PATIENTS’ PERSPECTIVES OF TECHNOLOGY FACILITATED CARDIAC CARE AND ITS ASSOCIATION WITH HEALTH BEHAVIOR AND OUTCOMES

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Date 5/10/13
ABSTRACT

Few studies have documented patients’ perspectives on interventions designed to change health behaviors. Understanding constructs of interventions that patients identify support health behavior choices may help explain variation in interventions effectiveness. Therefore, our objective was to understand patients’ perspectives of participating in studies that incorporated technology to improve health outcomes and the impact of the intervention on health behaviors.

In-depth interviews were conducted with patients in two studies incorporating technology to improve health outcomes. Transcripts of interviews were analyzed using content analysis and grounded theory approaches. Health behavior surveys were used to assess the association between the intervention and health behaviors.

Establishing bi-directional conversations between patients and providers is a key factor to improve cardiac care and to positively influence health behaviors. Bi-directional conversations occur when patients are comfortable to honestly share their intentions to adhere to evidence based recommendations. Furthermore, providers are comfortable to hear divergent opinions of the recommendations and work with patients towards an agreed upon treatment plan. Active participation in this decision-making process of healthcare removes barriers of communication and empowers patients to share concerns, fears, and issues providing clinicians with information about barriers to adherence.
Additionally, we found increased interactions with health professionals augmented by technology improve knowledge of cardiac issues and health behaviors.

Our findings complement previous research and contribute a deeper level of understanding factors associated with positive health behaviors. Bi-directional communication is necessary for comprehensive decision-making. Future interventions designed to improve medication adherence should incorporate these patient-identified factors.

The form and content of this abstract are approved. I recommend its publication.

Approved: P. Michael Ho
DEDICATION

I would like to dedicate this work to my family and friends. Your support and encouragement was profoundly appreciated and invaluable in achieving this goal.

To my beloved sister, Sandy: who raised me, as a daughter; encouraged me to reach for my highest goals, as a sister; and supported me through life, as a dear friend. I will forever be in your debt and miss you deeply.

To my children, Raymond and Caitlyn, who keep me young in mind and spirit. Your continued love and encouragement make my heart sing.

To my brother, Jim, your love and support have kept me sane. Thank you for taking the time from your vacation in Yellowstone to listen to my comprehensive exam presentation.

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To my friends who have also loved, supported, and encouraged me, even when you thought I was crazy. Thank you for listening to all my worries.

And finally, to my husband, Ed, who always sees the best in me and has given me the confidence to pursue my goals, at any age. I am truly grateful. Your unconditional love for the last 37 years has enriched my life and nourished my soul.
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<td>A1C</td>
<td>Hemoglobin A1C</td>
</tr>
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<td>ACS</td>
<td>Acute coronary syndrome</td>
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<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>BP</td>
<td>Blood pressure</td>
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<tr>
<td>CABG</td>
<td>Coronary artery bypass grafting</td>
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<td>CAD</td>
<td>Coronary artery disease</td>
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<tr>
<td>CHD</td>
<td>Coronary heart disease</td>
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<tr>
<td>CO</td>
<td>Colorado</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
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<tr>
<td>DBP</td>
<td>Diastolic blood pressure</td>
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<td>DM</td>
<td>Diabetes mellitus</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
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<tr>
<td>HBM</td>
<td>Health Belief Model</td>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>Hg</td>
<td>Mercury</td>
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<tr>
<td>HTN</td>
<td>Hypertension</td>
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<td>IMAGE-ACS</td>
<td>Improving Medication Adherence through Graphically Enhanced Interventions in Acute Coronary Syndromes study</td>
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<tr>
<td>IRB</td>
<td>Internal review board</td>
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<tr>
<td>IVR</td>
<td>Interactive voice response</td>
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<tr>
<td>JNC 7</td>
<td>Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure</td>
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<tr>
<td>LDL</td>
<td>Low density lipoprotein</td>
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<tr>
<td>MeSH</td>
<td>Medical subject heading</td>
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<tr>
<td>Abbreviation</td>
<td>Definition</td>
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<tr>
<td>MI</td>
<td>Myocardial infarction</td>
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<tr>
<td>MM</td>
<td>Millimeter</td>
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<tr>
<td>MRC</td>
<td>Medical research council</td>
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<tr>
<td>NC</td>
<td>North Carolina</td>
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<tr>
<td>NCBI</td>
<td>National Center for Biotechnology Information</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
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<td>NLM</td>
<td>National Library of Medicine</td>
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<tr>
<td>NSTEMI</td>
<td>Non-ST-Elevation myocardial infarction</td>
</tr>
<tr>
<td>PA</td>
<td>Physician’s assistant</td>
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<tr>
<td>PCP</td>
<td>Primary care provider</td>
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<tr>
<td>PDC</td>
<td>Percent of days covered</td>
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<td>PRODCLIN</td>
<td>Product confidence limits for Indirect effects</td>
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<td>RCT</td>
<td>Randomized control trial</td>
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<td>ReComp</td>
<td>Refill compliance method</td>
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<td>SAS</td>
<td>Statistical analysis system</td>
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<td>SBP</td>
<td>Systolic blood pressure</td>
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<td>SDM</td>
<td>Shared decision-making</td>
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<td>SEAMS</td>
<td>Self-efficacy for appropriate medication use scale</td>
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<td>SES</td>
<td>Socio-economic status</td>
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<td>SOC</td>
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<td>STEMI</td>
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<td>Telephone-Linked Care</td>
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<td>TTM</td>
<td>Transtheoretical Model of Behavior Change</td>
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<tr>
<td>UA</td>
<td>Unstable angina</td>
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<tr>
<td>USA</td>
<td>Unstable angina</td>
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<tr>
<td>VA</td>
<td>Veteran's Affairs</td>
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<td>WA</td>
<td>Washington</td>
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CHAPTER I
INTRODUCTION

Brief Overview

Cardiovascular disease (CVD) is the single leading cause of death and disability in the United States. Prevention and management of CVD is a public health goal that remains a major challenge. Treatment of CVD involves medication therapy where appropriate and patients’ adherence to lifestyle changes and/or medications. However, adherence rates are about 50% for medications and are much lower for lifestyle changes; significantly jeopardizing treatment success. The consequences of poor health behaviors are worsening disease status and increased mortality rates for patients while increasing health care costs to society. Therefore, improving CVD outcomes remains a challenge and is dependent on understanding and improving patients’ health behaviors.

Recent studies of cardiovascular outcomes explore the effectiveness of multifaceted interventions targeting health behaviors and medication adherence with varying results. These multifaceted interventions generally incorporate more than one component: communication technologies, home monitoring, patient education, and frequent interactions with providers through technology. Because health behaviors are multi-factorial in nature, multifaceted interventions are usually more successful than unimodal interventions. Knowledge of the patient choices and understanding the reason behind their decisions may explain the varying degrees of effectiveness of these interventions. Patients choose to participate in interventions and choose to execute the prescribed behaviors. Furthermore, they have the option of either not doing what has been requested or modifying their behavior in such a way that it changes the integrity of the intervention. Yet, few cardiovascular studies have investigated the
effectiveness of multifaceted interventions on patients’ outcomes and their health behavior decisions from the perspective of the individual participant.

Understanding how the intervention modifies patients’ health behaviors is important to the overall success of the intervention. There are numerous health behavior theories that help explain the multitude of factors that influence human behavior. One such model is the Transtheoretical Model of Behavior Change (TTM), \(^{(27-31)}\) which focuses on the decision-making abilities of the individual. Investigation of specific constructs of TTM (self-efficacy and stage of change) may shed light on whether or not the intervention influenced changes in the patients’ health behavior.

Therefore, this thesis gathers an in-depth understanding of the patients’ experience of participating in multifaceted cardiac interventions and their perspective of how the interventions affect their health behavior decisions and outcomes. The investigation uses qualitative analyses that incorporate an iterative, inductive, and deductive toolkit of analytical strategies. In addition, this thesis assesses the association of an intervention on cardiovascular outcomes mediated by specific health behavior components (self-efficacy and stage of change) using both univariate and multivariate quantitative analyses.

**Theoretical and Empirical Frameworks**

Theoretical and empirical frameworks provide researchers with concepts, principles, and rules for shaping and conducting research. \(^{(32-33)}\) This thesis utilizes multiple frameworks to support the various components of the research. A pragmatic paradigm is used to provide a conceptual framework for this research and supports the use of a mixed methodology. \(^{(32-33)}\) To further ground the methodological development of this thesis, additional substantive theoretical and empirical frameworks support the
use of obtaining patients’ perspectives of their experience with the interventions. Theories of Ray Pawson (31) and the Medical Research Council (37-38) explore the importance of subjective views of an intervention and understanding why they are useful and needed. Finally, the Transtheoretical Model of Behavior Change is used to explain the factors that influence human behavior. In the following discussion, we delve into each framework and describe how it supports this thesis.

A pragmatic paradigm focuses on the outcomes of research, such as the actions, situations, and consequences of inquiry, rather than precursor conditions. (32-36) Patton defines pragmatism as using what works to find solutions to problems. (33) Pragmatism examines practical consequences and empirical findings in order to decide which action to take as one attempts to better understand real world phenomena. (35) Therefore, a pragmatist is not committed to one philosophy, such as positivism that quantitative researchers may ascribe to or constructivism that a qualitative analyst may believe. Pragmatists are open to many approaches to collecting and analyzing data. (32-33) The goal is to draw from the strengths of each philosophy and methodology within the philosophical paradigm and to minimize the weaknesses of both. (35) Consequently, a pragmatic paradigm is ideal for inquiry into health services research where the intent is to evaluate quality of care, develop clinical practice guidelines, and foster effective interventions to improve quality of care. (35)

Health services outcomes research examines the effects of interventions and policies on the health outcomes of individuals and society. (34) Examination of health care utilization, cost, and clinical effectiveness lend themselves to quantitative inquiry. However, other complex aspects such as organizational change, implementation of evidence-based guidelines, and patients’ perceptions of their clinical care are well suited for qualitative inquiry. (34) Therefore, a pragmatic paradigm is valuable for this research
because we can capitalize on the use of a mixed methodology and utilize the strengths of both qualitative and quantitative inquiry.

To further ground the methodological development of this thesis we use the theories of Pawson (31) and the Medical Research Council. (37-38) Theories of Ray Pawson and the Medical Research Council (37-38) explore the importance of subjective views of an intervention and understanding why they are useful and needed are presented.

The theoretical framework of Ray Pawson (31) supports exploring individual perspectives of the intervention participants. Pawson notes that interventions are based on hypotheses and multifaceted interventions, by definition, have more than one theory. (25, 31) The success of an intervention depends on the cumulative success of the entire sequence of theories as well as the efficacy of each step in a long implementation chain. Interventions are open systems, active, and permeable, and therefore have intended and unintended outcomes. (31) Multifaceted interventions offer resources and advice, which may be welcome, heeded, and acted upon. Equally, they may be missed, ignored, forgotten, and thus overlooked; or just not done. (31) Interventions work through the patients’ reasoning, which are the triggers of change intended by the intervention. Knowledge of that reasoning is integral to understanding interventions outcomes. (31) Patients choose to make the interventions work and have the ability to respond in ways that were not expected, thus shaping and reshaping the intervention. (31) What this means is that patients’ select medical advice or aspects of interventions they believe to be beneficial or are conducive to their lifestyle, which affects the outcome of the intervention. Thus, when assessing the effectiveness of the interventions, it is very important to understand the patients’ perspective of the interventions.

Therefore, due to the complexity of multifaceted interventions, evaluations assessing the effectiveness are difficult and must take into account the various
components of the intervention that may act independently and interdependently. In addition, evaluations need to consider patient and organizational factors and the number and difficulty of behaviors required by those receiving the intervention.\(^{(37-38)}\) The empirical framework of the Medical Research Council (MRC)\(^{(37-38)}\) for designing and evaluating multifaceted interventions paradigm includes the importance of going beyond evaluating overall effectiveness to studying the component processes and how they vary among patients.\(^{(37-38)}\) The Conceptual Model of this thesis stems from the Medical Research Council framework, which defines multifaceted interventions as having interacting components. In order to properly evaluate the multifaceted interventions it is important to not only understand which components the patients believe to be effective but also take into account the effectiveness of the combined intervention. The evaluation must also consider how the intervention affected the patients’ health behavior to fulfill the prescribed lifestyle changes and improve adherence. In addition, it is important to understand how the effects vary between patients and sites. Finally, the evaluation results may be used to improve the overall effectiveness of the intervention.\(^{(37-38)}\)

To fully understand the patients’ perspectives of their experience of the intervention and the effect the intervention may have had on the patients’ health behaviors we must be aware of the factors that influence health behaviors. Therefore, this thesis uses the Transtheoretical Model (TTM) to help explain and explore the factors that influence patients’ behaviors. TTM focuses on the decision making abilities of the individual and includes four main constructs: the stages of change, processes of change, self-efficacy, and decisional balance.\(^{(27-31)}\) Attempting to understand a concept as complex as health behavior necessitates using a model that works towards classifying and explaining the multitude of factors that can and do influence human behavior.\(^{(39-40)}\)
The TTM indicates that health behavior change is a process where patients are at various level of motivation to change. The process is described as cyclical where people enter and exit at any point and often recycle. The specific points are described as “stages” and there are five distinct stages. Therefore, interventions may affect change in their stage, thus improving their motivation to change and support their effort to improve their health behavior with skills and information. (39-40) For that reason, this thesis assesses the change in behavioral constructs after participation in the study. A comparison between the intervention and the usual care groups is also assessed. The final assessment investigates if health behaviors mediate the association of the intervention with adherence outcomes.

Theoretical and empirical frameworks provide researchers with concepts, principles, and rules for shaping and conducting research. To ensure valid creation and integration of evidence to produce a high quality research project, this thesis is being guided by multiple frameworks to ensure valid creation and integration of evidence to produce a high quality research project.

**Purpose**

The primary purpose of this thesis is to gather an in-depth understanding of the patients’ experience of participating in multifaceted cardiac interventions and their perspectives of how the interventions affect their health behavior decisions and outcomes.

The secondary purpose is to assess the association of an intervention on cardiovascular outcomes mediated by specific health behavior components (self-efficacy and stage of change).
Conceptual Framework

Source

The Medical Research Council defines complex interventions to be those “built up from a number of components, which may act both independently and interdependently”. Thus the evaluation is challenging because interpreting the results can be difficult. Are the results due to an effective/ineffective study design or due to the effective/ineffective implementation of the study design by the facility? Finally, is it clear whether or not the patients’ participation is in accordance with the prescribed process of the intervention? To answer these questions, the MRC proposes a framework to define the problem: design and evaluate the intervention simultaneously. This iterative process separates the individual components allowing for a better understanding of each part and how it affects the other component through simultaneous evaluations. A greater understanding of the individual components facilitates a more effective intervention.

Although we cannot retrospectively follow the MRC framework, we can prospectively apply the concept of evaluation of the participants’ perspectives of the intervention and apply the lessons learned back into the study design. The knowledge gained from the patients will improve the intervention constructs and facilitate the translational process into clinical cardiac care.

Therefore, our Conceptual Model stems from the Medical Research Council’s framework that an optimized intervention has multiple components intended to improve clinical outcomes (Figure 1). These interventions need appropriate evaluations that assess the various components as well as the overall effectiveness.

Evaluation of multifaceted interventions therefore, includes both understanding which components the patients believe to be effective as well as understanding their
Figure 1. Modified Medical Research Council’s Evaluation for Complex Interventions Conceptual Model

Optimize Intervention

**Multifaceted Interventions**

1) Organizational factors (e.g., Interactive Voice Response System)

2) Provider interventions (e.g., prescribed medication regimen)

3) Patient Interventions (e.g., educational material)

Optimize Evaluation

**Patients’ Perspectives**

Aims 1 and 3

Health Behavior Constructs

Aim 2

Implementation

Improved Outcomes
perceptions of the effectiveness of the combined intervention. The optimized evaluation also takes into account how the intervention affected outcomes such as patients’ health behavior to fulfill the prescribed components (i.e., life style changes and improved adherence to the interventions’ components).

**Model domains**

We describe the optimized intervention domain, which includes the factors defining the multifaceted intervention: 1) Organizational factors (e.g., Interactive Voice Response System IVR) 2) Provider interventions (e.g., prescribed lifestyle change); and 3) Patient Interventions (e.g., educational material). The optimized evaluation domain includes factors that enhance the traditional effectiveness evaluations. The mixed methodology in this thesis uses 1) semi-structured interviews to obtain the patients’ perspectives as determined in Aims 1 and 3 and 2) health behavior surveys to assess the association of the multifaceted intervention and specific constructs of patients’ health behaviors as determined in Aim 2. The populations in this thesis originate from multifaceted interventions.

These interventions need appropriate evaluations that assess the various components as well as the overall effectiveness. Our intention is to evaluate the multifaceted interventions, understand which components the patients believe to be effective and assess the effectiveness of the combined intervention. This objective is obtained by evaluating individual participants’ opinions and beliefs and how the intervention affected the outcomes such as patients’ health behavior to fulfill the prescribed components (i.e., life style changes and improve adherence to the interventions’ components). The final step is to then apply the lessons learned in back into the study design that will improve the successful intervention and facilitate the translational process into clinical cardiac care.
CHAPTER II

REVIEW OF THE LITERATURE/BACKGROUND

Literature Review

The primary purpose of this literature review is to appraise papers that describe in-depth experiences of participating in technology facilitated, multifaceted cardiac interventions from the patients’ perspective and how the interventions affected their health behavior decisions. The secondary purpose is to examine articles that assess the effect interventions had on specific health behavior components and their association with cardiovascular outcomes. The literature search was conducted using two databases: MEDLINE and PubMed. MEDLINE is the U.S. National Library of Medicine’s (NLM) premier bibliographic database that contains references to journal articles in life sciences with an emphasis on biomedicine. MEDLINE records are indexed with Medical Subject Headings (MeSH). PubMed is also a bibliographic database that includes MEDLINE, as well as, life science journals, and online books. It also covers behavioral sciences, chemical sciences, and bioengineering. It is a free resource developed and maintained by the National Center for Biotechnology Information (NCBI) at the NLM, located at the National Institutes of Health (NIH).

The literature search is stratified into three main subject areas: cardiology, hypertension, and acute coronary syndrome. MeSH terms were utilized in the PubMed and MEDLINE databases to identify literature relevant to the three stratifications plus additional relevant subjects including adherence, technology, qualitative analysis, and health behavior components: stages of change and self-efficacy. The nine main MeSH terms include: 1) Cardiology, 2) Hypertension, 3) Acute Coronary Syndrome, 4) Patient Compliance OR Patient Adherence OR Medication Adherence; 5) Qualitative OR
Interview, 6) Interactive Voice Response, and 7) Blood Pressure Home Monitoring, 8) Stages of Change, and 9) Self-Efficacy.

These terms were then combined appropriately to narrow each search. All searches were limited to 1995 through March 2012 to capture investigations of patients’ perspectives of participating in multifaceted cardiac interventions and the assessment of the effect interventions had on health behavior components; specifically, stages of change and self-efficacy.

Results of Literature Search

Table 1 displays the results of the literature search, beginning with nine main MeSH terms then combining relevant topics to discern appropriate articles to this literature review. The goal of the literature review is to identify and select articles that concentrate on each major subject area. Article significance is determined by the relationship to one of the main subject areas in the outline and the search was narrowed to include specific articles that relate to the questions of this thesis.

Individually, each of the major subject areas yielded the following citations: Cardiology 146,257; Hypertension 342,973; Acute Coronary Syndrome 13,897; Adherence 3,967; Qualitative OR Interview 224,166; and Interactive Voice Response 319 of which 20 abstracts and 13 full text articles were reviewed. Home Blood Pressure Monitoring yielded 9,663, Stages of Change 14,080, and lastly, Self-Efficacy 27,155 citations.

To narrow the search, Cardiology was combined with “interactive voice response” and three articles were reviewed to reveal one full text paper that was reviewed. Next, cardiology was combined with “qualitative” or “interview” and 1,209 articles were found. Lastly, cardiology was combined with both “interactive voice response” and “qualitative” or “interview”; no citations were found.
Cardiology was then combined with adherence terms (Patient Compliance OR Patient Adherence OR Medication Adherence) where 542 citations were found, 40 abstracts and 10 full text papers were reviewed. Adherence was combined with technology where 167 citations were found, 48 abstracts and 5 papers were reviewed. Consequently, “qualitative” was added to the previous combination to yield 14 citations, of which two abstracts and one full text was reviewed. Finally, “interactive voice response” was added to the previous search and no citations were found.

For the final two Cardiology searches, cardiology was combined with “Stages of Change” and “adherence” where four citations were shown, four abstracts and two full text articles were reviewed. Lastly, cardiology was combined with “Self Efficacy”, which narrowed the search to 14 citations, of which eight abstracts and two full texts were reviewed.

Hypertension was combined with qualitative with 2,347 citations. It was then combined with “Blood Pressure Home Monitoring” where 1,017 citations were found, 50 abstracts were reviewed, and five full text articles were reviewed. All three subjects were combined to narrow the search to 20 citations, five abstracts, and two full text articles, which were reviewed. Hypertension was then combined with “Interactive Voice Response” with 11 citations, four abstracts and three full text papers reviewed. Lastly, hypertension was combined with “Interactive Voice Response” and “qualitative” where one paper was cited and reviewed.

Acute Coronary Syndrome was combined with “Interactive Voice Response”, two citations were found but neither was appropriate. Acute Coronary Syndrome was combined with “adherence” where 85 citations were revealed, 10 abstracts and two full texts were reviewed. One hundred and twenty one citations were found when Acute Coronary Syndrome was combined with “qualitative”; eight abstracts were reviewed and
none were found to be relevant. When all three subjects were combined, ACS, “adherence”, and “qualitative” five citations were found, of which two abstracts and full text articles were reviewed, yet, when “Interactive Voice Response” was added no citations were found. The last two additions to the ACS search included adding “Stages of Change” to ACS and adherence where no citations were revealed and “Self Efficacy” was added to ACS and “adherence” with one citation, abstract, and full text was reviewed.

Additional searches were performed to specifically look for the use of the validated health behavior surveys Stages of Change for Adherence with Medication (Willey et. al) and Self-Efficacy for Appropriate Medication Use Scale (SEAMS – Risser et. al) as evaluative tools in medication adherence interventions. Therefore, self-efficacy was added to adherence and 1,755 citations were found. When the survey was searched, 23 citations with one abstract and full text were reviewed. Lastly, Stages of Change and “adherence” were combined to show 155 citations, 20 abstracts, and eight full texts reviewed.

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Background

Study Populations

Cardiovascular disease (CVD) is the single leading cause of death and disability in the United States, with one in three American adults (about 82,600,000) having one or
more types of cardiovascular disease and accounts for 33.6% of all deaths. (1, 2) CVD’s are chronic conditions that are among the most costly health problems facing our nation. In fact, the estimated cost in 2010 was more than $444 billion, which includes lost productivity from deaths and disability and healthcare expenditures: this economic burden will become even greater as the U.S. population ages. (2) It is estimated that by 2030, 40.5% of the US population is projected to have some form of CVD. (1) Therefore it is imperative to investigate interventions to ameliorate the effects of CVD and improve outcomes of patients with CVD.

This thesis uses populations with hypertension and coronary heart disease, specifically acute coronary syndrome, to explore the proposed hypotheses and questions.

Hypertension (HTN) is one of the major causes of cardiovascular morbidity and mortality worldwide. HTN affects about 76.4 million people in the United States age 20 and older and the prevalence increases with advancing age. Yet, hypertension is only controlled to guideline recommended levels in 48-50% of the population who are aware that they have hypertension. (2,-24-25) Treatment of hypertension involves medication therapy where appropriate and patients’ adherence to lifestyle changes and/or medications. However, adherence rates are about 50% for medications and are much lower for lifestyle changes, significantly jeopardizing treatment success. (3-7)

Treatment success is defined by the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) (43-45) who has classified blood pressure (BP) based on the average of two or more properly measured, seated readings on each of two or more office visits. The classifications are: Normal is defined as systolic blood pressure (SBP) <120 mm Hg and diastolic blood pressure (DBP) <80 mm Hg; Prehypertension SBP 120-139 mm Hg or
DBP 80-89 mm Hg; Stage 1 Hypertension SBP 140-159 mm Hg or DBP 90-99 mm Hg; Stage 2 Hypertension SBP ≥ 160 mm Hg or DBP ≥100 mm Hg. Patients with prehypertension who also have diabetes mellitus or chronic kidney disease, and whose SBP ≥ 130 mm Hg and DBP ≥ 80 mm Hg should be considered candidates for appropriate therapy. \(^{(43)}\)

Consequences of hypertension are well known and include: risk of heart attack; stroke; kidney disease; and death from both ischemic heart disease and stroke, which increases progressively and linearly with levels of hypertension. Cardiovascular disease risk doubles for each increment of 20/10 mm Hg and is continuous, consistent, and independent of other risk factors. \(^{(43)}\) “It has been estimated that a 5 mm Hg reduction of the systolic blood pressure in the population would result in a 14 percent overall reduction in mortality due to stroke, a 9 percent reduction in mortality due to coronary heart disease, and a 7 percent decrease in all-cause mortality.” \(^{(43)}\) Thus, there is a public health incentive to reduce the prevalence and outcomes of hypertension in the United States. Therefore, using this population to explore an in-depth understanding of the effects of multifaceted interventions expands the literature regarding the subjective perceptions of the mechanisms of a hypertension intervention.

The second population of this thesis is Coronary heart disease (CHD), also called coronary artery disease (CAD). CAD is caused by the atherosclerotic stenosis and occlusions of the coronary arteries. In this complex process, plaques of cholesterol and other waste products build up in the linings of the heart arteries, causing blockage of blood flow to the heart. Oxidized low density lipoprotein (LDL) is the basis for the cholesterol build up and the initiator of the inflammatory response, which eventually calcifies arteries causing the narrowing and hardening of the arteries (stenosis). As this process continues, blood flow is inhibited, preventing oxygen rich blood from reaching
the myocardium (ischemia) leading to symptoms such as chest pain (angina). This process also causes the arteries to become vulnerable to injury and tears. The end result of this process may be a myocardial infarction (MI) or death if the blockage is complete. (44-45)

Patients who present with a myocardial infarction (MI) or unstable angina (UA) are defined with the term of “acute coronary syndrome” (ACS). MI symptoms are classified and treated clinically into categories based on the presence of ST segment elevations myocardial infarction (STEMI) or absence of ST segment elevations (NSTEMI) on the presenting ECG and abnormal elevations of myocardial biomarkers (i.e. troponin). (44-46) UA is defined as chest pain or discomfort that is accelerating in frequency or severity and may occur while at rest but does not result in myocardial necrosis. (1) Consequences of ACS may lead to death, heart failure, or life-threatening arrhythmias. To improve outcomes, treatment of ACS, after the initial hospital management, involves medication therapy and lifestyle changes. However, non-adherence to proven cardio-protective medications contributes to the persistently high risk of adverse outcomes following ACS hospitalization. (47) Consequently, it is important to investigate interventions that ameliorate the effects of ACS, such as improving adherence to medication regimens and prescribed life-style changes.

Accordingly, prevention of CVD by ameliorating causes, such as hypertension, and improving CVD outcomes, following ACS, is imperative if we are to improve morbidity and mortality rates in the United States. Using multifaceted interventions and further exploring patients’ health behavior changes that may have occurred during the study may improve the overall effectiveness of the interventions. Improving the effectiveness of CVD interventions may in turn save lives and improve healthcare costs.
Health Behavior

Treatment of CVD usually involves medication therapy and lifestyle changes. Successful treatment of CVD depends in part on patients’ health behavior, such as their adherence behavior. Health behavior theories indicate that personal factors, (e.g. self-efficacy and stage of change) and environmental factors, (e.g. relationships with their family, friends, and health care providers), influence each other and ultimately affect patients’ health outcomes such as adherence to lifestyle changes and adherence to medications. Current adherence theories are more successful in explaining non-adherence than improving adherence. Numerous studies addressing adherence in the general population have found adherence rates are about 50 percent for medications and are much lower for lifestyle modifications. The World Health Organization has categorized potential reasons for medication non-adherence into five broad groupings, including: health system, condition, patient, therapy, and socioeconomic-related factors. In comparison to patients with acute conditions, patients with chronic conditions have been shown to have lower adherence rates with the most dramatic drop in adherence being noted after the first six months of therapy. Therefore, understanding health behavior theory is important to understanding patients’ adherence behavior to interventions intending to improve clinical outcomes.

In an effort to explain and understand health behaviors academicians have constructed multiple health behavior theories, yet, none are mutually agreed upon. One health behavior model is the Transtheoretical Model (TTM), which focuses on the decision-making abilities of the individual. This model includes four main constructs: the stages of change, processes of change, self-efficacy, and decisional balance. TTM is a systematic integration of multiple theories and conceptualizes behavior change as a process that unfolds over time where the person progresses through five stages of
change: pre-contemplation, contemplation, preparation, action, and maintenance. Relapse prompts a cyclical movement back through the initial stages. The stages signify a period of time and represent when people change. (27-31)

Pre-contemplation is the stage where patients have no intention of changing behavior in the foreseeable future, such as the next six months. Patients are unaware or under-aware of the consequences of their behavior, or patients may have failed attempts to change and are discouraged to try again. (27-31)

Contemplation is the stage in which patients are aware of a problem and are intending on making a change within the next six months but have not yet made a commitment to take action. Contemplators are weighing the pros and cons of their dysfunctional behavior against changing their behavior. (27-31)

Preparation is when patients are intending to make a behavior change within the next month and are making some small behavioral changes. Patients may move to the next stage after they have selected a plan of action and are confident they can follow through with the plan. (27-31)

Action is the stage in which patients have made efforts to modify their behavior, experiences, and/or their environment within the last six months to address their dysfunctional behavior. Action requires significant behavior changes and requires commitment of time and energy. (27-31)

Maintenance, the final stage, begins after the Action stage and extends indefinitely. The patient works to prevent relapse and consolidate the gains made in the Action stage. Patients are less tempted to relapse and more confident in maintaining their positive health behavior. (27-31)

The second construct, processes of change, describes how people change. Change processes are cognitive and behavioral activities that are used to progress
through the stages of change. Ten processes identified with the most theoretical and empirical support has been assembled based on principal components analysis. (27) The first five processes are experiential and include: consciousness raising, dramatic relief, self-reevaluation, environmental reevaluation, and self-liberation and are used in the early stages. The last five processes are behavioral and are most useful during the latter stages and they include: social liberation, counter conditioning, stimulus control, contingency management, and helping relationships. Exploring and understanding the specific processes and the movement of stage of change adds to the assessment of health behavior components. (27-31)

Stages of change are also related to self-efficacy, which is described as the confidence to cope with stressful situations and not relapse to unhealthy behavior. The patient must have the capability to perform the appropriate behavior and have the perception that a positive outcome will occur. Self-efficacy is a critical factor that determines a person’s behavior change and may be a main cognitive barrier to adherence. The self-efficacy construct integrated into the TTM is based on the research by Albert Bandura who first identified the significance of self-efficacy and behavioral change. (27-31, 51-52)

The last construct of TTM is decisional balance, which refers to patients weighing the benefits and costs of changing their behavior. Decisional balance varies through the stages of change and has been demonstrated to be a good predictor through the stages. (27)

To fully understand the integration of the TTM model and the study design proposed, one must acknowledge the strengths and limitations of integrating the two. Health behavior models define what to measure and therefore, are inherently linked to the measurements defined. (53) Each theoretical model describes health behavior using
unique concepts and verbiage. TTM describes behavior change as a process, broken down into stages, which are able to evaluate specific variables associated with that stage. TTM works well with research and interventions because of its individualized design, which integrates well with our study design.

Yet, the weakness of the study design and the health behavior model integration is the inability to assess the thought process of how people change their behavior. This cannot be appropriately assessed by either quantitative or qualitative measurements due to the fact that most people are not consciously aware of their reasoning. Thus, when we assess their level of stage of change with the SOC survey, we have a “value” of their motivational level, but not their thought process. For example, saying that they like the IVR because they need external motivation from the IVR calls or persuasion from the study personnel.

The ultimate strength of this study is the mixed methodology design, which utilizes triangulation and allows researchers to better understand subtleties, as well as cross-validate findings that we are able to assess.

Mixed methodology utilizing inductive (emerging from the ground up, originating from data obtained by observation or open-ended responses and develops into an understanding by the researcher) and deductive (starting with extant hypotheses, theoretical frameworks) thinking in conjunction with quantitative assessments allows researchers to better understand patients’ health behaviors and tease out factors that support positive health behaviors. Triangulating qualitative data with quantified self-identified, self-efficacy measures of adherence along with assessing readiness to change adherence behavior strengthens the validity and analytical rigor of this thesis.

Therefore, this thesis uses the TTM to understand and explore two specific constructs of patients’ health behavior: The cycle of where patients are in the stage of
change and their level of confidence. Additionally, this thesis assesses if those factors are associated with their ability to follow through with the prescribed health behaviors and whether or not the technology facilitated intervention influenced changes in the patients’ health. In addition, the information may help explain some of the variability in the effectiveness of interventions.

Technologies

In the last decade communication and monitoring technology have become a significant part of health care and are likely to play an important part in supporting patients to become more informed and activated to improve health outcomes and reduce costs. \((56)\) Interactive voice response (IVR) technology and blood pressure home monitoring are successful technologies in cardiac care. \((8-25)\) IVR is a computer-based telephone system which initiates calls, receives calls, provides information, and collects data from users. IVR systems are comprised of three components: 1) a standard microcomputer, 2) specialized hardware that interfaces with telephone systems to place calls, and 3) software that controls the calling operations. The hierarchically structured messages are composed of statements and queries that determine the process of the calls sent and received. The IVR system does not require any specialized communication platforms, such as the Internet and therefore can be implemented rapidly. The data collected from patients using the telephone touch pad are stored and may be used to generate graphs and charts for analyses or reported back to the patients for their review. \((58-59)\) Most patients report that they are willing to participate in IVR-based technology programs and some form relationships with the technology. \((11, 14, 60-64)\)

The IVR system has been used for disease management, conversing with patients between doctor office visits, home monitoring, ordering medications, educational messaging, administration of questionnaires and surveys, medication refill
and appointment reminder calls, and is a conduit to valid, reliable and clinically meaningful information about the patient’s health status.  

Home blood pressure (BP) monitoring, using validated devices, is recommended by the American Heart Association and has been shown to lead to greater BP reduction when compared to usual care up to 12 months when used in combination with clinical support modalities. In addition to monitoring the effects of treatment, increasing evidence indicates that home BP readings predict cardiovascular events. Lastly, use of home blood pressure monitoring has been shown to increase patient involvement in the management of their hypertension and produce beneficial changes in their health behavior.

Multifaceted interventions incorporating telehealth technologies such as telephonic interactive voice response (IVR), voice messaging, and electronic home monitors have been shown to improve cardiovascular outcomes. Yet, few studies using IVR and home BP monitoring investigate the patients’ perspective of the intervention, the mechanics, their feelings about the intervention, and how it affected their health behavior. The knowledge of their perspective is integral to understanding the interventions outcomes.

**Methodologies**

To understand the effectiveness of technology facilitated interventions from the perspective of the participant, as well as the association of specific health behavior constructs and these interventions, a mixed methodology analysis is employed.

The mixed methodologies used in this study include quantitative and qualitative analyses. Quantitative approaches alone are not well suited to examine complex aspects of healthcare such as adherence behavior, decision-making processes, and patients’ perceptions of quality of care. Qualitative methods are better suited to
understand complex social processes, capture patients’ perspectives of the phenomenon being investigated, and to explore beliefs, values, and motivations that are the basis of health behaviors. Using both methodologies and multiple populations is a concept of triangulation, which is a technique that strengthens the validity of the study.

Triangulating with both quantitative and qualitative methodologies employs skills in observation and recording numbers. This allows for a more natural and practical research approach because complex behaviors are more thoroughly explained with both numbers and words. The purpose of triangulation is to test for consistency. Understanding inconsistencies from different types of data that are sensitive to alternative aspects of the phenomenon in question offers deeper insight into the relationship between the inquiry approach and the phenomenon. Utilizing both inductive and deductive thinking allows researchers to better understand patients’ health behaviors and tease out factors that support positive health behaviors. Triangulating qualitative data with quantified self-identified self-efficacy of adherence and assessing readiness to change adherence behaviors strengthens the validity and analytical rigor. By combining the two data gathering techniques, researchers are able to clarify subtleties as well as cross-validate findings. In addition, by using mixed methods, it is possible to investigate whether/how data from patient interviews and standardized instruments converge or depart. This may give further insight into patients’ health behaviors.

Objective and subjective coding scheme and analytic techniques, content analysis and grounded theory, are used to assess the qualitative findings. Content analysis has been defined as, “any qualitative data reduction and sense-making effort that takes a volume of qualitative material and attempts to identify core consistencies
and meanings,” (56) and “a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns.” (68) Both quantitative and qualitative forms of content analysis exist. Some methodologists believe in blending the two, resulting in counting themes and patterns derived from both inductive and deductive reasoning. (69)

The constructionist methodology of Grounded Theory approaches are utilized to investigate the experience of having an ACS event and conceptualize the latent patterns and structures of the process and consequences. Grounded Theory is the systematic generation of theory from systematic research. It is a set of rigorous research procedures leading to the emergence of conceptual categories. These concepts/categories are related to each other as a theoretical explanation of the action(s) that continually resolves the main concern of the participants in a substantive area.” (70-71) A constructionist perspective focuses on the subjective interrelationship between the researcher and the patient and the interrelated construction of the meanings of the analyses. (71) The objectives of theory generation in grounded theory can be explanatory and predictive, based in the positivist framework, as well as, understanding and interpretive, based in the interpretive philosophy. (71) The pragmatic framework of this thesis and following the constructivist perspective allows utilization of both methodologies to derive the theory.

This thesis utilizes a blending technique of the two qualitative methodologies using inductive and deductive analyses, as well as objective and subjective perspectives to obtain the most robust findings.

The approach used to integrate the quantitative and qualitative data is a merging data approach. This approach is achieved by reporting the two types of data together and is presented in the discussion section of the thesis. (54)
Gaps in the Literature

Cardiac Technology Facilitated Interventions and Patients’ Perspectives

The literature review identified several papers that are closely associated to the questions and hypotheses stated in this thesis addressing the importance of understanding, from the perspective of the patient, how technology affected their cardiac care and health behaviors.

Friedman et al. (17) were pioneers in 1996 utilizing a telecommunications system to monitor and counsel hypertensive patients. Using a telephone based system they were able to monitor self-report home BP results, medication adherence, medication knowledge and side effects. The telecommunication system also provided education and motivational counseling to improve adherence.

The randomized control trial found significant differences between the intervention and the usual care groups for the primary and secondary outcomes. Patients’ attitudes and reactions to the telephone based system were obtained using an a priori structured interview of the system with a 5-point Likert scale and an overall satisfaction question using a visual analog scale.

Yet, as previously stated, interventions work through the patients’ reasoning. Knowledge of that reasoning is integral to understanding the interventions outcomes and using only deductive assessments of the patients’ perspectives falls short of the expansive investigational ability that inductive qualitative inquiry can unfold. Inductive qualitative inquiry can explore how and why phenomena occurred and it can determine how patients interpret specific constructs, such as self-esteem. (35) Since the data is based on the patients’ own meanings it can describe in rich detail how an intervention functions or not in a local context. (35)
Therefore, Friedman et. al missed an opportunity to gather information that could have given insight into the reasons for the success of their study and guide implementation into standard clinical practice.

Piette et al.\(^{(15,16, 72)}\) were also at the forefront using IVR technology in various chronic diseases and continue to lead innovative applications. Yet, they too used quantitative surveys to assess patient centered outcomes and thus were unable to fulfill these gaps in the assessment of interventions by not considering patients’ perspectives of the difficulty of behaviors required by those receiving the intervention. Thus missing the importance of going beyond evaluating overall effectiveness to understanding the component processes and how they vary among patients.

One paper that did use an open-ended qualitative inquiry was Reidel et al.’s\(^{(22)}\) pilot non-randomized study that used an IVR system to improve medication adherence in chronic diseases. The pilot was terminated because of technical problems with the phone system.

A qualitative analysis was employed to obtain facilitators and barriers of the IVR system use through a structured survey that focused on the technical aspects of the system. Open-ended questions were asked to investigate the participants understanding of the purpose and usefulness of the calls and the identified population used in this study may not have been in need of IVR medication reminders. Hence, the qualitative inquiry enabled this pilot to be informative and add to the literature by identifying specific barriers to implementation of an IVR system.

Consequently, the literature was lacking a study that assessed a randomized control trial from the perspective of the patient and evaluated how technology is affecting their cardiac care and health behavior, until the publication of Lambert-Kerzner et al.,
“Patients’ Perspectives of a Multifaceted Intervention with a Focus on Technology: A Qualitative Analysis” in 2010, (25) which fulfilled Aim 1 of this thesis.

Until February of 2012, our study was the single investigation that used in depth qualitative inquiry to explore patients’ experiences of a CVD intervention. Jones et al. (73) used a qualitative constant comparative methodology to explore the reasoning of the patients behavior during the TASMINH2 (14, 73) trial. This study evaluated a self-monitoring system and self-titration of their medication in a hypertensive population. Researchers found that patients were confident about self-monitoring of their blood pressures and felt their home readings were more valid than the office readings. Mixed findings were reported regarding patients’ confidence with self-titration. Although many patients were confident with the self-monitoring, few wished to continue with a self-management plan after the study. (73)

Health Behavior Constructs as Evaluative Tools

One of the main determinants of treatment success of CVD is dependent on patients’ health behavior. It is important to understand if there is an association between specific constructs of health behavior and CVD outcomes such as improved adherence, especially if the intent of an intervention is to modify behavior. Investigation of specific constructs (ie. stage of change and self-efficacy) could shed light on whether or not the intervention influenced such changes.

Therefore, the literature search looked for papers that addressed these specific constructs as evaluative tools when assessing interventions. Studies that specifically used the health behavior constructs of stages of change and self-efficacy were searched. Specific tools to evaluate self-efficacy and stage of change in medication adherence are limited and include Willey’s “Stages of Change for Adherence with
Medication Regiments for Chronic Diseases"^{(74)} and Risser’s Self-Efficacy for Appropriate Medication Use Scale (SEAMS) survey.^{(75)}

Dr. Kripalani one of the authors of the SEAMS scale, used it in the piloted randomized control trial “The Improving Medication Adherence through Graphically Enhanced Interventions in Acute Coronary Syndromes (IMAGE-ACS)” study^{(76)} that he presented as an abstract at the Health Literacy Annual Research Conference. At discharge ACS patients were randomized to the literacy intervention and the baseline surveys. Follow-up with phone administered surveys occurred one to two weeks later. As described in the abstract, the results of their study indicate that the intervention showed a significant improvement in self-efficacy in the intervention group compared to the usual care group. No other published studies were found that used this survey as an evaluative pre-post tool.

Most studies use TTM theory to individualize medication adherence interventions and some used a SOC survey as an evaluation pre-post tool.^{(77-80)} Johnson et al^{(79)} investigated adherence to both antihypertensive and lipid lowering drugs using an individualize SOC intervention and evaluated the movement between stages, which were significant.^{(78-79)}

One study examined patients’ readiness for substance cessation and psychotropic medication adherence on admission to a residential substance abuse treatment program and again 30 days after discharge.^{(80)} The study did not include a stage of change intervention in the program but assessed patients SOC using the same survey we are using. Therefore, this paper is the only study found to use the survey as an evaluation tool without including the stage of change concept in the intervention, which is exactly how we are using the SOC survey. The study is not a CVD study and they were unable to evaluate individual movement between the stages only the
proportion of patients in each stage pre and post. Thus, there are no studies found that address the proposed hypothesis using these specific tools in the cardiovascular population.

Therefore, the proposed research is needed to address the following gaps in the literature: 1) patients’ perspectives of their cardiac care using technology, specifically of an intervention to improve medication adherence, 2) investigation into the association of a cardiac intervention on the health behavior construct of stage of change (SOC) using individual data and the association with adherence outcomes, 3) investigation into the association of a cardiac intervention on the health behavior construct of self-efficacy using individual data and the association with adherence outcomes.

To date, no studies found explore the complex nature and interplay of patients’ perspectives of cardiac care interventions using technology and health behavior constructs with a mixed methodology. Although quantitative studies are abundant in cardiac literature, none use a mixed methods approach to understand the complexity of this phenomenon.

**Patients’ Perspectives of Technology Facilitated Care Outside Cardiology**

Patients’ perspectives of their experiences with interventions that include technology are uncommon in the literature for cardiology as well as other disease states. Sixteen papers were found, outside of cardiology that initially appeared to be applicable, yet only five were appropriate and will be included in this review. None of the studies were randomized control trials (RCTs). Two studies randomized the subjects into two different interventions but neither used control groups. Two papers evaluated non-randomized interventions using web-based tools. One addressed improving older adults’ experience with IVR systems.
A focus of this thesis investigates patients’ perspectives of IVR technology and most of the subjects in the studies are from the Veteran’s Affairs (VA) population where the average age is approximately 65 years of age. Therefore, Miller et. al’s paper “Improving Older Adults’ Experience with Interactive Voice Response Systems” (81) is of interest. The aim of the study was to identify areas of difficulty in IVR use and to propose strategies for improvements. The most common difficulties included: confusing/difficult instructions and being cut off for not responding fast enough or making a mistake. Additional complaints included voices speaking too quickly, too many options to choose from, and having to provide the same information multiple times. They did, however, report that the IVR systems were patient – meaning that they were able to have the information repeated multiple times.

The ideal system was described using the following themes: friendly, polite, with short, clear, and unambiguous instruction. Patients would like the ability to adjust the volume and the speed of the conversation. They wanted to remove patronizing phrases such as “Good job;” additionally, if a break was needed, patients wanted to be able to pause the process and not have to start over. The authors concluded that improving the design of IVR algorithms to detect difficulties during an ongoing IVR exchange and individualizing algorithms may increase the acceptability of the systems with older adults.

Recently, communication and monitoring technology have become a significant part of health care and are likely to play an important part in supporting patients to become more informed and activated to improve health outcomes and reduce costs. (56) Interactive Voice Response technology has become a useful tool in the process. Therefore, Miller et. al’s study is important and informative and may be interesting to compare and contrast the findings of this thesis with Miller et. al’s findings.
“Personal relationships with an intelligent interactive telephone health behavior advisor system: a multimethod study using surveys and ethnographic interviews”\(^{(64)}\) was a two arm randomized trial that compared two Telephone-Linked Care (TLC) health behavior change programs. One arm promoted regular physical activity and the other healthy eating. Kaplan et. al were pioneers in 2003 using a qualitative approach to assess the patients’ perspectives. The grounded theory analysis revealed that patients formed personal relationships with TLC in three different ways: 1) They expressed feeling of love, 2) They expressed feelings of guilt, and 3) They expressed feelings of ambiguity or ambivalence over whether they were talking to a machine or to a person.

The findings of this innovative study design implemented in 2003, using quantitative and qualitative inquiry, illustrates why attitudinal surveys alone are not able to understand participants’ reactions to technology. The authors were able to understand why people had the reactions shared in the quantitative surveys and what accounted for their different reactions. The authors also indicate that more work was needed to “understand the phenomena of relationship formation with technologies, of how these relationships reflect projections of values and goals, and of how both of these affect health behavior change.”\(^{(64)}\)

McTigue et. al's\(^{(82)}\) investigation into patients’ perceptions of an online behavioral weight loss intervention in a primary care setting found that the program improved communications with primary care physicians (PCPs). The study found that interactions, which acknowledged patients’ efforts to change lifestyles and / or offered encouragement and support, were positively received. Other patients spoke of the positive coordination of the program with their health care. In conclusion, the authors indicated that online technology may be helpful for self-management and improved clinical counseling in the primary care setting.
Although interesting, McTigue et. al’s paper did not delve into the participants' perspective of the technology of the online program. Yet, it may be interesting to compare McTigue et. al’s findings to this thesis in regard to patients' perceptions of how technologies improve relationships with their providers.

m-Health and e-Health are two new forms of incorporating technology into the practice of medicine and public health. The two most recent papers explore the patients’ perspectives when using these technologies in the HIV population. “Challenges in Using Mobile Phones for Collection of Antiretroviral Therapy Adherence Data in a Resource-Limited Setting” by Haberer et. al. (83) investigated the use of cell phones, IVR technology, and short message service (SMS) text messaging to collect adherence data in children’s’ caregivers in Mbarara, Uganda.

Qualitative findings revealed typical issues of using a cell phone such as technical challenges using the phones, keeping the phones charged, calls being dropped, and forgetting to have their phones with them at all times. The emerging themes identified a poor understanding of how to respond to the IVR or SMS prompts. Challenges in training indicate that participants are hesitant to acknowledge a lack of understanding during the sessions and suggest that repeated training sessions over time may improve the response rates and data collection. Yet, all participants said the technologies are acceptable and some felt that the calls and text messages served as adherence reminders.

The final paper examined was “Consumer e-health education in HIV/AIDS: a pilot study of a web-based video workshop” by Laura O’Grady. (84) The qualitative study assessed HIV/AIDS patients’ feedback of an integrated web-based consumer health education environment. Overall, the participants did not find the forum to be of value for learning about treatment information. They indicated that the structure was not well
organized and that there was too much information. Technical problems and specific issues of techniques used by the workshop presenter were also identified. Constructive comments shared specified that individual learning styles were nicely addressed in the workshop with multiple forms of information provided (written documents, videos, or audios).

The results of this study indicate that although the practice of medicine desires and utilizes technology, there may be too much of a good thing at work. Further research is needed to assess where and when this type of technology may be warranted.

The additional literature search to assess participants’ perspectives of technology facilitated care outside of cardiology revealed that the patients’ perspective is also rare in other conditions. Few studies have assessed the perspective of the participants in their evaluation of interventions even though it has been identified as an essential element for an effective assessment. Theoretical and empirical frameworks support the importance of exploring subjective views when assessing effectiveness. As previously stated, patients choose to participate in interventions and choose to execute the prescribed behaviors. They also have the option of not doing what has been requested or modifying the behavior in a way that changes the integrity of the intervention. Therefore, knowledge of patients’ choices and understanding the reason behind their decisions may explain the varying effectiveness of these interventions. (26)
CHAPTER III

STUDY HYPOTHESES, RESEARCH METHODS AND ANALYSIS PLAN

Overview of Study Hypotheses, Research Methods, and Analysis Plan

The primary purpose of this thesis is to gather an in-depth understanding of the experience of participating in technology facilitated multifaceted cardiac interventions and to appreciate from the patients’ perspective how the interventions affect their health behavior decisions.

The secondary purpose is to assess the association of technology facilitated interventions on cardiovascular outcomes mediated by specific health behavior components.

To accomplish the defined goals a mixed methodology analysis is employed. The qualitative analyses incorporate an iterative, inductive and deductive toolkit of analytical strategies, drawing on multiple types of analyses. Both univariate and multivariate quantitative analyses assess possible associations between the health behavior variables and outcomes.

Aim 1: Gather an in-depth understanding of the phenomena of participation in a pharmacist lead, multi-faceted intervention of hypertensive patients using an Interactive Voice Response System and Home Blood Pressure Monitor

Rationale

In an effort improve cardiovascular outcomes, multifaceted interventions targeting healthy behaviors and medication adherence have been employed. To fully understand the effectiveness of these interventions it is important to obtain and assess the patients’ perspective of their experience. In addition, the evaluation needs to
understand what the patient perceives to be effective components of the multifaceted intervention.

The literature search found no studies that addressed the proposed question. Therefore, this research is needed to speak to this important gap in the literature.

**Objective**

*What are patients’ perspectives of participation in a multifaceted intervention?*

- **Specific Aim 1:** Use semi-structured, one-on-one qualitative interviews to gather the participants perspective of the effectiveness of the multi-faceted intervention.

- **Specific Aim 2:** Use semi-structured, one-on-one qualitative interviews to gather the participants perspectives of the impact of the intervention on their health behavior.

- **Specific Aim 3:** Propose a theoretical model of a hypertension management.

**Design**

Participants in the “Improving Blood Pressure in Colorado” a randomized control study\(^{(9,18,25)}\) are interviewed for this Aim. The study investigates the use of a pharmacist-led multifaceted intervention to improve blood pressure (BP) control, using an IVR system, a home blood pressure monitor and patient education. Using the IVR system, patients report their home BP results on a weekly basis. The IVR system averages the measurements and provides feedback to the patient about their level of control. If patients do not report BP measurements to the IVR system after 11 days, the IVR system delivers reminder calls to patients. The pharmacists receive reports on patients’ home measurements and work with the patients through in-person or telephone visits to achieve blood pressure goals. In addition, the IVR system allows patients to request a call from the pharmacist, connect to the pharmacy refill line or the nurse line,
or listen to educational messages. Patients in both arms receive an educational booklet on hypertension as well as comprehensive education on hypertension (e.g., diet, exercise).\textsuperscript{(9, 18, 25)}

**Subjects**

One hundred and forty-six participants of the “Improving Blood Pressure in Colorado” a randomized control study\textsuperscript{(9, 18, 25)} are interviewed for this Aim. The patients are enrolled from the Denver Veterans Affairs Medical Center and the Denver Health Medical Center.

Inclusion criteria include patients with uncontrolled hypertension defined as elevations in two of the three most recent electronic BP measurements (>140 mm Hg for systolic or >90 mm Hg for diastolic; for patients with diabetes mellitus or chronic kidney disease, >130 mm Hg for systolic or >80 mm Hg for diastolic), taking four or fewer antihypertensive medications, and are greater than 17 years of age.\textsuperscript{(18, 25)}

During the last study visit, the patients are interviewed about their experience with the multifaceted intervention.

**Data**

During the last study visit, patients are interviewed about their experience with the study to gather in-depth understanding of the phenomena of participation in a multifaceted intervention. Due to issues such as illiteracy, cultural barriers, and prior experience with low response rates with surveys, qualitative interviews were chosen to investigate patients experience and their opinion of the effectiveness of a multifaceted intervention. The data are collected in-person, using semi-structured, one-on-one, open-ended interviews. We chose questions that addressed each component of the patients’ overall experience during the study and the effect of the study on the patients’ health behavior.\textsuperscript{(9, 18, 25)}
The interview guide includes 16 semi-structured, open-ended questions that address general items for both arms of the study such as: details about taking their medications and any difficulties and the effect of the study on their health behaviors. Additionally, the intervention group are asked specific questions about their experience with the following: 1) Details regarding taking their BP readings at home and any issues they experienced; 2) Utilization of the IVR system to include details of the various components of the system and any problems; 3) Working with the study pharmacists and the effects on their BPs, medication adherence, and overall health; and 4) The effects of participation in the BP study on their health behavior and utilization of healthcare. (25)

Study staff conduct and audio-tape the interviews, which ranged from 40 to 60 minutes. The audiotapes are transcribed verbatim. This qualitative study was approved as part of the randomized controlled trial by the Colorado Multiple Institutional Review Board. (25)

Baseline demographics including age, sex, race, ethnicity, socioeconomic status (SES), marital status, and highest education level are obtained to characterize the study population.

Analysis

- **Specific Aim 1**: Use an iterative, inductive and deductive toolkit of analytical strategies, drawing primarily on qualitative content analysis and consultative and reflexive analysis to assess the participants’ perspective of the effectiveness of the multi-faceted intervention.

- **Specific Aim 2**: Use an iterative, inductive and deductive toolkit of analytical strategies, drawing primarily on qualitative content analysis and consultative and
reflexive analysis to assess the participants’ perspective of the impact of the intervention on their health behavior.

- **Specific Aim 3**: Use an iterative, inductive and deductive toolkit of analytical strategies, drawing primarily on qualitative content analysis and consultative and reflexive analysis to generate a theoretical model of hypertension management.

An iterative, deductive and inductive toolkit of analytical strategies, drawing primarily on qualitative content analysis, and consultative and reflexive analysis is used for the analyses. All transcripts are analyzed by the first author and random transcripts are analyzed by one of the research assistants using qualitative content analysis methods. The analysis begins with repeated readings to achieve immersion followed by initial coding using an emergent rather than an *a priori* approach, in order to emphasize respondent perspectives and de-emphasize researchers’ assumptions. Subsequent analysis uses a deductive approach to capture the essence of the impact of the multifaceted intervention. Words, sentences, and paragraphs are treated as coding units or “meaning units”.

After the initial coding is complete, codes are compared and reconciled and emergent themes are identified through intersubjective agreement, and are then presented to a senior qualitative analyst for review. Throughout the analysis, the findings are continually checked and compared with the rest of the data in order to determine new codes, themes or patterns. The preliminary results are reviewed by members of the thesis committee, to assess their evocativeness, thoroughness, and comprehensiveness. For analytical rigor, the senior qualitative analyst completes a final review. The accountability of the results is supported by confirming patient reported use of the IVR system among those randomized to the intervention and also
with an investigation of an association between participants’ self-report of a positive impact of the intervention and achieving blood pressure goals.

**Outcome Measures**

An analytic summary of the interviews was written and published. In the publication, patients’ own words and narratives were presented to preserve the tone and emotion of the patients’ experiences and increased the theoretical depth of the final description. In addition, a theoretical model of a hypertension management was presented in the paper.

**Aim 2: Assess the association of technology facilitated interventions on medication adherence mediated by health behaviors**

**Rationale**

In an effort to improve cardiovascular outcomes, multifaceted interventions targeting healthy behaviors and medication adherence have been employed. Understanding how the interventions affect health outcomes, such as medication adherence, is important to the overall success of the intervention. In addition, understanding if and how these outcomes are modified by health behaviors may shed further light on how the intervention affected the outcomes.

We have chosen the Transtheoretical Model of Behavior Change (TTM) to explore if health behaviors modify the cardiovascular outcomes. The TTM focuses on the decision-making abilities of the individual and will help us clarify the effects of the intervention on patients’ health behavior. Investigation of specific constructs of TTM (self-efficacy and stage of change) may shed light on whether or not the intervention influenced changes in the patients’ health behavior, which ultimately may affect the outcomes of medication adherence. To evaluate the health behavior constructs, we have
employed the Self-Efficacy for Appropriate Medication use Scale (SEAMS)\(^{(75)}\) and Stages of Change (SOC)\(^{(74)}\) questionnaires for self-efficacy and stage of change constructs respectively.

In the literature search, no studies were found that address the proposed hypotheses using these specific tools. Therefore, this research is needed to address this important gap in the literature.

**Objectives**

*Multi-faceted points of care (as provided in our study by Interactive Voice Response (IVR), additional provider involvement, and education) improve medication adherence. We hypothesize that the effect of the intervention on medication adherence will be mediated by the construct of health behavior, as measured by the Self-Efficacy for Appropriate Medication use Scale (SEAMS)\(^{(75)}\) and Stages Of Change (SOC)\(^{(74)}\) questionnaires.*

- **Specific Aim 1**: We assess the association of the study intervention on health behavior by analyzing the change in results from the SEAMS\(^{(75)}\) and SOC\(^{(74)}\) that were administered at baseline and the one year follow up.
- **Hypothesis 1**: Subjects randomized to the intervention group have significantly improved change in health behavior as compared to the subjects randomized to the control group.
- **Specific Aim 2**: We assess how the association of the intervention on medication adherence is mediated by health behavior.
- **Hypothesis 2**: The association of the intervention on medication adherence is mediated by health behavior. The constructs, self-efficacy and motivation, significantly mediate the association between the intervention and medication adherence.
Design

In order to examine the association of an intervention on health behavior, we are collecting data on a subset of the subjects from the study “Multi-Faceted Intervention to Improve Cardiac Medication Adherence And Secondary Prevention Measures - The Medication Study” (47), a randomized control study. This study assesses if the intervention that included the following core components: collaborative care (between pharmacists, primary care providers, and cardiologists), patient education (tailored to patient needs and provided on a regular ongoing basis), tailoring of medication regimens (i.e., simplification of dosing, use of pill boxes, synchronization of refill dates), and tele-monitoring via IVR technology as well as patient-specific aides based on identified needs (47) improve patients medication adherence rates.

Patients are consented and then randomized 1:1 to either intervention or usual care. Approximately one week post discharge, the intervention patients meet with the study pharmacist in-person or if a patient is unable to make an in person visit, on the phone. The pharmacist performs a medication reconciliation and answers any questions related to medications, emphasizing the importance of continuing to take medications as prescribed. If questions arise about medications and/or if the indication for a medication is unclear based on the discharge instructions, the pharmacist contacts the patient’s PCP to resolve discrepancies. (47)

Approximately one month post discharge the study pharmacist checks in with the patient to ensure comprehension of: 1) their medications, 2) the role of the study pharmacists to aid their adherence behavior, 3) the use of the phone messages, and 4) to answer any questions. The intervention patients are then followed by the pharmacist for the study period of one year. Intervention patients also receive two types of IVR calls: refill reminder calls and IVR educational calls. The refill reminder calls occur when
patients’ cardio-protective medications are due to be refilled and last for one year while the educational calls are discontinued after six months. Patients in both arms receive educational information; the intervention patients receive this information at the beginning of the study, whereas the usual care arm receives the educational information at their last visit. This study was approved by the Colorado Multiple Institutional Review Board. (47)

During the first and last study visit, patients complete the quantitative surveys of the health behavior components. At the last study visit, the study personnel also collect a blood pressure measurement as well as verification of a lipid profile that has been completed within three months of the final visit. (47)

Subjects

This Aim includes a subset of 42 subjects from the “Multi-Faceted Intervention to Improve Cardiac Medication Adherence and Secondary Prevention Measures - The Medication Study” (47) study and are from the following sites: Durham NC, Seattle WA, and Denver CO. The majority of the patients are from the Denver site (N = 33), Seattle (N = 5), and Durham (N = 4) only contributing a small percentage of the study subjects. The uneven distribution was due to the fact that Seattle and Durham had very few participants, 23 and 10 respectively. Moreover, the decision to include these surveys occurred after the initial approval of the study, which missed obtaining baseline data for about 20 patients.

Eligibility criteria include all patients admitted to the medical center with acute coronary syndrome (ACS) as the primary reason for hospital admission. In addition, they need to use the VA for their usual source of care, or will commit to having their primary care in the future, and are at least 18 years of age.
During the first and last study visit, this subset cohort completes the quantitative surveys. The Stages of Change for Medication Adherence (SOC) (74) and Self-efficacy for Appropriate Medication Use Scale (SEAMS) (75) are the two surveys used in this study to measure health behavior.

**Data**

Self-efficacy for Appropriate Medication use Scale (SEAMS) (75) – is a tool to evaluate self-efficacy, which is the confidence in one’s ability to perform a given task such as taking one’s medications. This is an important determinant of medication adherence.

Thirteen questions are evaluated using a 1-3 scale. The total SEAMS (75) score is the final outcome. The range is 13-39.

Stages of Change for Medication Adherence (SOC) (74) – is a validated tool used to identify patients with potential adherence problems and to identify the stage that patients are at regarding their readiness/motivation to change their adherence behavior.

The five stages are:

1 = Pre-contemplation
2 = Contemplation
3 = Preparation
4 = Action
5 = Maintenance

**Covariates**

In order to characterize the study population, the following baseline demographics that include age, sex, race, body mass index (BMI), diabetes mellitus (DM), and history of coronary artery disease (CAD) are obtained to characterize the study population. We will assess how balanced the 2 study arms are for each covariate
and will include any significantly unbalanced covariate in the analysis in order to obtain result estimates adjusted for the potential confounding of the unbalanced variables.

**Analysis**

- **Specific Aim 1**: We assess the association of the study intervention with health behavior by analyzing results from the SEAMS \(^{(75)}\) and SOC. \(^{(74)}\) The change from baseline is used as the outcome measure for both surveys in order to estimate the effect of the intervention on health behavior during the study period. The outcome measures are examined using descriptive statistics (means and medians, standard deviations and quartiles). Unadjusted differences between treatment arms are estimated using t-tests.

- **Specific Aim 2**: We examine the extent to which health behavior mediates the effect of the intervention on medication adherence.

The analyses utilize a Mediation Model that assesses if the intervention is a predictor of medication adherence and if so, to what degree the effect of the intervention is mediated by health behaviors. The analysis first examines the effect of the intervention on medication adherence (c) (Figure 2), and then uses a mediation model to examine to what extent this relationship is mediated by health behaviors.

![Figure 2. Primary Outcome](image)

To assess c, we use a modified Refill Compliance (Recomp) method \(^{(47)}\) to measure percent of days covered (PDC) by medications. The ReComp score is a
validated tool to measure adherence and designed for use with administrative pharmacy fill records. Recomp is a single composite algorithm that incorporates information on both medication gaps and proportion of days covered. The modification for Recomp includes assessing new prescriptions in the same class and adjusting the PDC due to the overlap with the original prescription, adjusting for medications on hand from the prior 180 days, and removing inpatient days from the calculation to give patients credit for the medications not used. Data on outside hospitalizations are unavailable and remains a limitation because we are unable to remove these inpatient days from the calculation that would give patients credit for the medications not used. We are collecting this information but will not be able to include this in the analyses.

Recomp first assesses improvement to the individual classes of medications, then averages the PDC of the four classes of cardiac medications. It has been shown that improved clinical outcomes, such as control of hypertension, are a function of adherence to the regimen rather than to individual medications. (47)

The first step in the mediation analysis (Figure 2) involves using a regression analysis \( Y = \beta_1 + \beta_2 X + \epsilon_1 \) to assess the effect of the intervention (the independent variable, \( X \)) on medication adherence (the outcome variable, \( Y \)). (90, 91) Next, we use a regression model (a) \( M = \beta_2 + \beta_3 X + \epsilon_2 \) to assess the effect of the intervention on health behaviors (the potential mediator, \( M \)) (Figure 3). Finally, the regression model (b) \( Y = \beta_3 + \beta_4 X + \beta_5 M + \epsilon_3 \) is used to estimate the effect of health behavior on medication adherence while controlling for the intervention (Figure 3).
The mediated effect and its significance are estimated by the product $a \times b$ and its 95% confidence interval. This confidence interval is created finding the 95% asymmetric confidence limits using the PRODCLIN macro developed by MacKinnon, a more powerful method for creating the confidence interval for a product than the methods previously developed by both Baron and Kenny (1986) and Sobel (1990). The degree to which the relationship between $X$ and $Y$ is mediated by $M$ is found by comparing the direct effect of $X$ on $Y$ (found by $c$) to same effect in the presence of the mediator (found by $c' Y = i_3 + c'X + bM + \epsilon_3$). The proportion of the direct effect of the intervention ($X$) on medication adherence ($Y$) that is mediated by health behaviors ($M$) is reported in order to provide a quantifiable measure of the extent to which mediation is occurring. This difference, $c - c'$, is equivalent to the product $a \times b$, the term tested to determine whether the observed degree of mediation is statistically significant.

- **Sub Aim 2.1:** We examine the extent to which SOC mediates the effect of the intervention on medication adherence.
- **Sub Aim 2.2:** We examine the extent to which SEAMS mediates the effect of the intervention on medication adherence.
Outcome Measures

- **Primary Outcome Measure**

  The primary outcome measure for this Aim is medication adherence. This outcome is ascertained in the study “Multi-Faceted Intervention to Improve Cardiac Medication Adherence and Secondary Prevention Measures - The Medication Study” \(^{47}\) a randomized control study. We use the modified Refill Compliance (Recomp) method \(^{47}\) to measure percent of days covered (PDC) by medications described above.

- **Secondary Outcome Measure**

  The study utilizes two secondary outcome measures, SEAMS \(^{75}\) and SOC \(^{74}\) to assess the association of the intervention with health behavior. They are also used to investigate whether or not they mediate the relationship between the intervention and medication adherence.

**Power and sample size estimates**

- **Primary Outcome Measure**

  The power and sample size estimates were calculated in the original randomized control study proposal. They aimed to enroll 280 patients, and even with 10% lost to follow-up, they would still have 252 patients (126 patients in each group) at the end of study which is more than sufficient to assess the primary and secondary outcomes based on the sample size calculations.

- **Secondary Outcome Measure**

  For our sample size calculation the estimated SD came from the pooled estimate of Dr. Kripalani’s study, \(^{78}\) from the effect size of SEAMS scores, mean (SD) of 4.0 (5.66), with a power of 90% with an alpha of 0.05. The resulting sample size calculation is 44 in each group.
Aim 3: Gather patients’ perspectives of how their experience with multifaceted interventions influenced their health behavior and its effect on their health outcomes after experiencing an ACS event

Rationale

In an effort to improve cardiovascular outcomes, multifaceted interventions targeting healthy behaviors and medication adherence in an ACS population have been employed. To fully understand the effectiveness of these interventions it is important to obtain and assess the patients’ perspective of their experience. In addition, the evaluation needs to understand what the patient perceives to be effective components of the multifaceted intervention, so that further implementation can focus on the successful components.

The literature search found no studies that address the proposed question. Therefore, this research is needed to speak to this important gap in the literature.

Objective

What are patients’ perspectives of experiencing an ACS event and how does that affect their health behaviors?

- **Specific Aim 1**: Use semi-structured qualitative interviews to gather patients’ perspectives of experiencing an ACS event and how that affects their health behaviors.

What are patients’ perspectives of their relationships with providers involved with their ACS care and the impact on their health behaviors?

- **Specific Aim 2**: Use semi-structured qualitative interviews to gather patients’ perspectives of their relationships with their providers and the impact on their health behaviors.
Do patients’ believe technology improves their health behavior and health outcomes?

- **Specific Aim 3:** Use semi-structured qualitative interviews to gather their opinions and beliefs of whether or not technology improves their health behavior and health outcomes.

**Design and Subjects**

This Aim uses the same randomized control trial population as Aim 2. Please refer to Aim 2 for the specific details of this population. Sixty-four patients were interviewed. The majority of the patients are from the Denver site (N = 51), Seattle (N = 7), Little Rock (N = 3), and Durham (N = 3). The uneven distribution is due to the fact that Seattle (N= 23) and Durham (N = 10) had very few participants. Little Rock was not able to support the qualitative inquiry, although the Denver study coordinator did speak with three patients from Little Rock before we reached saturation.

**Data**

During the last study visit, patients are interviewed about their experience with the study to gather in-depth understanding of the phenomena of participation in a multifaceted intervention. Due to issues such as illiteracy, cultural barriers, and prior experience with low response rates with surveys, qualitative interviews are used to investigate patients experience and their opinion of the effectiveness of a multifaceted intervention. The data is collected in-person, using semi-structured, one on one, open-ended interviews. We chose questions that address each component of the patients’ overall experience during the study and the effect of the study on the patients’ health behavior.

The initial interview guide contains 14 semi-structured, open-ended questions for the intervention group and 10 for the usual care group. The questions address general
items for both arms of the study such as: sharing their experience about having had an ACS event, associations they believe exist between their medications and their cardiac issues, and how their health has changed since their ACS event. In addition, we ask about their relationships and communication with their providers when they are discussing their medication. We also ask about barriers and facilitators regarding taking their medications and the effect of the study on their health behaviors. The intervention group is asked specific questions about patient experience with the following: 1) their opinions about the reminder calls and the educational calls 2) working with the study pharmacists and the effects medication adherence and overall health; and 3) the effects of participation in the study on their health behavior. Over time, the interview guide was adjusted to reflect the iterative process in the Grounded Theory analytic approach.

Study staff conducts and audio-tapes the interviews, which range from 40 to 60 minutes. The audiotapes are transcribed verbatim. This qualitative study was approved as part of the randomized controlled trial by the Colorado Multiple Institutional Review Board. (47)

Baseline demographics that include age, sex, race, BMI, DM, and history of CAD are obtained to characterize the study population.

Analysis

- **Specific Aim 1:** Use an iterative, inductive and deductive toolkit of analytical strategies, drawing primarily on grounded theory, and consultative and reflexive analysis to assess the participants’ perspective of experiencing an ACS event.
- **Specific Aim 2:** Use an iterative, inductive and deductive toolkit of analytical strategies, drawing primarily on grounded theory, and consultative and reflexive analysis to analyze patients’ perspectives of their relationships with their providers.
• **Specific Aim 3**: Use an iterative, inductive and deductive toolkit of analytical strategies, drawing primarily on qualitative content analysis, and consultative and reflexive analysis to analyze their opinions and beliefs if technology improves their health behavior and health outcomes.

All transcripts are analyzed by members of the study team using grounded theory and content analysis methods. In order to emphasize respondent perspectives and de-emphasize researchers assumptions, the analysis begins with repeated readings to achieve immersion followed by initial open coding using an emergent rather than an *a priori* approach. Words, sentences, and paragraphs are treated as coding units or “meaning units”. In compliance with a constructivist grounded theory approach, we used a constant comparative method of going in and out of the data, as new interviews were completed, analyzed, and compared to previous data. As patterns, relationships, themes, and theory emerged and were analyzed, we advanced the investigation with thematic and theoretical sampling. This means that the questionnaire was changed to reflect the further inquiry into the specific information (themes and or theory) that was emerging from the data. This allows the researchers to confirm, refute, or expand the findings.

Subsequent analysis uses a deductive approach to capture the essence of the impact of the multifaceted intervention. The analysis involves a content analysis to assess the classification and quantification of patients’ beliefs in the validity of the components of the multifaceted intervention.

The preliminary results are reviewed by members of the thesis committee, to assess their evocativeness, thoroughness, and comprehensiveness. For analytical rigor, we have organized the analytical process with in-depth training of interviewers and analysts. A code book is produced that is compiled with emergent and *a priori* stable
codes. To establish coding reliability we assess an inter-coder reliability as is a measure of agreement. To add to the analytical rigor, we provide an audit trail that documents all analytic procedures and decisions. Finally, we triangulate the results from the qualitative findings, observations, and the quantitative findings.

**Outcome Measures**

An analytic summary of the interviews is written. The emergent categories and theories are documented and presented in the resulting thesis. Patients’ own words and narratives are used to preserve the tone and emotion of their experiences and increase the theoretical depth of the final description.

**Integration of Aims**

An integration of the two forms of data, quantitative and the qualitative, are combined for the strengths of both to answer the research question. A merging data approach is used to integrate the quantitative and qualitative data. This approach is achieved by reporting the two types of data together and is presented in the final analysis section of the thesis. The quantitative data are presented with the qualitative quotes that either support or refute the quantitative results.

“Not everything that can be counted counts and not everything that counts can be counted.”

Albert Einstein
CHAPTER IV

STUDY RESULTS

Aim 1 Gather an in-depth understanding of the phenomena of participation in a pharmacist lead, multi-faceted intervention of hypertensive patients using an Interactive Voice Response System and Home Blood Pressure Monitor

Results

Participants Baseline characteristics were comparable between the two groups, except that usual care patients were more likely to have diabetes or chronic kidney disease (74\% vs. 58\%; p = 0.045) (Table 2). Most of the study participants were male (81.5\%), and the overall racial makeup was 52\% non-Hispanic White, 23\% Hispanic, 19\% African American, and 4\% Native American. The majority of the study subjects were 50 years and older (87\%). Four of the 32 intervention patients interviewed at Denver Health and three of the 46 intervention patients interviewed at the VA had not used the IVR system, yet we have included their interviews in the analysis. \(^{(25)}\)

Experiences Participants reported a range of intervention effects, from no effect to significant effect upon their health behavior and control of their hypertension. A majority (75\%) of study participants indicated that they experienced a positive effect from the study, such as building a relationship with the medical personnel, feeling empowered to engage in bi-directional conversation with their healthcare provider or increased participation in their healthcare, improving their health behavior, and increasing their healthcare knowledge. Eighty-six percent of the intervention and 62\% of the usual care patients indicated that they experienced a positive effect. Eighty-two percent of women compared to seventy-three percent of men, found the study to have a positive effect. More African American (89\%) participants than Hispanic (71\%) and non-Hispanic White (74\%) participants indicated a positive effect. No difference was found in the percent of
patients experiencing a positive effect between the two study sites, a notable result
given the difference in study populations and healthcare systems. Predominately older
men are enrolled in the Veterans Affairs Health Care System, while Denver Health is a
local safety net hospital that cares for many of the indigent population of Denver,
Colorado.\(^{(25)}\)

Table 2. Aim 1 Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Intervention N = 78</th>
<th>Usual Care N = 68</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>64 (82)</td>
<td>55 (81)</td>
</tr>
<tr>
<td>Female</td>
<td>14 (18)</td>
<td>13 (19)</td>
</tr>
<tr>
<td><strong>Mean AGE (SD)</strong></td>
<td>61.7 (10.1)</td>
<td>61.0 (11.5)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>41 (53)</td>
<td>35 (51)</td>
</tr>
<tr>
<td>Non-White</td>
<td>37 (47)</td>
<td>33 (49)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>18 (23)</td>
<td>23 (34)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>59 (76)</td>
<td>44 (65)</td>
</tr>
<tr>
<td><strong>Co-morbidities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DMCKD</td>
<td>45 (58)</td>
<td>50 (74)</td>
</tr>
<tr>
<td>CAD</td>
<td>14 (18)</td>
<td>11 (16)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>11 (14)</td>
<td>8 (12)</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>5 (6)</td>
<td>7 (10)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>4 (5)</td>
<td>1 (0.02)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>54 (69)</td>
<td>50 (74)</td>
</tr>
<tr>
<td>Stroke History</td>
<td>12 (15)</td>
<td>8 (12)</td>
</tr>
</tbody>
</table>

Data are expressed as n and percent (%) or mean ± SD unless otherwise noted

Of the 37 study participants who did not report a positive experience, most (70%)
were usual care patients who shared that the study had no effect on their blood
pressure. The remaining 11 (30%) who did not report a positive experience were
intervention patients who had not worked with the study pharmacist. Two patients had
negative comments about the study. One subject, who never used the IVR system, did not like being contacted when he did not report his BP measurements. Another patient was fearful the pharmacist would replace his PCP and the study would “get his doctor in trouble because my blood pressure’s been up.” However, he indicated improving his medication adherence had resulted in a positive effect, “… it proved it right there in my readings this morning. It’s working”. Some patients mentioned personal issues that the intervention was unable to address such as financial problems, pharmacy rules, and transportation issues that could be barriers in their ability to improve their medication adherence. When asked “What makes it difficult to take your medicines?” two patients responded with, “If the water was shut off.” and “Just when I can’t afford them.”

Of those who had positive experiences, the data suggests six main themes related to the successful reduction of blood pressure. The themes are: 1) Improved relationships with medical personnel; 2) Increased knowledge of hypertension; 3) Increased participation in their healthcare and personal empowerment; 4) Greater understanding of the impact of health behavior on BP; 5) High satisfaction with technology, including the BP cuffs and the IVR system; and 6) The effects of the study on the patients’ healthcare utilization. Each is discussed in further detail. 

**Improved Relationships with Medical Personnel** Thirty-two percent of the intervention patients indicated that the multi-faceted intervention created relationships that made them feel cared about and encouraged them to become more active in their healthcare. Some patients spent more time than others with the study personnel because they contacted the pharmacists with questions or their home BPs warranted the study pharmacist intervention. Many of these patients attributed improved medication adherence and BP reduction to their positive relationships with the pharmacist. They felt that this positive relationship was unusual in routine clinical practice. In the words of one
participant who was initially frustrated with the technology but was very appreciative of the support and concern that he received from the study personnel, “Oh, it was great, you got me spoiled there for a minute it was like somebody really cared for…my high blood pressure …”(25)

**Increased Knowledge of Hypertension** Though all study patients enrolled in the intervention had uncontrolled hypertension, most had limited knowledge about its causes and/or consequences, as well as comprehension of the therapies utilized to treat it. The relationships that developed between some of the patients and the study personnel supported a level of comfort and trust, which allowed give-and-take in the educational process regarding BP. Seventy-eight percent of the intervention group indicated that their overall awareness of blood pressure increased, including the definition of systolic and diastolic numbers, the ramifications of too much salt and lack of exercise, and the overall importance of blood pressure on their health status. As one participant put it, ……when they take my blood pressure I didn’t know what the numbers meant at all and now I know what they mean so that’s helped me a lot because you know they check my blood pressure, ok, I don’t know if it’s normal. It’s high, it’s low, so I started asking question and now I know what it means so that helped me a lot.

More African American participants (85%) in the study said that their knowledge of blood pressure increased from participation in the study, compared to 68% of both Hispanic and non-Hispanic White counterparts. Interestingly, 60% of participants in the usual care group also indicated that being in the study increased their knowledge of blood pressure. Comments from some in the group suggest that the personal interaction and the educational information they received gave them the impetus to lose weight, exercise, and to adhere to their prescribed medications. (25)

**Increased Participation in their Healthcare and Personal Empowerment** Almost half of the participants (47%) from the intervention arm said that they became active participants in their healthcare by exercising more, eating healthier foods, and sharing
their home BP measurements with their primary care providers (PCPs). In addition, 27% of the intervention patients expressed that the knowledge and experience they obtained from the study empowered them to increase their interactions and communications with their PCPs. The knowledge and information (i.e., home BP measurements) they brought to the PCP visit facilitated a bi-directional conversation that supported their self-care as well as assisted their clinicians in the management of their hypertension. As one patient said, “So, it’s made me have a two way street with my PCP.” Interestingly, patients from both study arms reported more confidence in their ability to change their beliefs and behaviors. A minority (10%) of usual care patients also indicated that the added knowledge and understanding of the dynamics of hypertension increased their confidence about the disease, which lead to better communication with their PCPs. In the words of one such usual care patient,

Well, after reading the book that you gave me, I realized that things weren’t looking, … good for me ’cause I have an aneurysm in my brain that is inoperable and I realized after reading that I could blow my head off and I started going to my doctor every two weeks to get the blood pressure under control, and I started losing weight, going on a diet. I started walking, I started eating healthier and I’ve lost quite a few pounds. (25)

Among the intervention group, 59% of African Americans, 37.5% of Hispanics, and 44% of non-Hispanic Whites shared that they increased their participation in their healthcare. Regarding their feelings of empowerment, 29% of non-Hispanic Whites reported that they were more empowered to interact with their healthcare providers as a result of the study, 25% of Hispanics and 24% of African Americans reported that they felt more empowered to interact with their PCP as a result of the study. Comparison of the two sites indicates that 24% of the patients from the VA and only 12% of Denver Health patients became empowered to interact more with their PCP as a result of the study. (25)
Six participants shared that fear was either a motivator or an inhibitor of participation in their healthcare. These patients were fearful of learning that they had a serious problem, afraid to learn how high their BP was, afraid of their physician, and/or fearful of losing their job if they took excessive time off to go to the doctor. One man explained how Colorado is a no fault state and that he could be fired for missing work because of his surgeries. Another explained that he was afraid of his doctor and therefore, “I do exactly what she says.” For such participants, the support and tools (e.g. education about BP management and observing the consequences of appropriate health behavior from home BP measurement) provided by the study were helpful in addressing and thus partially alleviating some fears. (25)

Greater Understanding of the Impact of Health Behavior on BP Some of the patients (36%) were able to translate their behaviors such as eating too much salt, or medication non-adherence to the home blood pressure readings. A few subjects said specific issues such as forgetting to take their blood pressure measurements and/or difficulty finding time to perform the measurement impeded their ability to comply with study requirements. As one participant said,

*think taking my BP regularly really made me show that I did need to take the medication and that was somewhat motivating, … even though I didn’t cheat or fudge on it, on taking the medication … I often thought … I don’t think this might be doing anything…so it did show that the medication was important.* (25)

Fifty-nine percent of African Americans in the intervention group indicated that they were able to transform the information they received into improved understanding of their health behavior, while only 37.5% of Hispanics and 24% of non-Hispanic Whites did so. (25)

Satisfaction with IVR Technology and Home BP Monitoring The technology utilized in the study consisted of an electronic blood pressure cuff and an IVR telephone system. Overwhelmingly (94%), the patients reported having no difficulties taking their
blood pressure at home. In fact, a couple of the patients said that they “enjoyed” taking their blood pressures at home. Similarly, a significant majority of patients (90%) found the IVR system to be user-friendly and supported their efforts to lower their blood pressure and address other issues such as talking with a nurse, or contacting smoking quit lines and exercise programs. Participants particularly noted the ease of contacting the study pharmacist, refilling their prescriptions, and appreciated the reminder calls. As one participant said, “the fact is if they [the IVR] hadn’t called a lot of times I probably wouldn’t have done as well as I did.”

Despite the overall satisfaction with the technology, some patients became frustrated when the system was unavailable and they were unable to report their BP results. A few subjects reported other issues with the system, such as having difficulty pushing the buttons on their cell phones and the system was initially cumbersome. One participant indicated that the phone system wasn’t an issue for the first few months but after a while it became tiresome. He suggested a website may be easier and more convenient for some. Two patients were concerned about the cost when using their cell phones. Ultimately, most patients said the system was successful in supporting them to attain their blood pressure goals. A couple of the patients even enjoyed something akin to a “relationship” with the IVR system that supported their goal of reducing their blood pressure levels. “She [the IVR] would say you reached your goal congratulations, and I was elated to hear that so I worked that much harder the next time so I could hear those words again.”

**Healthcare Utilization** Overall, the intervention had mixed effects on healthcare utilization outside the study. Some participants reported that the intervention controlled their hypertension with appropriate medication adjustments and this resulted in less urgent care visits. Others realized they needed to be more concerned about their
hypertension and consequently increased their visits with their PCP. Healthcare utilization was not a major issue for most of the study participants. Only 15% of the intervention participants and 10% of the usual care patients said the study had any effect on their healthcare utilization. \(^{(25)}\)

When considering the generalizability of this intervention, a couple of patients shared their opinions of the potential positive effects of this type of program on the medical system and specific populations such as the Latino community. \(^{(25)}\) “Great program. Should expand it because … the Latin community, we just naturally eat bad and could use more help like this.”

The Association Between Program Impact and BP Control An additional analysis assessed the association between patients’ report of a positive impact of the program and achieving blood pressure goals. In the intervention group, most of the patients (86%) shared that the study had a positive effect and of those patients, the majority (68%) reached their systolic goal. Among intervention patients who reached their systolic blood pressure goal, most (89%) felt the study had a positive effect. In the usual care group, 62% indicated they experienced a positive effect from participating in the study and of these participants 55% reached their systolic BP goal. Overall, 50% of the usual care patients reached their systolic goal. As one might expect, it appears that those participants who had a positive experience with the program also had a positive impact on their blood pressures. As one participant said

…you’re going to save a lot of lives and it’s going to prevent a lot of strokes and heart attacks ‘cause … they don’t seem to realize and neither did I until I got more education about blood pressure … how important this is to monitor your blood pressure ….and … I think it’s going to help diabetes people … I’ve noticed my [A1C] level dropped some too with the blood pressure … \(^{(25)}\)
Aim 2: Assess the association of technology facilitated interventions on medication adherence mediated by health behaviors

Results

Participants. Forty-two patients are in the analysis. The randomization resulted in 20 patients assigned to the intervention group and 22 in the control group. Baseline demographics including age, sex, race, BMI, DM, and CAD history were obtained to characterize the study population and were found to be comparable between the two groups (Table 3). All but one of the participants were male (98%), and the overall racial makeup was 79% White, 14% African American, 5% Hispanic, and 2% Native American. The mean age of the population was 65 years (SD 9.0).

Due to the number of patients at the sites who were not administered the surveys; we assessed their baseline characteristics to determine if there were any significant differences between the two groups. No significant differences between the patients who received the surveys compared to those who did not were found (Table 4).

Primary Outcome. The medication adherence intervention significantly improved patients’ adherence to their cardiac medications compared to the control group. The mean Recomp score for the intervention group is 0.80 (SD 0.12, 95% CI (0.75, 0.86)). The control group’s mean Recomp score is 0.67 (SD 0.16, 95% CI (0.60, 0.74)). The difference is 0.133, 95% CI (0.043, 0.222) \( p = 0.0045 \) and is defined in the mediation model as \( c \) (Table 5).
Table 3. Aim 2 Demographics and Covariates

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Intervention N = 20</th>
<th>Usual Care N = 22</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Male</td>
<td>20 (100)</td>
<td>21 (95.5)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0 (0)</td>
<td>1 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Mean AGE (SD)</td>
<td>65.45 (10.43)</td>
<td>65.18 (7.76)</td>
<td>0.92</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>White</td>
<td>13 (65)</td>
<td>20 (91)</td>
<td></td>
</tr>
<tr>
<td>Non-White</td>
<td>7 (35)</td>
<td>2 (9)</td>
<td></td>
</tr>
<tr>
<td>Co-morbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>32.9 (8.4)</td>
<td>31.2 (6.8)</td>
<td>0.48</td>
</tr>
<tr>
<td>DM</td>
<td>8 (40)</td>
<td>7 (32)</td>
<td>0.75</td>
</tr>
<tr>
<td>CAD</td>
<td>11 (58)</td>
<td>15 (68)</td>
<td>0.53</td>
</tr>
</tbody>
</table>

Results are expressed as n (%) or mean (SD)

Table 4. Aim 2 Demographics and Covariates of those who were administered the survey vs those who were not administered the surveys

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Surveys N = 42</th>
<th>No Surveys N = 66</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Male</td>
<td>41 (97.6)</td>
<td>63 (95.5)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1 (2.4)</td>
<td>3 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Mean AGE (SD)</td>
<td>65.3 (9.0)</td>
<td>66.3 (9.5)</td>
<td>0.58</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td>0.31</td>
</tr>
<tr>
<td>White</td>
<td>33 (78.6)</td>
<td>46 (69.7)</td>
<td></td>
</tr>
<tr>
<td>Non-White</td>
<td>9 (21.4)</td>
<td>20 (30.3)</td>
<td></td>
</tr>
<tr>
<td>Co-morbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>32.0 (7.5)</td>
<td>30.8 (6.4)</td>
<td>0.40</td>
</tr>
<tr>
<td>DM</td>
<td>15 (35.7)</td>
<td>28 (42.4)</td>
<td>0.49</td>
</tr>
<tr>
<td>CAD</td>
<td>26 (61.9)</td>
<td>37 (56.1)</td>
<td>0.55</td>
</tr>
</tbody>
</table>

Results are expressed as n (%) or mean (SD)

- **Specific Aim 2.1**: The self-efficacy (SEAMS survey) mean baseline score is 31.95 (SD 6.72) 95% CI (29.86, 34.05). For the intervention group the mean baseline score is 33.45 (SD 5.32, 95% CI (30.96, 35.94)) and the usual care group is 30.59 (SD
There is no significant difference between the two groups ($p = 0.17$) (Table 5).

The SEAMS mean 12 month score is 34.55 (SD 4.47) 95% CI (33.16, 35.94). For the intervention group the mean 12 month score is 35.25 (SD 4.54, 95% CI (33.12, 37.38)) and the usual care group is 33.91 (SD 4.41, 95% CI (31.96, 35.86)). There is no significant difference between the two groups ($p = 0.34$) (Table 5).

Table 5. Aim 2 Results

<table>
<thead>
<tr>
<th>Analyses</th>
<th>Overall</th>
<th>Intervention N = 20</th>
<th>Usual Care N = 22</th>
<th>$P$ Value</th>
</tr>
</thead>
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<tr>
<td>Mean RECOMP SCORE (SD)</td>
<td></td>
<td>0.80 (0.12)</td>
<td>0.67 (0.16)</td>
<td>0.0045</td>
</tr>
<tr>
<td>Mean SEAMS SURVEY (SD)</td>
<td></td>
<td>31.95 (6.72)</td>
<td>33.45 (5.32)</td>
<td>30.59 (7.64)</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td>34.55 (4.47)</td>
<td>35.25 (4.54)</td>
<td>33.91 (4.41)</td>
</tr>
<tr>
<td>12 Months</td>
<td></td>
<td>1.8 (3.8)</td>
<td>3.3 (7.8)</td>
<td>0.42</td>
</tr>
<tr>
<td>Difference (a)</td>
<td></td>
<td>1.8 (3.8)</td>
<td>3.3 (7.8)</td>
<td>0.42</td>
</tr>
<tr>
<td>Mean SOC SURVEY (SD)</td>
<td></td>
<td>4.62 (0.88)</td>
<td>4.80 (0.62)</td>
<td>4.46 (1.06)</td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
<td>4.83 (0.76)</td>
<td>4.85 (0.67)</td>
<td>4.82 (0.85)</td>
</tr>
<tr>
<td>12 Months</td>
<td></td>
<td>0.05 (0.94)</td>
<td>0.36 (0.73)</td>
<td>0.23</td>
</tr>
<tr>
<td>Difference (a)</td>
<td></td>
<td>0.05 (0.94)</td>
<td>0.36 (0.73)</td>
<td>0.23</td>
</tr>
<tr>
<td>Baseline SEAMS and Recomp</td>
<td></td>
<td></td>
<td></td>
<td>0.0012</td>
</tr>
<tr>
<td>Baseline SOC and Recomp</td>
<td></td>
<td></td>
<td></td>
<td>&lt;.0001</td>
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</tbody>
</table>

Results are expressed as n (%) or mean (SD)

The mean change (SD) from baseline to the end of the study period for the SEAMS survey was 2.6 (6.0). No significant difference was found in the change of the self-efficacy (SEAMS survey) in taking medications between the control group compared to the intervention group. The mean difference score from baseline to one year in the
control group is 3.32 (SD 7.83) compared to the intervention group 1.80 (SD 3.79) with the difference of -1.52 95% CI (-5.42, 2.38) \( p = 0.44 \) indicating there is no difference between the two groups (Table 5). This path is denoted by (a) in the mediation model.

The SOC mean baseline score is 4.62 (SD 0.88, 95% CI (4.34, 4.89)). For the intervention group the mean baseline score is 4.8 (SD 0.62, 95% CI (4.51, 5.09)) and the usual care is 4.46 (SD 1.06, 95% CI (3.99, 4.92)). There is no significant difference between the two groups (\( p = 0.20 \)) (Table 5).

The SOC mean 12 month score is 4.83 (SD 0.76, 95% CI (4.60, 5.07)). For the intervention group the mean 12 month score is 4.85 (SD 0.67, 95% CI (4.54, 5.16)) and the usual care is 4.82 (SD 0.85, 95% CI (4.44, 5.20)). There is no significant difference between the two groups (\( p = 0.9 \)) (Table 5).

Similar results are found in the SOC survey as was found in the SEAMS survey that assesses the motivation to change adherence behaviors. The mean difference score from baseline to one year in the control group is 0.36 (SD 0.73) compared to the intervention group 0.05 (SD 0.94) with the difference of -0.31 95% (-0.84, 0.21) There is no significant difference between the two groups (\( p = 0.23 \)). This path is denoted by (a) in the mediation model.

Therefore, no significant association exists between the medication adherence intervention and health behaviors, self-efficacy (SEAMS survey) or motivation (SOC survey).

Based on the findings of a small change occurring from baseline to the 12 month follow up for both surveys, an additional analysis was investigated. We looked to see if there was an association between the baseline SEAMS and SOC surveys and the dependent variable of medication adherence. The mean of the SEAMS baseline data is 31.95 (SD 6.72). A significant association exists with patients’ baseline self-efficacy and
the medication adherence at 12 months ($p = 0.0012$). We also risk adjusted using all the
covariates and the no significant adjustments were observed. The mean of the SOC
baseline data is 4.62 (SD 0.88). A significant association was found between the
baseline stage of change scores and the patients' medication adherence at 12 months
($p <.0001$). Therefore, health behaviors constructs, self-efficacy and motivation, are
important constructs for prediction of medication adherence. Evaluation of self-efficacy
and motivation should be determined to assess the patients' ability to adhere to
recommended medical treatment and if needed, interventions aimed to improve patients’
self-efficacy and motivation, should be initiated to support patients’ adherence to their
prescribed therapies.

- **Specific Aim 2.2**: No significant association exists between the medication
adherence intervention and the change from baseline to 12 month time frame for the
health behaviors, self-efficacy (SEAMS survey) or motivation (SOC survey). Therefore,
based on the mediation model, these health behavior constructs do not seem to mediate
the relationship between the medication adherence intervention and the outcome of
medication adherence. Yet, this is an educational process and therefore, we continued
the analysis for the experience.

The mediation model uses the coefficients of the individual analyses (paths) to
compute the mediation analysis; therefore the coefficients will be identified in the
following discussion.

The mediation model assesses the extent to which a variable (health behavior)
mediates the effect of the independent variable (intervention) on a dependent variable
(medication adherence). The association between the intervention and health behaviors
is described above and denoted by (a).
The second step in the medication model is to determine the extent to which the variable (change in health behavior) is associated with the dependent variable (medication adherence) while controlling for the independent variable (intervention) and denoted by (b). A significant association was found in both health behavior constructs. The effect of self-efficacy (SEAMS survey) on medication adherence while controlling for the intervention, this path is denoted as (b) was -0.009 (SE 0.003) \( p = 0.01 \) and the effect of motivation (SOC survey) was -0.060 (SE 0.025) \( p = 0.017 \).

The same models are used to assess the association of the intervention on medication adherence while controlling for health behavior, denoted as \( (c') \). There was a significant association for both analyses. The SEAMS survey estimate was 0.119 (SE 0.041) \( p = 0.006 \) and the estimate of motivation (SOC survey) was 0.113 (SE 0.042) \( p = 0.011 \).

The estimate of the effect of the intervention on medication adherence that is mediated by self-efficacy (SEAMS survey) is therefore \(-1.518 * -0.009 = 0.014 \) (95% CI -0.022, 0.058) which accounts for 12.4% of the total effect. Self-efficacy is not a statistically significant mediator (\( \alpha = 0.05 \)) of the effect of the intervention on medication adherence, as evidenced by the 95% confidence interval containing 0. Similarly, the effect of the intervention on medication adherence that is mediated by stage of change (SOC survey) is \(-0.314 * -0.064 = 0.020 \) (95% CI -0.010, 0.059) which accounts for 17.7% of the total effect. The same conclusion is reached that stage of change does not significantly mediate the relationship between the intervention and medication adherence.
Aim 3: Gather patients’ perspectives of how their experience with multifaceted interventions influenced their health behavior and its effect on their health outcomes after experiencing an ACS event

Results

Participants Sixty-four patients were interviewed. Majority of the patients were from the Denver site (N = 51), Seattle (N = 7), Little Rock (N = 3), and Durham (N = 3). The uneven distribution was due to the fact that Seattle and Durham had very few participants. Little Rock was not able to support the qualitative inquiry; therefore, the Denver team contacted the three subjects included in this inquiry. The randomization resulted in 33 patients assigned to the intervention group and 31 in the control group. Baseline demographics included age, sex, race, BMI, DM, and CAD History were obtained to characterize the study population and were found to be comparable between the two groups (Table 6). Most participants were male (97%), and the overall racial makeup was 75% White, 11% African American, 8% Hispanic, 2% Pacific Islander, Asian 1%, and 3% Native American. The majority of the study participants were 50 years and older (95%) with a mean age of 66.5 years.

Experiences The intent of this research was to explore the experience of having an ACS event and how this event affected patients’ lives, health, and health behaviors. In addition, we inquired about patients’ relationships with their health care providers and attempted to delve into the meaning of bi-directional conversations. Due to the use of a grounded theory approach that resulted in thematic and theoretical sampling, multiple iterations of the interview guide evolved so that not everyone was asked the same questions; which may affect an exact reporting of the proportion of respondents. A strong attempt was made to discern the true denominator. In addition, patients gave opinions and insights that were not specifically asked for in the interview guide, such as
their opinion of the care they received at the VA, therefore, these values are not exact. Yet, this is not of concern for the authors; because qualitative analysis use of numbers is for descriptive context only.

Table 6. Aim 3 Demographics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Intervention N = 33</th>
<th>Usual Care N = 31</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>32 (96.97)</td>
<td>30 (96.77)</td>
</tr>
<tr>
<td>Female</td>
<td>1 (3.03)</td>
<td>1 (3.23)</td>
</tr>
<tr>
<td><strong>Mean AGE (SD)</strong></td>
<td>66.00 (9.78)</td>
<td>67.10 (9.73)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>24 (73)</td>
<td>24 (77)</td>
</tr>
<tr>
<td>Non-White</td>
<td>9 (27)</td>
<td>7 (23)</td>
</tr>
<tr>
<td><strong>Co-morbidities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean BMI (SD)</td>
<td>32.0 (7.4)</td>
<td>32.0 (7.1)</td>
</tr>
<tr>
<td>DM</td>
<td>14 (42)</td>
<td>10 (32)</td>
</tr>
<tr>
<td>CAD</td>
<td>20 (63)</td>
<td>18 (58)</td>
</tr>
</tbody>
</table>

Data are expressed as n and percent (%) or mean ± SD unless otherwise noted

Experiencing an ACS event was a profound, life changing, event for most (67%) patients in the Medication Study. Some (23%) said there was no change or that they just accepted the event and moved on. The remaining 10% did not address the question. The consequences of the ACS event were determined by how patients perceived the experience.

Consequences of the ACS events were varied. Several patients (36%) stated their life changed because of physical limitations, which consequently affected specific aspects of their lives. A few (N = 3) men indicated a loss in their self-identity, while others said their family roles changed based on their level of physical ability, and relationships with significant others were also affected. Two patients felt less worthy and
now were unsure of who they were, and what contribution they could make to the family and society. Some patients (34%) described being fearful, concerned, devastated, and depressed. They acknowledged being physically and mentally challenged, and some shared that they were now physically restricted and regretful of their limitations. In addition, a few patients (8%) became fearful of overly exerting themselves, which may cause another attack. A few of these patients described realizing their mortality and their fear of dying. These factors resulted in either motivating or hindering their ability to effectively change their health behaviors. A couple of gentlemen were surprised and disappointed to have had a heart attack despite their previous positive health behaviors. Therefore, these patients needed to redefine how to live their lives and reassess their priorities.

On the other hand, six patients indicated that having the ACS event caused them to become reflective and were thankful to have survived. Some patients believed that going forward they needed to take care of themselves for their families, as well as for themselves. Eight patients shared that they physically felt better after their attack, and the improvement motivated them to effectively change their health behavior. Consequently, these patients and others (34%) became motivated to be active participants in their health care, such as changing their lifestyle to become healthier, being aware of good nutritional habits, and adhering to the prescribed medication regimens. Thus, these patients were able to move forward and address the needed change in their health behaviors.

In addition to how this event affected patients’ lives, health, and health behaviors, we inquired about patients’ relationships with their health care providers. Overall, many patients (48%) shared that they were grateful for the quality care they received at the VA and that they had good communication with their providers and had no problems talking
openly and honestly with their doctors (84%). Patients shared that providers who were “regular” people were comfortable to talk with and to even express disagreement. Patients who were comfortable with their providers described them as patient, understanding, and took the time to discuss the details and reasons for each of the patient’s medications. These patients expressed the importance of the good communication with their providers, including the ability to be “heard,” and to discuss their care, especially their medications. Good communication between patients and providers involves having both parties be comfortable being truly honest and open.

The honest and open conversation between patients and providers is defined as a bi-directional conversation. This occurs when the perspectives of both the provider and the patient are accounted for in the conversation and where patients are truly comfortable disagreeing with the providers’ recommendations and the provider is open to hear the patients’ perspective. In our study those who experienced bi-directional conversations (67%), suggested it supported their quality of care. Patients realized that high-quality care requires both the provider and the patient to be active participants in this relationship. As one gentleman said, “I don’t think they know the whole story about the individual. They are a lot smarter than I am on everything, but sometimes, there’s things they don’t take into consideration.” Others added that it was their responsibility to tell the provider “everything” and to help the providers remember specific details about themselves because the providers were busy and had limited time with each patient. Another patient shared, “You know in the long run, people can prescribe medication but it is up to me to decide if I will take it or not, and I take it by the way.” The patients enjoyed these respectful and equivalent relationships.

However, everyone did not share the same experience. Some patients (16%) did not share that the communication with their providers was good and one patient
stated that “doctors are not gurus; they are just people like me”. Some patients were just not comfortable discussing differing opinions and being honest with their providers. Six people specifically said they would not tell their provider if they disagreed with the prescribed treatment. Finally, a couple of patients shared that their providers were not open to hear patients’ opinions. One patient who was not “forthcoming” about his non-adherence said he was conflicted about the side effects of his medications but not comfortable discussing this with his provider. The lack of open communication prevented the patient from obtaining the best care from his clinician because the physician lacked the appropriate information to determine the best treatment plan.

This discussion regarding the lack of communication with providers regarding medications exposed an underlying issue of medication adherence. Many people (48%) shared dislike for taking medications and a few wanted to get off of them as soon as possible. This was true even though they believed that they would be on them indefinitely. However, the real question is how many of these people share their honest opinions and feelings with their providers and more importantly, how many share their honest adherence behavior? Yet, the most common barriers to medication adherence identified were forgetfulness and being out of their routine (41%).

Lastly, we explored patients’ experiences with the Medication Study, specifically; we addressed their perspectives of being in the study, working with the pharmacists, and receiving the IVR messages. Content analysis revealed that most patients in the intervention arm (67%) had a positive experience in the study. The positive experience was directly correlated with patients’ interaction with the study pharmacist, as one caretaker said,

….before the study I did not know who to call at the VA to get clarification. But knowing that the pharmacist is a phone call away and that is a person I can ask about his medications it has helped me a great deal keep the medications organized and the pill box up to date and correct.
The IVR messages, including both educational messages and cardiac medication refill reminder calls, received mixed reviews. Overall, 67% of the group randomized to the intervention group reported receiving the messages and 33% indicated they did not receive or did not remember receiving the calls. Yet, only 42% of participants in the intervention group shared they believed the messages had a positive effect on their adherence behavior. One patient said that overall, the messages made him feel cared about and the refill messages were helpful. A couple of patients shared insights about the refill messages, with one saying that it would have been helpful to know which medication needed to be refilled, because the messages were generic only indicating that their prescriptions needed to be refilled. Other patients shared that the repeated messages were annoying because they would continue after the medications had been filled.

Of those who had shared their perspectives about medication adherence, the data suggests five main themes related to the support medication adherence: 1) Bi-directional conversations; 2) Support of others; 3) Fear; 4) Positive attitudes; and 5) Establishing a routine utilizing a pill box. Each is discussed in further detail.

**Bi-directional conversations/relationships:** Patients indicated the importance of communication between patients and providers. Sixty-seven percent of all patients identified having bi-directional conversations between themselves and providers, which appears to be a key element of medication adherence.

*They’ve always communicated to me that the absolute importance of it, without being nasty. You know, it’s not like a Daddy/Mommy relationship and you are the child. It’s always on an adult level. You know nobody’s pointing a gun at me saying you gotta’ take your pill.*

Patients who are comfortable being honest with their providers are active participants in the shared decision-making process that is essential for adherence. As one patient said, “….how [would he] know what was best for me if I can’t tell him how I feel about it.” Of
those who do not share their opinions and felt they were not listened to, one said, “…but I just don’t want to argue with him to tell him, he’s not in my body. And I know what I feel and he can’t tell me what I feel.”

Some patients shared that basic communication was lacking and it caused concern. If patients do not understand how medications work, their adherence is affected, as one patient said, “Well they keep telling me that everything is fine, [if] everything is fine, then I don’t see the reason why I can’t get off of them [medications].”

Providers must be open to hear the honest perspective of the patient without judgment. Furthermore, providers have to take the time to be sure the patient understands the evidence based recommendations and also work with the patient toward a mutually agreed upon treatment plan. When asked if he felt comfortable telling a provider that he didn’t agree with him a patient said, “Oh yea I do… but they don’t. Well you know it’s my body, and I have to live in it, they don’t. And still another shared:

and he’s acting like I got no business being there, there’s nothing wrong with me, telling me we just did an arteriogram several months ago and there wasn’t any problem and stuff like that and that just kinda ticked me off! Nobody knows my body like I know my body! And he finally agreed to do another arteriogram and that’s when they found out that one graft was 100% blocked!

And still another said, “I found for myself because I didn’t ask the questions or perhaps the doctor didn’t fill me in enough on the medication itself or the pharmacist…. the doctors don’t think that we’re capable of understanding sometimes.”

Support of others. Patients (22%) shared that having other people to remind them, help organize their medications, and overall encouragement was helpful. A patient shared, “…well the people that know I am taking the medicine, that’s the first thing… did you bring your medicine? …. They, they’re making sure that, you know, I am taking my medicine.”
Fear was described as a double edged sword. Fear of having another cardiac event or dying (8%) motivated people to follow prescribed behaviors such as adhering to the medication regimen, eating healthy, and exercising. As one patient shared,

*She goes I’m going to be honest with you, you won’t survive the next one. So that changed things, whoah, and then my two grandkids, they are only four and three. That’s another thing…yea…keeps making sure I’m going to take my medicines…..*

Yet, it also caused five people to not exercise in fear of exacerbating their condition. As described by the following statements, “*More than anything else my mental state is that I’m afraid to do some things for fear that I will have a heart attack.*” and another said;

*You don’t uh…you don’t have the motivation you had before, you always have a shadow in the back of your mind you know, that I wouldn’t push myself to hard is it just could cause it worse damage or is it going to get me in better shape?*

**Positive attitudes** For some patients (36%), the experience of an ACS event affected their attitudes towards living and reassessing their priorities. Patients believed that going forward they needed to take care of themselves for their families as well as for themselves. “*Well, it is the attitude I have that these medications are good for me.*” And another shared,

*It means that I need to take better care of myself. Give up the old habits of smoking, which I did a year ago, and to take my prescribed medication on time. Try to eat a balanced diet and try to keep my health better and my weight down, cholesterol down. There’s just so many things we have to live for, we have, you know, grandchildren, we have three little great granddaughters and they’re from two years old to nine months, so. And my wife, you know, her and I we’ve, you know, since high school, fifteen years old, you know, so, you know, I have a lot to live for so I got to watch my health.*

Another person shared: *Going from not being used to taking any at all, to taking six a day…it was a little bit hard. It was a change. Lately, sometimes I forget, you know you get caught up in a rush or doing different things and you know, I forget. Or I take them late, but I’m trying to stay with it.*
Establishing a Routine Utilizing a Pill Box

When asked what advice patients gave for being adherent, patients overwhelmingly (52%) declared having a routine and/or using a pill box to organize the multitude of medications. As one man eloquently said,

...well I realized that I was of the age that I needed to buy one of those plastic trays where you lay your meds for a week and you know, that becomes a bit of a ritual. You lay out your meds and you take them. I have also asked my family to help remind me and usually when they remind me I have already taking the med anyway, but it helps to have someone else looking out for you.

Theory Generation

Experiencing an ACS event can be a profound, life changing event. Consequences of this experience vary depending on the individual. Some patients become motivated to be proactive in their health behavior, while others become indifferent and/or depressed. Ultimately, these consequences affect the actions and attitudes towards medication and health behavior adherence and the interpretation of the meaning of adherence.

Consequences of the experience can be defined in basic terms of positive and negative. Those who are empowered to find affirmative aspects of their experience, even through fear and limitations, and are able to go forward with appropriate health behaviors are identified as positive in nature. These patients are proactive participants in their health care: adopting healthy lifestyle behaviors, being aware of good nutritional habits, and adhering to the prescribed medication regimens. They understand the importance of communication between patients and providers and the significance of bi-directional relationships. Patients who are positive understand that quality health care requires both the provider and the patient to be active participants in this relationship. In addition, they believe that it is the patients’ responsibility to tell the provider “everything” and to help the providers remember specific details about themselves because providers are busy and have limited time with each patient. Patients who are comfortable being
honest with their providers feel they are “heard” and are comfortable discussing their care, especially their medications.

For patients to be comfortable being honest with their providers, the providers need to be patient, understanding, and take the time to discuss the details and reasons for each of the patient’s medications. Thus, patients and providers build these respectful and equivalent ‘bi-directional’ relationships, where ultimately the patients’ are inclined to follow the prescribed treatment plans because they feel they are involved with the decision-making process of the treatment plan.

Conversely, when the consequences of the experience result in patients who are consumed with fear and/or depression or who have difficulty going forward, they are identified as negative in nature. Fear and depression have profound impact on patients’ perspectives of themselves and their outlook on life. Fears of exacerbating their condition prevent people from exercising, while the fear of medication interactions and side effects inhibit medication adherence. Depression caused by perceived and real physical limitations can affect a person’s self-identity, negatively impact their relationships with significant others, and subsequently, affects their self-care. Patients feel less worthy and unsure of who they are and what contribution they make to the society, family, and themselves. These factors hinder patients from being proactive in their health care.

Communication between patients and providers is another important factor for patients to be proactive in their health care. Lack of basic communication is problematic for patients, especially when they are consumed with fear or depression. In order to obtain clear and accurate information to appropriately adjust their health behaviors, patients must be comfortable asking clarifying questions and sharing their opinions, even if they diverge from those of the providers. Patients want to be listened to and to feel
heard; a perceived condescending attitude can affect how patients proceed with their health behavior decisions. If patients do not understand how medications work, their adherence is affected. Therefore, appropriate communication embedded in the respectful and equivalent ‘bi-directional’ relationship between patients and providers is needed to support patients’ health behavior decisions and ultimately, their actions.

Patients experiencing an ACS event are faced with profound health care decisions. Bi-directional conversations and relationships between patients and providers can be a key factor of adherence to evidence-based therapies that will lead to better outcomes. Patients are aware when patient-provider communication is not appropriate, especially when the power structure prevents an open and honest relationship. Patients are aware when providers willingly involve them in the decision-making process and when they are not. Yet, the traditional definition that “medication adherence usually refers to whether patients take their medications as prescribed (eg, twice daily), as well as whether they continue to take a prescribed medication” \cite{96} does not specifically involve the agreed upon decision of both provider and patient. This antiquated physician-centered model of care where the “doctor knows best” still exists, even though adherence has been defined as “the active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result”. \cite{96, 97} Therefore, work is needed to further disseminate and implement theories of patient centered care and shared decision-making models, which have been shown to: improve standards in care, to have positive effects on patient outcomes, and to improve satisfaction and adherence. \cite{97, 98} Yet, for the process to be effective there must first be an authentic communication between patient and provider, where the provider shares their opinion regarding the treatment options and the patient shares honestly what they are willing and able to do to adhere to the proposed treatment options. This model
mandates that both parties are open to sharing and to hearing others opinions and working towards a mutually agreed upon treatment plan. The clinician must be open to hear divergent opinions of what may be best for the patient, from the patients’ perspective. The patient must be open to share what they will honestly do based on what treatment options have been proposed. Only then can a true shared decision-making process occur.
CHAPTER V
DISCUSSIONS

Aim 1 Gather an in-depth understanding of the phenomena of participation in a pharmacist lead, multi-faceted intervention of hypertensive patients using an Interactive Voice Response System and Home Blood Pressure Monitor

The objective of this study was to better understand patients’ experiences with a multifaceted intervention that included interactions between patients, healthcare providers, and the healthcare system. The multifaceted intervention also required explicit behaviors from participants, which necessitates the need to understand what was effective from the perspective of the participants. On the basis of the experiences shared by patients from both study arms, we propose a model to improve health behavior and clinical outcomes in patients with uncontrolled hypertension. As displayed in Figure 4, the multifaceted intervention facilitates bi-directional conversations between patients and healthcare providers through the IVR system. The technology supports this process by providing patients with immediate feedback about home BP measurements and the opportunity to request follow-up calls from the pharmacist. Furthermore, patients directly witness the benefits of diet, exercise, and/or medications through home blood pressure monitoring, which re-enforces the importance of these mediators in reducing BP. Healthcare providers are able to follow patients’ home BP measurements and can contact them as needed to reinforce medication adherence and make medication dose adjustments based on the reported measurements. The IVR reminder messages sent to those who have not entered home BP measurements within eleven days further reinforces the importance of home BP monitoring and increases contacts between patients and the healthcare system. Consequently, patients feel cared for, feel that they are an integral part of their healthcare, and are empowered to be active
Figure 4.

The Theoretical Model of a Hypertension Management

Uncontrolled Hypertensive Patients

Multifaceted Intervention

Patients
Patient feels cared about
Patient more confident to converse with medical personnel

Knowledge
Understands the disease and it’s consequences

Physiological
Feels better and sees results

IVR System
Facilitates patients interactions with the medical personnel regarding outcomes

Medical Personnel
Builds Relationships thru Bi-Directional conversations with patients

Surrogate Outcome
Patients report results to IVR system or directly to medical personnel

Behavioral Changes
Takes Medications - Changes Diet - Increases Activity Levels - Visit’s PCP - Monitors Surrogate Outcome Resulting in Control of Clinical Issue
Figure 4 Legend. The Theoretical Model of a Hypertension Management
This is the proposed theoretical model to improve health behavior and clinical outcomes
in patients with uncontrolled hypertension derived from the patients’ interviews about
their perspectives of the multifaceted study.
participants in their own healthcare, taking a proactive approach to medication adherence, monitoring their BP, and having the confidence to engage in bi-directional conversation with their health professionals.\(^{(25)}\)

The literature supports the individual components of the model that includes appropriate medication regimens, patient education, and addressing individuals’ needs for mutual working relationships with medical personnel for hypertension management.\(^{(25)}\) Previous studies have concluded that an organized system of regular follow-up, stepped care approach to a patients’ hypertension regimen, and integration of technology can improve BP control.\(^{(25)}\) However, the literature lacks a model that integrates these components into an organized system supporting patient care on multiple levels, which is the foundation of our theoretical framework. In addition, there has been little research focusing on the participants’ perspectives of the different components of a hypertension intervention. The proposed model illustrates a process that addresses needs of the patient, healthcare providers and the healthcare system. The IVR system aids in the education of the patients, serves as a repository of BP results, and is a liaison between the healthcare provider and the patient. The IVR system provides patients with a mechanism to receive feedback about their home BP measurements, have questions answered, and to request pharmacist support, which empowers them to actively participate in their healthcare. The IVR system also supplies healthcare providers with more BP measurements yielding a greater basis in which to make clinical decisions regarding the need to intensify therapy. This is in contrast to usual clinical care, where BP measurements are only available when patients come in for a clinic visit, which can be stressful for some patients. From the perspective of the healthcare system, this model of care delivery moves away from the traditional episodic based care to a more patient-centered model where care delivered is specifically
responsive to patient needs, (e.g., when BP is elevated or when patients request a call from the pharmacist) and is consistent with the chronic nature of hypertension. \(^{(25)}\)

Key questions in an intervention evaluation are whether or not the intervention is effective in everyday practice and whether or not the results vary between sites and among patients. \(^{(25)}\) This study was conducted as a practical clinical trial by selecting clinically relevant alternative study components to compare, including a diverse population of study participants, and recruiting participants from heterogeneous practice settings. \(^{(25)}\) The feedback regarding the program from participants was similar across sites but some differences were also noted. We found that a higher percentage of African American compared to Hispanic and White patients reported an increase in knowledge and participation in their healthcare but a lower percentage reported being more empowered to interact with their PCPs. These findings should be further explored in subsequent studies to potentially tailor interventions to specific patient populations. \(^{(25)}\)

In addition, our objective to evaluate the intervention from the patients’ perspective confirmed that the individual components: increased patient education, increase interaction with providers, and technology integrated into a multi-faceted intervention was indeed effective to improve patients’ health behavior to lower their blood pressures.

Potential limitations of Aim 1 should be acknowledged. The results of this study are based on the people who enrolled in the study and may be subject to attribution bias. In addition, there is the possibility of a social desirability bias where patients respond in a certain way to please the interviewer. The study results are based only on interview data and did not include any direct observations of the patients using the study components. Finally, there were a greater number of usual care patients with diabetes or chronic kidney disease and we are not aware if the presence of these co-morbidities had a differential impact on achievement of BP goals between the two groups. \(^{(25)}\)
In conclusion, the proposed theoretical model of a clinical management system (Figure 4) that includes IVR, integrates patients and healthcare providers in the process of improving BP control. Patients are no longer on the sidelines of their care and are immersed in the direct consequences of their behaviors regarding diet, physical activity, and medication adherence. Healthcare professionals have the opportunity to develop a mutual working relationship with patients that is facilitated by technology. When appropriately integrated, we believe this model will support patients to adhere to prescribed medical regimens that have been mutually developed and agreed upon. The findings from this study can provide the framework for the development of subsequent interventions to change patient and healthcare provider behavior as well as clinical outcomes of patients with hypertension. This model may also inform interventions for other chronic conditions, such as diabetes. 

Aim 2: Assess the association of technology facilitated interventions on medication adherence mediated by health behaviors

In this study, we hypothesize that the multi-faceted intervention, Medication Study, would improve medication adherence after experiencing an ACS event. In addition, we hypothesize that the impact of the intervention on medication adherence would be mediated by constructs of health behavior, as measured by the Self-Efficacy for Appropriate Medication Use Scale (SEAMS) and Stages of Change (SOC) questionnaires.

Our findings support the primary hypothesis; the intervention significantly improved medication adherence compared to the usual care with a mean (SD) Recomp score (0.80 {0.12} vs. 0.67 {0.16} \( p = 0.005 \)). This difference is likely due to the increase interaction with the study pharmacist and the additional contacts via the phone.
messages, which are components of the intervention. These findings suggest that increased interactions with the healthcare system can improve medication adherence.

The secondary hypothesis that the impact of the intervention on medication adherence would be mediated by constructs of health behavior is not supported. Health behavior was not found to be a mediator of the association between the intervention and medication adherence. Although there was no statically significant difference found, a greater change was seen in the control arm with both SEAMS and SOC surveys. It appears the SEAMS results were affected by two extreme outliers in the control group, which had a greater influence on the results due to the small sample size. Further sensitivity analyses were performed and indicated the outliers did have an impact, although not significant, on the outcome. For the SEAMS survey, a greater change was seen in the intervention arm (mean change 1.80 SD 3.8) compared to the control arm (mean change 1.35 SD 4.75).

In addition, the sample size was limited; therefore, the study did not have the power to detect a significant difference. Going into the study, we were hoping the intervention would improve self-efficacy by 4 units, and planned a total sample size of 252 to test this. We based our calculations on Dr. Kripalani’s self-efficacy trial that supplied us with an effect size of four and mean standard deviation of 5.66. This study would have been successful if an appropriate sample size had been obtained because we had sufficient power to detect a significant difference even with half the sample size. Unfortunately, our sample size of 42 was only 17% of the planned sample size, thus affecting our ability to detect a difference of four units.

To assess the results from a clinical perspective, one could surmise that patients in the control group were left to their own volition to be adherent to their medication,
therefore becoming more motivated and confident and resulting in no significant differences between the two randomized groups.

Even though a significant association between the intervention and the mediators was not found and therefore, there was no reason to continue with the mediation analysis, we decided, for the educational experience, to continue. The exercise provided a tangible demonstration that clearly identified the steps involved in a mediation analysis and strengthened, for the doctoral student, the understanding of the mediation theory.

Further investigation into mediation theory generated profound discoveries. Health behavior theories, including the Transtheoretical Model (TTM) identify self-efficacy and motivation to change behaviors as specific constructs and may well be mediators between an intervention and an outcome. Yet, detecting their influence in a mediation model may be difficult. Mac Kinnon et al. identified that the lack of an observed association of a mediator may be because the specific health behavior construct, such as self-efficacy, was not specifically targeted in the intervention. Neither self-efficacy to adhere to cardiac medications nor motivation to change medication adherence behaviors were constructs specifically targeted in the Medication Adherence study. In addition, Williams and Dunsiger identified that the temporal ordering of constructs is important in the context of mediation analyses but is rarely achieved in practice. Typically, measurement of the mediator and the outcome occur immediately prior to the intervention, at Time 1. The mediator is measured again at Time 2 and the outcome at Time 3. Thus, giving the appearance of a temporal ordering of constructs, yet the findings may reflect change in both the mediator and the outcome that occurred between Times 1 and 2 leaving the researchers unsure as to what change
occurred first. (97) This dilemma would appropriately apply to our study design as we measured the mediator and the outcome at the same time points.

Williams and Dunsiger (99) offer a suggestion of measuring the mediator immediately prior to the intervention and immediately after the intervention and the outcome measured at a later point. They believe this design may support the hypothesis that the change in the mediator preceded the change in the outcome. Of course this design may suggest a causal relationship, a randomized control trial would be needed to further support the theory of causation. In addition, they leave open the option that some other unmeasured construct may be the true mediating factor. However, they conclude this type of evidence may be as close as we can come to supporting the hypothesized mediational path.

The results of the mediation analyses, indicating a small change in the health behavior from baseline to 12 months and the change in health behaviors that was significantly associated with medication adherence, while controlling for the intervention, were grounds for an additional investigation. We hypothesized that patients who began the study with high confidence and high motivation to take their medications were significantly associated with medication adherence. Therefore, we assessed the association between the baseline surveys and medication adherence and found a significant association between both surveys and medication adherence. These findings indicate that self-efficacy and motivation are predictive of medication adherence and although the data did not support our hypothesis, they may indeed mediate the relationship between the intervention and medication adherence.

We have learned from this study that specifically targeting the mediation constructs in an intervention and paying strict attention to the timing of the mediation constructs assessment in the intervention evaluations may improve our understanding of
adherence behavior, which in turn may improve adherence to medications. Self-efficacy and motivation are important constructs in determining patients’ ability to adhere to recommended medical treatment. Therefore, before initiating cardiac therapy, evaluation of patients’ levels of self-efficacy and motivation should be determined. If those evaluations do not reflect adequate levels of self-efficacy and motivation, appropriate interventions aimed to improve these levels should be initiated to support patients’ adherence to their prescribed therapies.

**Aim 3: Gather patients’ perspectives of how their experience with multifaceted interventions influenced their health behavior and its effect on their health outcomes after experiencing an ACS event**

The objective of this study was to better understand how a multi-faceted intervention designed to improve adherence to cardiac medications, impacts patients’ experiences after an ACS event. We also wanted to delve further into the significance of bi-directional conversations between providers and patients and its effect on medication adherence in a post ACS population.

On the basis of the experiences shared by patients in the randomized control trial, bi-directional conversations between patients and providers is the focal point of the emerged theory of important factors that affect adherence to medical regimens. Our theory identifies how patients respond to experiencing an ACS event, with fear or affirmation, initiates their journey into recovery. The theory goes further to assess the importance of communication with family and friends, as well as clinical providers. The communication between patients and providers must be an authentic and truthful. Where the provider shares their opinion regarding the treatment options and the patient shares honestly what they are willing and able to do to adhere to the proposed treatment
options. This model mandates that both parties are open to sharing and to hearing others opinions and working towards a mutually agreed upon treatment plan.

The literature supports the individual components of our theory. Health behavior theories such as the Health Belief Model (HBM)\(^{(40, 53)}\) indicate that health actions are motivated by the degree of fear (perceived threat) and the expected fear reduction of actions, given that the reduction outweigh the barriers to taking action (net benefits). The HBM defines four constructs, which represent the perceived threat and net benefits.\(^{(40, 53)}\) This theory supports our findings that fear was an important factor of adherence. Patients identified fear as a double-edged sword, with some patients sharing how fear motivated them to improve their health behaviors, while others told of the inability to exercise for fear of having another event. Health behavior literature confirms the concept that fear, positive attitudes, and social support are all factors that affect patients’ health behavior decisions.

Fishbein and Ajzen’s Theory of Reasoned Action\(^{(40, 53)}\) supports our findings that positive attitude and social support affect adherence behavior. According to this theory, a patient’s intention to perform a specific behavior is a function of two individual factors: their attitude, either positive or negative, toward the behavior and the influence of the social environment (norms) on the behavior. Attitudes are a function of beliefs. If people believe that performing a behavior will lead to a positive outcome then they will have a positive attitude performing that behavior. The social norms are the patients’ beliefs that certain individuals or groups believe the patients should or should not perform the defined behavior.\(^{(40, 53)}\) In addition, a recent systematic review by Scheurer et al.\(^{(101)}\) found that practical social support was most consistently associated with greater medication adherence.\(^{(101)}\) The multiple studies included in the review, as well as the results of the review, back our findings that patients in our study indicated their
adherence was supported by family and friends. Thus, our results are in concordance with the previous literature regarding positive attitudes, social support, and fear constructs.

Further concordance with the literature includes the World Health Organization categorizing potential reasons for medication non-adherence and four of the five groupings included the health system (providers and system factors), the condition (ACS), the patient (deciding to adhere or not), and the therapy (side effects). It has also been documented that poor relationships and poor communication between providers and patients affects non-adherence. In addition, the concept of shared decision-making (SDM), which debuted in the 1980’s has similar conclusions. The original focus of SDM was on potentially life threatening illnesses, it is now expanding into all aspects of clinical practice. SDM is defined as “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences.” Elwyn et al. go further to describe that the skills of SDM are unlikely to be developed unless the provider agrees with the guiding ethical principles. At the core of SDM is the acceptance that individual self-determination is a desirable goal and that providers need to support patients to achieve this goal, wherever feasible. SDM is very supportive of our findings of open communications, supporting patients to be involved in their healthcare, and encouraging patients to distribute their deliberation process (i.e. talk with their family and friends). Although, if a provider does not agree with the guiding ethical principles of shared decision-making, they are unlikely to be willing to participate in the process of shared decision-making and accepting that individual self-determinations is a desirable goal. Thus, for the
model to be successful, both parties of the clinical encounter need to understand and be willing to participate in the process.

Our findings fill the gap in the literature on medication adherence by using bi-directional communication between provider and patient to go deeper into the shared decision-making process. At the present time, numerous studies describe decision-making tools, which may be no more than additional information used to persuade patients to follow the evidenced based treatment options. Bi-directional conversations help to remove barriers of communication and empower patients to share concerns, fears, and personal issues giving the provider important information regarding potential barriers to adherence (social and psychological states and issues). Therefore, bi-directional conversations and relationships allow exploration to empower patients to be active participants in their healthcare and give providers the opportunity to understand the honest adherence behavior of their patients and to assess true treatment effectiveness, which may improve health outcomes.

The objective of this study was also to better understand patients’ experiences with a multifaceted intervention that included interactions between patients, healthcare providers, and the healthcare system. The multifaceted intervention required minimal behaviors from participants, yet we need to understand what was effective from the perspective of the participants. The increased interaction with the pharmacist supported patients with their medication adherence. The one-on-one personal interactive relationship allowed bi-directional conversations to occur that addressed patients’ concerns with their medications. Questions, clarifications, and explanations went as deep as the patient needed to understand why and how to adhere to the prescribed regimen. The pharmacist reconciled any medication issues, attempted to synchronize the refill dates of the cardiac medications so that refills all occurred on the same date, or
as close as possible, instead of usual practice where medication refill dates vary tremendously. The pharmacist also educated the patient about the importance of their medications and provided a pill box. This bi-directional relationship was available throughout the study period and supported the intervention patients in adhering to the prescribed cardiac medications.

The intervention incorporated phone messages to support patients by reminding them to refill their cardiac medications and the importance of adherence to medications and lifestyle changes. This increased interaction with the healthcare system was a positive experience for some patients, as one patient said that he felt cared about due to receiving the messages.

Thus, based on the feedback from the patients’ both positive and negative we can conclude that the individual components: increased patient education, increase interaction with providers, and technology integrated into this multi-faceted intervention was indeed effective to improve patients’ health behavior to adhere to their medication and lifestyle changes. The feedback about the phone messages being annoying after the medication were refilled and not knowing which medication needed to be refilled will be helpful for improving the system.

In conclusion, patients experiencing an ACS event are faced with profound health care decisions. Evidence-based medicine indicates that health behavior decisions have substantial consequences on clinical outcomes. Improving health behavior decisions, especially adherence to medical regimens known to improve outcomes, is a complex process that includes all facets of the healthcare system. This study focuses on the significance of the interaction between the patient and the provider and the importance of how technology facilitates the interaction. These profound relationships, which utilize open communication and bi-directional relationships, affect
the health behaviors of patients and may have strengthened the impact on clinical outcomes. Bi-directional conversations give patients’ the confidence to honestly share their health behavior limitations, which in turn give providers the honest depiction of what the patient will do and therefore, can ascertain the most appropriate treatment options. Providers will also be given insight into the real effectiveness of their treatment plans.

**Integration of Aims 1-3**

The primary purpose of this thesis was to gather an in-depth understanding of the experience of participating in technology facilitated multifaceted cardiac interventions and how the interventions affect health behavior decisions from the patients’ perspective. The secondary purpose was to assess the association of the impact of technology facilitated interventions with cardiovascular outcomes mediated by health behavior. To accomplish these goals, we completed three distinct aims in which the patient populations were derived from two cardiovascular randomized controlled clinical trials. After completion of the individual aims, we merged the data to triangulate the findings. By combining the patients’ perspectives and the study outcomes, we were better able to understand the patients’ experiences of participating in these multifaceted interventions and the effect of the interventions on their health behaviors.

Triangulating the data was important to fully understand the complexity of the effect of the interventions on patients’ behavior. Multifaceted interventions provide options for resources and advice, which may be welcomed, heeded, and acted upon. What this means is that patients select medical advice or aspects of interventions they believe to be beneficial or conducive to their lifestyle. This preferential uptake of intervention components potentially affects the outcome of the study. Understanding
which components patients adopt and the reasons for their choices are important towards understanding why interventions are effective.

Therefore, we used both qualitative and quantitative data for the inquiry. The qualitative data revealed that the patients’ experiences during the intervention affected their health behaviors. Most patients indicated that overall, the interventions positively affected their health behaviors. Patients in the “Improving BP in Colorado” (Aim 1) said that they were no longer on the sidelines of their care and instead were aware of the direct consequences of their behaviors regarding diet, physical activity, and medication adherence. The home BP monitors, the IVR system, and the increased interaction with the study pharmacists were the individual components to the intervention. Each component individually and collectively supported the patient to improve their health behavior. For example, patients shared that the BP monitor allowed them to see the effects of medication adherence. The IVR and the pharmacists were very important because from their interactions the patients increased their knowledge of their healthcare needs, felt cared for, and empowered the patients to take control of their healthcare. Therefore, they were more inclined to eat healthier food, exercise more, and take their medications as prescribed. These results were fully supported by the quantitative findings of a significant improvement of the systolic blood pressures in the intervention group compared to the control group. Patients in the “Medication Study” (Aim 3) also indicated that the intervention improved adherence behaviors. The increased interaction with the study pharmacists was again important for the same reason of feeling cared for. The participants shared that the Medication Study’s phone messages reminded them to refill their cardiac medications and reinforced the importance of adherence to medications and lifestyle changes. These results were likewise fully supported by the quantitative findings of a significant improvement the
cardiac medication adherence in the intervention group compared to the control group. The quantitative data also elucidated a positive association of the Medication Study with health behavior constructs self-efficacy (empowerment) and motivation to adhere to medications. Thus, triangulation of data allowed us to understand specific components patients adopted and the reasons for their choices, which is important towards understanding why interventions are effective.

The qualitative interviews gave us further insight into the importance of feeling cared about and of developing bi-directional conversations, which augment these feelings. Bi-directional conversations are defined as discussions that flow from the provider to the patient and from the patient back to the provider and require both the provider and the patient to be active participants in the discussion. The patients’ responsibility is to be honest with the provider, which helps providers to know specific details about the patients’ health behaviors. Patients who are comfortable being honest with their providers feel they are “heard”, feel cared about, and are comfortable discussing their care. Yet, for patients to be comfortable being honest with their providers, the providers need to be open to hear the patients’ perspective without judgment. The provider needs to be patient, understanding, and take the time to discuss the details and reasons for the prescribed treatment plan. The bi-directional conversations increased patients’ knowledge about appropriate health behaviors, health issues and medication. For the providers, the bi-directional conversations gave providers truthful information about the patients. Thus, patients and providers build respectful and equivalent relationships. These relationships embody the caring phenomenon and further support patients' to improve health behaviors.

These respectful and equivalent relationships help to empower patients and remove barriers of communication. Removing the barriers of communication, empowers
patients to share preferences, concerns, fears, and personal issues giving the provider important information regarding potential barriers to adherence (social and psychological states and issues). This allows patients to work with the providers towards mutually agreed upon treatment plans because they are involved with the decision-making process of the treatment plan. Given the honest depiction of the treatment plan, providers are given insight into the real effectiveness of their treatment plans. Therefore, appropriate communication embedded in the respectful and equivalent bi-directional relationship between patients and providers support both patients and providers to fulfill their role in the healthcare treatment model.

Using a mixed methodology we were able to explore the proposed questions and hypotheses to understand deeper insight into evaluating the effectiveness of multifaceted interventions and the relationship between the quantitative findings and the phenomenon of experiencing the intervention from the perspective of participants. Had we only used quantitative data, we would not have been able to discern which components of the intervention patients believed to be important. Utilizing qualitative methodologies allowed us to tease out factors that supported positive health behaviors (feeling cared about, increased interactions healthcare, bi-directional relationships). In addition, we were able to explore the reasoning of negative health behaviors (fear, disagreement with prescribed treatment). Equally, using only qualitative data would limit our ability to assess the objective effectiveness of the intervention. This pragmatic approach enabled us to examine the practical consequences and empirical findings of the multifaceted interventions to decide which factors were effective and should be maintained in the intervention to improve the outcomes (increased interactions with health providers, IVR, screening of self-efficacy). Consequently, this pragmatic paradigm was ideal for inquiry into this health services research where the intent was to
evaluate and foster effective interventions to improve quality of care, specifically in the CVD population. CVD outcomes is a challenge, this thesis adds important information and insights to the literature to better understand patients’ perspectives regarding their CVD treatment, health behaviors, and outcomes.

Next Steps

To expand this research, next steps will need to explore the efficacy of utilizing bi-directional conversations in a shared decision-making model (SDM). SDM is the contemporary health care model and for it to be successful bi-directional relationships need to be an important component. Yet, the literature indicates that the skills of SDM are unlikely to be developed unless the provider agrees with the guiding ethical principles. Therefore, we believe an assessment of providers and administrators’ biases, and perceptions of barriers and facilitators of establishing bi-directional conversations and relationships in the healthcare environment needs to be obtained.

Additionally, we hypothesize that it is not cost effective to have PCPs develop these relationships due to the time commitment need to develop the relationship. Thus, a model that includes Health Coaches provided with training in performing bi-directional conversations in a shared decision-making model could be explored for efficacy and cost effectiveness.

Finally, based on our findings, we believe development of a screening questionnaire that includes specific constructs that either supported or hindered patients’ ability to follow through with healthy behaviors is needed. Specific constructs include: increased interactions with pharmacists, nurses, or other healthcare providers; reminder systems; home monitoring, educational programs; exercise programs. In addition, the questionnaire would include components that the literature identifies to be important
constructs in determining patients' ability to adhere to recommended medical treatment: depression, self-efficacy, motivation, health literacy, and cognitive impairment.

In conclusion, these future steps will further explore ideas and concepts identified by patients and researchers through the inquiry of this thesis.

**Limitations**

Potential limitations of the study should be acknowledged. The results of this study are based on the people who enrolled in the studies and may be subject to attribution bias. Thus, the experience of participation in the study may have influenced participants' perspectives of their interactions with their providers. However, we also interviewed control patients who only received usual care, therefore, we obtained balanced perspectives. In addition, there is the possibility of a social desirability bias where patients respond in a certain way to please the interviewer, and may not have truly reflected their opinions of the study. Yet, because the interviewers were not in any power structured role, we believe patients were not influenced to please the interviewers. The qualitative study results are based only on interview data and did not include any direct observations of the patients using the intervention components. In addition, systematic differences of the interviewers may have impacted the results. Therefore, varied results may have emerged that otherwise would have been more consistent. Furthermore, less sophisticated interviewers may not have delved as far into the perspectives of subjects than more advanced may have, thus missing potentially important data. However, the data was evaluated by a multidisciplinary group who were able to interpret the findings in a broader context.

The number of quantitative surveys obtained was dependent on the site decision to participate or not in this sub-analysis, thus affecting our ability to detect a difference.
Self-report survey data may be affected by recall bias or the desire to please. However, because the interviewers were not in any power structured role, we believe patients were not influenced to please the interviewers. Finally, the Recomp method used to assess the medication adherence does not exactly determine actual usage of medications by patients, we were unable to identify discontinued medications, and the inability to assess outside hospitalization may affect the results. These limitations may have affected our conclusions of the adherence pattern of the subjects in this analysis. However, this methodology is the most appropriate to assess multiple medications taken across multiple classes, which the literature has identified improve clinical outcomes, such as control of hypertension, which are a function of adherence to the regimen rather than to individual medications.

In conclusion, we do not believe the identified limitations of this thesis bias the results due to the mixed methodology and triangulation of the data that allowed us to test for consistency. Understanding inconsistencies from different types of data that are sensitive to alternative aspects of the phenomenon in question offered deeper insight into the relationship between the inquiry approach and the phenomenon identified in this inquiry.
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APPENDIX A

SELF-EFFICACY FOR APPROPRIATE MEDICATION USE SCALE

(SEAMS SURVEY)
Self-efficacy for Appropriate Medication Use Scale (SEAMS)

How confident are you that you can take your medicines correctly.....

(1) When you take several different medicines each day.
   □ Not confident   □ Somewhat confident   □ Very confident

(2) When you take medicines more than once a day.
   □ Not confident   □ Somewhat confident   □ Very confident

(3) When you are away from home.
   □ Not confident   □ Somewhat confident   □ Very confident

(4) When you have a busy day planned.
   □ Not confident   □ Somewhat confident   □ Very confident

(5) When they cause some side effects.
   □ Not confident   □ Somewhat confident   □ Very confident

(6) When no one reminds you to take the medicine.
   □ Not confident   □ Somewhat confident   □ Very confident

(7) When the schedule to take the medicine is not convenient.
   □ Not confident   □ Somewhat confident   □ Very confident

(8) When your normal routine gets messed up.
   □ Not confident   □ Somewhat confident   □ Very confident

(9) When you are not sure how to take the medicine.
   □ Not confident   □ Somewhat confident   □ Very confident

(10) When you are not sure what time of day to take your medicine.
    □ Not confident   □ Somewhat confident   □ Very confident

(11) When you are feeling sick (you know, like having a cold or the flu).
    □ Not confident   □ Somewhat confident   □ Very confident

(12) When you get a refill of your old medicines and some of the pills look different than usual.
    □ Not confident   □ Somewhat confident   □ Very confident

(13) When a doctor changes your medicines.
    □ Not confident   □ Somewhat confident   □ Very confident
APPENDIX B

STAGES OF CHANGE FOR MEDICATION ADHERENCE

(SOC SURVEY)
Stages of Change for Medication Adherence

1. People sometimes find it difficult to take their medication as directed by their physician. As directed means consistently taking the amount of medication prescribed by your physician at the time(s) prescribed by your physician. Please find the statement that best describes the way you feel right now about taking your (high blood pressure/protease inhibitor) medication as directed.

   A. No, I do not take and right now am not considering taking my medication as directed.
   
   B. No, I do not take but right now am considering taking my medication as directed.
   
   C. No, I do not take but am planning to start taking my medication as directed.
   
   D. Yes, right now I consistently take my medication as directed.

If the answer to question 1 is D, then:

2. How long have you been taking your medication as directed?
   A. ≤3 months
   
   B. >3 months to 6 months
   
   C. > 6 months to 12 months
   
   D. >12 months
Aim 1 Interview Guide
Improving Blood Pressure in Colorado
PI: P. Michael Ho, MD, Ph. D.
COMIRB # 06-0950

Qualitative – Interview Guide

“To help make this a better program, we would like to ask you questions about your experience with this study, is that ok with you? To be sure we collect all of the information you share we would like to audio tape this conversation with you, is that ok?”

Intervention Patients
1. “Please describe your experience when you took your blood pressure readings at home, please include the number of times each day and week.” (If issues or further explanation is required– “please explain what you mean by that.”)

2. “Please describe any difficulties or problems you had with taking your BP at home.” (If issues or further explanation is required– “please explain what you mean by that.”)

3. “Please describe your experience when you used the IVR system, please include the number of times each week.” (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Please describe any difficulties or problems you had with using the IVR system.” (If issues or further explanation is required– “please explain what you mean by that.”)

5. “Could you tell us about your experience when the IVR system called you?” (If issues or further explanation is required – “please explain what you mean by that.”)

6. “Could you tell us about your experience when you used any of the extra options on the IVR system?” Please include which options you used. (If issues or further explanation is required – “please explain what you mean by that.”)

7. “Please describe your experience when you take your medicines, please include the number of times each day.” (If issues or further explanation is required – “please explain what you mean by that.”)

8. “What makes it difficult to take your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

9. “Under what circumstances do you stop taking your medicines?” (If issues or further explanation is required – “please explain what you mean by that.”)

10. “What effects did working with the pharmacist have on your effort to care for your health?” (If issues or further explanation is required – “please explain what you mean by that.”)

11. “What effects did working with the pharmacist have on your efforts to take your meds?” (If issues or further explanation is required – “please explain what you mean by that.”)
12. What effects did working with the pharmacist have on your efforts to control your BP?" (If issues or further explanation is required – “please explain what you mean by that.”)

13. “Tell us how your participation in this study has affected your decisions to see your doctor or not see her/him?” (If issues or further explanation is required – “please explain what you mean by that.”)

14. “What barriers have kept you from seeing your doctor?” (If issues or further explanation is required – “please explain what you mean by that.”)

15. “How has the program helped you to reduce doctor visits?” (If issues or further explanation is required – “please explain what you mean by that.”)

16. “How has it helped you during visits?” (If issues or further explanation is required – “please explain what you mean by that.”)

Usual Care Patients
1. “Please describe your experience when you take your medicines, please include the number of times each day.” (If issues or further explanation is required – “please explain what you mean by that.”)

2. “What makes it difficult to take your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

3. “Under what circumstances do you stop taking your medicines?” (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Tell us how your participation in this study has affected your decisions to see your doctor or not see her/him?” (If issues or further explanation is required – “please explain what you mean by that.”)

5. “What barriers have kept you from seeing your doctor?” (If issues or further explanation is required – “please explain what you mean by that.”)

6. “How has the program helped you to reduce doctor visits?” (If issues or further explanation is required – “please explain what you mean by that.”)

7. “How has it helped you during visits?” (If issues or further explanation is required – “please explain what you mean by that.”)
Qualitative Interview Guide for Medication Adherence Study

“To help make this a better program, we would like to ask you questions about your experience with this study, is that ok with you? To be sure we collect all of the information you share we would like to audio tape this conversation with you, is that ok?”

**General questions for both arms:**

1. “Please tell me what does it mean to you to have a heart condition?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. “Do you believe your health has changed over this past year?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. If yes, “please tell me how you think it has changed?”
   b. If no, “please tell me why you think it hasn’t changed?”

3. “Please tell me what you think is the connection between your heart medicines and your heart condition?” (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Do you believe that the medicines have any effect on your health?” (If issues or further explanation is required – “please explain what you mean by that.”)

5. “Please tell me what you like and dislike about taking medicines?” (If issues or further explanation is required – “please explain what you mean by that.”)

6. “Please tell me how do you feel when the doctor is talking to you about your medicines?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. “Do you feel you can tell him/her that you disagree?”
   b. “Do you feel you can tell him/her that you don’t like a particular medicine, or how many times you have to take it?”

7. “What are some things that get in the way of you taking your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

8. “Do you have any suggestions for helping people to take prescribed medications?” (If issues or further explanation is required – “please explain what you mean by that.”)

**Intervention Arm:**

1. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”)
2. What effects did working with the pharmacist have on you?” (If issues or further explanation is required – “please explain what you mean by that.”)

3. “What effects did working with the pharmacist have on your efforts to take your meds? (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Tell me your thoughts about the IVR educational messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)

5. “Tell me your thoughts about the IVR system medication refill reminder messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)

6. “Do you believe the way the medical staff (doctor, nurse, pharmacist) interacts with you has an effect on your decision to take your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

Control patients:
1. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. “Do you believe the way the medical staff (doctor, nurse, pharmacist) interacts with you has an effect on your decision to take your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)
Qualitative Interview Guide for Medication Adherence Study

“To help make this a better program, we would like to ask you questions about your experience with this study, is that ok with you? To be sure we collect all of the information you share we would like to audio tape this conversation with you, is that ok?”

**General questions for both arms:**

1. “Please tell me what does it mean to you to have had a heart attack?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. “Do you believe your health status has changed over this past year?” (If issues or further explanation is required – “please explain what you mean by that.”)  
   a. If yes, “please tell me how you think it has changed?”  
   b. If no, “please tell me why you think it hasn’t changed?

3. “Please tell me what do you believe having had a heart attack and medicines have to do with each other?” (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Do you believe that the medicines have any effect on your health status?” (If issues or further explanation is required – “please explain what you mean by that.”)

5. “Please tell me what you like and dislike about taking medicines?” (If issues or further explanation is required – “please explain what you mean by that.”)

6. “Please tell me how do you feel when the doctor is talking to about your medicines?” (If issues or further explanation is required – “please explain what you mean by that.”)  
   a. “Do you feel you can tell him/her that you disagree?”  
   b. “Do you feel you can tell him/her that you don’t like a particular medicine  
   c. Or how many times you have to take it?”

7. “What are some things that get in the way of you taking your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

8. “Do you have any suggestions for helping people to take prescribed medications?” (If issues or further explanation is required – “please explain what you mean by that.”)

**Intervention Arm:**

1. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”)
2. What effects did working with the pharmacist have on you?“ (If issues or further explanation is required – “please explain what you mean by that.”)

3. “What effects did working with the pharmacist have on your efforts to take your meds? (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Tell me your thoughts about the IVR educational messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)
   a. What impact of the messages on your health behavior?
   b. What impact of the messages on your health status?

5. “Tell me your thoughts about the IVR system medication refill reminder messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)
   a. What impact of the messages on your health behavior?
   b. What impact of the messages on your health status?

6. “Do you believe the personality of the medical staff (doctor, nurse, pharmacist) has an effect on your decision to take your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

**Control patients:**
1. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. “Do you believe the personality of the medical staff (doctor, nurse, pharmacist) has an effect on your decision to take your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)

3. What impact being in the study had your health behavior?

4. What impact of being in the study have on your health status?

**Questions about costs for final study visits:**
1. Over the past year, how much, on average, did you pay out of pocket for your “heart” medications each month?

2. Are there any “heart” medications you don’t refill because of the cost?

3. Do you have insurance (other than VA) to help with medication costs?

4. Is there anything else about medication costs you would like us to know?
Qualitative Interview Guide for Medication Adherence Study

“To help make this a better program, we would like to ask you questions about your experience with this study, is that ok with you? To be sure we collect all of the information you share we would like to audio tape this conversation with you, is that ok?”

General questions for both arms:
1. “Please tell me about having had a heart attack/heart condition?” (If issues or further explanation is required – “please explain what you mean by that.”)
2. “Do you believe your health has changed over this past year?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. If yes, “please tell me how you think it has changed?”
   b. If no, “please tell me why you think it hasn’t changed?”
3. “Please tell me your thoughts and opinions about your medicines and how they relate to your heart? (If issues or further explanation is required – “please explain what you mean by that.”)
4. “Please tell me about your relationship with your providers?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. “If you disagree with your provider how do you feel about sharing that with them?” (If issues or further explanation is required – “please explain what you mean by that.”)
5. “What are some things that get in the way of you taking your medicine?” (If issues or further explanation is required – “please explain what you mean by that.”)
6. “Do you have any suggestions for helping people to take prescribed medications?” (If issues or further explanation is required – “please explain what you mean by that.”)
7. Please tell me what you believe are important factors in keeping you healthy? (If issues or further explanation is required – “please explain what you mean by that.”)

Intervention Arm:
1. “Please tell me about your experience in this study?”
2. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”) Be sure to go further if response is yes/no.
3. What effects did working with the pharmacist have on you?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. “Were there any effects on your efforts to take your meds? (If issues or further explanation is required – “please explain what you mean by that.”)

4. Did you receive any computerized messages from this study?

5. If yes: “Tell me your thoughts about the IVR educational messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)
   a. What impact of the messages on your eating or exercising habits?

6. If yes: “Tell me your thoughts about the IVR system medication refill reminder messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)
   a. What impact of the messages on taking your medicines?

7. Please tell me your thoughts and opinions of using phone technology (Educational voice messages and reminders to pick up your medicines or other things you know about) in your medical care?

Control patients:
1. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. Please tell me your thoughts and opinions of using phone technology (Educational voice messages and reminders to pick up your medicines or other things you know about) in your medical care?

Questions about costs for final study visits:
1. Over the past year, how much, on average, did you pay out of pocket for your “heart” medications each month?

2. Are there any “heart” medications you don’t refill because of the cost?

3. Do you have insurance (other than VA) to help with medication costs?

4. Is there anything else about medication costs you would like us to know?
Qualitative Interview Guide for Medication Adherence Study

“To help make this a better program, we would like to ask you questions about your experience with this study, is that ok with you? To be sure we collect all of the information you share we would like to audio tape this conversation with you, is that ok?”

**General questions for both arms:**

1. “Please tell me about having had a heart attack/heart condition?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. “Do you believe your health has changed over this past year?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. If yes, “please tell me how you think it has changed?”
   b. If no, “please tell me why you think it hasn’t changed?”

3. “Please tell me your thoughts and opinions about your medicines and how they relate to your heart? (If issues or further explanation is required – “please explain what you mean by that.”)

4. “Please tell me about your relationship with your providers?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. Do you comply with the directions your provider gives you? For example people have told us that they do everything their providers say to do: they take all their meds and do all the things like exercise and eat right OR they don’t do any of the things the provider says to do. Where do you fit?
   b. “If you disagree with your provider how do you feel about sharing that with them?” (If issues or further explanation is required – “please explain what you mean by that.”)
      i. So when you didn’t agree with them were you comfortable telling them you didn’t agree?
      ii. If you don’t agree again where do you fit in the spectrum of complying with their directions?

5. “Do you have any suggestions for helping people to take prescribed medications?” (If issues or further explanation is required – “please explain what you mean by that.”)

6. Please tell me what you believe are important factors in keeping you healthy? (If issues or further explanation is required – “please explain what you mean by that.”)
**Intervention Arm:**

1. “Please tell me about your experience in this study?”

2. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”) Be sure to go further if response is yes/no.

3. What effects did working with the pharmacist have on you?” (If issues or further explanation is required – “please explain what you mean by that.”)
   a. “Were there any effects on your efforts to take your meds? (If issues or further explanation is required – “please explain what you mean by that.”)

4. Did you receive any computerized messages from this study?

5. If yes: “Tell me your thoughts about the IVR educational messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)
   a. What impact of the messages on your eating or exercising habits?

6. If yes: “Tell me your thoughts about the IVR system medication refill reminder messages?” Please explain in full detail. (If issues or further explanation is required – “please explain what you mean by that.”)
   a. What impact of the messages on taking your medicines?

7. Please tell me your thoughts and opinions of using phone technology (Educational voice messages and reminders to pick up your medicines or other things you know about) in your medical care?

**Control patients:**

1. “Did participating in this study affect your understanding of medicines in general?” (If issues or further explanation is required – “please explain what you mean by that.”)

2. Please tell me your thoughts and opinions of using phone technology (Educational voice messages and reminders to pick up your medicines or other things you know about) in your medical care?

**Questions about costs for final study visits:**

1. Over the past year, how much, on average, did you pay out of pocket for your “heart” medications each month?

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4. Is there anything else about medication costs you would like us to know?