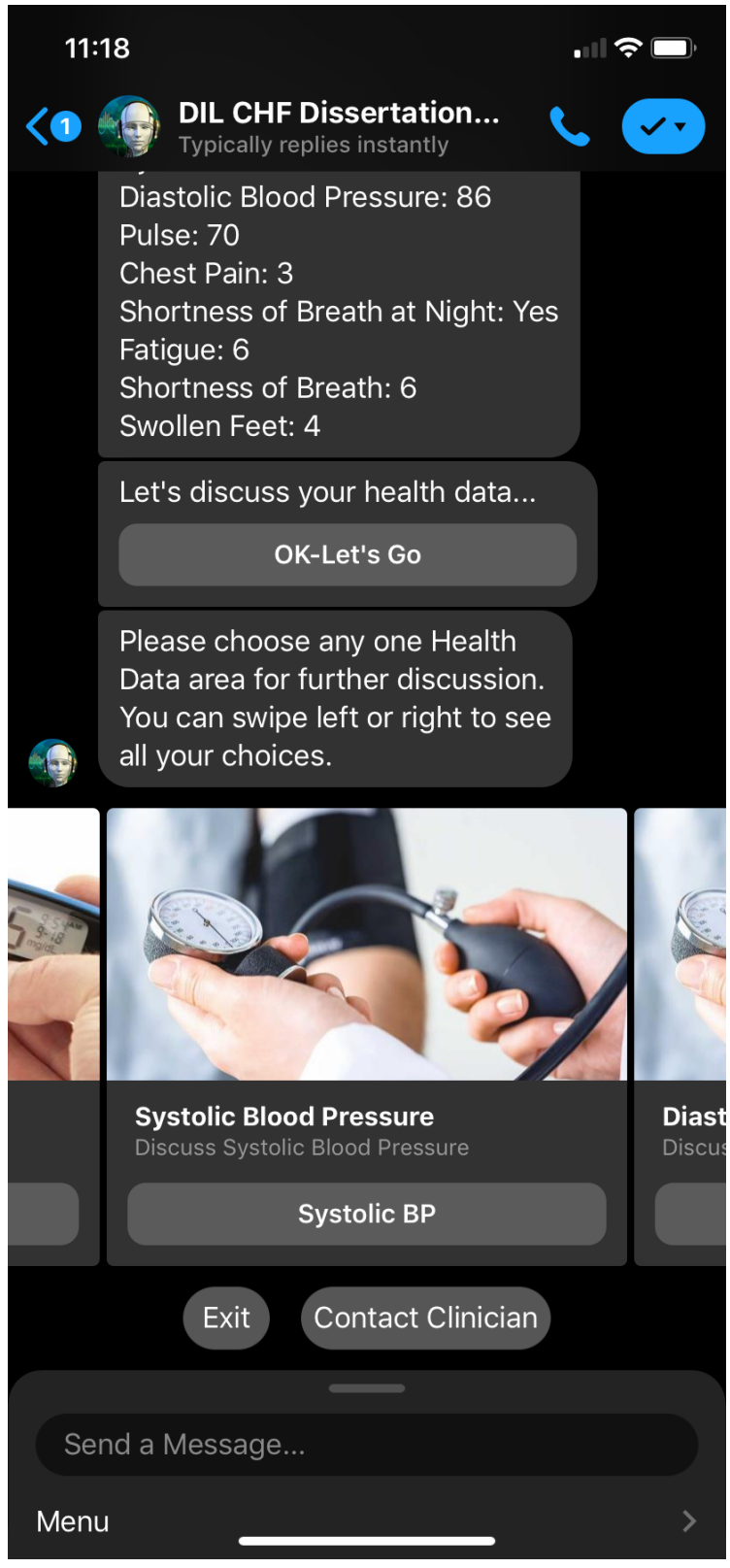


Figure 12: DIL Review Systolic BP Data

The conversation goes on from there. Of course, the conversation can also branch out to other areas based on the user's responses. For example if the patient was out of medications, and that was the reason for not taking the prescribed drugs, it will be a very different conversation.

The conversations are recorded for further review by a nurse and clinician for two main reasons:

1. To remove any errors in interpretation by the system.
2. To improve the system's future conversational capabilities.

The Researcher foresees DIL taking on more responsibilities with advancement of technology. A future enhancement can potentially be to mimic the Provider for Patients at different risk levels, and ask natural questions that a trained provider - a nurse or a doctor might ask.

System Architecture

This research is problem-solving in essence, being as it is about designing and building an ICT-based intervention to help solve the self-care needs of patients.

DIL is not envisioned to replace a human intervention, but rather to complement any human intervention. It is one extra tool to address the limited resource problem that is very apparent in current scenario.

The real-world design of DIL incorporates a combined strategy design that starts with a flexible design and uses exploratory interviews and empirical data to understand the processes and people and is followed by a fixed design phase that incorporates a focused experiment [33].

First, it defines the problem, giving due consideration to barriers to self-management and the burden of Heart failure on patients, their families, and society at large. It then demonstrates, through a review of behavioral science theories relevant to the problem of motivating sustained Heart Failure self-management activities as well as existing IS research in the problem domain, the inadequacy of existing solutions to the problem. Thereafter, it develops and presents a purposeful IT artifact that adequately addresses the knowledge gap and solves the problem. The artifact is then evaluated through an experimental study. Finally the significance, contributions, and implications of the study to IS research as well as to the problem environment and the society at large are communicated through a dissertation report.

Like all Design Science projects, the design and development of DIL also went through multiple iterations, trials and errors. At the inception stage, the idea was to have a voice enabled bot with Artificial intelligence. Technologies like Nuance Mix were

explored for Text-to-Speech and Speech-to-Text conversions using Mix.nlu for natural language understanding and processing. Although the Nuance platform has big advantages like cross-platform support and support for multiple languages, development on the platform has a significant learning curve. A prototype was developed and discarded as the bot never functioned as desired; there were many issues with text-to-speech and speech-to-text conversions that needed further research and knowledge of the platform to solve. It was often the case that the bot did not understand human utterances, and needed further training.

The researcher also explored the Azure Bot services; Microsoft has excellent documentation and tutorial videos to help developers create intelligent bots using LUIS (Language Understanding Intelligent Services) framework. Azure Bot service also has support for multiple channels where the bot can be deployed. The prototype developed used Skype to communicate with users. The system showed much promise, but still had room for improvement especially with understanding voice resulting in errors in Speech-to-text conversions. At the time Azure Bot Services were not free, and the investment required in terms of money and time to master and develop a sophisticated bot was beyond the scope of a Dissertation project.

After investing about nine months trying to develop a functional voice-enabled bot that never livd up to expectations, the researcher went back to the drawing board, and decided to simplify the project and limit its scope by making it a chatbot. According to Nir Eyal in an article in Chatbots Magazine titled, "Bots and A.I. In Behavioral Concept with Nir Eyal", ”Of all the ways humans communicate, texting might be the most direct. Text carries less superfluous information than other ways of sending information. With text, there are no voice intonations to decipher or accents to understand, no facial gestures to interpret, and no body language to translate. Text is something computers can understand and process quickly and it’s why messaging is a great place for humans and A.I. to work together to serve customer needs.” [65].

The researcher still plans to have a voice enabled bot as a future version of the current project that can be taken up after the dissertation is complete. The current iteration of DIL had three primary design objectives:

- It must be easy to use
- It can be deployed in the shortest time possible
- It must be easily deployable on a platform that most users are familiar with.

With these design objectives in mind, the researcher finally chose the Chatfuel development platform, and Facebook Messenger as the deployment platform. Chatfuel is the world's leading chatbot platform for Facebook Messenger; the development environment is mostly drag and drop building blocks that can be build and deployed in really quick time. With more than 2.4 billion active monthly users, Facebook and Facebook Messenger is widely popular and most users are extremely familiar with the platform. This minimizes the learning curve for the users to use such a system. Facebook Messenger also has cross-platform support - it works seamlessly on both iOS and Android based mobile phones and on desktop. Chatfuel offers basic artificial

intelligence support, but keeping future needs and visions for the system in mind, provisions were made for Natural Language Processing (NLP) and Artificial Intelligence (AI) module by integrating with Google's AI.API.

So, DIL is in essence a "Chat-Bot" system, that uses the Facebook Messenger platform to communicate with the patient. The fundamental architecture of DIL draws inspiration from [34, 39], and uses Motivational Interviewing (MI) [35].

Figure 13 shows the System architecture:

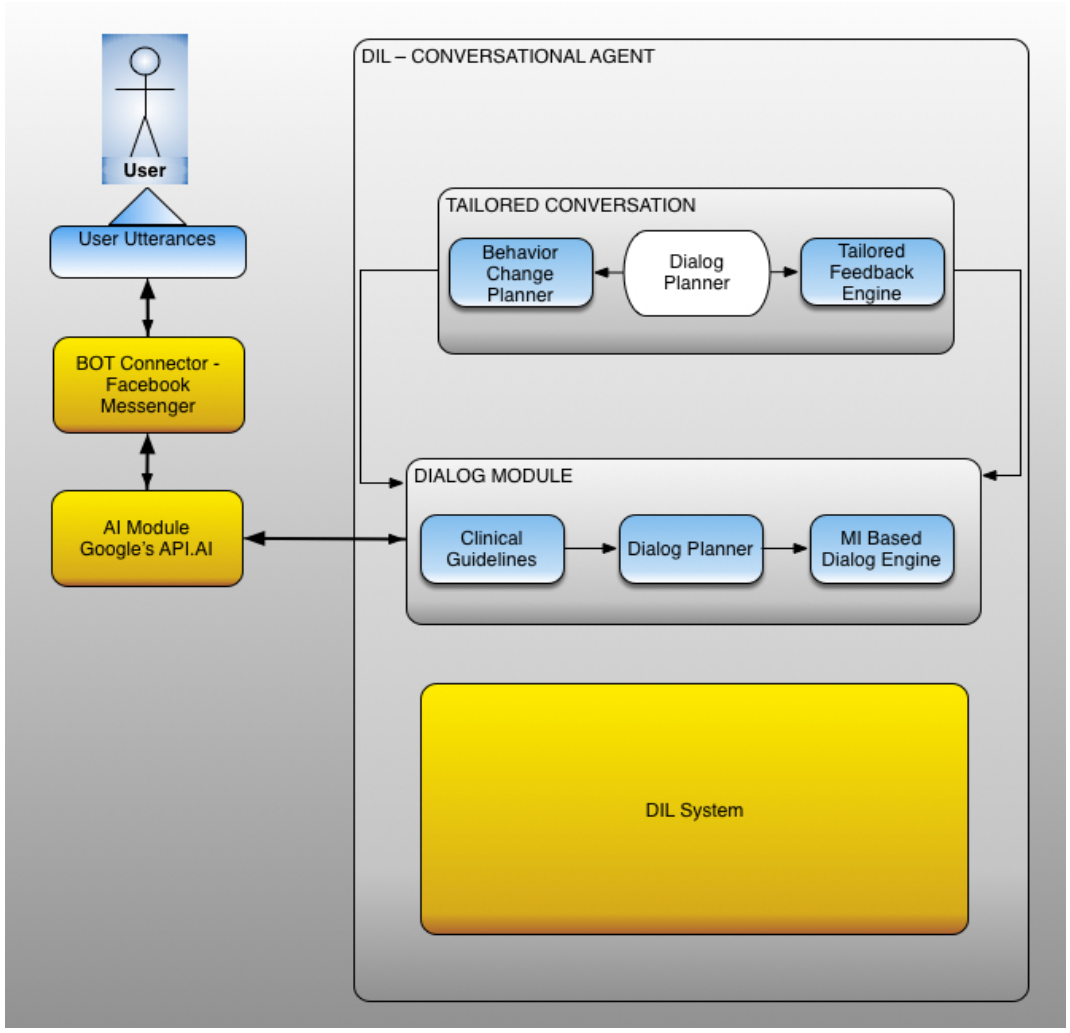


Figure 13: DIL System Architecture

As mentioned in previous sections, DIL uses the Home monitoring dashboard and the MyHeart system as a starting point, and builds on it. All patients were given a set of home monitoring devices to measure health data like a blue-tooth enabled weight scale and a blood pressure monitor. The patients were also given a Android based tablet with the MyHeart app installed. A unique profile was created for every patient. The MyHeart app would collect the data whenever the patients measured weight, blood pressure and pulse rate. The users also answered some symptomatic questions like sleep and restlessness, fatigue and tiredness, shortness of breath, swollen ankles etc. - symptoms that could be critical indicators that something was nice. These health data were uploaded to patient health dashboard (Figure 7). DIL reviews this dashboard data to initiate conversations with patients (figure 8). DIL uses the MyHeart rule based Expert System [32] to determine patient's risk profile, and customizes the conversation using MI [35] and other persuasive techniques like motivational messages, photos, videos and healthcare articles. The ultimate goal is to provide positive reinforcements for patients who are doing well, and motivate people who are not doing so

well to do better, and hopefully achieve that by promoting behavior change like controlling diet, exercising daily, and taking medications on a timely manner.

3.3 RESEARCH DESIGN

In this study, the researcher conducted an investigation to test the null hypothesis that there is no difference in health and behavioral outcomes due to intervention of a Conversational Agent based IT artifact like DIL.

Participants in the trial were all heart-failure patients at various stages of recovery. They were monitored for two weeks prior to DIL's intervention. These patients all used the Home Monitoring system [32]. They used the MyHeart [32] application in conjunction with bluetooth enabled self monitoring devices like a weight scale, a blood pressure monitor and uploaded the data using a tablet to a health dashboard (figure 7). The patients all answered 21 questions of the "Minnesota Living With Heart Failure" questionnaire (see Appendix C) at the beginning of the trial to gauge an understanding of the quality of life.

Figure 14 shows a typical Home monitoring setup.

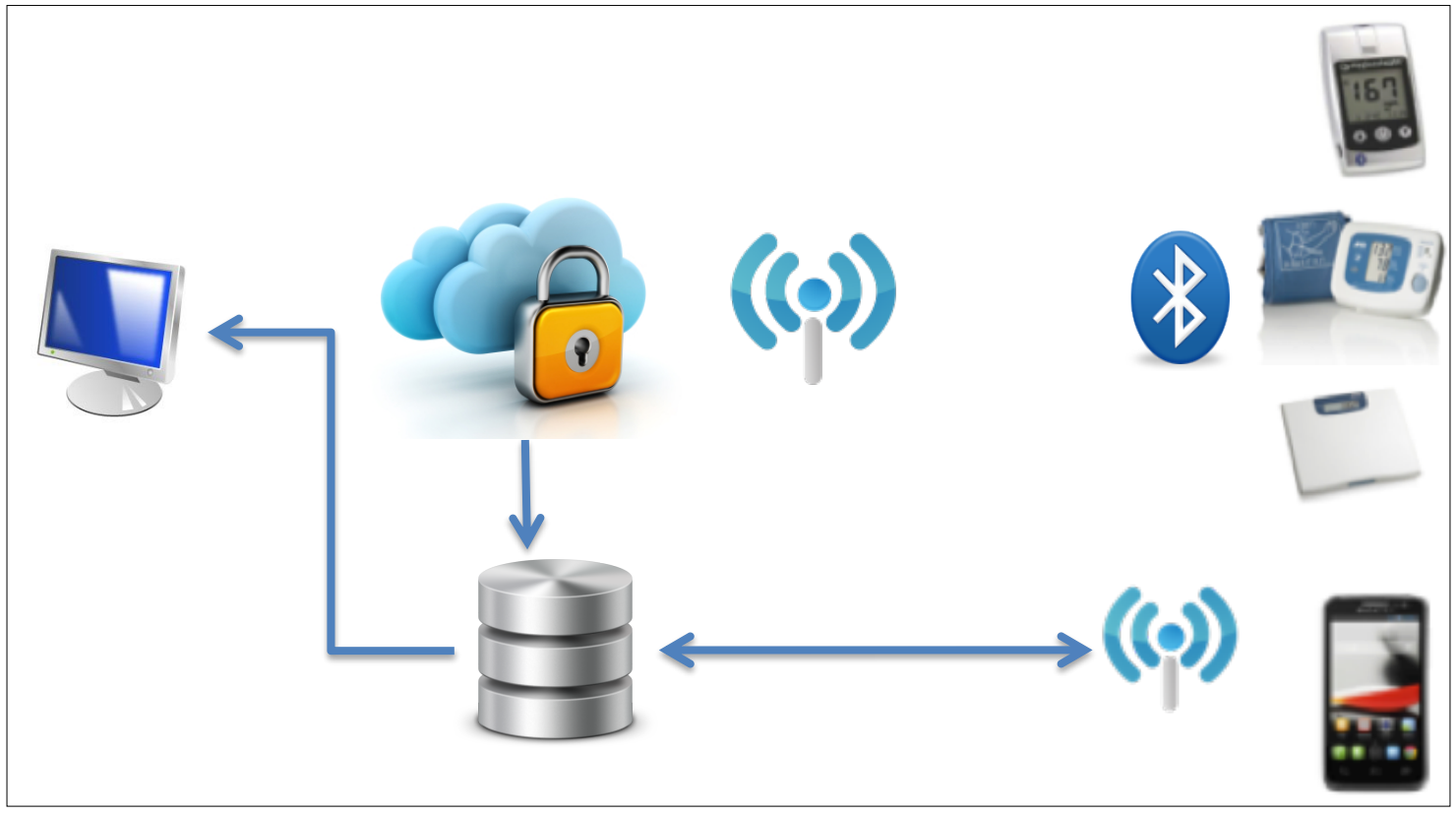


Figure 14 - Home Monitoring setup [32]

DIL intervened at the end of two weeks, and conversed with patients multiple times a week for the next 4 weeks. During this time the patients continued to use the Home Monitoring system, measured and uploaded their health data to the Health dashboard.

At the end of the trial, the Patients once again answered the "Minnesota Living with Heart Failure" questionnaire (Appendix C). They also participated in two surveys - a "DIL User Satisfaction & System Usability" survey (Appendix A) and a second survey

on the "Perceived Helpfulness of DIL" (Appendix B). The Researcher compared the Health dashboard data before DIL's intervention to the dashboard data during intervention.

Quantitative data was collected by comparing Health dashboard data, from the "Minnesota Living With Heart Failure" questionnaire, and from the "DIL Usability survey." Qualitative data was obtained from the "Perceived Helpfulness of DIL" survey. Survey items included patient's feedback on the design and usability of the IT artifact DIL, and questions about patient perceptions and experiences.

To determine if there is a difference in health and behavioral outcomes, a study comparing Health data before and after DIL's intervention was needed; therefore, the most appropriate research strategy was mixed-method design. According to Creswell, triangulation mixed-methods design enables the concurrent collection of quantitative and qualitative data and comparison [49]. Concurrent triangulation design will enable the researcher to use separate quantitative and qualitative methods to assess and cross-validate the results of the data collection [50]. Johnson and Onwuegbuzie (2004) [51] and Ercikan and Roth (2006) [52] asserted both quantitative and qualitative methods have merit and advocated that the best research design is mixed methods. “Both quantitative and qualitative researchers describe their data, construct explanatory arguments from the data, and speculate about why the outcomes they observed happened as they did” (Johnson & Onwuegbuzie, p. 15) [51]. “Gaining an understanding of the strengths and weaknesses of quantitative and qualitative research puts a researcher in a position to mix or combine strategies and to use the fundamental principal of mixed research” (Johnson & Onwuegbuzie, p. 18). Thus, the most ideal research method was a mixed-method design through which the researcher was able to have the knowledge gained by qualitative as well as quantitative research.

3.4 DATA COLLECTION PROCEDURES

INSTRUMENTATION

The following instruments were used to collect data during the trial:

- Patients completed the Minnesota Living with Heart Failure questionnaire (MLHFQ) at the beginning of the trial, and again at the end of the trial.
- Health vital data like weight, blood pressure and pulse readings were monitored, and recorded on the Home monitoring dashboard. The data for two weeks before DIL's intervention were compared to data for four weeks during DIL's intervention, mean scores for patients were calculated and a paired t-test was conducted for statistical significance.
- A post-trial survey on the "User satisfaction and System Usability" was completed by the every patient.

- Each patient also completed a post-trial survey on the "Perceived helpfulness of DIL."

Treatments

Each patient was given a training on the use of Home monitoring devices like weight scale, blood pressure monitor, and the use of the MyHeart app on the tablet to record the measurements. The patients were also trained on the IT artifact DIL; accounts were setup for using DIL and the MyHeart app.

Survey Administration

The patients filled out the Minnesota Living Heart Failure survey by hand, and completed the other two surveys online that were specifically designed for this research on Qualtrics.

IRB - Institutional Review Board - Claremont Graduate University

The design research plan for the system was reviewed by the Institutional Review Board (IRB) at Claremont Graduate University. CGU Human Subjects Protection Staff members reviewed the study and determined it to be exempt from IRB supervision on March 28, 2018 (Appendix D).

3.5 DATA ANALYSIS

Study participants

Five heart-failure patients participated in the study. They were recruited by reaching out to known physicians, friends and family. Each patient completed the entire duration of the trial, which included measurement of weight, blood pressure and pulse readings using bluetooth enabled weight scale and blood pressure monitors, and answering health symptom questions. The patients used an Android powered tablet and the MyHeart app to collect and upload these data to the Home monitoring dashboard (figure 7) [32].

The patients also completed the "Minnesota Living with Heart Failure" questionnaire (see appendix C) before and after the trial. At the conclusion of the trial, they participated in two surveys - the "DIL Usability" survey, and the "Perceived Helpfulness of DIL" survey (see appendix).

Analysis of Research Questions

Research Question 1

How much engagement can DIL elicit?

The conversation between DIL and the patients were recorded for data analysis purposes. A broadcast message from DIL was sent to patients everyday at 8:00 pm. The patients typically responded and conversed with DIL about 3 times a week.

The chat session duration varied slightly from person to person with the mean time spent at 18 minutes per session.

A post survey on User's satisfaction of DIL (see appendix A) was also used to gauge Patients' experience with DIL.

Research Question 2

Can DIL be as persuasive as a human health care worker?

The researcher wanted to find out if the patients will be as receptive chatting with DIL as they will be talking with humans. The research compared results from before and after the intervention of DIL, and measured improvements in health and behavioral outcomes, if any, to determine the effectiveness of the DIL as a tool for persuasion, and elicit compliance to clinical and behavioral guidelines.

The researcher used quantitative data by comparing before and after scores of health parameters on the health dashboard (figure 7), and quality of life scores by using the "Minnesota Living with Heart Failure" questionnaire (Appendix C). A paired T-test is the ideal statistical measure to compare before and after scores within the same group as in this case, and was used to test the Null Hypothesis, "there is no difference in health and behavioral outcomes due to intervention of a Conversational Agent based IT artifact like DIL."

Research Question 3

Can an Assistive Technology like DIL lower the Caregiver burden in scaling with a large population?

The researcher also wanted to determine if DIL can fill the gap of scalability of human support, and its effectiveness. To that effect it was important to find out what the patients felt about interacting with DIL, and their experience. Did they find DIL helpful in achieving better health and behavioral outcomes, was extremely important to know because if DIL can complement the efforts of the caregiver community, and motivate people to do better, then the fundamental problem of resource constraint is addressed to a large extent. The researcher used Qualitative data - a post-trial survey, "Perceived Helpfulness of DIL" (see Appendix B) to gather patients' feedback.

CHAPTER 4: RESULTS

As stated in Chapter 1, the purpose of this study is to evaluate the artifact, DIL, a conversational agent for heart-failure patients. Can DIL elicit behavior change, and better adherence to clinical guidelines for the patients in the study group were the driving question for this research. The study used a mixed-methods design to explore the research questions as completely as possible. Chapter 4 presents a summary of the data collected during the study.

4.1 PARTICIPANT DEMOGRAPHICS

There were five participants in the trial. The participants ranged in age; they were all male. Table 3 shows the Patient age groups. All the patients belonged to the Asian American community, and lived in Southern California.

Table 3 - Participant Age Group

Age	40-50	50 +
Participants	3	2

Table 3: Participant Age Group

4.2 FINDINGS FOR RESEARCH QUESTION 1

ENGAGEMENT

The patients typically chatted with DIL about 3 times a week. Each chat session reviewed the latest health dashboard data.

Figure 15 shows Patient Responses. The patients conversed on a variety of different topics ranging from fluctuation in weight, Systolic and Diastolic Blood pressure, diet, exercise, and medicine. Over a four week period during DIL's intervention, DIL sent messages to the patients every day for four weeks. Every patient's response rate was different, which was expected. Patient 1 responded 26 times, while patient 5 responded 11 times.

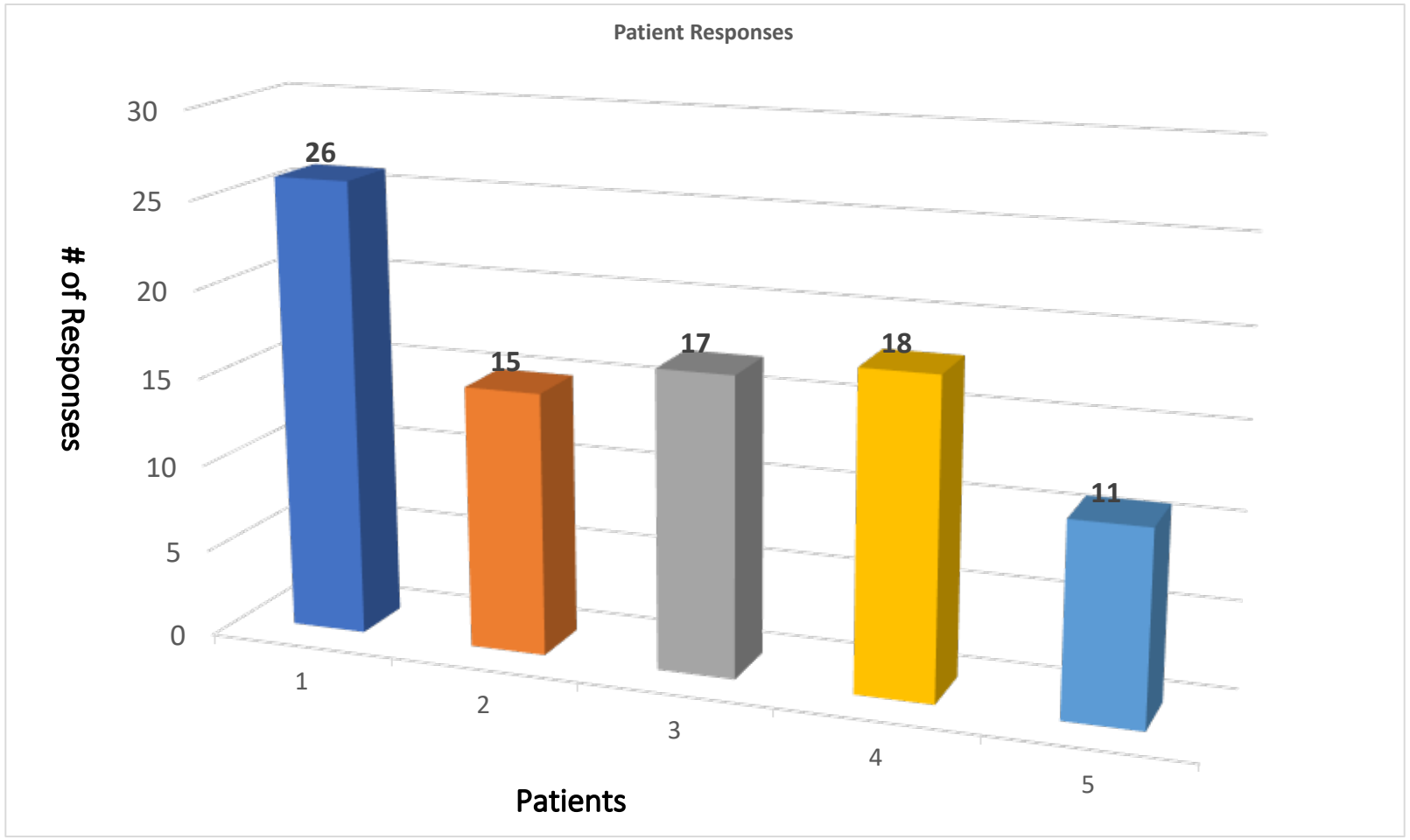


Figure 15: Patient Responses

The response percentage varied from 93% at the high end to 39% at the low end. The mean patient response rate was 62.14%.

The Response Rate is shown in Figure 16.

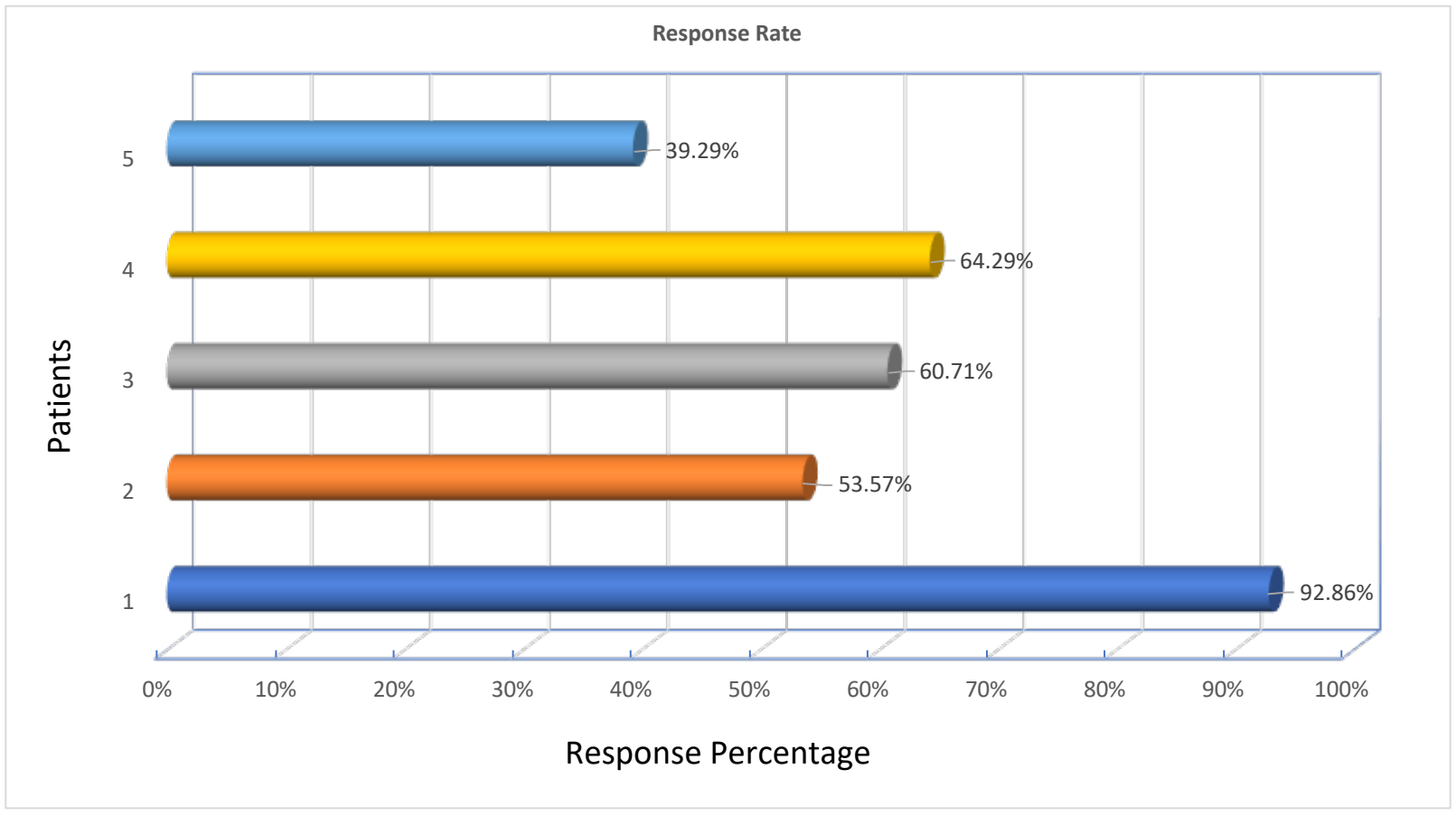


Figure 16: Patient Response Rate

To accurately measure Patient Engagement, the Patient responses and response rate is not enough. It is important to see how much time the patients spent with DIL. As mentioned before, DIL sent a message to the patients everyday at 8:00 PM. The average time spent conversing with DIL varied slightly from patient to patient with 20 minutes at the high end for patient 4 to 15 minutes at the low end for patient 2. The average chat duration with DIL is 18 minutes. Figure 17 shows the Chat Duration by patients.

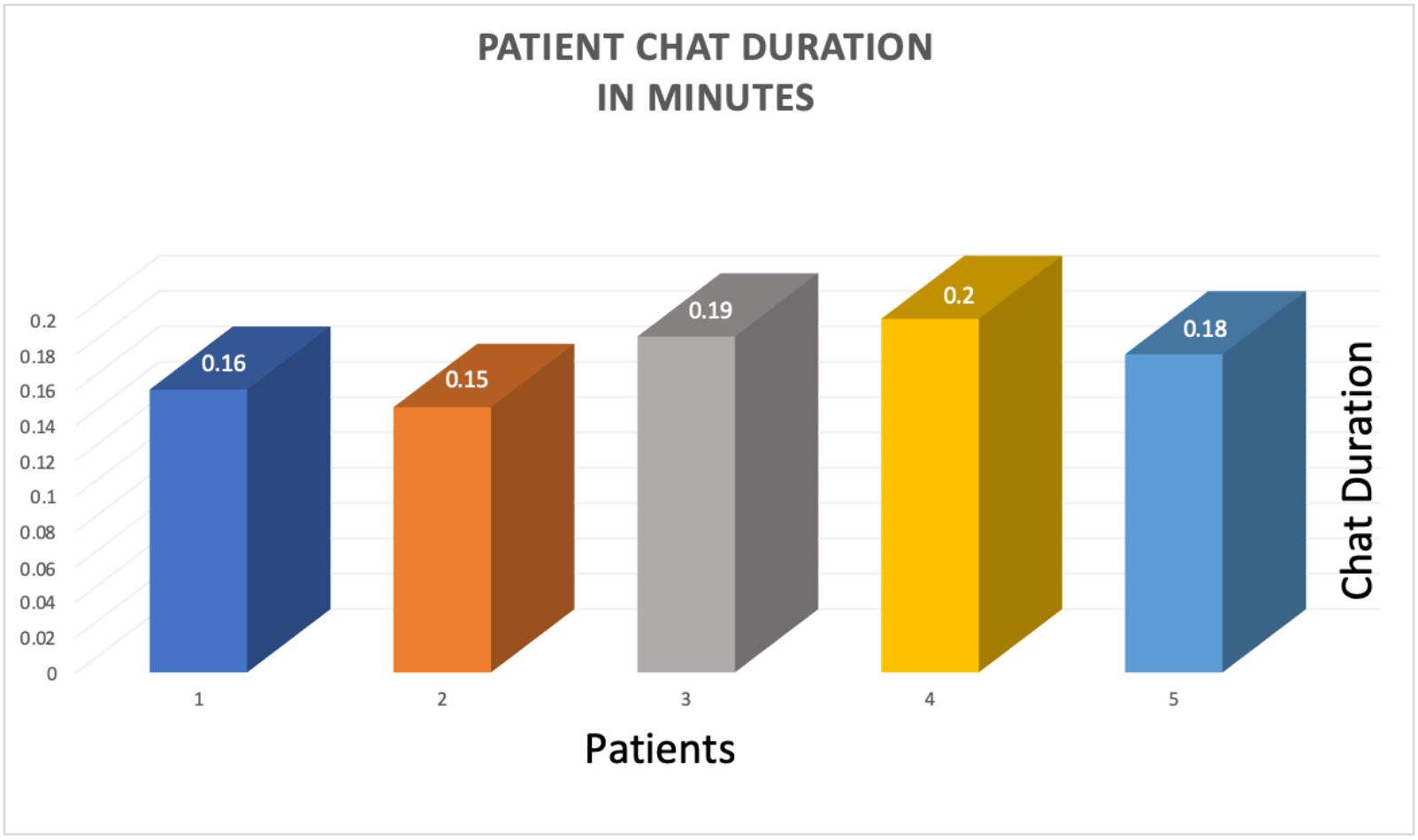


Figure 17: Patient Chat Duration

User Satisfaction

Each of the patients took an exit survey and provided feedback on their satisfaction level and the usability of the system. The survey consisted of 21 questions; the questions were specially selected based on QUIS and System Usability Scale.

Tables 4 through 8 shows the results and individual scores for every patient after completing the survey. The individual patient score calculation is a slightly modified version of the System Usability Score calculation based on a 10 question survey on a Likert scale of 1-5 [53,54], and were calculated in the following way:

- For each of the odd numbered questions, 1 was deducted from the score.
- For each of the even numbered questions, the patient response value was deducted from maximum score possible (9 for Qs 1-19, 10 for Qs 20 & 21).
- The scores were then added and multiplied by 2.

- This total score was then divided by the maximum number of points possible (9x19 + 2x10 = 191)

A score of 80 and above is an 'A' - the patients love the IT artifact, and will most likely recommend the system. A score of 68 is generally considered the average score - a 'C', which means usability of the system is OK but could improve. A score of 51 or under is 'F', which means usability has to be a priority and needs to be fixed.

Table 4: DIL User Satisfaction & System Usability
After DIL's Intervention - Patient 1

	Question	Patient Response	Patient Score
1	Design	9.00	8.00
2	Difficulty	9.00	0.00
3	Usability	9.00	8.00
4	Reading Characters on Screen	9.00	0.00
5	Organization of Information	8.00	7.00
6	Sequence of Screens	8.00	1.00
7	Use of terms throughout system	8.00	7.00
8	Terminology related to task	9.00	0.00
9	Position of messages on screen	9.00	8.00
10	Prompts for input	9.00	0.00
11	Error Messages	8.00	7.00
12	Learning to operate the system	9.00	0.00
13	Performing tasks straighforward	9.00	8.00
14	Help messages on screen	9.00	0.00
15	Supplemental reference materials	8.00	7.00
16	System speed	9.00	0.00
17	System reliability	8.00	7.00
18	Correcting your mistakes	9.00	0.00
19	Designed for all levels of users	9.00	8.00
20	I will use the system frequently	10.00	0.00
21	I felt very confident using the system	10.00	9.00
	Total Possible Score (19*9 + 2+10) = 191	**185.00**	**170.00**
	Questions 1-19 - scale of 1 through 9 *Questions 20 & 21 - scale of 1 through 10*	**0.97**	**0.89**

Table 4: DIL User Satisfaction & System Usability After DIL's Intervention - Patient 1

Table 5: DIL User Satisfaction & System Usability
After DIL's Intervention - Patient 2

	Question	Patient Response	Patient Score
1	Design	8.00	7.00
2	Difficulty	7.00	2.00
3	Usability	8.00	7.00
4	Reading Characters on Screen	9.00	0.00
5	Organization of Information	7.00	6.00
6	Sequence of Screens	8.00	1.00
7	Use of terms throughout system	7.00	6.00
8	Terminology related to task	8.00	1.00
9	Position of messages on screen	8.00	7.00
10	Prompts for input	9.00	0.00
11	Error Messages	7.00	6.00
12	Learning to operate the system	7.00	2.00
13	Performing tasks straighforward	8.00	7.00
14	Help messages on screen	7.00	2.00
15	Supplemental reference materials	7.00	6.00
16	System speed	9.00	0.00
17	System reliability	9.00	8.00
18	Correcting your mistakes	7.00	2.00
19	Designed for all levels of users	8.00	7.00
20	I will use the system frequently	9.00	1.00
21	I felt very confident using the system	8.00	7.00
	Total Possible Score (19*9 + 2+10) = 191	**165.00**	**170.00**
	Questions 1-19 - scale of 1 through 9 *Questions 20 & 21 - scale of 1 through 10*	**0.86**	**0.89**

Table 5: DIL User Satisfaction & System Usability After DIL's Intervention - Patient 2

Table 6: DIL User Satisfaction & System Usability
After DIL's Intervention - Patient 3

	Question	Patient Response	Patient Score
1	Design	9.00	8.00
2	Difficulty	8.00	1.00
3	Usability	8.00	7.00
4	Reading Characters on Screen	9.00	0.00
5	Organization of Information	9.00	8.00
6	Sequence of Screens	8.00	1.00
7	Use of terms throughout system	9.00	8.00
8	Terminology related to task	8.00	1.00
9	Position of messages on screen	8.00	7.00
10	Prompts for input	9.00	0.00
11	Error Messages	8.00	7.00
12	Learning to operate the system	8.00	1.00
13	Performing tasks straighforward	9.00	8.00
14	Help messages on screen	8.00	1.00
15	Supplemental reference materials	8.00	7.00
16	System speed	9.00	0.00
17	System reliability	9.00	8.00
18	Correcting your mistakes	8.00	1.00
19	Designed for all levels of users	8.00	7.00
20	I will use the system frequently	10.00	0.00
21	I felt very confident using the system	10.00	9.00
	Total Possible Score (19*9 + 2+10) = 191	**180.00**	**180.00**
	Questions 1-19 - scale of 1 through 9 *Questions 20 & 21 - scale of 1 through 10*	**0.94**	**0.94**

Table 6: DIL User Satisfaction & System Usability After DIL's Intervention - Patient 3

Table 7: DIL User Satisfaction & System Usability
After DIL's Intervention - Patient 4

	Question	Patient Response	Patient Score
1	Design	8.00	7.00
2	Difficulty	8.00	1.00
3	Usability	6.00	5.00
4	Reading Characters on Screen	8.00	1.00
5	Organization of Information	8.00	7.00
6	Sequence of Screens	7.00	2.00
7	Use of terms throughout system	8.00	7.00
8	Terminology related to task	8.00	1.00
9	Position of messages on screen	8.00	7.00
10	Prompts for input	8.00	1.00
11	Error Messages	7.00	6.00
12	Learning to operate the system	8.00	1.00
13	Performing tasks straighforward	8.00	7.00
14	Help messages on screen	6.00	3.00
15	Supplemental reference materials	8.00	7.00
16	System speed	8.00	1.00
17	System reliability	6.00	5.00
18	Correcting your mistakes	6.00	3.00
19	Designed for all levels of users	6.00	5.00
20	I will use the system frequently	8.00	2.00
21	I felt very confident using the system	8.00	7.00
	Total Possible Score (19*9 + 2+10) = 191	**156.00**	**172.00**
	Questions 1-19 - scale of 1 through 9 *Questions 20 & 21 - scale of 1 through 10*	**0.82**	**0.90**

Table 7: DIL User Satisfaction & System Usability After DIL's Intervention - Patient 4

Table 8: DIL User Satisfaction & System Usability
After DIL's Intervention - Patient 5

	Question	Patient Response	Patient Score
1	Design	9.00	8.00
2	Difficulty	8.00	1.00
3	Usability	8.00	7.00
4	Reading Characters on Screen	8.00	1.00
5	Organization of Information	8.00	7.00
6	Sequence of Screens	8.00	1.00
7	Use of terms throughout system	9.00	8.00
8	Terminology related to task	9.00	0.00
9	Position of messages on screen	8.00	7.00
10	Prompts for input	8.00	1.00
11	Error Messages	9.00	8.00
12	Learning to operate the system	9.00	0.00
13	Performing tasks straighforward	9.00	8.00
14	Help messages on screen	8.00	1.00
15	Supplemental reference materials	8.00	7.00
16	System speed	9.00	0.00
17	System reliability	9.00	8.00
18	Correcting your mistakes	8.00	1.00
19	Designed for all levels of users	8.00	7.00
20	I will use the system frequently	10.00	0.00
21	I felt very confident using the system	9.00	8.00
	Total Possible Score (19*9 + 2+10) = 191	**179.00**	**178.00**
	Questions 1-19 - scale of 1 through 9 *Questions 20 & 21 - scale of 1 through 10*	**0.94**	**0.93**

Table 8: DIL User Satisfaction & System Usability After DIL's Intervention - Patient 5

The patients also made the following general comments about their experience with DIL.

Table 9 - General Comments by patients about their experience with DIL

1	The app is very well designed. It prompts me to monitor my health on regular basis.
2	It reminds on timely basis & keep consistency. Because of daily reminders from DIL, I make it a point to walk for at least 20 minutes every day.
3	It would have been better if I could talk to the system.
4	Motivational messages in video format would have been more helpful.
5	Great product to help track health goals .

Table 9: Patient general feedback about DIL

4.3 FINDINGS FOR RESEARCH QUESTION 2

The researcher used two instruments to answer Research question 2. First, Health dashboard results from before and after DIL's intervention were compared to see potential improvements in health and behavioral outcomes. Second, data from the "Minnesota Living with Heart Failure" questionnaire were compared to determine the patients' quality of life.

DESCRIPTIVE STATISTICS - HEALTH DASHBOARD RESULTS

For health dashboard results, the researcher compared before and after means of the following vitals:

- Weight
- Systolic Blood Pressure
- Diastolic Blood Pressure
- Pulse

Weight

Table 10 shows the mean values and the paired t-test result for Weight for the 5 patients.

Table 10: Comparison of Mean Values of Weight before and during DIL's Intervention

	Mean Weight Before DIL's Intervention	Mean Weight During DIL's Intervention	Difference of the Means - D	D^2
Patient 1	164.60	151.00	13.60	184.96
Patient 2	197.90	189.47	8.43	71.12
Patient 3	185.56	185.71	-0.15	0.02
Patient 4	129.29	128.31	0.98	0.96
Patient 5	190.57	190.82	-0.25	0.06
			∑ = 22.61	∑ = 257.12
μ	173.58	169.06		
SD	27.69	28.08		
Variance	766.48	788.39		
N	5	5		
Df	4	4		
t-value =	**1.63**	**t-critical =**	**2.776**	**p=0.05**

Table 10: Comparison of Mean Values of Weight before and during DIL's Intervention

For patients with heart failure, it is absolutely critical to take medications on time, get some form exercise on a daily basis, and eat healthy. Monitoring weight multiple times a week to look for abnormal fluctuations in weight is extremely important. The researcher monitored and compared mean weight of the patients for two weeks before DIL's intervention with the mean weight of the patients during DIL's intervention for 4 weeks. A paired t-test was conducted by comparing the mean weights; although there is a slight drop in the mean weight of the patients (μ), it was found to be not statistically significant (t=value = 1.63, *p=0.05*).

Systolic Blood Pressure

Table 11 shows the mean values and the paired t-test result for Systolic Blood Pressure for the 5 patients.

Table 11: Comparison of Mean Values of Systolic Blood Pressure before and during DIL's Intervention

	Mean Systolic BP Before DIL's Intervention	Mean Systolic BP During DIL's Intervention	Difference of the Means - D	D^2
Patient 1	113.10	120.77	-7.67	58.82
Patient 2	156.30	146.73	9.57	91.52
Patient 3	132.00	135.06	-3.06	9.36
Patient 4	125.56	137.72	-12.17	148.03
Patient 5	134.71	124.73	9.99	99.74
			∑ = -3.34	∑ = 407.46
μ	132.33	133.00		
SD	15.78	10.41		
Variance	249.01	108.29		
N	5	5		
Df	4	4		
t-value =	**-0.15**	**t-critical =**	**2.776**	**p=0.05**

Table 11: Comparison of Mean Values of Systolic Blood Pressure before and during DIL's Intervention

As in weight, the systolic Blood pressure is also an important vital to monitor multiple times a week as fluctuations beyond a normal range can be an indicator that something is not right. Systolic Blood Pressure readings were monitored for two weeks before DIL's intervention, and for four weeks during DIL's intervention. The mean values were compared, and a paired t-test was conducted. The mean values (μ) were virtually unchanged, and was not statistically significant (t-value=-0.15, *p=0.05*).

Diastolic Blood Pressure

Table 12 shows the mean values and the paired t-test result for Diastolic Blood Pressure for the 5 patients.

Table 12: Comparison of Mean Values of Diastolic Blood Pressure before and during DIL's Intervention

	Mean Diastolic BP Before DIL's Intervention	Mean Diastolic BP During DIL's Intervention	Difference of the Means - D	D^2
Patient 1	73.50	71.15	2.35	5.50
Patient 2	65.60	62.53	3.07	9.40
Patient 3	86.89	84.24	2.65	7.04
Patient 4	83.11	90.39	-7.28	52.97
Patient 5	86.00	80.64	5.36	28.77
			∑ = 6.15	∑ = 103.69
μ	79.02	77.79		
SD	9.19	11.01		
Variance	84.49	121.30		
N	5.00	5.00		
Df	4	4		
t-value =	**0.56**	**t-critical =**	**2.776**	**p=0.05**

Table 12: Comparison of Mean Values of Diastolic Blood Pressure before and during DIL's Intervention

Like Systolic Blood Pressure, Diastolic Blood Pressure was also measured multiple times a week. Diastolic Blood pressure readings were taken for two weeks before DIL's intervention, and for four weeks during DIL's intervention. The mean values were compared, and a paired t-test was conducted. The mean values (μ) were virtually unchanged, and was not statistically significant (t-value=0.56, *p=0.05*).

Pulse

Table 13 shows the mean values and the paired t-test result for Pulse readings for the 5 patients.

Table 13: Comparison of Mean Values of Pulse before and during DIL's Intervention

	Mean Weight Before DIL's Intervention	Mean Weight During DIL's Intervention	Difference of the Means - D	D^2
Patient 1	68.40	64.62	3.78	14.32
Patient 2	68.30	61.60	6.70	44.89
Patient 3	80.00	74.65	5.35	28.65
Patient 4	88.89	91.22	-2.33	5.44
Patient 5	56.29	59.45	-3.17	10.04
			∑ = 10.34	∑ = 103.35
μ	72.37	70.31		
SD	12.47	13.06		
Variance	155.53	170.57		
N	5.00	5.00		
Df	4	4		
t-value =	**1.02**	**t-critical =**	**2.776**	**p=0.05**

Table 13: Comparison of Mean Values of Pulse before and during DIL's Intervention

Pulse readings are also an important vital to monitor on a regular basis as abnormal heart beat can be a sign of worry. The patients' pulse readings were recorded multiple times a week for two weeks before DIL's intervention and for four weeks during DIL's intervention; the mean values were compared and found to be almost unchanged. A paired t-test result of the means showed no statistical significance (t-value=1.02, $p=0.05$).

Descriptive Statistics - Quality of Life

The "Minnesota Living with Heart Failure" questionnaire was used before and after DIL's intervention to gauge improvements in Health outcomes and Quality of Life of the patients. The questionnaire is comprised of 21 important physical, emotional and socioeconomic ways heart failure can adversely affect a patient's life. After receiving brief standardized instructions, the patient marked a 0 (zero) to 5 scale to indicate how much each itemized adverse of heart failure has prevented the patient from living as he or she wanted to live during the past 4 weeks. The questionnaire is simply scored by summation of all 21 responses.

This patient-reported outcome can be used to determine whether a treatment for heart failure is effective for improving patients' quality of life by reducing the adverse impact of heart failure.

Table 14 summarizes the findings before DIL's intervention. Table 15 shows the results for the same questionnaire taken by the patients after the trial period.

Table 14: Minnesota Living with Heart Failure Questionnaire - Before DIL's Intervention

	Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Mean	SD	Variance
1	causing swelling in your ankles or legs?	0	3	0	0	0	0.6	1.34	1.80
2	making you sit or lie down to rest during the day?	0	3	4	3	4	2.8	1.64	2.70
3	making your walking about or climbing stairs difficult?	0	4	3	4	4	3	1.73	3.00
4	making your working around the house or yard difficult?	0	5	3	4	3	3	1.87	3.50
5	making your going places away from home difficult?	1	5	4	3	4	3.4	1.52	2.30
6	making your sleeping well at night difficult?	2	5	4	2	3	3.2	1.30	1.70
7	making your relating to or doing things with your friends or family difficult?	1	5	3	4	3	3.2	1.48	2.20
8	making your working to earn a living difficult?	2	5	3	5	4	3.8	1.30	1.70
9	making your recreational pastimes, sports or hobbies difficult?	2	5	3	5	4	3.8	1.30	1.70
10	making your sexual activities difficult?	0	5	4	4	4	3.4	1.95	3.80
11	making you eat less of the foods you ilke?	3	5	4	5	5	4.4	0.89	0.80
12	making you short of breath?	3	5	1	3	4	3.2	1.48	2.20
13	making you tired, fatigued, or low on energy?	4	5	5	3	4	4.2	0.84	0.70
14	making you stay in hospital?	0	0	0	2	3	1	1.41	2.00
15	costing you money for medical care?	5	5	3	5	4	4.4	0.89	0.80
16	giving you side effects from treatment?	1	5	4	4	4	3.6	1.52	2.30
17	making you feel you are a burdento your family or friends?	4	0	1	4	3	2.4	1.82	3.30
18	making you feel a loss of self control in your life?	4	5	3	4	5	4.2	0.84	0.70
19	making you worry?	4	5	3	4	5	4.2	0.84	0.70
20	making it difficult to you to concentrate or remember things?	4	5	4	3	4	4	0.71	0.50
21	making you feel depressed?	4	3	4	4	4	3.8	0.45	0.20
	TOTAL	**44**	**88**	**63**	**75**	**78**	**69.6**		

Table 14: Minnesota Living with Heart Failure Questionnaire - Before DIL's Intervention

Table 15: Minnesota Living with Heart Failure Questionnaire - After DIL's Intervention

	Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Mean	SD	Variance
1	causing swelling in your ankles or legs?	0	3	0	0	0	0.60	1.34	1.80
2	making you sit or lie down to rest during the day?	0	3	4	3	4	2.80	1.64	2.70
3	making your walking about or climbing stairs difficult?	0	4	3	3	4	2.80	1.64	2.70
4	making your working around the house or yard difficult?	0	5	3	4	3	3.00	1.87	3.50
5	making your going places away from home difficult?	1	4	3	3	3	2.80	1.10	1.20
6	making your sleeping well at night difficult?	1	4	3	2	3	2.60	1.14	1.30
7	making your relating to or doing things with your friends or family difficult?	1	5	2	3	3	2.80	1.48	2.20
8	making your working to earn a living difficult?	2	5	2	4	4	3.40	1.34	1.80
9	making your recreational pastimes, sports or hobbies difficult?	1	4	2	4	4	3.00	1.41	2.00
10	making your sexual activities difficult?	0	5	3	4	4	3.20	1.92	3.70
11	making you eat less of the foods you ilke?	3	5	4	5	5	4.40	0.89	0.80
12	making you short of breath?	2	5	1	3	4	3.00	1.58	2.50
13	making you tired, fatigued, or low on energy?	3	4	4	2	4	3.40	0.89	0.80
14	making you stay in hospital?	0	0	0	0	0	0.00	0.00	0.00
15	costing you money for medical care?	4	5	3	4	4	4.00	0.71	0.50
16	giving you side effects from treatment?	1	4	3	4	3	3.00	1.22	1.50
17	making you feel you are a burdento your family or friends?	3	0	0	3	3	1.80	1.64	2.70
18	making you feel a loss of self control in your life?	3	4	2	4	5	3.60	1.14	1.30
19	making you worry?	3	5	2	4	5	3.80	1.30	1.70
20	making it difficult to you to concentrate or remember things?	3	5	4	3	4	3.80	0.84	0.70
21	making you feel depressed?	3	3	4	3	4	3.40	0.55	0.30
	TOTAL	**34**	**82**	**52**	**65**	**73**	**61.2**		

Table 15: Minnesota Living with Heart Failure Questionnaire - After DIL's Intervention

Figure 18 shows the change in the Mean score for the patients.

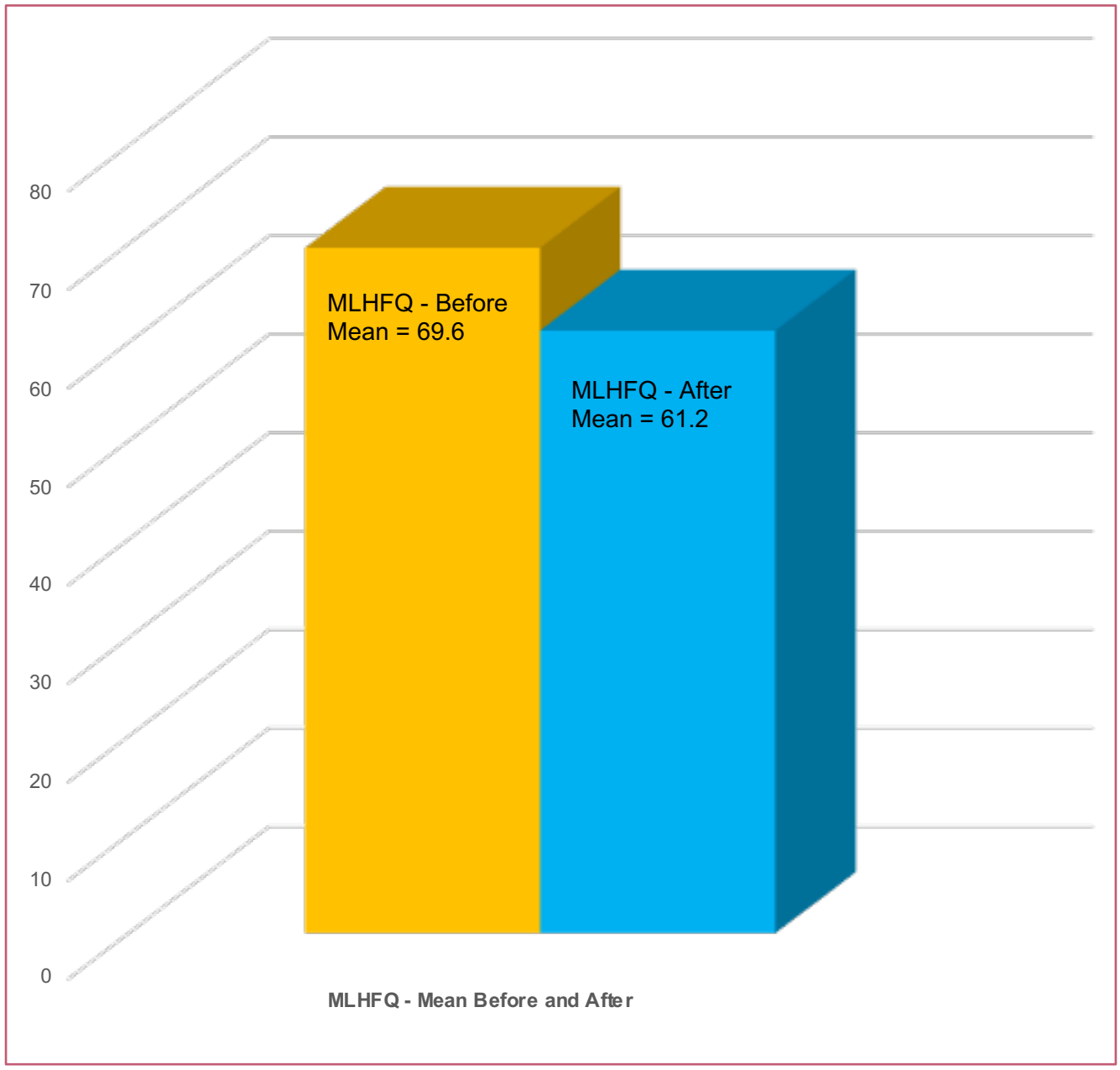


Figure 18: Change in Mean Score - Minnesota Living with Heart Failure Questionnaire - Before and After

4.4 FINDINGS FOR RESEARCH QUESTION 3

A qualitative survey, "Perceived Helpfulness of DIL" (see Appendix C) was used to gather the Patients' experience interacting with DIL. Did the patients find DIL helpful to keep them motivated, and help in better adherence to clinical guidelines like taking medications on time, controlling their diet, and exercise were important criteria to determine if DIL can complement a human case worker like a nurse or a clinician.

The following figures show the patients' responses to this qualitative survey:

RESPONSE TO QUESTION 1 - OVERALL HOW HELPFUL OR UNHELPFUL WAS DIL?

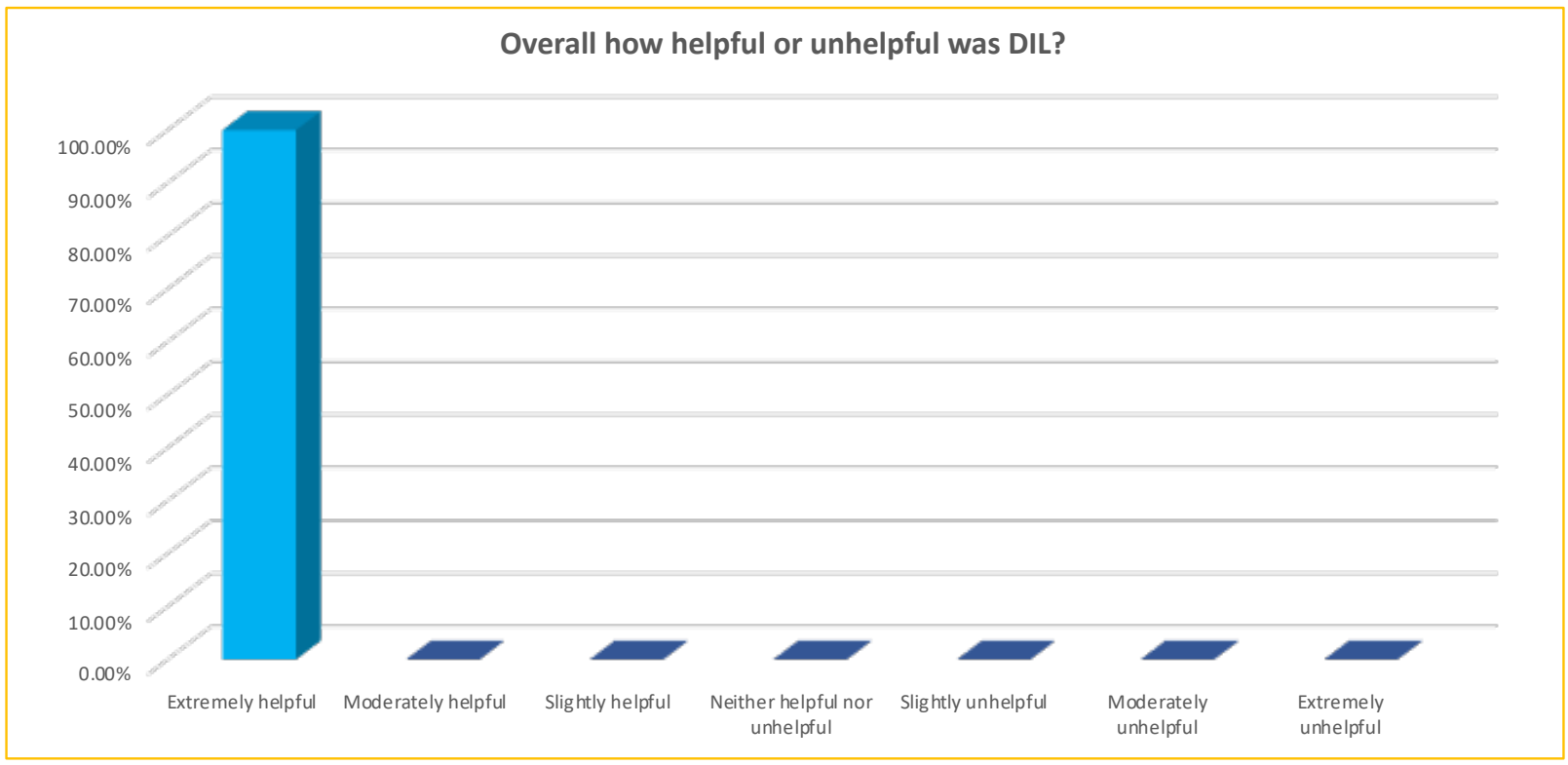


Figure 19: Patient response to "Overall how helpful or unhelpful was DIL?"

Table 16 shows the distribution.

#	Answer	%	Count
1	Extremely helpful	100.00%	5
2	Moderately helpful	0.00%	0
3	Slightly helpful	0.00%	0
4	Neither helpful nor unhelpful	0.00%	0
5	Slightly unhelpful	0.00%	0
6	Moderately unhelpful	0.00%	0
7	Extremely unhelpful	0.00%	0
	Total	100%	5

Table 16: Patient response to "Overall how helpful or unhelpful was DIL?"

When asked about the helpfulness of DIL in motivating them to stay the course - taking medications on time, controlling their diet and exercise, all five patients responded that they found DIL extremely helpful.

Response to question 2: Was Conversing with DIL Easy

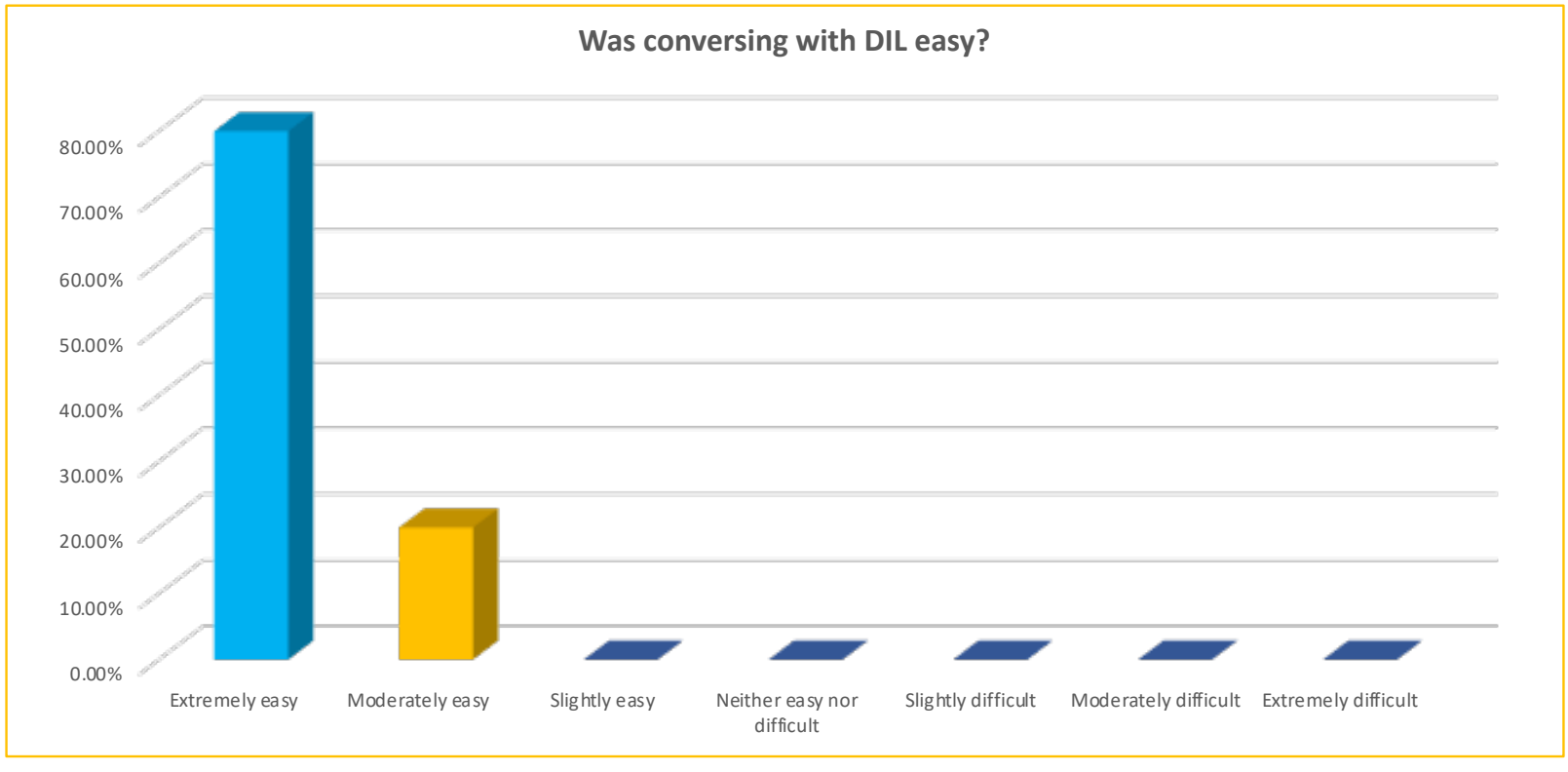


Figure 20: Patient response to "Was conversing with DIL easy?"

Table 17 shows the distribution.

#	Answer	%	Count
1	Extremely easy	80.00%	4
2	Moderately easy	20.00%	1
3	Slightly easy	0.00%	0
4	Neither easy nor difficult	0.00%	0
5	Slightly difficult	0.00%	0
6	Moderately difficult	0.00%	0
7	Extremely difficult	0.00%	0
	Total	100%	5

Table 17: Patient response to "Was Conversing with DIL easy?"

In response to the question about conversing with a chatbot like DIL, 4 out of the 5 patients (80%) found it to be extremely easy, and 1 patient, the oldest patient at 70+ years of age (20%) found it to be moderately easy.

Response to Question 3: "Were the Motivational Messages Useful?"

Figure 21: Patient response to "Were the motivational messages useful?

Table 18 shows the distribution.

#	Answer	%	Count
1	Extremely useful	20.00%	1
2	Very useful	80.00%	4
3	Moderately useful	0.00%	0
4	Slightly useful	0.00%	0
5	Not useful at all	0.00%	0
	Total	100%	5

Table 18: Patient response to "Were the motivational messages useful?"

With regard to the motivational messages, 1 patient (20%) found them to be "extremely useful", the other 4 (80%) found them to be "very useful". As a general feedback on the User satisfaction and usability survey (Table 9), one patient actually said that motivational messages in video format would have been more helpful. It is an area that definitely needs further consideration.

Response to Question 4: How helpful or unhelpful were the links to various published articles on relevant topics?

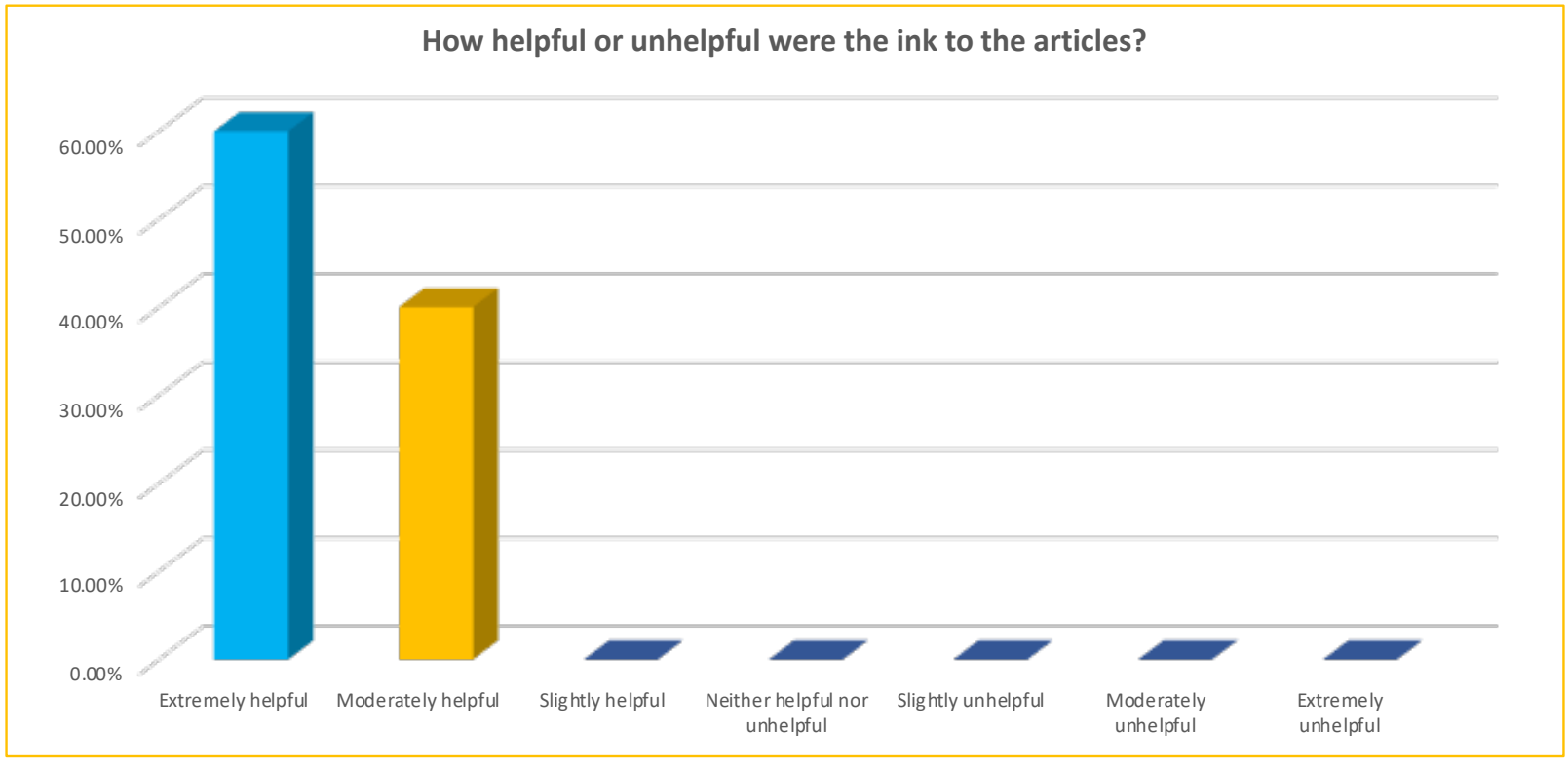


Figure 22: Patient response to "How helpful or unhelpful were the links to articles?"

Table 19 shows the distribution.

#	Answer	%	Count
1	Extremely helpful	60.00%	3
2	Moderately helpful	40.00%	2
3	Slightly helpful	0.00%	0
4	Neither helpful nor unhelpful	0.00%	0
5	Slightly unhelpful	0.00%	0
6	Moderately unhelpful	0.00%	0
7	Extremely unhelpful	0.00%	0
	Total	100%	5

Table 19: Patient response to "How helpful or unhelpful were the links to articles?"

In order to motivate patients to do better, DIL often referred the patients to relevant health articles in leading journals freely available on the web. Three patients (60%) found these articles to be "Extremely helpful", and two patients (40%) found them to be "Moderately helpful."

Response to Question 5: "Did DIL help you in improving your lifestyle and adherence to clinical guidelines?"

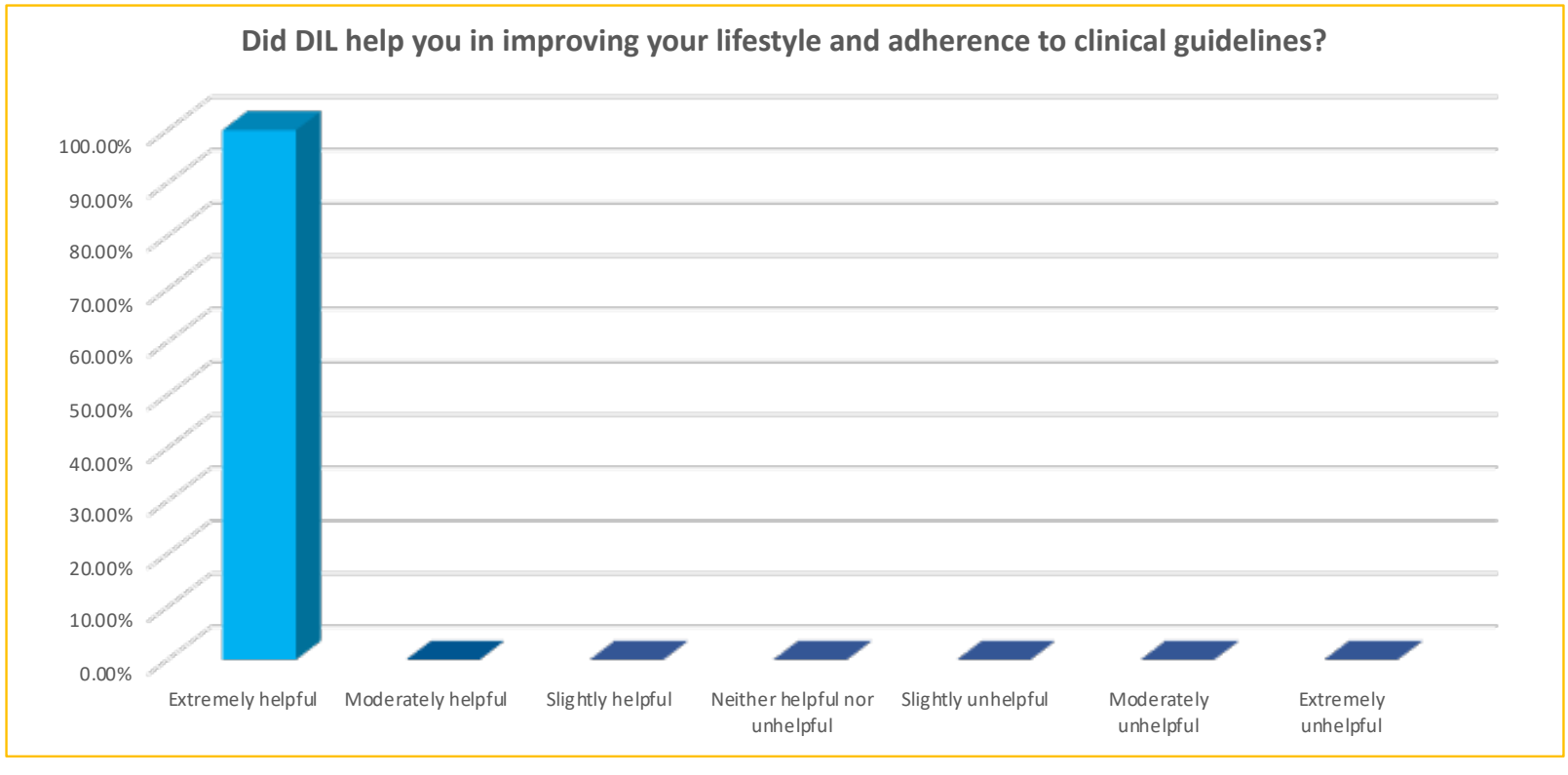


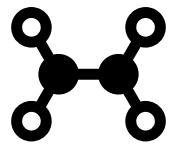
Figure 23: Patient response to "Did DIL help you in improving your lifestyle and adherence to clinical guidelines?"

Table 20 shows the distribution.

#	Answer	%	Count
1	Extremely helpful	100.00%	5
2	Moderately helpful	0.00%	0
3	Slightly helpful	0.00%	0
4	Neither helpful nor unhelpful	0.00%	0
5	Slightly unhelpful	0.00%	0
6	Moderately unhelpful	0.00%	0
7	Extremely unhelpful	0.00%	0
	Total	100%	5

Table 20: Patient response to "Did DIL help you in improving your lifestyle and adherence to clinical guidelines?"

Finally when the patients were asked about DIL's role in helping them improve their lifestyle and adherence to clinical guidelines, all five patients (100%) found DIL to be "Extremely helpful." This finding was confirmed again when the mean scores of the Minnesota Living with Heart failure questionnaire from before and after DIL's intervention were compared; it showed a significant improvement (figure 16).



CHAPTER 5: DISCUSSION

Chapter 5 consists of three sections. First is a summary of the research problem, the research methods used in the study, and the data analysis. The second section consists of the research findings, conclusions, and implications for further practice. The third section and conclusion to the chapter will include recommendations for further research.

5.1 SUMMARY OF RESEARCH PROBLEMS AND RESEARCH METHODS

Chronic conditions are increasingly impacting life expectancy and the cost of healthcare all over the world. Among these conditions, Cardiovascular Disease (CVD) stands out because its prevalence continues to rise. Congestive Heart Failure (CHF) is the most common Medicare diagnosis. In 2012, the American Heart Association reported that 1 out of 5 of individuals with CHF dies within a year of diagnosis [2]. According to 2018 report the estimated annual incidence of heart attack in the US is 720,000 new attacks and 335,000 recurrent attacks. Average age at the first heart attack is 65.6 years for males and 72.0 years for females. Approximately every 40 seconds, an American will have a heart attack [1].

CHF also incurs the highest cost for diagnosis and treatment. A 2009 report estimated these costs to be around 37.2 billion dollars [1]. 21.2% of Medicare patients diagnosed with CHF were readmitted to the hospital within 30 days of discharge [1]. A 2018 report estimated direct and indirect cost of heart disease in 2013 to 2014 (average annual) was $204.8 billion. Heart attacks ($12.1 billion) and Coronary Heart Disease ($9.0 billion) were 2 of the 10 most expensive conditions treated in US hospitals in 2013. Between 2013 and 2030, medical costs of Coronary Heart Disease are projected to increase by about 100 percent.

The cost of these readmissions exceeded $15 billion per year (MedCAP) [1]. As readmissions continued, the Center for Medicare and Medicaid Services (CMS) decided to penalize hospitals with high CHF readmission rates by not reimbursing them for the services they provide since prior studies show that CHF hospital readmissions could be reduced with quality outpatient services and adherence to care.

As patients move into their home setting when discharged from the hospitals there is a discontinuity in care services that these highly vulnerable patients need. The high readmission rates for heart failure cases have often been attributed to the lack of effective strategies to support the transition in care from the hospital to the home environment.

In spite of best intentions, and effort, it is simply not possible for the caregiver community to reach out to each and every patient in their homes and follow up with them. There are simply too many patients and not enough nurses, clinicians, and doctors. The problem in essence is that human support simply cannot scale to meet the growing needs of a rising elderly population who are living with Heart Failure.

The purpose of this study was to evaluate the artifact, DIL, a conversational agent for heart-failure patients. The researcher was particularly interested to find out if DIL can elicit behavior change, a change in quality of life, and better adherence to clinical guidelines for the patients in the study group.

The research questions guiding the study were broadly divided into two main categories - Human-computer interaction, and Complimenting the Care-giver community. The questions were:

1. *How much engagement can DIL elicit?*
2. *Can DIL be as persuasive as a human health care worker?*
3. *Can an Assistive Technology like DIL lower the Caregiver burden in scaling with a large population?*

Five heart-failure patients in their home setting participated in this study. They were each given a set of home monitoring devices like bluetooth enabled weight scale, blood pressure and pulse monitor, and a tablet with MyHeart app installed [32]. The patients were asked to measure weight, blood pressure and pulse, and answer symptomatic questions if possible everyday during the study period. The measurements were uploaded automatically to the Home minoring dashboard (figure 7). The patients were monitored for two weeks prior to DIL's intervention and for a further four weeks during DIL's intervention. The patients completed the Minnesota Living with Heart failure questionnaire before and after the study. They also participated in two other surveys - a survey on the Perceived Helpfulness of DIL, and a User satisfaction and System Usability survey (see appendix). Quantitative data from the home monitoring dashboard were compared from before and during DIL's intervention, and descriptive statistical analysis were performed to determine any noticeable improvement health outcome measurements.

5.2 STUDY CONCLUSIONS

Conclusions for Research Question 1

To answer the question about the engagement DIL can elicit, two different measures were used. First the user engagement was measured, and then quantitative data was used to measure the User satisfaction and their feedback on System usability.

Figure 15, 16 & 17 shows the User engagement over the trial period, and indicated a better than expected user participation. DIL sent messages every day for four weeks, and patients responded multiple times a week to converse with DIL, and discuss the data recorded by the Home monitoring devices. The patient engagement was extremely good with a mean engagement percentage of 62.14%. The patients also spent considerable time chatting with DIL with a mean chat duration at 18 minutes.

The quantitative data as measured by the User Satisfaction and System Usability survey indicated an average score of almost 90 for every patient (see tables 4 through 8). This means that the patients were highly satisfied with the functionality of the system, and would not only use the system again, but also recommend to friends and family.

Overall conclusion to Research Question 1 is extremely positive; it can be safely said that DIL scored high on User engagement and satisfaction, which is also confirmed by the General Feedback and Comments as shown on Table 9. Comments like *"The app is very well designed. It prompts me to monitor my health on regular basis", "It reminds on timely basis & keep consistency"* and *"Great product to help track health goals"* only reinforces the positive user experience. This is probably also the reason for high engagement between DIL and the patients because when users' experiences with a technology artifact is positive, they are more likely to use the system.

Conclusions for Research Question 2

Research question 2 was perhaps the most important question of the study - if DIL can be as persuasive to positively change and reinforce a patient's behavior as a human caregiver normally would. The researcher used quantitative and qualitative data to answer this question.

First, the Health dashboard measurements were compared from two weeks prior to DIL's intervention to four weeks during DIL's intervention. In particular, vital health parameters like fluctuations in weight, systolic and diastolic blood pressure, and pulse readings were compared. The mean scores for the five patients from before and during DIL's intervention were compared, and a paired t-test within the group was performed for a p-value of 0.05.

Table 21 summarizes the findings.

Table 21: t-value, t-ctitical and p-value for Vital Health Parameters

	T-value	T-critical	P-value	Statistical Significance
Weight	1.63	2.776	0.05	Not significant
Systolic Blood Pressure	-0.15	2.776	0.05	Not significant
Diastolic Blood Pressure	0.56	2.776	0.05	Not significant
Pulse	1.02	2.776	0.05	Not significant
n=5	df=4			

Table 21: t-value, t-critical and p-value for Vital Health Parameters

None of the health parameters that were measured showed any significant statistical change due to DIL's intervention. While at first, this might look discouraging for this research, but it is actually not a bad thing. The study duration was short - a total of six weeks, two weeks before DIL's intervention, and four weeks during DIL's intervention. A significant fluctuation is not desirable during such a short duration as any such change will be a cause of concern and would be considered a high-risk. All the five patients had good family support, are well educated, and understand how to manage a chronic disease like heart failure better than the average population to begin with. In essence they were adhering to clinical guidelines like taking medications in a timely manner, controlling their diet and exercising on a regular basis. Given this scenario, the slight improvements in the mean values for all the four health parameters that were measured was actually an excellent health and behavioral outcome.

The second instrument used to answer Research question 2, was the qualitative survey - Minnesota living with Heart Failure questionnaire (MLHFQ). The patients took the survey at the beginning of the trial, and again at the conclusion of the trial, and the results are extremely encouraging (see tables 14 and 15, and figure 17). There are twenty one questions on this survey that can be divided up into two broad categories - physical and emotional domain. Questions 1-7, 12 and 13 ask questions about physical limitations, and fall under the Physical domain. Questions 17-21 ask questions mainly about the patients' emotional state, and fall under the emotional domain [55]. The patients respond to each question on a Likert scale of 0-5, and the total score is calculated by adding up the response to each question. The mean score of each of the patients' total scores from before the trial was compared to the mean score from after the trial. As shown in Figure 17, the mean scores showed significant improvement (Mean before = 69.6, and Mean after = 61.2). A change of 4 in the Mean score is considered significant.

Overall conclusion to Research question 2 is mixed at worst, and positive at best. The health dashboard results - changes in weight, blood pressure and pulse readings, although not statistically significant showed slight improvements. None of the patients showed any decline on their health and behavioral outcomes during the trial period, and none needed clinical intervention during the trial period. On the quality of life survey, every patient felt significantly more positive on both physical and emotional domain questions, and had a positive outlook on their quality of life going forward. Monitoring their critical health data on a regular

basis, and positive reinforcements from DIL motivated them to do better and continue to lead a healthy lifestyle. One patient said, *"...because of daily reminders from DIL, I make it a point to walk at least 20 minutes every day."*

Conclusions to Research Question 3

The researcher used a Qualitative survey, "Perceived Helpfulness of DIL" to answer research questions 3 and 4. The survey results are shown in Figures 18 through 22 and Tables 16 through 20. The findings indicate an extremely positive feedback from the patients on DIL's helpfulness on their quality of life and achieving a better health and behavioral outcome. Each of the five patients gave an "extremely positive" to "mostly positive" response to this five-question survey.

Because the results of this study are exceptionally positive and the participants in this study had never used an IT artifact like DIL before, there is a possibility of a “novelty effect” leading to patient approval. The novelty effect is a common reactive-effect which can threaten external validity. The novelty effect refers to the success of a treatment because it is new and different. Lodico, Spaulding, and Voegtle (2006) [56] wrote, “After a while, the novelty wears off and the new treatment is no better than the old treatment” (p. 199). In essence, “the novelty effect means that a treatment is effective only when it is new and novel and that the treatment’s effectiveness will not generalize beyond this initial period of time” (p. 199).

Although it is possible the novelty effect may have caused the extremely positive results, this is unlikely due to several reasons. First, all the patients in the study are well educated and well versed in modern technology. They were all very familiar with social media technologies like Facebook and Facebook Messenger, and other web 2.0 technologies, and are active participants on social media. Second, although the patients have not encountered a conversational agent like DIL for chronic disease management before, they were familiar with chat-bots. So the technology in itself was not totally new.

Overall conclusion to Research question 3 is positive; given the extremely positive experience of the patients, there is definitely room for such an IT artifact in supporting patients as they make the transition from hospital to the home setting. Although it can be argued that the patient population in the trial was small and did not adequately represent the patient population with Heart Failure at large, and further exploration is definitely required, the early results indicate that DIL can play a role in alleviating the caregiver burden.

5.3 SCOPE AND LIMITATIONS

SETTING AND SAMPLE SIZE

Generalizability of findings is one of the potential limitations of this study because:

- The sample size is small (n=5 for patients) and participants could refuse to continue with the study, experience deterioration in health, or even pass away.

However, Nielson & Lauder [43] argue that 3-5 participants is a sufficient sample size to test the usability of a system. Further, it is expected that the research will motivate future research to replicate the artifact and test the design in other healthcare contexts.

CONTROL AND VALIDITY

Given that the evaluation uses a field experiment and there is a lack of control over variables in the environment, the validity of findings might be questionable because the variables of interest are not measured accurately. For example, seasonal effects might influence the number of hospitalizations in heart failure patients as changes in weather and flu season are correlated to higher admission rates. Thus, the results could be biased.

RESOURCES

It is anticipated that interviewing clinicians and patients will be challenging due to the limited time they have.

TECHNOLOGY BARRIERS

Learning how to use a new technology and adapting to it is not a trivial task especially since participants will be involved in the first iterations of designing and testing the application. Technical issues such as, software bugs, connectivity issues, or locked mobile phones are real problems that must be addressed and dealt with as and when they arise.

5.4 RESEARCH IMPLICATIONS

The data gathered during the research and its analysis, especially the findings with respect to the research questions paints an extremely positive picture for an IT artifact like DIL. As mentioned in Chapter 1, with proper disease management, early symptoms of disease exacerbation could be detected and treatments could be initiated to prevent them [3], lowering the risk of deteriorating quality of life, death, or readmission to the hospital. Therefore, the American Heart Association recommends patient education and close monitoring to improve treatment adherence [6]. Because of the large number of people living with Heart Failure, and because it is simply not possible to reach out and address the growing needs of patients, an alternative strategy, an IT artifact like DIL is the need of the hour. This study validates DIL as a useful tool that can potentially fill in the gap.

The study was limited in the sense that the patient group was small and not diverse enough, so a study with a larger patient population with a greater degree of variety in terms of ethnicity, financial background, and age groups representing all strata of the society, will be ideal. The study period was small (only six weeks). To really evaluate the potential and capability of an IT artifact like DIL, a longer term trial of three months to six months would have been ideal, but such a lengthy study was beyond the scope of this dissertation.

Further research is definitely needed, but the findings of this study indicates that conversational agents like DIL can play an important role in chronic disease self-management.

CONTRIBUTIONS TO THE FIELD OF IS&T

The research used Design Science Research principles. The primary contribution is the The artifact: DIL - a Conversational Agent for individuals with Heart Failure; a chatbot that combines expert opinions with theories from healthcare, psychology, and technology. Although Conversational Agents are not new, the specific application of such a system to work with Heart Failure patients is new. This type of system was not found to exist at the beginning of this research project.

This research can also inform the design of future Conversational Agent systems and bring awareness of strategies to develop better customized interventions. Because these strategies will be discovered in a natural setting, they will be feasible and could form a foundation to develop guidelines for efficient self- management.

CONTRIBUTIONS TO THE FIELD OF PRACTICE AND HEART FAILURE

This research will hopefully empower and motivate patients and facilitate better communication among patients and clinicians. Communication is key to improving health outcomes and reducing readmissions. The artifact DIL is a direct attempt to address the Resource Problem, specifically overloading and shortage of staff issue. All conversations between DIL and an individual

patient is recorded for further review by a knowledgeable healthcare worker like a Doctor, nurse or a clinician. These recordings can provide valuable insight about a patient's health, her adherence to clinical guidelines, and eventually progress towards better health and lifestyle.

Contribution to Theory and Knowledge

Due to lack of sufficient resources in the caregiver community, lack of understanding of clinical guidelines and best practices, and lack of motivation, a significantly large number of patients fall through the crack and do not receive the support they need, and are at high risk, despite best efforts from the care givers. So, the problem is definitely mature enough that demands a mature solution and intervention, and as outlined in previous sections is an ideal scenario for an IT artifact like DIL.

Figure 24 shows the DSR-Knowledge Contribution Framework [62].

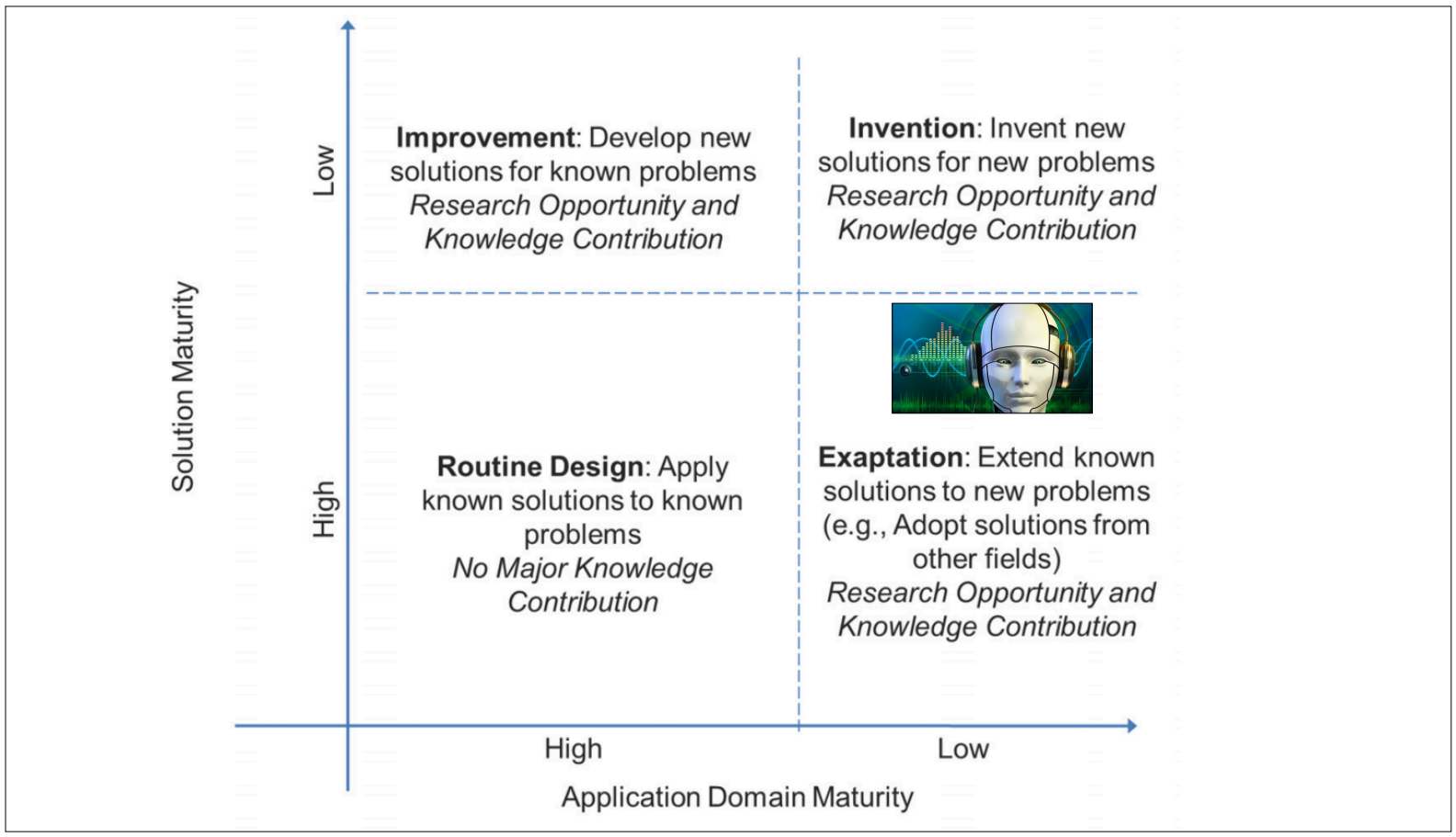


Figure 24: Overlaying the IT artifact DIL on the Knowledge Contribution Framework [62]

Gregor and Hevner [62] developed a 2x2 contribution framework. The framework positions contribution based on the maturity level of the solution and application domain. As shown in Figure 23, there are four types of contributions: Routine Design, Exaptation, Improvement, and Invention.

DIL is a Conversational Agent specifically designed for Heart Failure patients with the primary objective of complementing the caregiver community who are over-burdened and under-staffed; assisting patients in self care and management of their chronic condition, motivating them to adopt better behavior and a healthy lifestyle, and eventually achieving better health outcomes.

A Conversational Agent based intervention is not new. Research has shown large success in achieving behavioral change with this kind of approach, and has previously been tried in a variety of settings from Alcohol consumption [25], promoting health behavior change in heart attacks [26], psychosocial intervention deployed on hand-held computers [27], hospital discharge nurse that explains written hospital discharge instructions to patients with low health literacy [23], psychotherapy [28], and as health dialog systems [29].

DIL borrows ideas and best practices from previously tried and tested applications in different settings, and aims to design and implement a Conversational Agent in the specific domain of Heart Failure patients that has not been tried before. In this regard, the IT artifact DIL falls in the Exaptation quadrant of the Knowledge Contribution Framework [62].

5.5 FUTURE RESEARCH

Although the study was well received by the patients participating in the trial, and the findings were encouraging, there is surely room for improvement. As mentioned in Chapter 3 the study went through multiple iterations of Design and Build. The initial idea was to develop a voice-enabled bot, which was later discarded, as the performance of voice bots in the first prototype never achieved the minimum threshold of acceptable quality. This is definitely an area that needs further investigation and due-diligence because the future is most certainly voice where patients can talk to an artifact like DIL instead of chat.

Another limitation of the study was the short duration of only six weeks. A future random control trial with a minimum of ten patients over three to six months will be ideal to really gauge the impact of DIL on behavior and health outcomes - an improvement on all health vitals like weight, blood pressure and other symptoms will really validate the efficacy of a conversational agent like DIL. If possible, the trial should include two groups of patients - the first group will receive support from nurses and clinicians, and the second group will be supported by DIL. At the end of the trial health and behavioral outcomes can be compared to measure the effectiveness of DIL.

Further an integration with IBM Watson - a rule based expert system that can accurately predict the recurrence of heart failure by monitoring a patient's individual responses during conversation with DIL and his or her health dashboard results will go a long way in addressing the resource problem mentioned in earlier sections. A more in depth data analysis of patient's responses and dashboard results using machine learning and artificial intelligence will make DIL smarter, and further customize and tailor conversations based on every patient's individual needs.

Finally the current artifact was limited to home monitoring dashboard results. In an ideal scenario, DIL will not only review these dashboard results, but further integrate with the patients' electronic health records residing in the primary care physician's office, and take advantage of the rich repository of patient health information. DIL can then mine that data, and provide a more comprehensive picture of the patients' health, and develop the capability to truly converse with patients using Natural Language Processing (NLP) in an intelligent way. DIL can also proactively notify the doctors, nurses and members of the caregiver community when it identifies patients with high risk, so that the doctors and the nurses can follow up with patients before something goes wrong.

As technology continues to mature, with machine learning and artificial intelligence, and other Personal Healthcare devices become an everyday part of human life, a voice-enabled Health assistant that is smarter and can review not only the home-monitoring health data but a patient's complete medical history, something along the likes of Siri, Alexa, Cortana or Google

Assistant is what the patients will demand. Such a system can not only cater to Heart Failure patients but all patients with chronic conditions.

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APPENDIX

APPENDIX A - DIL-QUESTIONNAIRE FOR USER INTERFACE SATISFACTION

Start of Block: OVERALL REACTION TO SOFTWARE

Q1 Design

Terrible Wonderful

0 1 2 3 4 5 5 6 7 8 9

() 

Q2 Difficulty

Difficult Easy

0 1 2 3 4 5 5 6 7 8 9

() 

Q3 Usability

Frustrating Satisfying

0 1 2 3 4 5 5 6 7 8 9

() 

End of Block: OVERALL REACTION TO SOFTWARE

Start of Block: SCREEN

Q4 Reading characters on screen

Hard Easy

0 1 2 3 4 5 5 6 7 8 9

()

Q5 Organization of information

Confusing Very Clear

0 1 2 3 4 5 5 6 7 8 9

()

Q6 Sequence of screens

Confusing Very Clear

0 1 2 3 4 5 5 6 7 8 9

()

End of Block: SCREEN

Start of Block: TERMINOLOGY AND SYSTEM INFORMATION

Q7 Use of terms throughout system

Inconsistent Consistent

0 1 2 3 4 5 5 6 7 8 9

()

Q8 Terminology related to task

Never Always

0 1 2 3 4 5 5 6 7 8 9

()

Q9 Position of messages on screen

	Inconsistent					Consistent				
	0	1	2	3	4	5	6	7	8	9
()										

Q10 Prompts for input

	Confusing					Clear				
	0	1	2	3	4	5	6	7	8	9
()										

Q11 Error Messages

	Unhelpful					Helpful				
	0	1	2	3	4	5	6	7	8	9
()										

End of Block: TERMINOLOGY AND SYSTEM INFORMATION

Start of Block: LEARNING

Q12 Learning to operate the system

	Difficult					Easy				
	0	1	2	3	4	5	6	7	8	9
()										

Q13 Performing tasks is straightforward

	Never					Always				
	0	1	2	3	4	5	6	7	8	9
()										

Q14 Help messages on the screen

Unhelpful Helpful

0 1 2 3 4 5 5 6 7 8 9

() 

Q15 Supplemental reference materials

Confusing Clear

0 1 2 3 4 5 5 6 7 8 9

() 

End of Block: LEARNING

Start of Block: SYSTEM CAPABILITIES

Q16 System speed

Too slow Fast enough

0 1 2 3 4 5 5 6 7 8 9

() 

Q17 System reliability

Unreliable Reliable

0 1 2 3 4 5 5 6 7 8 9

() 

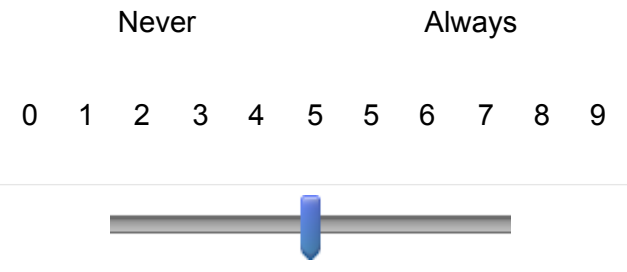
Q18 Correcting your mistakes

Difficult Easy

0 1 2 3 4 5 5 6 7 8 9

() 

Q19 Designed for all levels of users

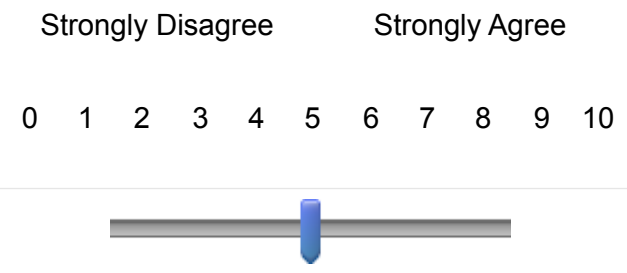


()	

End of Block: SYSTEM CAPABILITIES

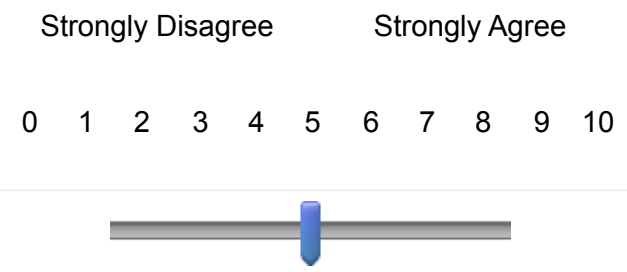
Start of Block: GENERAL FEEDBACK

Q20 I will use the system frequently



1 ()	

Q21 I felt very confident using the system



()	

Q22 Other Comments

_____

_____

_____

_____

_____

End of Block: GENERAL FEEDBACK

APPENDIX B - DIL-PERCEIVED HELPFULNESS

Start of Block: SURVEY INSTRUCTIONS

Welcome Message
Welcome! The purpose of this survey is find the effectiveness of DIL in helping you lead your life better in your own home setting.
Please answer all questions to the best of your understanding.

End of Block: SURVEY INSTRUCTIONS

Start of Block: Helpfulness of DIL

Q1 Overall how helpful or unhelpful was DIL?

- ◯ Extremely helpful (1)
- ◯ Moderately helpful (2)
- ◯ Slightly helpful (3)
- ◯ Neither helpful nor unhelpful (4)
- ◯ Slightly unhelpful (5)
- ◯ Moderately unhelpful (6)
- ◯ Extremely unhelpful (7)

Q2 Was conversing with DIL easy?

- ◯ Extremely easy (1)
- ◯ Moderately easy (2)
- ◯ Slightly easy (3)
- ◯ Neither easy nor difficult (4)
- ◯ Slightly difficult (5)
- ◯ Moderately difficult (6)
- ◯ Extremely difficult (7)

Q3 Was the motivational messages useful?

- ◯ Extremely useful (1)
- ◯ Very useful (2)
- ◯ Moderately useful (3)
- ◯ Slightly useful (4)
- ◯ Not useful at all (5)

Q4 How helpful or unhelpful are the links to various published articles on relevant topics?

- ◯ Extremely helpful (1)
- ◯ Moderately helpful (2)
- ◯ Slightly helpful (3)
- ◯ Neither helpful nor unhelpful (4)
- ◯ Slightly unhelpful (5)
- ◯ Moderately unhelpful (6)
- ◯ Extremely unhelpful (7)

Q5 Did DIL help you in improving your lifestyle and adherence to clinical guidelines?

- ◯ Extremely helpful (1)
- ◯ Moderately helpful (2)
- ◯ Slightly helpful (3)
- ◯ Neither helpful nor unhelpful (4)
- ◯ Slightly unhelpful (5)
- ◯ Moderately unhelpful (6)
- ◯ Extremely unhelpful (7)

End of Block: Helpfulness of DIL

APPENDIX C - MINNESOTA LIVING WITH HEART FAILURE

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	**No**			**Very Little**		**Very Much**
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

11/10/04

APPENDIX D - IRB

Claremont Graduate University
Institutional Review Board

March 28, 2018
IRB #: 3104
Title of Study: DIL-An AI Conversational Agent for CHF Patients
Determination: EXEMPT

Dear Sanjoy Moulik,

Thank you for submitting your research protocol to the IRB at Claremont Graduate University for review. Based on the information you have submitted, we consider your study *exempt from IRB supervision* under CGU policy and federal regulations at 45 CFR 46.101(b)(2) and 45 CFR 46.101(b)(4).

Please note that a series of suggestions may also be attached to this email. These are suggestions to develop or improve your research protocol. These suggestions are highly recommended but not required. You do not need to send anything back to the IRB.

Exempt status means that so long as the study does not vary significantly from the description you have given us, further review in the form of filing annual Renewal or project Closure forms is not necessary. You may specify in relevant study documents, such as consent forms, that CGU human subjects protection staff members have reviewed the study and determined it to be exempt from IRB supervision. The IRB does not "*approve*" (or disapprove) studies that are exempt, so kindly avoid use of this verb.

Please note carefully that maintaining exempt status requires that (a) the risks of the study *remain minimal*, that is, as described in the application; (b) that *anonymity or confidentiality* of participants, *or protection* of participants against any higher level of risk due to the internal knowledge or disclosure of identity by the researcher, is maintained as described in the application; (c) that *no deception* is introduced, such as reducing the accuracy or specificity of information about the research protocol that is given to prospective participants; (d) the research *purpose*, *sponsor*, and recruited *study population* remain as described; and (e) the principal investigator (PI) continues and is not replaced.

Changes in *any such features* of the study as described may affect one or more of the conditions of exemption and would very likely warrant a reclassification of the research protocol from exempt status and require additional IRB review. If any such changes are contemplated, please notify the IRB as soon as possible and before the study is begun or changes are implemented. If any events occur during the course of research, such as unexpected adverse consequences to participants, that call into question the features that permitted a determination of exempt status, you must notify the IRB as soon as possible.

If Applicable: most listservs, websites, and bulletin boards have policies regulating the types of advertisements or solicitations that may be posted, including from whom prior approval must be obtained. Many institutions and even classroom instructors have policies regarding who can solicit potential research participants from among their students, employees, etc., what information must be included in solicitations, and how recruitment notices are distributed or posted. You should familiarize yourself with the policies and approval procedures required of you to recruit for or conduct your study by listservs, websites, institutions, and/or instructors. Approval or exemption by the CBU IRB does not substitute for these approvals or release you from assuring that you have gained appropriate approvals before advertising or conducting your study in such venues.

The IRB may be reached at (909) 607-9406 or via email to irb@cgu.edu. KGI personnel with questions about their exempt status should contact KGI's Office of Research and Sponsored Projects at (909) 607-9313 or irb@kgi.edu. The IRB wishes you well in the conduct of your research project.

150 East Tenth Street • Claremont, California 91711-6160
Tel: 909.607.9406

ORIGINAL

Revised 10/14/2016. *Check the IRB FORMS page www.cgu.irb/irbforms to be sure this is the current application form*	
Claremont Graduate University **Institutional Review Board (IRB)** **Application for Research Project Review** ***Please submit a signed or scanned original to irb@cgu.edu*** or to office located at135 East Twelfth St. Mail address: Office of Research and Sponsored Programs 150 East Tenth St., Claremont, CA 91711	**LEAVE BLANK—FOR IRB USE ONLY.** IRB NUMBER & DATE RECEIVED: **Action Taken:** ☑ Exempt from IRB Coverage ☐ Approved under Expedited Review ☐ Approved by Board ☐ Disapproved by Board AUTHORIZED SIGNATURE & DATE: 3/27/18

RECEIVED
MAR 19 2018
IRB # 3104

To obtain IRB review of a **research project with human participants***, submit this completed form to the IRB with all of the indicated attachments. Allow sufficient time for review before starting the project. Please consult the IRB ***website*** www.cgu.edu/irb and complete human subjects ***training*** as described there before submitting an application. Review pertinent FAQs and ***contact*** irb@cgu.edu or 909-607-9406 with questions.

***Research** as used here means a systematic investigation designed to develop or contribute to generalizable knowledge. This includes research, development, testing, and evaluation. *This does not typically include classroom exercises, demonstrations, or other course requirements that receive grades.* Research does not include customer satisfaction or quality assurance surveys or similar data collections designed to improve the operations of a single institution.

Human participants means living individuals about whom an investigator obtains data through intervention or interaction with the individual or obtains identifiable private information about identifiable individuals from a separate source such as medical or school records or other individuals such as relatives. CGU academic policy requires that the Institutional Review Board (IRB) reviews all research projects at Claremont Graduate University involving human participants.

Name of Study (Maximum 100 characters, *including spaces*): DIL-An AI Conversational Agent for CHF Patients

PROJECT SUMMARY (Maximum *200 characters, including spaces*):
This project aims to design and evaluate DIL, an AI bot that will complement the work of clinicians to achieve adherene to clinical and behavioral guidelines for the patients in their home setting.

PRINCIPAL INVESTIGATOR: Sanjoy Moulik	E-MAIL ADDRESS: sanjoy.moulik@cgu.edu
DEPARTMENT: CISAT	TELEPHONE: (949) -2925127
MAILING ADDRESS: Street: 130 East 9th Street City: Claremont State: CA Zip Code: 91711	CO-PI, if any (Names, email addresses, affiliations—use additional pages if needed):
PURPOSE OF RESEARCH : Ph.D. Dissertation If Other, explain (80-character limit):	IRB approval requested from another institution? ☒NO ☐YES (*insert additional pages if needed*) Status [Select] Date: Institution: Status [Select] Date: Institution:
Is this project a sub-study of another project? ☒ NO ☐YES* *If yes, *attach* information that is pertinent to the approval of the primary project. However, in this application form, include only the particulars that pertain to the study under direct review.	Has this project received or requested external funding? ☒ NO ☐YES--if yes, list: Status Date Source [Select] [Select] [Select]
STUDY SITES if other than CGU (*insert additional pages if needed*) :	

PARTICIPANTS (check all that apply):	TYPE OF DATA (check all that apply):
☒ Adults (18 years or older) ☐ Minors (Less than 18 years) ☒ Medical or other clinical patients ☐ Non-English Speaking ☐ Mentally or Developmentally Disabled or Impaired ☐ Prisoners, Parolees, or Incarcerated ☐ Elected or Appointed Public Officials or Candidates	☒ Interviews (Face to Face) ☒ Questionnaires or Surveys ☐ Existing Data Banks, Archives or Documents ☐ Physiological Measurements or Blood Samples ☐ Observations/Record of Public Record ☐ Educational Tests ☐ Filming, Video or Voice-Recording
NATURE OF INFORMATION TO BE OBTAINED:	OTHER:
☐ Participants and their responses ***cannot*** be identified ***by the researcher(s)*** ☒ Only standard educational strategies or techniques ☐ Collected with permission or in collaboration with another agency/institution	☒ Research conducted in an educational setting ☐ Project involves temporary deception of participant ☐ Project is time sensitive due to an unforeseen research opportunity (not due to a late start on this application) (***Please explain time sensitivity in a cover memo***)

The Principal Investigator and co-Principal Investigators (if any) each affirms by signature the following (***if attestation is transmitted electronically, the message from each PI/coPI must state the following***):

(1) All procedures performed during this project will be conducted by individuals legally and responsibly entitled to do so, and any significant systematic deviation from the submitted protocol (for example, a change in principal investigator, sponsorship, research purposes, participant recruitment procedures, research methodology, risks and benefits, or consent procedures) will be submitted to the IRB for approval prior to its implementation.

(2) I/we will comply with all federal, state, and institutional policies and procedures to protect human subjects in research;

(3) I/we understand the ethical responsibilities of research investigators and have received the required **training** in human research participant protection as specified at www.cgu.edu/irb;

(4) I/we will assure that the consent process and research procedures as described herein are followed with every participant in the research; and

(5) I/we will promptly report any deviations or adverse events to the IRB.

PRINCIPAL INVESTIGATOR SIGNATURE:	DATE: 1-26-2018
CO-PRINCIPAL INVESTIGATOR SIGNATURE (add others below if applicable):	DATE:

Student Principal Investigators are required to include an endorsement from their faculty advisor. The signature below certifies the following (***if attestation is transmitted electronically, the message from each faculty advisor must state the following***) **As faculty advisor, I have reviewed and approved this complete Application and its attachments and I accept responsibility to supervise the work described herein in accordance with applicable institutional policies.**

FACULTY ADVISOR SIGNATURE (if applicable):	DATE: 1-26-2018.
Faculty Advisor Name: Dr. Samir Chatterjee	
Email: samir.chatterjee@cgu.edu	Telephone: (909) -6074651
Office Address: 130 East 9th St., Claremont, CA 91711	

Additional CO-PRINCIPAL INVESTIGATOR SIGNATURE (*In ink*):	DATE:
Additional CO-PRINCIPAL INVESTIGATOR SIGNATURE (In ink):	DATE:

Attach additional pages if needed

APPENDIX E - INFORMED CONSENT FORM

Informed Consent Form for
"DIL - A Conversational Agent for Congestive Heart Failure Patients "

You are being asked to participate in a research project conducted by Sanjoy Moulik, a doctoral student in the Center for Information Systems and Technology (CISAT), Claremont Graduate University (CGU). The research project will be supervised by Dr. Samir Chatterjee, a distinguished faculty at CISAT, Claremont Graduate University. You are being asked because of your willingness and non-coerced offer to volunteer for the study described below.

PURPOSE: The purpose of this study is to evaluate and better understand the impact of technology especially persuasive messages from an artificial intelligent bot on promoting behavior change for those who suffer from chronic illnesses such as Congestive Heart Failure (CHF). A persuasive message is a communication between the bot and you via Facebook Messenger Service on cell phones or other delivery method that includes information about your current and past physical activity, recommendations on how you can improve your physical activity, diet and wellbeing factors and motivational messages intended to encourage you to become more active in your life. Quantitative data such as blood pressure, blood glucose, and weight will be collected via wireless home-monitoring devices and stored in a secured cloud server. These measurements will form the basis of conversation between DIL and the participants. The goal is to mine the data and provide suggestions for a healthier lifestyle, and to reduce hospital readmissions.

PARTICIPATION: Your participation in this study is expected to take about two months of your time. A typical conversation with DIL will take about 20 minutes, 1-2 times a week.

We will collect your blood pressure, weight, blood glucose data by using home-monitoring devices. By participating in this study, you will be asked to take your blood pressure, blood glucose and weight reading at least once per week using the provided devices. The blood pressure monitor will require you to simply place an arm cuff around your arm and to press a "Start" button to take a blood pressure reading. The blood pressure device will automatically expand the arm cuff, determine your blood pressure, and deflate the arm cuff once the measurement is done. Your weight will be determined using a typical weight scale. Operating the scale is as simple as stepping on the scale to determine your weight. Each device will be connected to your computer so that your information may be recorded. This information is tracked to understand how your physical activity may or may not affect your blood pressure and weight.

The setup of the home-monitoring devices will take about 1 week and about 2-3 hours each day. This will include all testing and making sure that everything is safely done. These devices will be placed discretely so to minimize any unsightly looks in your house. No damage will be done to your home in placing the sensors. All devices will be connected to your computer so that your weight, blood pressure, and blood glucose data may be recorded. If you feel uncomfortable at any time during the study with having this type of information collected, you may request any or all of the devices to be removed.

The information collected in this study will be used by our team to initiate a communication between DIL - an AI bot and you via Facebook Messenger service a few times during the week. Included in the message will be motivational information and suggestions of how you might improve your adherence to clinical and behavioral guidelines. You are not required or obligated to follow any improvement suggestion. To communicate with the Bot, you will be asked to use Facebook Messenger. If you do not know how to use a computer or a smartphone, we will provide training to you. You will not be required to respond to any message.

You will be asked to complete a simple phone-based survey at the beginning and end of the study. This information will be collected to help the research team to adjust the study for improvement or to better understand the impact of the study on improving your adherence.

This study requires different types of technology to be used. All technology has been selected to be easy for you to use. You will not be responsible for setting up the technology or for maintaining the technology. In the event that a technical problem does occur, you are asked to contact Sanjoy Moulik at the IDEA Lab, Claremont Graduate University, so that he may correct the problem within 24 hours. This may require him or a member of the team to enter your home. We will contact you to setup a time that is convenient for you to have us enter your home.

Once the study is completed, all technology used in the study will be removed and your home will be placed back to its original condition, as prior to the start of the study. Lastly, at the end of the study, you will be given the option of keeping a copy of all the data collected and any outcomes that may result from the study. The information collected during the one-month study period will be used for research and development purposes, which you will be allowed to read upon the completion of the document.

RISKS & BENEFITS: Minimal risk exists in your participation in this study. All you are required to do is carry on a conversation with DIL, and measure your weight, blood pressure, and blood glucose with the devices that are provided to you.

As a participant, you are formally instructed that our system is not a real-time monitoring or emergency medical system. It will be important to know that messages are automated and are not read by health care personnel. Furthermore, a lack of response by our system to critical health information should be not construed as reassurance. Hence you should always follow your normal course of action; in the event that you do not feel well, please get in touch with your Care giver, and seek medical attention as soon as possible. The only difference among patients using our system and those not using the system is the actual self-reporting of self-management practices not the practices themselves.

The research in this study is expected to benefit the scientific community by increasing the understanding of how computer technology can be used to improve adherence and promote better health.

The expected contribution of the study is to produce a novel artifact and demonstrate the efficacy and utility of the tool to assist patients with heart failure in improving their self-care. If conversations with DIL can achieve better adherence to clinical and behavioral guidelines, the patients will directly benefit from a better quality of life.

COMPENSATION: You will receive $15 Starbucks gift card as a token compensation for your participation.

VOLUNTARY PARTICIPATION: Please understand that your participation is completely voluntary. Your decision whether or not to participate will in no way affect your current or future relationship with CGU or its faculty, students, or staff. You have the right to withdraw from the research at any time without penalty. You also have the right to refuse to answer any question(s) for any reason, without penalty.

CONFIDENTIALITY: Your individual privacy will be maintained in all publications or presentations resulting from this study. All data collected in the study will be maintained in a secure computer by the research team. No data that can identify you by name or other identifiable marks will be shared during or after the study to the research community (e.g., journal publications, conferences, etc.); confidentiality and anonymity of your information will be strictly maintained, and all physical documents (e.g., completed survey forms) will be shredded upon the completion of the study.

FURTHER INFORMATION:
If you have any questions or would like additional information about this research, please contact Sanjoy Moulik at:

Mailing Address	**Phone Number**	**email Address**
Sanjoy Moulik IDEA LAB 130 East 9th St Claremont, CA 91711	949-292-5127 (24 hours)	sanjoy.moulik@cgu.edu Sanjoy.moulik@gmail.com

This study and its procedures have been approved by the Claremont Graduate University Institutional Review Board. This Board is responsible for ensuring the protection of research participants. The CGU Institutional Review Board, which is administered through the Office of Research and Sponsored Programs (ORSP), may be contacted at (909) 607-9406 with any questions.

A signed copy of this consent form will be given to you.