

IMPROVING MEDICATION ADHERENCE IN UNDERREPRESENTED PATIENTS
WITH HEART DISEASE: PILOTING A MOTIVATIONAL INTERVENTION

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IMPROVING MEDICATION ADHERENCE IN UNDERREPRESENTED PATIENTS
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ABSTRACT

Essential to reducing the risk of recurrence in individuals with cardiovascular disease (CVD), adherence to cardioprotective medications has been shown to decrease risk of cardiac-related hospitalization and mortality. Rates of nonadherence to these medications are high. Furthermore, racial and socioeconomic disparities in adherence are evident. Financial, informational, behavioral, and combined approach interventions to improve cardioprotective medication adherence utilize a variety of delivery methods (e.g., in-person, electronically, by mail). Intervention success rates have ranged from no improvement to moderate improvement in adherence. However, intervention generalizability is limited by: (1) underrepresentation of patients with low-income and racial minorities, (2) outcomes that do not adequately capture typical medication regimens, and (3) feasibility at a wide-scale level given their time and resource-intensive nature.

This study aimed to address these limitations by developing and piloting a brief motivational interviewing (MI) session to increase medication adherence rates in patients with CVD, recently discharged from the hospital. It was hypothesized that the intervention group receiving a telephone-based brief MI counseling session for medication adherence (i.e., MI-medication Group) would show higher adherence to cardioprotective medications, assessed by both objective pharmacy fill data (Hypothesis 1) and by self-report data

(Hypothesis 2) compared to the other two study groups (i.e., standard of care [SC Group] and MI for cardiac rehabilitation [CR] intervention group [MI-CR Group]). Further, this study examined the Information, Motivation, Behavioral Skills model (IMB) within the MI-medication Group as secondary outcomes. The MI-medication Group was hypothesized to experience a significant increase in medication *information* (Hypothesis 3), autonomous and controlled *motivation* to adhere to medications (Hypothesis 4), and *behavioral skills* (Hypothesis 5) from Time 2 to Time 3.

Missing data precluded statistical testing of Hypothesis 1. Descriptive statistics for the received pharmacy data are presented and suggests mixed findings. Hypothesis 2 was not supported. Within the MI-medication Group, medication knowledge (*information*) and controlled *motivation* did appear to increase from Time 2 (approximately 1-week post-discharge) to Time 3 (approximately 5-weeks post-discharge). Changes in autonomous *motivation* and *behavioral skills* were not observed. Clinical and theoretical implications are discussed.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the College of Arts and Sciences have examined a dissertation titled “Improving Medication Adherence in Underrepresented Patients with Heart Disease: Piloting a Motivational Intervention,” presented by Jillian Mae Ricks Clark, candidate for the Doctor of Philosophy degree, and certify that in their opinion it is worthy of acceptance.

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LIST OF ABBREVIATIONS

Angiotensin Receptor Blockers = ARB

Cardiac Rehabilitation = CR

Cardiovascular Disease = CVD

Coronary Heart Disease = CHD

Information, Motivation, Behavioral Skills model = IMB

Medication Possession Ratio = MPR

Motivational Interviewing = MI

Self-Efficacy for Appropriate Medication Use Scale = SEAMS

Standard of Care = SC

Truman Medical Center = TMC

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CHAPTER 1

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death in the United States (Go et al., 2013). Approximately 635,000 Americans will experience an initial cardiac event each year, and those who have experienced an initial cardiac event are at greater risk for subsequent cardiac events, such as recurrence or cardiac-related mortality (Thune et al., 2011). Racial and socioeconomic disparities in CVD are evident as African Americans have higher rates of initial and recurrent cardiac events compared to European Americans, and those who are socioeconomically disadvantaged are at greater risk for cardiac-related mortality (Cooper et al., 2000; Go et al., 2013). Modifiable risk factors, such as high blood pressure and high cholesterol, are associated with increased risk for subsequent cardiac events and can be controlled by cardioprotective medications. Adherence to cardioprotective medications reduces the risk of secondary outcomes in CVD (Ho et al., 2006; Ho et al., 2008).

Despite improved outcomes in CVD with adherence to cardioprotective medications, rates of nonadherence remain high. One-fourth of patients do not fill prescribed heart medications following hospital discharge, and one-third discontinue at least one medication within a month of discharge (Jackevicius, Li, & Tu, 2008). For those who are persistent in filling their medications, medication possession ratios (MPR) indicate high rates of nonadherence. African Americans and individuals who are socioeconomically disadvantaged are at higher risk for cardioprotective medication nonadherence and nonpersistence (Charles,

Good, Hanusa, Change, & Whittle, 2003; Lewey et al., 2013; Mann, Woodard, Muntner, Falzon, & Kronish, 2010).

Interventions to improve medication adherence have shown no improvement to moderate improvement in adherence (Cutrona et al., 2010; van Dalem, Krass, & Aslani, 2012). Interventions aimed at alleviating financial burden have supported slight improvement, though rates remain well below desired adherence rates (Choudhry et al., 2011). Interventions aimed at promoting motivation and confidence to adhere have shown promise (Ogedegbe et al., 2008; Paradis, Cossette, Frasure-Smith, Heppell, & Guertin, 2010; Zarani, Besharat, Sarami, & Sadeghian, 2010). Furthermore, interventions utilizing motivational interviewing (MI) have had moderate success in increasing adherence rates in patients with heart failure and physical health conditions often comorbid with CVD (i.e., hypertension). MI shows promise in addressing medication adherence in individuals with CVD; however, these prior intervention studies are limited by: 1) lack of sustainability (Bouvy et al., 2003; Faulkner, Wadibia, Lucas, & Hilleman, 2000), 2) lack of generalizability to socioeconomically and racially diverse patients within the United States (Bouvy et al., 2003; Paradis et al., 2010; Zarani et al., 2010), 3) lack of generalizability to broader CVD diagnoses (Paradis et al., 2010), and 4) focusing on outcomes that do not represent typical cardioprotective medication regimens or do not distinguish medication adherence from general self-care (Bouvy et al., 2003; Faulkner et al., 2000; Ogedegbe et al., 2008; Paradis et al., 2010; Zarani et al., 2010;).

The Information, Motivation, Behavioral Skills model (IMB; Fisher & Fisher, 1992) provides a framework for examining psychological constructs related to preventive health

behaviors, such as cardioprotective medication adherence, and incorporates constructs that are targeted by MI. The IMB model proposes that medication adherence information, motivation, and behavioral skills predict likelihood of adhering to medication regimens. Medication adherence information and motivation work through medication adherence behavioral skills in influencing medication adherence. Prior research examining IMB constructs in relation to medication and self-care adherence in CVD samples and related diagnoses supports the associations purposed by the model (Zarani, Sarami, & Sadeghian, 2014).

This study designed and assessed a brief, sustainable motivational intervention to promote medication adherence to four categories of commonly prescribed cardioprotective medications in socioeconomically and racially diverse patients with CVD in the United States. This approach addressed prior research limitations. It was hypothesized that the intervention group receiving a telephone-based brief MI counseling session for medication adherence (i.e., the MI-medication Group) would show higher adherence to cardioprotective medications, assessed by both objective pharmacy fill data (Hypothesis 1) and by self-report data (Hypothesis 2) 5-weeks post-discharge compared to the other two study groups (i.e., standard of care [SC Group] and MI for CR intervention group [MI-CR group]). Further, this study examined the IMB model within the MI-medication Group as secondary outcomes. The MI-medication Group was hypothesized to experience a significant increase in medication *information* (Hypothesis 3), autonomous and controlled *motivation* to adhere to medications (Hypothesis 4), and *behavioral skills* (Hypothesis 5) from Time 2 to Time 3.

Missing data precluded statistical testing of Hypothesis 1; however, descriptive statistics are presented with mixed findings. Hypothesis 2 results did not support the efficacy of the brief MI counseling session for medication adherence in improving cardioprotective medication adherence in this sample. Limitations of these data (e.g., social desirability) are discussed and should be considered in interpreting the results of the current study. Increases in both medication *information* and controlled *motivation* over time were observed in the MI-medication Group participants; however, no change in autonomous *motivation* or medication adherence *behavioral skills* was observed. These improvements as secondary outcomes of the MI intervention are discussed. Future research should examine IMB model constructs as related to cardioprotective medication adherence, as well as secondary outcomes from MI interventions or potential mechanisms of change.

CHAPTER 2

REVIEW OF THE LITERATURE

Cardiovascular Disease and Health Disparities

Cardiovascular disease (CVD) is a class of diseases involving the heart or blood vessels and is the leading cause of death in the United States. In 2009, 32.3% of all deaths were attributed to CVD (Go et al., 2013). Approximately 15.4 million American adults have coronary heart disease (CHD), a common form of CVD that is comprised of myocardial infarction and angina pectoris, among others. An estimated 635,000 Americans will experience an initial cardiac event in 2013 and 280,000 will have a recurrent attack. Those who have experienced a recent cardiac event are at higher risk for subsequent events (Thune et al., 2011).

Racial and socioeconomic disparities in risk factors for CVD and CVD occurrence are evident. Specifically, blacks and American Indians/Alaska Natives had the highest prevalence of risk factors in developing CVD. Additionally, black men and women have higher incidence rates than their white counterparts for initial and recurrent cardiac events and CHD-related mortality. Education and income also were negatively related to prevalence of risk factors in developing CVD (Go et al., 2013). Socioeconomic status is also associated with risk for CHD-related mortality, with those categorized as having lower socioeconomic status at greater risk, a health disparity that appears to be widening (Cooper et al., 2000).

Several modifiable risk factors for CVD have been highlighted as intervention points in primary and secondary prevention of CVD. Modifiable risk factors such as high blood pressure and high cholesterol levels are associated with an increased risk for CHD and

recurrent cardiac events, and can be controlled by diet, exercise, and medication (Centers for Disease Control and Prevention, 2012). With death rates attributed to CHD declining since 1968, an estimated 44% of this reduction has been attributed to the unique contribution of reductions in cholesterol, blood pressure, smoking prevalence, and physical inactivity (Ford et al., 2007). Adherence to treatment recommendations, such as cardioprotective medications, that address these modifiable risk factors reduces the risk of secondary outcomes in CVD.

Cardioprotective Medication and Adherence

Cardioprotective medications are essential in secondary prevention efforts to reduce the risk of recurrence in individuals with CVD. Medications commonly prescribed to treat CHD are intended to control blood pressure, lower cholesterol, and prevent platelet clotting. Cardioprotective medication categories include: 1) P2Y12 platelet inhibitor (e.g., clopidogrel), 2) Angiotensin receptor blockers (e.g., lisinopril; ARB), 3) Statins (e.g., rosuvastatin), and 4) Beta blockers (e.g., metoprolol). P2Y12 platelet inhibitors are often prescribed with aspirin to prevent clotting from the collection of platelets. ARBs assist in controlling blood pressure and improve blood flow in blood vessels throughout the body. Statins are intended to lower blood cholesterol by preventing the liver from making cholesterol. Beta blockers control high blood pressure and manage chest pain.

Nonadherence to cardioprotective medications has been shown to increase the risk of cardiac-related hospitalization, revascularization, and mortality in individuals with CVD (Ho et al., 2006; Ho et al., 2008; Rasmussen, Chong, & Alter, 2007). Specifically, individuals who are nonadherent have increased mortality risk ranging from 1.5 to 1.9 times greater than

those who are adherent to cardioprotective medications (Ho et al., 2006; Ho et al., 2008). A dose-response-like relationship has also been associated with mortality risk in patients prescribed statins post-acute myocardial infarction, with those most adherent having the lowest risk, intermediate adherers having a 12% higher risk, and poor adherers having a 25% higher risk of mortality (Rasmussen et al., 2007).

Despite evidence suggesting improved outcomes with adherence, rates of nonadherence to cardioprotective medications remain high. Estimates have suggested that 24% of patients do not fill prescribed cardioprotective medications following hospital discharge (Jackevicius et al., 2008), 33% of patients discontinue at least one medication and 12% of patients discontinue all medications within a month of discharge (Ho et al., 2006), and 20-80% of patients are nonadherent over extended follow-up periods (Newby et al., 2006). Prescription fill rates and adherence rates may vary by cardioprotective medication type, with one study reporting rates of not filling ARBs within one year of discharge being as high as 29.1%, not filling beta-blockers around 6%, rates of not filling statins as high as 7.1%, and not filling clopidogrel as high as 88.5%. Further, adherence rates as calculated by the medication possession ratio (MPR), with greater than .80 indicative of acceptable adherence, have also indicated differences by medication category, with high adherence to statins (MPR = 82.7 to 84.2) and less adherence to beta-blockers (76.1 to 80.6), ARBs (MPR = 69.4 to 77.8), and clopidogrel (MPR = 40.1 to 54.5; Hlatky et al., 2013). Similarly, another study reported rates of adherence, calculated by the mean MPR, of 49.0% for statins, 45% for beta-blockers, 35.9% for ARBs, and 38.9% for all three medication classes (Choudry et al., 2011).

Cardioprotective Medication Adherence in Underrepresented Patients

Racial and socioeconomic disparities in cardioprotective medication adherence are evident, and mimic disparity trends of CVD-related risk factors for onset and death (Lloyd-Jones et al., 2010). Those with lower incomes and who are non-white are at higher risk for nonadherence, yet these groups are often underrepresented in the CVD literature (Charles et al., 2003; Lewey et al., 2013; Mann et al., 2010). Specifically, a systematic review and meta-analysis of 22 prior studies sought to identify predictors of non-adherence to statins. Results indicated that patients with incomes in the highest tertile were 15% more likely to be adherent compared to those with incomes in the lowest tertile. And, lower out-of-pocket costs for statin medications also were associated with better adherence (Mann et al., 2010). Further, in a study comparing cardioprotective medication adherence in African-American Veterans (n = 833) and European-American Veterans (n = 4436), results indicated that African-American Veterans were less likely to be adherent to ARBs (81.4% and 87.6%, respectively), calcium-channel blockers (75.3% and 81.7%, respectively), and statins (59.9% and 74.1%, respectively), as assessed by an adherence ratio calculation (Charles et al., 2003). In a meta-analysis of 11 studies, nonwhite patients were 53% more likely to be nonadherent to statin medications than white patients, a trend that was consistent when controlling for socioeconomic status, insurance status, or out-of-pocket expense (Lewey et al., 2013). Thus, estimates of adherence rates to cardioprotective medications suggest high nonadherence among disadvantaged and underrepresented groups, which has been related to increased risk of negative outcomes for these individuals with CVD. By extension, interventions to address nonadherence to cardioprotective medications are warranted to limit negative outcomes, such

as mortality and revascularization, following CVD, especially in underrepresented populations.

Interventions to Improve Treatment Adherence

Interventions to improve treatment adherence, including cardioprotective medications, have taken many forms, with success rates varying from no improvement to moderate improvement in adherence (Cutrona et al., 2010; van Dalem et al., 2012). Important to understanding adherence among underserved patients is elucidating the role of financial barriers on adherence. An intervention designed to eliminate financial burden, by eliminating payment and copayment requirements for cardioprotective medications prescribed after myocardial infarction, indicated improvement in adherence rates by 4.4 to 6.2% as measured by the mean MPR. However, even with these improved rates, adherence rates for those receiving the intervention ranged from 41.1 to 55.1%, well below the “full adherence” rate suggested by the article (80%). This finding suggests factors (e.g., psychological) beyond tangible resources play an important role and impact adherence (Choudhry et al., 2011). Interventions aimed at promoting medication knowledge have shown no improvement to moderate improvement in adherence (Faulkner et al., 2000; Saito & Saruta, 2003). Further, interventions incorporating components aimed at promoting motivation and confidence for cardioprotective medication adherence have produced promising results (Ogedegbe et al., 2008; Paradis et al., 2010; Zarani et al., 2010).

Motivational Interviewing (MI) has been examined as a potential intervention approach to enhance adherence to treatment recommendations in individuals with CVD. MI is a client-centered approach aimed at promoting health behavior change by the exploration

of ambivalence (Miller & Rollnick, 2002; Rollnick & Miller, 1995). MI utilizes a style of communication, or *spirit*, which is designed to strengthen motivation and enhance self-efficacy for a specific health behavior goal. The MI *spirit* emphasizes a partnership approach, acceptance, compassion, and evocation. This *spirit* is communicated through core skills such as open-ended questions, reflective listening, affirmations, summarizations, and providing information, which are utilized during the four processes of MI: 1) engaging, 2) focusing, 3) evoking, and 4) planning (Miller & Rollnick, 2013). The process of engaging requires the establishment of rapport and a working alliance. Focusing, or deciding on and maintaining a direction in the communication about change, is the subsequent process of focus following development of rapport. Once a focus is determined, evoking involves eliciting the patient's motivations for health behavior change. Lastly, upon reaching a readiness for change, the process of planning incorporates supporting commitment to change and discussion of a specific plan to implement change.

MI has been found to have significant effects on several health behaviors and health outcomes. One systematic review and meta-analysis reported that MI had a significant effect in 74% of randomized controlled trials and a significant impact on outcomes such as body mass index, HbA_{1c}, blood cholesterol, and blood pressure (Rubak, Sandbaek, Lauritzen, & Christensen, 2005). Another meta-analysis indicated that MI was an equally effective approach to other treatments and better than no treatment for alcohol, drugs, and diet and exercise (Burke, Arkowitz, & Menchola, 2003). Specific to medication adherence, a systematic review and meta-analysis concluded that MI was effective at improving medication adherence. Phone-based MI was determined to be superior to usual care when

assessing adherence outcomes via categorical variables, though it was not found to be superior when assessed via a continuous variable. Authors suggested that findings from one study included in their meta-analysis might have created heterogeneity, thus contributing to non-significant findings when assessed with a continuous variable (Palacio et al., 2016). Within the CVD literature, the use of MI is limited; however, there have been promising results indicating usefulness in improvements in physical activity (Brodie & Inoue, 2005), and self-care behaviors (Riegel et al., 2006; Zarani et al., 2010). Further, a study using MI to promote self-care behaviors in patients with heart failure showed improvements in self-care behaviors and the majority of participants also reported improvements in self-care confidence and heart failure knowledge. This study highlighted the importance of self-efficacy and knowledge in performance of preventive health behaviors and the impact of MI on these constructs (Riegel et al., 2006).

Additionally, in a sociodemographic representative sample of patients with heart failure (n=30), participants were randomized to either a control group, who received standard of care (SC), or an experimental group who received MI for a self-care behavior related to heart failure during three encounters (one in-person and two via phone) over the course of 10 days. The five, self-chosen self-care behaviors consisted of fluid restriction, low-salt diet, daily weights measurement, exercise, and medication adherence. Results indicated that participants receiving the intervention had higher reports of confidence in completing self-care behaviors than the control group; however, there was no significant difference in frequency of self-care behaviors performed (Paradis et al., 2010). Results for each self-care behavior were not presented independently, thus the impact of the intervention on medication

adherence cannot be determined (whether defined as confidence in or completing the behavior). Additionally, the generalizability of the results of this study is limited by the sample size and only to patients with heart failure. Nonetheless, the results of this study support the continued investigation of this intervention method in encouraging adherence to treatment recommendations in patients with CVD.

MI also has been incorporated as a component of an intervention to improve treatment adherence (e.g., cardiac rehabilitation [CR], medication adherence, smoking cessation) in patients who underwent coronary artery bypass grafting (CABG; n=152). The intervention examined in this study was designed in accordance with the Information, Motivation, Behavioral Skills model (IMB) and was delivered in a group-based format in one session with a 120-minute duration. Findings indicated a significant improvement in adherence to treatment recommendations for CABG patients receiving the IMB based intervention (Zarani et al., 2010). Generalizability of these results is limited by the study location, as the study was conducted with Iranian patients, and the inability to examine the impact of the intervention on specific treatment recommendations. This study does suggest the necessity of continued investigation of MI in encouraging treatment recommendations, specifically cardioprotective medication adherence, in patients with CVD, as well as the applicability of the IMB model in relation to medication adherence.

MI has been shown to be successful in increasing medication adherence rates in health populations related to CVD. For instance, MI was delivered during a 30 to 40-minute counseling session at three, six, nine, and twelve months to African American patients with hypertension. Medication adherence to hypertensive medications was assessed by Medication

Event Monitoring Systems, or electronic medication bottles that record every date and time that a patient opens the bottle. Results indicated a significant effect of the MI intervention on adherence with 57% of those receiving the intervention maintaining adherence post-treatment compared to 43% (Ogedegbe et al., 2008). Results of prior studies examining the influence of MI in enhancing medication adherence in individuals with health conditions similar to CVD suggest MI is a successful approach to increasing medication adherence rates.

Information, Motivation, Behavioral Skills Model

Developing interventions to enhance treatment adherence in CVD patients is essential and there is growing evidence to suggest that MI is effective. Further research should not only examine the usefulness of MI, but also assess the mechanisms of action. Several social and health psychological theories propose psychosocial variables that have direct and indirect effects on health behaviors, such as adherence to prescribed medication. The IMB model is a relatively new framework that also incorporates constructs that are intended to be enhanced by MI (Fisher & Fisher, 1992).

The IMB model (see Figure 1) describes the mechanisms by which behavioral interventions can affect health behaviors, like medication adherence. The IMB model proposes that the extent to which individuals are informed (e.g., medication and medication adherence knowledge), motivated to act (e.g., autonomous motivation and controlled motivation), and have adequate behavioral skills relevant to the behavior (e.g., perceived medication adherence self-efficacy); they will be likely to initiate and maintain the preventive behavior. The IMB model suggests that medication adherence information and

motivation work by way of medication adherence behavioral skills; however, information and motivation can also have direct effects on medication adherence behavior when behavioral skills are not necessary. Further, the IMB model posits that information and motivation may not be associated with each other, as someone who is informed may not be motivated and vice versa (Fisher et al., 1992).

Use of the IMB model for treatment adherence in CVD patients is limited; however, interventions to improve general treatment adherence aimed at targeting the components of the IMB model have been effective (Zarani et al., 2010). Examination of the IMB in relation to treatment adherence in CABG patients also has supported the predictive abilities of the model, and suggests the motivation component of the IMB model is the greatest predictor of treatment adherence (Zarani et al., 2014), underscored by the modest gains in adherence from MI-based interventions discussed above.

Research on the relationship between information and treatment adherence in CVD populations is mixed. For instance, a computer-based intervention aimed to increase knowledge of heart failure showed significant gains in knowledge over an extended follow-up period, but did not improve compliance to heart failure treatment recommendations (Stömberg, Dahlström, & Fridlund, 2006). In a sample of 150 patients with chronic conditions such as Type 2 diabetes, hypertension, and hypercholesterolemia, there was a significant positive correlation between medication knowledge and medication adherence ($r = .20, p = .02$; Burge et al., 2005). Similarly, in a sample of 445 Korean Americans with high blood pressure, lower knowledge of blood pressure was associated with greater risk of intentional nonadherence to antihypertensive medication (Kim et al., 2007). An examination

of the relationship between the IMB model and treatment adherence within CABG patients (n = 152) reported that the information construct was not significantly related to general adherence (e.g., “I exactly followed my doctor’s suggestions”); however, the information construct was significantly associated with specific adherence behaviors such as stopping or reducing smoking (Zarani et al., 2014).

Behavioral skills, often operationalized as self-efficacy due to the difficulty of assessing skills, have also been shown to be positively related with treatment adherence in CVD patients. Self-efficacy has been found to have a positive association with medication adherence in a sample of African American participants with hypertension (Rimando, 2013). In a sample of 63 patients with heart failure, a positive significant association between self-efficacy for heart failure self-care behaviors and adherence to self-care behaviors was reported (Chen et al., 2014). These studies suggest the usefulness of the IMB model in predicting treatment adherence in CVD patients. Research on the IMB constructs as mechanisms of change in MI is limited, but promising. Prior research utilizing MI to promote treatment adherence in CVD patients has found improved treatment adherence self-efficacy (Paradis et al., 2010) and treatment adherence knowledge (Riegel et al., 2006) in individuals receiving MI. These findings suggest the IMB model may be useful in examining mechanisms of change in MI on medication adherence in individuals with CVD.

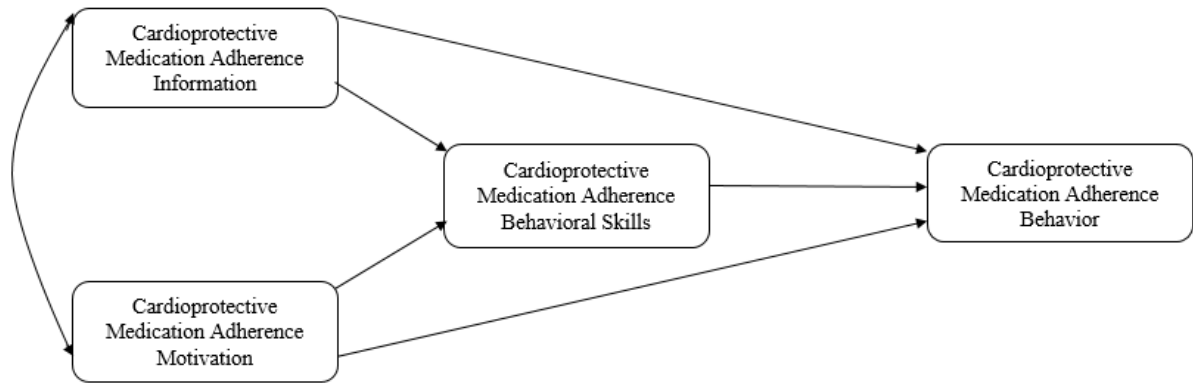


Figure 1. The IMB model for cardioprotective medication adherence.

Gaps in the Literature

Rates of nonadherence to cardioprotective medications are high, especially in socioeconomically and racially diverse populations, and are associated with greater risk of negative outcomes following CVD. Several interventions have been proposed and examined to improve adherence to cardioprotective medications. Although some have been found to improve adherence rates, many are limited by several factors: (1) sustainability due to their time- and resource-intensive nature (Bouvy et al., 2003; Faulkner et al., 2000), (2) not being representative of socioeconomically or racially diverse patients within the United States (Bouvy et al., 2003; Paradis et al., 2010; Zarani et al., 2010), (3) including only patients with heart failure and therefore not generalizing to broader CVD diagnoses (Paradis et al., 2010), and (4) focusing on outcomes that do not adequately capture typical medication regimens or do not distinguish adherence to medications from general self-care (Bouvy et al., 2003; Faulkner et al., 2000; Ogedegbe et al., 2008; Paradis et al., 2010; Zarani et al., 2010). This study addressed these limitations by developing and evaluating a brief, sustainable

motivational intervention to encourage medication adherence to four categories of commonly prescribed cardioprotective medications in socioeconomically and racially diverse patients with CVD in the United States.

The IMB model is a relatively new means of examining relationships between information, motivation, behavioral skills, and preventive health behaviors such as medication adherence. This model and its constructs have been supported in predicting preventive health behaviors and treatment adherence in patients with CVD and related health outcomes. This model is also unique in that it incorporates constructs that are intended to be enhanced by MI. Literature examining the IMB constructs as potential mechanisms of change is greatly limited; however, there is support suggesting MI promotes treatment adherence knowledge and self-efficacy (Paradis et al., 2010; Riegel et al., 2006).

This study designed and assessed a brief, sustainable motivational intervention to promote medication adherence to four categories of commonly prescribed cardioprotective medications in socioeconomically and racially diverse patients with CVD in the United States. Additionally, this study utilized the IMB model constructs to evaluate secondary outcomes within the intervention group.

Hypotheses

Hypothesis One

The intervention group receiving a telephone-based brief MI counseling session for medication adherence (MI-medication Group) will show higher adherence to cardioprotective medications as assessed by objective, pharmacy fill data 5-weeks post-

discharge compared to the other two study groups (i.e., standard of care [SC Group] and MI for CR intervention [MI-CR Group]).

Hypothesis Two

The MI-medication Group will show higher adherence to cardioprotective medications as assessed by self-report data 5-weeks post-discharge compared to the SC Group and MI-CR Group.

Additionally, this project explored the constructs of the IMB model as secondary outcomes within the MI-medication Group.

Hypothesis Three

There will be a significant increase in medication adherence *information* (of the IMB model), as assessed by heart medication knowledge, within the MI-medication Group from pre-intervention to post-intervention.

Hypothesis Four

There will be a significant increase in medication adherence *motivation* (of the IMB model), as assessed by measures of both autonomous motivation and controlled motivation, within the MI-medication Group from pre-intervention to post-intervention.

Hypothesis Five

There will be a significant increase in medication adherence *behavioral skills* (of the IMB model), as assessed by five items adapted from the Self-efficacy for Appropriate Medication Use Scale (SEAMS), within the MI-medication Group from pre-intervention to post-intervention.

CHAPTER 3

METHODOLOGY

Participants

Institutional Review Board approval was obtained prior to study initiation.

Participants were recruited from Truman Medical Center (TMC), an urban safety-net hospital serving a predominantly low-income, largely uninsured, ethnically-diverse population of patients. Participants were recruited as part of a larger pilot intervention study, intended to improve participation in CR. To allow for comparison, the patients recruited for this part of the study were determined by the same eligibility criteria: (1) referral to CR according to the AACVPR/ACCF/AHA guidelines (Thomas et al., 2010), (2) English speaking, (3) at least 18 years of age, (4) lack of physical or cognitive impairments that would limit patients' abilities to complete study materials, and (5) having not previously attended CR.

Recruitment efforts lasted approximately 14 months, from early-March 2015 to early-May 2016. During this time, 236 patients received stents at the hospital and were eligible for CR. Of the 236 potential patients, 90 were approached to participate in the study. Reasons for not approaching patients included: (1) they did not meet study eligibility criteria (e.g., already attended CR, non-English speaking), (2) it was logistically unable to consent them (e.g., Friday procedure with weekend discharge when study team was unavailable), (3) they were admitted during times when study team was unavailable (e.g., vacations), and (4) they did not survive to discharge or were unresponsive. Those who agreed to participate (n = 61) were allocated to one of three conditions (see Figure 2). The study sample size was consistent

with pilot studies examining interventions for self-care behaviors in CVD, and would allow for tests of feasibility, acceptability, and efficacy (Paradis et al., 2010).

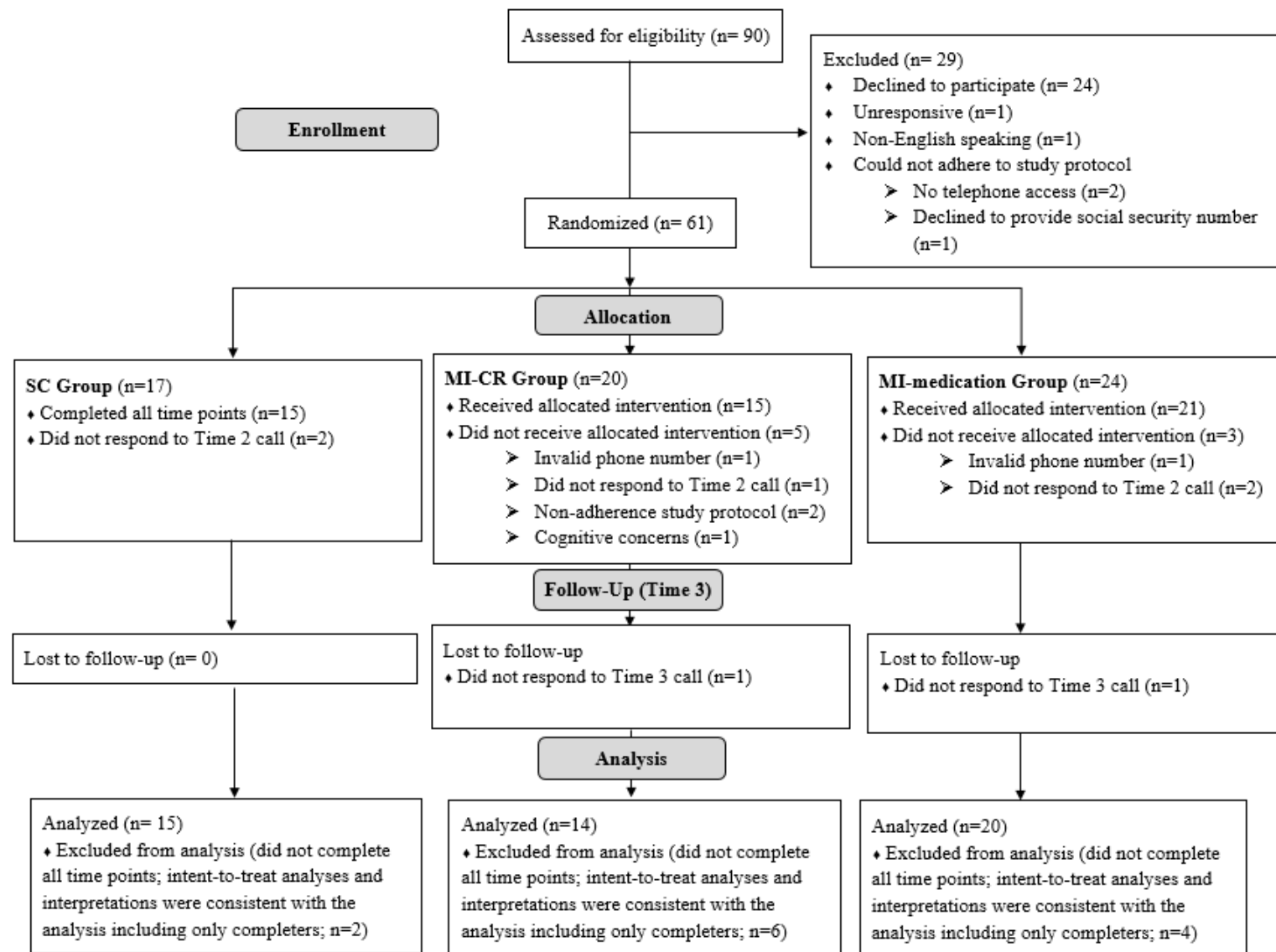


Figure 2. CONSORT diagram

Procedures

Prior to CR referral and to the SC pre-discharge pharmacist consultation regarding prescribed cardioprotective medications, eligible patients were approached to discuss the purpose of the study (i.e., “to learn how health care providers can best talk to patients about following treatment recommendations”). All participants who consented to the study were oriented to time and place. Consent documents (Appendix A-1), including pharmacy medical information release forms (Appendix A-2), were obtained and a baseline questionnaire was administered by reading the questions aloud for the participant, unless the participant requested to read it him/herself. Following the administration of the baseline survey (Time 1), a telephone-based appointment was scheduled with the participant for one-week post-discharge (Time 2) and five weeks post-discharge (Time 3). Participants were then randomly assigned to one of the following three groups: (1) SC Group, (2) MI-CR Group, or (3) MI-medication Group (the focus of this study). The CR nurse was made aware of the group assignment for the purposes of the CR intervention study; however, the pharmacist providing medication consultation prior to discharge was blind to group assignment. Participants received \$75 for their participation: \$10 at Time 1, \$25 at Time 2, and \$40 at Time 3.

Randomization Procedure

A block stratified randomization procedure was used to assign participants to study groups. For the initial 12 months of the study, participants were assigned to one of three groups. Due to efforts to oversample the MI-medication Group, during the month of March 2016, participants were randomized to either the SC Group or the MI-medication Group. Of

the 12 eligible patients approached during this month, nine agreed to participate in the study. During the last month of the study, participants were randomized to either the SC Group or the MI-CR Group. Of the six eligible patients approached during this time, four agreed to participate. Throughout the study, participants were stratified by two variables found to be predictive of cardioprotective medication adherence: CVD diagnosis classification (i.e., heart failure and non-heart failure; Bowry, Shrank, Lee, Stedman, & Choudhry, 2011), and race (i.e., white and non-white; Charles et al., 2003; Lewey et al., 2013).

An independent statistician generated a list of numbers (containing 1s, 2s, and 3s) that was at least 25 digits long for each of the four stratified groups: (1) heart failure and white, (2) non-heart failure and white, (3) heart failure and non-white, and (4) non-heart failure and non-white. This yielded a randomization schedule for at least 100 participants (which allowed for attrition). The statistician completed forms that contained the group assignments by stratified group, and put these forms within sequentially numbered envelopes for each stratified group. These envelopes were kept in a location accessible to research staff. Following successful recruitment of a participant, the researcher utilized the randomization envelopes in sequential order according to the stratified group in which the participant was classified. The sealed envelope along with the randomization tracking form (Appendix A-3) was delivered to a designated location accessible by the CR staff. The CR staff utilized the randomization envelope to assign participants to study groups, noting this on the form. A participant was considered enrolled once the CR staff delivered the CR referral in-person prior to discharge in accordance with the given study group. The randomization envelope was not opened until the CR staff located the participant and were present with the

participant. The CR staff then noted the study group assignment and additional randomization tracking information on the tracking form and returned this information to a designated location accessible by the researcher.

Study Groups

SC Group participants received CR referral and medication consultation consistent with usual care at TMC: an in-person consultation by the CR staff that provided verbal information regarding the patient's diagnosis and educational materials related to heart health and CR, and an in-person consultation with the pharmacist or pharmacy intern where he/she was given information regarding commonly prescribed cardioprotective medications (e.g., the intended purpose of each medication and medication side effects). Current SC protocol at TMC also consisted of a pharmacist or pharmacy intern contacting the patient within 72 hours of discharge to inquire as to whether he/she has filled his/her prescribed P2Y12 platelet inhibitor (e.g., clopidogrel), and to assist in troubleshooting difficulties in filling the medication if necessary.

Participants assigned to the *MI-CR Group* received the SC previously described. Additionally, during the CR referral, the CR staff showed a brief educational video describing CR and showing patient testimonials regarding expectations and actual experiences within CR. Further, these participants received a telephone-based, brief MI counseling session focusing on participation in CR one to two weeks post-discharge.

Participants assigned to the *MI-medication Group* (the focus of this study) received the SC procedures described above and one to two weeks post-discharge, the telephone-based, brief MI counseling session focusing on adherence to cardioprotective medications. At

least four attempts to reach participants in both intervention groups were made, dispersed at different times throughout the day and based on recommended times provided during the Time 1 survey administration.

Assessment

All participants were contacted by phone one to two weeks post-discharge (Time 2) and five weeks post-discharge (Time 3) to complete study questionnaires. Participants assigned to the MI-CR Group and the MI-medication Group received their brief MI counseling sessions following completion of the questionnaire during the Time 2 phone call. The final phase was to collect pharmacy fill data on cardioprotective medications from the pharmacies designated by each participant, and for which release of information forms were collected. Pharmacy fill data were collected for participants in all three groups. The pharmacy fill data were requested two-months post-discharge to assess medication fill data within seven days post-discharge and fill data five weeks post-discharge. These fill periods were determined due to the following considerations: (1) SC at TMC included a follow-up phone call within three days of discharge, thus the effectiveness of this phone call could be determined and baseline fill information could be obtained, (2) prior research indicated no difference in fill rates between seven days post-discharge and 120 days post-discharge, thus one month from the baseline medication fill assessment was likely indicative of medication adherence behavior (Jackevicius et al., 2008), and (3) a one month time period post-discharge is consistent with previous literature (Ho et al., 2006). A timeline of the procedures is provided in Appendix A-4.

Intervention Development

To promote motivation and self-efficacy to adhere to cardioprotective medications, a telephone-based, brief MI session was developed. Each session was conducted in accordance with a semi-structured adherence counseling script adapted from a prior behavior change script (Appendix B; Catley et al., 2012). During the interview portion of the telephone call, prior to delivery of the intervention, participants' cardioprotective medication adherence was assessed by self-report items inquiring about the number of times they had filled specific cardioprotective medications. Following the questionnaire administration, the counselor continued through the sequential steps: (1) assessing the participant's motivation and confidence for cardioprotective medication adherence, (2) eliciting benefits and barriers to adhering to medications and developing discrepancy, (3) exploration of barriers, problem solving and planning, and (4) summarizing session. The script included open-ended questions to participants; however, as participant responses differed, reflective listening and affirmation statements were client-centered and adhered to the MI *spirit*. The semi-structured script was designed to elicit change talk (e.g., disadvantages of status quo, optimism for change, intention to change) and promote self-efficacy and autonomy, constructs which have been suggested as mechanisms of action of the MI approach (Apodaca & Longabaugh, 2009; Riegel et al., 2006).

Interventionist and Intervention Fidelity

One Master's level professional (doctoral student), with prior MI training, via a workshop, four-month course, and additional experience with MI functioned as the study counselor. Prior to counseling participants, supervision on two practice sessions utilizing the study treatment manual was completed and met fidelity criteria. Early in the study, audio

recordings of two sessions were selected at random for supervision to verify fidelity, using a study-specific rating scale that assessed both protocol steps (e.g., reminder that session is recorded, initiated discussion of key points), and adherence to MI principles (e.g., elicited change talk).

Measures

Participant Characteristics and Medical Record Data

Demographic and medical information was collected from the participant and their medical record. This included the participant's gender, age, education, income, type of insurance, reason for CR referral, concomitant disease states, and prescribed cardioprotective medications.

Primary Dependent/Outcome Variable: Objective Medication Adherence

Objective cardioprotective medication adherence at Time 2 and Time 3 was measured by pharmacy fill data collected from the pharmacy at which the participant reported filling their medications. Medication fill information was requested from the pharmacy, including each medication filled, the date filled, and number of pills dispensed. A continuous single-interval medication availability ratio was calculated by dividing the number of days supplied by a pharmacy fill by the number of days before the next pharmacy fill for the same medication (Krousel-Wood et al., 2009). A higher ratio was indicative of greater adherence. Additionally, the ratio was dichotomized to indicate adherence ($\geq .80$) or non-adherence ($< .80$), consistent with Krousel-Wood et al. (2009). If the patient did not initiate a fill within the study window or did not request a second fill after their initial fill, they were assigned a ratio of 0.

Primary Dependent/Outcome Variable: Self-Report Medication Adherence

Self-report cardioprotective medication adherence was measured at Time 2 and Time 3 by an item asking participants to identify how many times they had filled each specific cardioprotective medication (e.g., P2Y12 platelet inhibitor, ARB, statins, and beta blockers) since their discharge from TMC. Response options were: “0”, “1”, or “2” (Appendix C-1). Participants were coded as “adherent” to each medication class if they reported an increased number of medication fills at Time 3 compared to Time 2. Participants with evidence of obtaining a medication fill greater than 30 days either by pharmacy or self-report evidence were also classified as “adherent.” Participants who did not indicate an increase in number of fills or provide evidence of extended coverage from initial fill were determined to be “non-adherent.” Dichotomized adherence categorization was utilized in data analyses.

Secondary Outcome: Medication Adherence Information

Heart medication adherence information was examined by four items created to assess heart medication knowledge, for each prescribed cardioprotective medication (e.g., antiplatelet, beta-blocker, statin, angiotensin system blocker, aspirin), at Time 2 and Time 3 (Appendix C-2). Participants were asked to describe what heart medications have been prescribed to them, what the medication is used for, the dosage of the medication, and if there are special instructions for the medication. Participants were asked to respond to these four items for each cardioprotective medication they were prescribed following discharge from TMC. If the participant was not able to freely recall the medication name, the participant was prompted by asking if they were prescribed it, and then he/she completed the

remaining three items. Each of the four items per medication class were coded dichotomously as to its accuracy (1 = *accurate*; 0 = *not accurate*). Total scores per medication classification were summed to create a composite score of medication knowledge. As participant prescriptions varied (i.e., not all participants were prescribed medications from all five classifications of medications), their total scores were then divided by the number of medications prescribed, providing a composite score of medication knowledge relative to number of medications prescribed. Higher scores indicated greater cardioprotective medication knowledge. A similar approach has been used in a pharmacist counseling intervention study (Williford & Johnson, 1995), and in a study of individuals with chronic conditions often concurrent with CVD, with acceptable reliability ($\alpha = .63$; Burge et al., 2005). In the current study, reliability was acceptable at both Time 2 ($\alpha = .79$) and Time 3 ($\alpha = .75$).

Secondary Outcome: Medication Adherence Motivation

Eight items from the Treatment Self-Regulation Questionnaire were adapted to measure autonomous motivation (four items) and controlled motivation (four items) to take heart medications at Time 2 and Time 3 (Williams, Grow, Freedman, Ryan, & Deci, 1996). Responses are made on a 7-point scale (*not at all true* to *very true*). The four autonomous motivation items were summed and then divided by four to calculate an average score, consistent with suggested scoring methods. Higher scores are indicative of greater autonomous motivation. In the current study, the reliability of the autonomous motivation items was acceptable at both Time 2 ($\alpha = .94$) and Time 3 ($\alpha = .92$). An average score for the four controlled motivation items was calculated by summing the items and dividing by four.

Higher scores are indicative of greater controlled motivation. In the current study, the reliability of the controlled motivation items was acceptable at both Time 2 ($\alpha = .81$) and Time 3 ($\alpha = .84$).

Secondary Outcome: Medication Adherence Behavioral Skills

Heart medication adherence behavioral skills were assessed by five items selected from the SEAMS at Time 2 and Time 3 (Appendix C-3). Example items from the measure include: “How confident are you that you can take your heart medicines correctly when you take several different medicines each day?” and “How confident are you that you can take your heart medicines correctly when you are away from home?” Response options were on a 3-point scale (*not confident to very confident*). Responses were summed, with higher scores indicating greater self-efficacy (or medication adherence behavioral skills). The original 13-item scale has been found to have acceptable reliability ($\alpha = .89$) within a sample of primarily low-income, minority individuals with CHD (Risser, Jacobson, & Kripalani, 2007). In the current study, the reliability of these five items was acceptable at both Time 2 ($\alpha = .75$) and Time 3 ($\alpha = .85$).

Intervention Acceptability

At Time 3, the MI-medication Group participants were asked to respond to six items created to understand their satisfaction with the intervention (Appendix C-4). Specifically, participants rated their feelings about the length of the counseling session, the number of counseling sessions offered, whether they would recommend the program to their friends/family, how satisfied they were with the program, how much the program influenced

their adherence to their medications, and what, if anything, they would change about the intervention. Response options are provided in the associated appendix.

Data Analysis

SPSS 24.0 (IBM Corp, 2016) was used for all data analyses. Descriptive statistics were calculated to understand participant characteristics, study constructs, and intervention acceptability for the MI-medication Group. Normality distributions were examined using skewness and kurtosis statistics and histogram plots. Levene's statistic was utilized to examine homogeneity of variance. *T*-tests and chi-square analyses were used to examine demographic (e.g., age, gender, race) differences between those who agreed to participate in the study and those who did not. *T*-tests and chi-square analyses were used to examine demographic (e.g., age, gender, race, income, education, employment status, and insurance status) differences between participants who completed all three time points of the study and those who did not. *T*-tests, chi-square analyses, and when appropriate, Kruskal-Wallis tests, were used to examine potential demographic and clinical differences by study group despite randomization. Cross-tabulation descriptive statistics were used to examine concordance between self-reported medication adherence and objective pharmacy data, by dividing the number of participants in which their data were concordant by the total number of participants. And, chi-squared analyses, paired samples *t*-tests, and the Wilcoxon signed-rank test were used to explore specific study hypotheses.

Influence of CR Attendance

Associations between CR attendance and medication adherence were explored to determine whether participants who participated in CR prior to completing Time 3 of the

study should be excluded from further analyses because of the possibly confounding effect of the program on outcomes (e.g., counseling about pharmacology potentially affecting medication adherence). Due to sample size limitations, Fisher's exact test was used to explore the potential for attendance at CR to differentiate self-report medication adherence within all participants as well as within MI-medication Group participants. Self-report medication adherence to each classification of medication was the dependent variable in each analysis, with those who attended CR prior to Time 3 assessment compared to those who did not attend CR prior to Time 3.

Hypothesis One

Mean and standard deviation statistics were calculated for the continuous single-interval medication availability ratio for each of the four medication classifications available via pharmacy data (i.e., P2Y12 platelet inhibitors, beta-blockers, statins, and ARB). Descriptive statistics were calculated by study group. Percentage of participants meeting adherence cut-offs by group are also presented. Due to limited available data, planned inferential statistics were not performed. Further information regarding findings can be viewed within the Results section.

Hypothesis Two

Separate chi-square analyses, and when appropriate due to sample considerations Fisher's exact test, were used to explore self-report medication adherence to four cardioprotective medications classes (i.e., P2Y12 platelet inhibitor, beta-blocker, statin, and ARB) across the three randomization groups. Intent-to-treat analyses were also completed using this data analytic method and included those who were prescribed medications from

each classification. Those with missing self-report medication data were considered “non-adherent.” An alpha level of .05 was used to determine statistical significance. Cramer’s V was calculated to examine the effect size, with .10 indicating a small effect, .30 indicative of a medium effect, and .50 indicative of a large effect.

Hypothesis Three

The difference between Time 2 and Time 3 medication information scores violated the assumption of normality required for a paired samples t -test. The non-parametric, Wilcoxon signed-rank test was used to examine differences in medication knowledge scores from Time 2 to Time 3 within the intervention group. Pearson’s correlation coefficient r was calculated using the equation $r = Z/\sqrt{N}$ to examine effect size, with $r = .10$ indicating a small effect, $r = .30$ indicative of a medium effect, and $r = .50$ indicative of a large effect (Cohen, 1992).

Hypothesis Four

The difference between Time 2 and Time 3 autonomous motivation scores violated the assumption of normality required for a paired samples t -test. The non-parametric, Wilcoxon signed-rank test was used to examine differences in autonomous motivation scores from Time 2 to Time 3 within the intervention group. Pearson’s correlation coefficient r was calculated using the equation $r = Z/\sqrt{N}$ to examine effect size, with $r = .10$ indicating a small effect, $r = .30$ indicative of a medium effect, and $r = .50$ indicative of a large effect (Cohen, 1992).

A paired samples t -test was used to examine mean differences in controlled motivation scores from Time 2 to Time 3. An alpha level of .05 was used to determine

statistical significance. Pearson's correlation coefficient r was calculated using the equation $r = \sqrt{t^2/t^2 + df}$ to examine effect size, with $r = .10$ indicating a small effect, $r = .30$ indicative of a medium effect, and $r = .50$ indicative of a large effect (Cohen, 1992).

Hypothesis Five

The difference between Time 2 and Time 3 medication adherence behavioral skills scores violated the assumption of normality required for a paired samples t -test. The non-parametric, Wilcoxon signed-rank test was used to examine differences in medication adherence behavioral skills scores from Time 2 to Time 3 within the intervention group. Pearson's correlation coefficient r was calculated using the equation $r = Z/\sqrt{N}$ to examine effect size, with $r = .10$ indicating a small effect, $r = .30$ indicative of a medium effect, and $r = .50$ indicative of a large effect (Cohen, 1992).

CHAPTER 4

RESULTS

Participants and Non-participants

Participants in this study did not differ from those who declined to participate by age [$t(85) = -1.27, p = .21$], gender [$\chi^2(1) = .27, p = .60$], or race [$\chi^2(1) = .12, p = .73$].

Completers and Non-completers

Those who completed all time points of the study ($n = 49$) did not differ from those who did not complete the study ($n = 12$) by age [$t(13.24) = .41, p = .69$], race [$\chi^2(1) = 1.86, p = .17$], income [$\chi^2(1) = .20, p = .65$], education [$\chi^2(1) = .50, p = .48$], and employment status [$\chi^2(1) = .05, p = .83$]. However, those who completed the study differed from those who did not complete the study in insurance status [$\chi^2(1) = 5.97, p = .02$]. Of those who completed the study, 77.6% had some form of insurance or the hospital discount program, whereas 41.7% of those who did not complete the study had insurance. All of those who did not complete the study were male.

Participant Characteristics and Group Comparisons

Participant characteristics for the total sample and each randomization group, as well as group comparisons, are presented in Table 1. Groups did not differ by age, gender, race, education, income, insurance status, relationship status, or diagnoses of myocardial infarction, hypertension, or hyperlipidemia. However, groups differed by employment status [$\chi^2(2) = 6.23, p = .04$]. The majority of those in the SC Group (82.4%) and the MI-CR Group (70.0%) were unemployed, whereas less than half of participants in the MI-medication Group (45.8%) were unemployed. Groups did not differ in the number of cardioprotective

medications prescribed, their knowledge of medications at Time 2, controlled or autonomous motivation to take medications as measured at Time 2, behavioral skills in taking medications as measured at Time 2, or self-reported medication adherence at Time 2.

Table 1.

Participant characteristics, study constructs, and univariate analyses

| | SC Group (<i>n</i> = 17) | MI-CR Group (<i>n</i> = 20) | MI- medication Group (<i>n</i> = 24) | |
|---|------------------------------|------------------------------------|--|------------------------|
| | <i>M (SD)</i> | | | <i>F (df)</i> |
| Age | 56.12 (7.27) | 57.05 (9.33) | 55.42 (9.53) | .184 (2,58) |
| Number Heart Medications Prescribed | 4.41 (.51) | 4.58 (.61) | 4.46 (.60) | .380 (2,57) |
| Medication Information, T2 | 2.39 (.83) | 2.33 (1.08) | 2.38 (1.16) | .012 (2,48) |
| Behavioral Skills, T2 | 14.60 (1.06) | 14.13 (1.46) | 14.33 (1.28) | .507 (2,48) |
| Controlled Motivation, T2 | 4.83 (1.91) | 4.08 (1.96) | 4.07 (2.07) | .764 (2, 48) |
| Autonomous Motivation, T2 | 6.68 (.82) | 6.77 (.36) | 6.94 (.22) | 4.272 (2) |
| | | % | | χ^2 (<i>df</i>) |
| Gender | | | | .598 (2) |
| Male | 76.5 | 75.0 | 66.7 | |
| Female | 23.5 | 25.0 | 33.3 | |
| Race | | | | 3.047 (2) |
| White | 76.5 | 50.0 | 54.2 | |
| Non-White | 23.5 | 50.0 | 45.8 | |
| Education | | | | .713 (2) |
| ≤High School Diploma/GED | 41.2 | 55.0 | 50.0 | |
| ≥Some college/2-year degree/trade school | 58.8 | 45.0 | 50.0 | |
| Income | | | | .731 (2) |
| ≤\$19,999 | 62.5 | 50.0 | 60.9 | |
| ≥\$20,000 | 37.5 | 50.0 | 39.1 | |
| Insurance | | | | 2.867 (2) |
| Insurance/TMC Discount | 76.5 | 80.0 | 58.3 | |
| None | 23.5 | 20.0 | 41.7 | |
| Relationship Status | | | | 1.497 (2) |
| Partnered | 29.4 | 25.0 | 41.7 | |
| Not Partnered | 70.6 | 75.0 | 58.3 | |
| Employment Status | | | | 6.231(2)* |
| Employed | 17.6 | 30.0 | 54.2 | |
| Not Employed | 82.4 | 70.0 | 45.8 | |

table continues

| | SC Group (n = 17) | MI-CR Group (n = 20) | MI- medication Group (n = 24) | χ^2 (df) |
|---|----------------------|----------------------------|--|---------------|
| | % | | | |
| Self-Report Medication Adherence, T2 | | | | |
| P2Y12 Platelet Inhibitor ^b | 100.0 | 93.3 | 100.0 | |
| Beta-Blocker ^b | 100.0 | 92.9 | 95.2 | |
| Statin ^b | 100.0 | 84.6 | 90.5 | |
| ARB ^b | 85.7 | 81.8 | 83.3 | |
| Diagnoses | | | | |
| Myocardial Infarction | | | | .094(2) |
| Yes | 58.8 | 55.0 | 54.2 | |
| No | 41.2 | 45.0 | 45.8 | |
| Percutaneous Coronary Intervention ^b | | | | |
| Yes | 100 | 100 | 83.3 | |
| No | 0 | 0 | 16.7 | |
| Angina ^b | | | | |
| Yes | 0 | 0 | 8.3 | |
| No | 100 | 100 | 91.7 | |
| Hypertension | | | | 3.892(2) |
| Yes | 88.2 | 80.0 | 62.5 | |
| No | 11.8 | 20.0 | 37.5 | |
| Hyperlipidemia | | | | .680(2) |
| Yes | 58.8 | 50.0 | 45.8 | |
| No | 41.2 | 50.0 | 54.2 | |

Note: T2 = Time 2.

^aKruskal-Wallis test.

^bChi-square analyses not completed due to violations of predicted sample size per cell.

*p≤.05

Influence of CR Attendance

Among all participants, those who attended CR prior to Time 3 data collection did not differ from those who did not attend CR prior to Time 3 data collection on self-reported medication adherence to P2Y12 platelet inhibitors ($p = .153$, Fisher's exact test), ARBs ($p = 1.000$, Fisher's exact test), statins ($p = 1.000$, Fisher's exact test), and beta blockers ($p = .732$, Fisher's exact test). Among participants randomized to the MI-medication Group, those who attended CR prior to Time 3 data collection did not differ from those who did not attend CR prior to Time 3 data collection on self-reported medication adherence to P2Y12 platelet inhibitors ($p = .136$, Fisher's exact test), ARBs ($p = 1.000$, Fisher's exact test), statins ($p = 1.000$, Fisher's exact test), and beta blockers ($p = .603$, Fisher's exact test). Attendance at CR does not appear to be related to self-reported medication adherence. Therefore, all participants with complete data, whether or not they attended CR, were included in further data analyses.

Hypothesis One

Complete responses from all designated pharmacies were received for 36 participants (59.0%). Table 2 provides mean continuous single-interval medication availability ratios for each medication classification by group, as well as percentage of participants considered to be adherent for those participants who had complete responses from pharmacies. Inferential statistics were not performed due to sample size limitations. Therefore, hypothesis one was not tested.

Table 2.

Continuous single-interval medication availability ratio of pharmacy data and percentage adherent by group

| | SC Group (<i>n</i> = 9) | MI-CR Group (<i>n</i> = 12) | MI-medication Group (<i>n</i> = 15) |
|--------------------------|-----------------------------|---------------------------------|---|
| | <i>M (SD)</i> | | |
| P2Y12 Platelet Inhibitor | .46 (.46) | .47 (.44) | .72 (.44) |
| Beta-Blocker | .40 (.48) | .20 (.36) | .39 (.49) |
| Statin | .46 (.45) | .22 (.44) | .37 (.48) |
| ARB | .91 (.13) | .26 (.43) | .44 (.53) |
| | Adherent (%) | | |
| P2Y12 Platelet Inhibitor | 44.4 | 33.3 | 69.2 |
| Beta-Blocker | 33.3 | 9.1 | 40.0 |
| Statin | 33.3 | 22.2 | 33.3 |
| ARB | 100 | 22.2 | 44.4 |

Hypothesis Two

Self-report medication adherence by medication classification and group is presented in Table 3. There were not statistically significant differences between study group and self-reported medication adherence to P2Y12 platelet inhibitors [$\chi^2 (2) = 4.89, p = .097$, Cramer's $V = .34$], beta-blockers [$\chi^2 (2) = 3.81, p = .162$, Cramer's $V = .29$], statins [$\chi^2 (2) = 5.20, p = .087$, Cramer's $V = .35$], or ARBs [Fisher's exact test = 1.49, $p = .603$] at Time 3. For both P2Y12 platelet inhibitors and statins, analyses suggested medium effect sizes, with the lowest self-reported adherence rates among participants in the MI-medication adherence group. Intent-to-treat analyses also indicated that there were not statistically significant associations between study group and self-reported medication adherence to P2Y12 platelet inhibitors [χ^2

(2) = 2.98, $p = .270$, Cramer's $V = .23$], beta-blockers [$\chi^2 (2) = 1.58, p = .503$, Cramer's $V = .17$], statins [$\chi^2 (2) = 5.85, p = .058$, Cramer's $V = .32$], or ARBs [Fisher's exact test = .68, $p = .820$] at Time 3. Therefore, hypothesis two was not supported.

For participants who completed all study time points and whose designated pharmacies responded to requests for data, 44.4% ($n = 12$) self-reported their beta-blocker medication adherence (either "non-adherent" or "adherent") to be concordant with adherence as determined by pharmacy records. Similar inconsistency was identified in the other medication classifications, with 38.5% ($n = 10$), 38.5% ($n = 10$), and 50.0% ($n = 7$), self-reporting adherence concordant with pharmacy records for P2Y12 platelet inhibitor, statin, and ARB medications, respectively.

Table 3.

Time 3 self-reported medication adherence by group

| | SC Group | MI-CR Group | MI-medication Group |
|----------------------------------|------------|-------------|---------------------|
| | % Adherent | | |
| Completers (<i>n</i> = 49) | | | |
| P2Y12 Platelet Inhibitor | 46.7 | 66.7 | 25.0 |
| Beta-blocker | 57.1 | 76.9 | 42.1 |
| Statin | 80.0 | 75.0 | 43.8 |
| ARB | 50.0 | 77.8 | 55.6 |
| Intent-to-treat (<i>n</i> = 61) | | | |
| P2Y12 Platelet Inhibitor | 41.2 | 44.4 | 20.0 |
| Beta-blocker | 50.0 | 52.6 | 34.8 |
| Statin | 70.6 | 52.9 | 31.8 |
| ARB | 28.6 | 46.7 | 41.7 |

Hypothesis Three

Descriptive statistics of IMB model constructs by group are presented in Table 4. For participants in the MI-medication Group ($n = 20$), medication adherence information at Time 3 ($Mdn = 2.90$, $M = 2.71$, $SD = .91$) was significantly greater than medication adherence information at Time 2 ($Mdn = 2.57$, $M = 2.34$, $SD = 1.16$), $z = -2.02$, $p = .04$, $r = -.32$. Eleven participants had improved scores across time, four remained the same, and five had worse scores at Time 3 compared to Time 2. Thus, hypothesis three was supported.

Hypothesis Four

For participants in the MI-medication Group ($n = 20$), autonomous motivation did not significantly differ from Time 2 ($Mdn = 7.00$, $M = 6.94$, $SD = .22$) to Time 3 ($Mdn = 7.00$, $M = 6.88$, $SD = .28$), $z = -1.09$, $p = .28$, $r = -.17$. One participant had an improved score over time, 17 remained the same, and two had decreased scores from Time 2 to Time 3.

MI-medication Group participants endorsed significantly greater controlled motivation at Time 3 ($M = 4.84$, $SD = 1.81$) compared to Time 2 ($M = 4.03$, $SD = 2.11$), $t(19) = -2.57$, $p = .02$, $r = .51$. Thirteen participants had improved scores over time, four remained the same, and three had decreased scores from Time 2 to Time 3. Thus, hypothesis four was partially supported.

Hypothesis Five

For participants in the MI-medication Group ($n = 20$), median medication adherence behavioral skills did not significantly differ from Time 2 ($Mdn = 15.00$, $M = 14.33$, $SD = 1.28$) to Time 3 ($Mdn = 15.00$, $M = 14.55$, $SD = .60$), $z = -.86$, $p = .39$, $r = .14$. Four participants had improved scores over time, 12 participant scores remained stable, and four

participants had decreased scores at Time 3 compared to Time 2. Thus, hypothesis five was not supported.

Intervention Acceptability

Most participants within the MI-medication Group were satisfied with the length of the intervention session (84.2%) and the number of intervention sessions (84.2%). Over 94% of participants were either “very satisfied” (84.2%) or “somewhat satisfied” (10.5%) with the program, with most (84.2%) willing to recommend the program to friends or family. Approximately 78.9% of participants indicated that the intervention had “a lot of influence” on taking their heart medications as prescribed, with 95.7% stating that would not change the intervention.

Table 4.

Descriptive statistics IMB model by group

| | SC Group | | MI-CR Group | | MI-medication Group | |
|----------------------------|---------------|-------------|---------------|-------------|---------------------|-------------|
| | <i>M (SD)</i> | range | <i>M (SD)</i> | range | <i>M (SD)</i> | range |
| Medication Information, T2 | 2.39 (.83) | .50-3.25 | 2.33 (1.08) | .80-3.80 | 2.38 (1.16) | .00-4.00 |
| Medication Information, T3 | 2.82 (1.09) | .00-4.00 | 2.61 (1.26) | .00-4.00 | 2.71 (.91) | .80-4.00 |
| Autonomous Motivation, T2 | 6.68 (.82) | 4.00-7.00 | 6.77 (.36) | 6.00-7.00 | 6.94 (.22) | 6.00-7.00 |
| Autonomous Motivation, T3 | 6.53 (1.15) | 3.00-7.00 | 6.91 (.16) | 6.50-7.00 | 6.88 (.28) | 6.25-7.00 |
| Controlled Motivation, T2 | 4.83 (1.91) | 1.00-7.00 | 4.08 (1.96) | 1.00-6.50 | 4.07 (2.07) | 1.00-7.00 |
| Controlled Motivation, T3 | 4.47 (2.32) | 1.00-7.00 | 4.50 (2.21) | 1.00-7.00 | 4.84 (1.81) | 2.50-7.00 |
| Behavioral Skills, T2 | 14.60 (1.06) | 11.00-15.00 | 14.13 (1.46) | 11.00-15.00 | 14.33 (1.28) | 11.00-15.00 |
| Behavioral Skills, T3 | 14.57 (1.34) | 10.00-15.00 | 13.79 (2.19) | 8.00-15.00 | 14.55 (.60) | 13.00-15.00 |

Note: T2 = Time 2; T3 = Time 3.

CHAPTER 5

DISCUSSION

The purpose of this study was to design and assess a brief, sustainable motivational intervention to promote medication adherence to four categories of commonly prescribed cardioprotective medications in socioeconomically and racially diverse patients with CVD in the United States. Further, this study utilized the IMB model constructs to examine secondary outcomes within the intervention group.

Hypothesis One

Complete responses from all designated pharmacies were received for 36 of the 61 randomized participants. Due to sample size limitations, inferential comparisons were not performed. Within MI-medication Group participants, the percentage of participants meeting a minimum adherence ratio ($\geq .80$) appears to be less for statins (33.3% compared to 49.0%), similar for beta-blockers (40.0% compared to 45.0%), and slightly more for ARBs (44.4% compared to 35.9%) when compared to participants with myocardial infarction who received an intervention aimed at promoting cardioprotective medication adherence through removal of financial barriers to obtaining the medications (Choudry et al., 2011). Observed mean continuous single-interval medication availability ratios in MI-medication Group participants suggest the highest rate of adherence to P2Y12 platelet inhibitors. This finding contrasts prior literature that suggested less adherence to clopidogrel, a P2Y12 platelet inhibitor, than other cardioprotective medications (Hlatky et al., 2013). MI-medication Group adherence rates to this medication category appear to be greater than the SC Group or the MI-CR Group. This trend in differences does not appear to be maintained across the four medication

classifications. Definitive conclusions are cautioned, as inferential statistics were not calculated. Direct comparisons with self-reported medication adherence is also difficult, as self-reported medication adherence in this study was not differentiated by medication classification. Generally, the percentage of participants considered to be adherent based on pharmacy data appears to be lower across all study groups than the percentage of participants considered to be adherent, when utilizing a cut-off of “6” or greater on the self-report medication adherence measure.

Cost of medications and insurance coverage are likely contributors to cardioprotective medication adherence (Kardas, Lewek, & Matyjaszczyk, 2013). Given the low reported income and high rates of not having insurance in the current sample, it is possible that these factors were related to varying adherence rates to certain cardioprotective medications. Sample size limitations in the current study precluded inferential comparisons of adherence by cardioprotective medication category between participants with insurance and those without insurance or participants with greater income and those with lower income. Future research should examine associations between cost of medication, insurance coverage and adherence to specific cardioprotective medications, specifically in underrepresented populations, to further inform intervention practices.

Hypothesis Two

MI-medication Group participants did not statistically significantly differ from the other group participants on self-reported medication adherence at Time 3. The effect sizes were considered small or medium, generally with lower adherence rates in participants in the MI-medication Group than the other study groups, thus hypothesis two was not supported.

Adherence rates varied from 25.0% to 55.6% in the MI-medication Group depending on the medication classification, indicative of general poor adherence. These reported adherence rates across the time of the study are also less than the initial adherence rates reported at Time 2 (83.3% to 100.0%), suggesting discontinuation of medication. The percentage of MI-medication group participants endorsing adherence in the current study is less than the range identified (67.9 to 91%) in prior studies of participants with hypertension (Krousel-Wood et al., 2009; Morisky et al., 2008), and the other study groups of the current study were also on the lower end of this range (46.7% to 80.0%). It is notable that comparison between studies is limited by differences in self-report methods for identifying adherence (e.g., single item versus multiple items). In the current study, inconsistencies in adherence were identified between self-reported adherence and objective pharmacy data. In several instances, the adherence percentages by group and medication classification were greater when identified via self-report in comparison to pharmacy data, suggesting the possibility of social desirability bias. Interestingly, when limited to just participants in the MI-medication Group, adherence as determined by self-report and objective data appeared to be slightly more consistent, with 50.0%, 50.0%, 63.6%, and 66.7% concordance for beta-blocker, P2Y12 platelet inhibitor, statin, and ARB medications, respectively.

One brief session utilizing MI may not be enough of a “dose” in terms of duration or frequency to observe change. A systematic review and meta-analysis of 72 randomized control trials utilizing MI for a variety of health behaviors (e.g., smoking cessation, weight-loss, physical activity, alcohol abuse) suggested that 64% of studies using an MI intervention less than 20 minutes showed an effect, whereas 81% of the studies using encounters of 60

minutes showed an effect (Rubak et al., 2005). This review also highlighted that the likelihood of finding an effect appeared to rise with number of encounters, with 40% and 87% of studies showing an effect with one session or more than five sessions, respectively. In contrast, another systematic review and meta-analysis suggested no difference of effect on medication adherence based on MI intervention duration (Palacio et al., 2016). Prior research reporting successful effects in implementing MI-based interventions for a variety of behavior changes with participants with CVD have utilized longer sessions (e.g., 120 minutes, Zarani et al., 2010) or multiple sessions (Brodie et al., 2005; Ogedegbe et al., 2008; Paradis et al., 2010; Riegel et al., 2006;). The current study attempted to design and assess a *brief* and *sustainable* intervention to increase cardioprotective medication adherence shortly after a cardiac event. Findings did not support the efficacy of this intervention in increasing medication adherence.

Several determinants of medication adherence have been identified, suggesting that adherence is a complex behavior that may require an individualized, multifaceted intervention to improve adherence (Kardas et al., 2013). A recent clinical pharmacist intervention showed promising impact on adherence to cardioprotective medications over 12 months in patients with hypertension through a three-element intervention: (1) medication review with associated advice regarding changes to the prescribing physician, (2) patient interview utilizing MI components, and (3) a minimum of 2 follow-up phone calls to the patient. Only 20.3% of participants receiving this multifaceted and collaborative approach were considered nonadherent compared to 30.2% of those within the usual care group as assessed 12 months after study initiation (Hedegaard et al., 2015). Taken together these

findings suggest that the utilization of MI within a comprehensive, multifaceted intervention may be promising for improving medication adherence in individuals with CVD. Future research should continue to explore the efficacy of interventions that incorporate MI spirit to increase medication adherence. Specifically, intervention immediately following a cardiac event is warranted, as a large percentage of patients are nonadherent to their cardioprotective medications during this time (Jackevicius et al., 2008; Ho et al., 2006).

Hypothesis Three

MI-medication Group participants had greater scores of medication adherence information, as measured by a composite medication knowledge score, at Time 3 compared to Time 2, thus supporting Hypothesis Three. This significant change suggests a medium effect size. The increase in medication knowledge is not limited to the MI-medication Group participants, as a statistically significant increase in medication adherence information was also noted in the SC Group ($z = -2.05, p = .04, r = -.40$), with a notable medium effect size. Further, while a statistically significant increase in medication information was not observed in MI-CR Group participants ($z = -1.51, p = .13, r = -.30$), a medium effect size was observed as well. These findings suggest that this change is not solely due to the intervention of focus in this study, and may instead be influenced by other factors. One potential factor related to changes in medication information may be attendance at CR. However, for the MI-medication Group participants, although not statistically significant, those who did not attend CR ($n = 9, z = -1.68, p = .09, r = -.40$) appeared to show improvements in medical information with a medium effect size, whereas those who did attend CR did not ($n = 11, z = -.85, p = .39, r = -.18$).

Prior research has highlighted lack of knowledge of the disease, treatment, and misunderstanding of prescriptions as being barriers to medication adherence across several health populations (Kardas et al., 2013). The IMB model posits that medication adherence information is related to adherence by way of medication adherence behavioral skills. Medication adherence information may also be directly related to medication adherence when behavioral skills are not necessary (Fisher et al., 1992). Within CVD-related populations, research on the relationship between information and treatment adherence has been mixed (Burge et al., 2005; Kim et al., 2007; Stömberg et al., 2006; Zarani et al., 2014).

There is limited research within CVD populations that has examined change in information, or knowledge, attributable to an MI intervention. Approximately 46.7% of 15 participants showed improved heart failure knowledge subsequent to an intervention utilizing MI and skill building to improve intent to perform heart failure self-care. Approximately 26.7% of participants endorsed decreased heart failure knowledge at the three-month follow-up of this study. Further, information giving was identified as a mechanism of intervention effectiveness through qualitative review (Riegel et al., 2006). In another study of an educational intervention utilizing MI spirit to improve knowledge, attitudes, and beliefs about acute coronary syndrome following initial diagnosis, findings suggested improved knowledge of acute coronary syndrome over time (O'Brien, McKee, Mooney, O'Donnell, & Moser, 2014). Approaches to inform patients while maintaining MI spirit have been suggested (e.g., elicit-provide-elicited) and have been determined a core skill for eliciting health behavior change (Rollnick, Miller, & Butler, 2008). Further research should examine

knowledge as a secondary outcome in MI interventions, specifically knowledge of cardioprotective medication and associations with medication adherence.

Hypothesis Four

Hypothesis Four was partially supported. Autonomous motivation did not change for participants in the MI-medication Group from Time 2 to Time 3. However, MI-medication Group participants did endorse greater controlled motivation at Time 3 compared to Time 2. This significant increase in controlled motivation is indicative of a large effect size. Controlled motivation reflects extrinsic motivation and has been suggested to be less advantageous in successful behavior change and maintenance of behavior, as the individual has not personalized genuine willingness to engage in the behavior (Williams et al., 1996).

The increase observed in the MI-medication Group over time may reflect participants engaging in more healthcare services (e.g., physician medical appointments, this study) following their cardiac event. These services may promote the perception of more social support for adherence to medications and exploratory analyses support this possibility. Statistically significant changes over time for both SC Group participants [$t(14) = 1.52, p = .15, r = .38$] and MI-CR Group participants [$t(13) = -.59, p = .57, r = .16$] were not observed; however, effect size calculations indicate a medium and small effect, respectively. The large effect size observed for the MI-medication Group suggests a greater difference over time for these participants compared to Groups 1 and 2. For MI-medication Group participants, a statistically significant difference in controlled motivation over time was observed in those who attended a CR orientation session [$n = 11; t(10) = -2.29, p = .05, r = .59$], suggesting a large effect size. Statistical significance was not supported in MI-medication Group

participants who did not attend CR [$n = 9$; $t(8) = -1.22$, $p = .26$, $r = .40$]; however, a medium effect was observed. Again, this suggests a greater difference for those enrolled in CR.

Another possible source related to extrinsic motivation to adhere may be the participant's familial social support. However, an exploratory bivariate correlation analysis of MI-medication Group participants between self-reported adherence to medications at Time 3 and a scale assessing familial assistance in medical care (e.g., attending doctors' appointments, picking up prescriptions, providing reminders to take medications; Sayers, White, Zubritsky, & Oslin, 2006) did not suggest statistically significant associations between variables ($n = 20$, $r = .12$, $p = .61$).

MI-medication Group participants endorsed high levels of autonomous motivation at both Time 2 ($M = 6.94$, $SD = .22$) and Time 3 ($M = 6.88$, $SD = .28$), suggesting that they experience high levels of intrinsic motivation. Similarly, both SC Group ($M = 6.53$, $SD = 1.15$) and MI-CR Group ($M = 6.91$, $SD = .16$) participants endorsed high levels of autonomous motivation at Time 3. Within MI-medication Group participants, score ranges at both Time 2 (6.00 to 7.00) and Time 3 (6.25 to 7.00) further suggest ceiling effect limitations on the ability to identify change in autonomous motivation over time. Nonetheless, 90% of MI-medication Group participants maintained or improved their autonomous motivation from Time 2 to Time 3. The ceiling effect observed in autonomous motivation is notable as MI is intended to address ambivalence for change and individual motivation for behavior change. These data indicate that participants already experienced high autonomous motivation, yet nonadherence was still evident. This suggests that other factors beyond intrinsic motivation (e.g., financial limitations, lack of insurance, unreliable transportation)

are likely influencing the participant's ability to adhere to their cardioprotective medications. An intervention solely designed to target autonomous motivation may not be the most effective approach with individuals with lower socioeconomic status. Future research should explore more comprehensive interventions aimed to promote maintenance of autonomous motivation and foster tangible support.

The IMB model asserts that both autonomous motivation and controlled motivation are critical influences on engagement in health behaviors (Fisher, Fisher, & Harman, 2003). Prior literature has supported this relationship, with one study suggesting motivation as the greatest predictor of treatment adherence in a sample of CVD patients (Zarani et al., 2014). Motivation has been suggested as a mechanism of change in MI for health behavior change (Copeland, McNamara, Kelson, & Simpson, 2015); however, mediational analysis evidence and examination of motivation within CVD samples as related to cardioprotective medication adherence is limited. The current study suggests that participants maintained a high level of autonomous motivation and gained controlled motivation, both of which may impact adherence to medications. While other theories of health behavior change (e.g., self-determination theory) may suggest that increased controlled motivation may lead to feelings of guilt and less advantageous benefits than autonomous motivation (Williams et al., 1996), the current data suggests that participants maintained high autonomous motivation, or intrinsic motivation, to adhere to medications. Further research is needed to better understand the relationships between both controlled and autonomous motivation and cardioprotective medication adherence. Additionally, studies examining motivation as a secondary outcome or

mechanism of change when utilizing MI for health behaviors, including cardioprotective medication adherence, are needed.

Hypothesis Five

For those in the MI-medication Group, medication adherence behavioral skills, as assessed by the SEAMS, did not differ from Time 2 to Time 3, thus Hypothesis Five was not supported. Participants in the MI-medication Group endorsed high levels of medication adherence behavioral skills, or self-efficacy, at both Time 2 (*Mdn* = 15.00, *M* = 14.33, *SD* = 1.28) and Time 3 (*Mdn* = 15.00, *M* = 14.55, *SD* = .60). Similarly, participants in the SC Group and the MI-CR Group also endorsed high levels of medication adherence behavioral skills at both time points. It is interesting to note that while statistically significant change in behavioral skills was not observed for the MI-medication Group participants, this was the only group that experienced an improved lower range score. Specifically, for MI-medication Group participants, behavioral skills score ranged from 11.00 to 15.00 at Time 2 and 13.00 to 15.00 at Time 3. Again, elevated mean scores suggest potential ceiling effect limitations on identifying change over time. MI is intended to promote self-efficacy in the identified behavior of interest. Again, these data suggest that factors beyond autonomous motivation and self-efficacy may be influencing adherence to medications. The MI intervention delivered in this study may not be adequate to address these other factors in a population with low socioeconomic status. Future research should explore comprehensive approaches to foster self-efficacy and address other tangible factors that may influence adherence.

The IMB model suggests that behavioral skills are a central factor related to medication adherence (Fisher et al., 1992). The positive relationship between behavioral

skills and medication adherence has been supported in both participants with varying health conditions (Kardas et al., 2013) as well as CVD samples (Zarani et al., 2014). Prior research examining the efficacy of a three-session MI intervention on self-care behaviors in participants with heart failure supported an increase in confidence, or self-efficacy, in heart failure-specific self-care (Paradis et al., 2010). Another study utilizing MI also supported increased confidence to engage in heart failure self-care behaviors in approximately 8 of the 15 participants receiving the intervention (Riegel et al., 2006). Further, a systematic review and meta-analysis of randomized control trials of MI suggested a statistically significant positive impact on patient confidence in approaching change when experiencing a chronic condition (Lundahl et al., 2013). The findings in the current study contrast these earlier research and review findings, as a change in behavioral skills was not identified in this study. Further research on behavioral skills, assessed as both self-efficacy to implement the behavior and accurate implementation of the behavior, as a secondary outcome in MI interventions for cardioprotective medication adherence is needed.

Limitations

The proposed study is not without limitations. First, due to the socioeconomic diversity of the patient population at TMC, it is not uncommon for patients to fill their prescribed medications at a variety of pharmacies, corresponding to cost for each specific medication. Further, we relied on pharmacies to provide us with medication fill data, one of the two main outcomes used in this study. Efforts to address these difficulties were made: (1) participants were asked to provide the contact information for any/all pharmacies they intended to use to fill their prescribed cardioprotective medications, (2) a release of

information consent form was obtained from participants, granting their permission for the release of medication fill data from their pharmacies, and (3) a minimum of three contact attempts to obtain data from pharmacies were made. Nonetheless, these challenges translated to high rates of missing data for the objective measure of medication adherence (approximately 41.0% missing data). To offset this, self-report data on medication adherence was obtained as a second main outcome variable. These data are self-report; therefore, response biases may have occurred. Specifically, participants were not blind to the intervention, so they may have responded in a way in which they believed the research team expected. Participants were asked to recall their medication adherence and pharmacy fill behaviors, which may allow for recall biases. Both self-reported and pharmacy data of dispensed medications were used as proxies for “adherence,” which does not allow for direct observation of adherence behaviors. Further, medication adherence and other questionnaire items assessing constructs of interest in this study are influenced by societal norms and expectations. As such, social desirability bias is possible. Given that data collection methods are largely self-report in nature, mono-method bias is also a plausible limitation of this study. Future research should examine the constructs discussed in the current study using objective medication adherence assessments and other methods to limit social desirability bias if possible.

Second, attrition for follow-up self-report data on medication adherence and the IMB constructs occurred for 19.67% of participants. Efforts to limit attrition by re-contacting participants via phone at different times of day, across several days, were made. Secondary phone numbers were obtained, if available, and used for subsequent contact attempts, if the

participant did not respond to initial attempts to the primary number. Reminder calls and text messages, if permitted, were placed for upcoming scheduled phone interactions.

Socioeconomic status of the eligible participant pool may have further affected not only participation in, but also completion of, the study. Multiple patients and participants expressed concerns regarding not having a working telephone or enough minutes within a cell phone plan to participate in the study. These logistical barriers to implementing an intervention via telephone within a socioeconomically diverse patient population should be considered, with alternative communication means explored in future studies.

Third, the proposed study excluded patients with stable coronary artery disease. The reasoning for this exclusion consisted of the following: (1) these patients may not take P2Y12 platelet inhibitors, and (2) these patients are not eligible for CR. To maximize the sample size for each analysis, we included patients most likely to be prescribed medications from each of four medication classifications. Further, to maximize comparability between the intervention group and the two control groups, the pool of eligible patients needed to be consistent, and therefore all patients needed to be eligible for CR.

Fourth, the sample size for this study was small, despite extending the study's recruitment period due to unanticipated difficulties recruiting eligible participants. It is hypothesized that reduced patient flow, and thus lower numbers of eligible patients, may have been affected by a change in hospital policy which lowered the maximum income cut-off for patients to be eligible for discounted medical care services through the hospital. However, this project was a pilot study to explore the efficacy of a telephone-based, brief MI session on cardioprotective medication adherence; as such, the sample size is consistent with

prior pilot studies in the field (Faulkner et al., 2000) and the preliminary outcome data were intended to inform future intervention directions. Fifth, we did not have the sample size to examine the IMB constructs as related to medication adherence via regression or path analysis. The analyses included in this study are intended to provide initial evidence that these relationships should be examined further in a larger scale study. Finally, data were collected from a single site hospital, with particular patient characteristics; therefore, generalizability may be limited.

Clinical and Theoretical Implications

In accordance with the American Heart Association's (AHA) mission and 2020 impact goal, development of interventions aimed at addressing health disparities is essential to improve the cardiovascular health of *all* Americans. Further, three of the seven steps identified to achieve this goal are directly relevant to cardioprotective medication adherence (i.e., manage blood pressure, take charge of cholesterol, and keep blood sugar, or glucose, at healthy levels; Go et al., 2013). The current study aimed to address this goal set forth by the AHA by developing and evaluating a brief, sustainable intervention to promote cardioprotective medication adherence in racially and socioeconomically diverse patients with CVD. Findings did not support the efficacy of the current intervention in improving cardioprotective medication adherence in this sample. Consideration of threats to validity (e.g., social desirability) are encouraged when interpreting the current data. Future research should consider treatment "dose" in MI interventions, as well as the inclusion of an MI consistent spirit in a multifaceted intervention for cardioprotective medication adherence to meet the complexity of medication adherence as a health behavior. Regarding examination

of the IMB model as secondary outcomes of the intervention, increases in both medication *information* and controlled *motivation* over time were observed in MI-medication Group participants. It is unclear whether these improvements are directly attributable to the MI intervention within this group. Future research should examine IMB model constructs as related to cardioprotective medication adherence, as well as secondary outcomes from MI interventions or potential mechanisms of change.

Ceiling effects were observed for autonomous motivation and behavioral skills constructs, both constructs of which MI is designed to foster. Even with MI-medication Group participants endorsing high motivation and self-efficacy to adhere to their cardioprotective medications, high rates of nonadherence were observed. This suggests that factors other than motivation and self-efficacy may be influencing participants' ability to adhere. This was a sample of participants with low socioeconomic status and tangible factors, such as reliable transportation, finances, and insurance coverage may present greater barriers to adherence that contest the participant's high motivation and self-efficacy. These tangible barriers should be examined in relation to their medication adherence behaviors. An intervention solely focused on promoting motivation and self-efficacy may not be adequate in this population to address and overcome these tangible barriers to medication adherence.

Although efficacy of the intervention as related to adherence was not supported, the delivery of the intervention was feasible and participants endorsed acceptability and satisfaction with the intervention. This suggests that utilization of an MI consistent *spirit* may increase controlled motivation, while fostering maintenance of medication knowledge, autonomous motivation and medication adherence behavioral skills. Combining this

communication approach with other supported clinical methods to address tangible barriers to adherence may offer a more adequate and comprehensive approach appropriate for underrepresented patient with CVD to promote cardioprotective medication adherence. Future research should explore psychological and tangible barriers to adherence and comprehensive intervention approaches within this population.

Appendix A. Study Documents and Timeline

A-1. Consent Form

CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

Increasing Adherence to Treatment Recommendations following a Cardiac Event

Introduction

You are being asked to volunteer for a research study. This study is being conducted at Truman Medical Center.

The researcher in charge of this study is Kymberley Bennett, Ph.D. While the study will be run by her, other qualified persons who work with her may act for her.

The sponsor of this study is the University of Missouri Research Board.

The study team is asking you to take part in this research study because you have experienced a cardiovascular event and are eligible to participate in cardiac rehabilitation. Research studies only include people who choose to take part. Please read this consent form carefully and take your time making your decision. A member of the research team will go over this consent form with you. Ask him/her to explain anything that you do not understand. Think about it and talk it over with your family and friends before you decide if you want to take part in this research study. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

Background

After a cardiovascular event, patients receive many health recommendations from their doctors. Taking medicines as prescribed, and attending a cardiac rehabilitation program, are both likely recommendations made to patients.

Purpose

The purpose of this research study is to understand how health care providers can best talk with their patients about treatment recommendations.

You will be one of about 120 subjects in the study at Truman Medical Center.

Study Procedures and Treatments

If you agree to be in the study, you will be asked to sign this consent form, and agree to the following procedures. While in the hospital at Truman Medical Center, you will complete an interview with a researcher that will take about 15 minutes. After you are discharged from the hospital, a researcher will call you on the telephone for a second interview. This second interview will be done about a week from now, and it will take about 20 minutes to complete.

Then, a third and final telephone interview will happen in about 5 weeks. That third interview will take about 30 minutes to complete. During these interviews, you will answer questions about your demographics (for example, your age and sex), and your feelings and experiences with cardiac rehabilitation, taking your medicines as prescribed, daily stress, and well-being.

If you agree to take part in this study, you will be involved in it for about a month and a half. In addition to the phone interviews, you will be randomly (like the flip of a coin or drawing numbers from a hat) chosen to be in one of three groups.

SC Group will receive information about cardiac rehabilitation and all prescribed medicines before going home from the hospital. This is normal care provided to all cardiac patients like you.

MI-CR Group will receive the same information as the SC Group, and will also see a brief, 9-minute video about cardiac rehabilitation before going home from the hospital. You will see this video when a nurse visits you to tell you about cardiac rehabilitation. The MI-CR Group also will take part in a counseling session on the phone with a trained counselor. This counseling session will happen immediately after the interview that is done 1 week after going home from the hospital. The counseling session will take about 10 minutes and focus on your beliefs about going to cardiac rehabilitation.

MI-medication Group will receive the same information as SC Group, and will take part in a counseling session to talk about taking prescribed medicines with a trained counselor on the phone. This counseling session will happen immediately after the interview that is done 1 week after going home from the hospital, and will take about 10 minutes.

The table below summarizes the phone interviews and counseling sessions for all 3 groups:

| | <i>Today and before going home</i> | <i>In about 1 week</i> | <i>In about 5 weeks</i> |
|---------------------|---|---|-------------------------|
| SC Group | Interview #1 (15 mins) | Interview #2 (20 mins) | Interview #3 (30 mins) |
| MI-CR Group | Interview #1 (15 mins) + Educational video (9 mins) | Interview #2 (20 mins) + Counseling session on attending cardiac rehabilitation (10 mins) | Interview #3 (30 mins) |
| MI-medication Group | Interview #1 (15 mins) | Interview #2 (20 mins) + Counseling session on taking prescribed medications (10 mins) | Interview #3 (30 mins) |

You will have a 1 in 3 chance of being assigned to 1 of these groups.

In order to monitor the quality of the counseling you may receive, and to be able to study the process of counseling, all of the counseling sessions will be audio-recorded.

We also will collect information about you from your medical files at Truman Medical Center. By signing this form, you approve the research team collecting information about your demographic information, your diagnosis, the medicines prescribed to you while in the hospital, whether you attended Truman Medical Center's cardiac rehabilitation program, and if so, how many sessions you completed.

If you take part in the MI-CR Group or MI-medication Group, we may find it helpful to collect more detailed information from you about your reactions to the video shown before hospital discharge, or the telephone counseling sessions after discharge. If we have follow up questions about what you liked and disliked about the study, would you be comfortable being re-contacted again in the future?

Please check if you consent (yes or no) to being re-contacted:

- Yes (If yes, please provide your initials: _____)
- No

Possible Risks of Taking Part in this Study

The risks of this study are the possible loss of privacy or breach of confidentiality. We will take measures to reduce this risk, such as assigning a study number to your data that is collected for the study. You may find it uncomfortable to talk about taking part in cardiac rehabilitation, or taking your medicines as prescribed. Some of the questions may make you feel embarrassed, or be irritating. You can stop a counseling session at any time, refuse to answer any question and/or withdraw from the study without penalty.

Possible Benefits for Taking Part in this Study

There may be no benefit to you for participating in this study. However, you may benefit from feeling more ready to participate in cardiac rehabilitation, or to take your medicines as prescribed. Your participation may help researchers learn about the best ways for health professionals to talk to people about treatment recommendations.

Costs for Taking Part in this Study

There will be no costs to you for participating in this study.

Payment for Taking Part in this Study

To compensate you for your time, you will be paid for each study interview you complete. You will be given a \$10 payment voucher that you can take to the TMC Cash Office immediately after you complete the first interview today (while you are still in the hospital).

Your name, address, and social security number will be provided to the Accounting Department at Truman Medical Center so that your payment may be processed. To comply with federal income tax laws, payments to you are reportable income.

You will be mailed either a check or gift card (your choice) for \$25 after you complete the second interview by telephone in about 1 week. You will also be mailed a check or gift card (your choice) for \$40 after you complete the third interview by telephone in about 5 weeks.

You will be provided your payment voucher, gift card, or check if you begin an interview. If you choose to end your interview early, or skip any questions, you will still receive your compensation. If you withdraw from the study (in other words, if you decide that you don't want to be contacted for any remaining interviews), you will not be compensated for interviews you don't take part in.

Alternatives to Study Participation

Study participation is completely voluntary. If you do not wish to participate in the study, you may still participate in cardiac rehabilitation. Also, you can choose not to participate in this study and not to participate in cardiac rehabilitation.

Confidentiality and Access to your Records

The Bar Code at the top of this consent form will be used to link this consent form and your participation in this research study to your Truman Medical Center permanent medical record. If you do not want this consent form or your participation in this study to be a part of your permanent medical record you cannot participate in this research study.

The results of this research may be published or presented for scientific purposes. You will not be named in any reports of the results. Your study or applicable medical records that have your identity in them may be shown to the study sponsor, the Institutional Review Board (IRB) (a committee that reviews and approves research studies), the Food and Drug Administration, or other governing agencies. This is to prove which study procedures you completed and to check the data reported about you. They may also review your medical records for any treatment you received before you agreed to take part in this study. This is to confirm your medical history and that you meet the requirements to be in this study. The study team will keep all information about you confidential as provided by law, but complete confidentiality cannot be guaranteed.

If you leave the study or are removed from the study, the study data collected before you left may still be used along with other data collected as part of the study. For purposes of follow-up studies and if any unexpected events happen, subject identification will be filed at Dr. Bennett's office at the University of Missouri, Kansas City under appropriate security and with access limited to medical research personnel only.

If you sign this consent form, you are allowing the study team and these other agencies to see your medical records.

The audio recordings of any telephone counseling sessions you complete will be saved indefinitely, and may be used for future research studies. They may be transcribed for use in the current study or for future studies. Identifying information (such as names) will be excluded from any data (such as transcripts) extracted from the recordings. Recordings will be identified only with study identification numbers. The recordings will be stored on a password protected, secured computer and secured backup storage.

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

In Case of Injury

The University of Missouri-Kansas City appreciates people who help it gain knowledge by being in research studies. It is not the University's policy to pay for or provide medical treatment for persons who participate in studies. If you think you have been harmed because you were in this study, please call the researcher, Dr. Kymberley Bennett, at 816-235-6370.

If there is an emergency, where you feel that you need to contact the researcher immediately, you should call Dr. Kymberley Bennett at 812-239-6820.

Contacts for Questions about the Study

You should contact the IRB Administrator of UMKC's Institutional Review Board at 816-235-5927 if you have any questions, concerns, or complaints about your rights as a research subject. You may call the researcher Dr. Kymberley Bennett at 816-235-6370 if you have any questions about this study. You may also call her if any problems come up.

Voluntary Participation

Taking part in this research study is voluntary. If you choose to be in the study, you are free to stop participating at any time and for any reason. If you choose not to be in the study or decide to stop participating, your decision will not affect any care or benefits you are entitled to. The researchers, doctors, or sponsors may stop the study or take you out of the study at any time:

- if they decide that it is in your best interest to do so,
- if you experience a study-related injury,
- if you need additional or different medication/treatment,
- if you no longer meet the study criteria, or
- if you do not comply with the study plan.

They may also remove you from the study for other administrative or medical reasons. You will be told of any important findings developed during the course of this research.

You have read this Consent Form or it has been read to you. You have been told why this research is being done and what will happen if you take part in the study, including the risks and benefits. You have had the chance to ask questions, and you may ask questions at any time in the future by calling Dr. Kymberley Bennett at 816-235-6370. By signing this consent form, you volunteer and consent to take part in this research study. Study staff will give you a copy of this consent form.

Signature (Volunteer Subject) Date Printed Name (Volunteer Subject)

Signature of Person Obtaining Consent Date Printed Name of Person Obtaining Consent

A-2. Pharmacy Release of Information Form

Request for Records from Other Facilities Authorization Form

Patient Name: _____

Date of Birth: _____

SSN#: _____

I, _____, hereby authorize the following entities:

- TMC Walgreens CVS Walmart _____
- Outpatient Pharmacy Pharmacy Pharmacy _____
- Pharmacy

to release/disclose the records of the above patient to Jillian Clark, MA, Kymberley Bennett, PhD, Andrew Smith, Pharm.D., and Delwyn Catley, PhD at the following entities:

Truman Medical Center-Hospital Hill
 2301 Holmes
 Kansas City, MO 64108
 (P): 816-404-1238 (F): 816-404-4199

University of Missouri-Kansas City
 Department of Psychology
 5030 Cherry St. Rm 214
 (P): 816-235-1064

The following medical records and information is authorized to be released: prescription fill information including prescription name and fill date for all cardioprotective medications from four medication classes—1) P2Y12 platelet inhibitor (e.g., Clopidogrel), 2) Angiotensin system blockers (e.g., Lisinopril/Losartan), 3) Statins (e.g., Rosuvastatin), and 4) Beta blockers (e.g., Metoprolol).

This information is released for the following purpose and that purpose only. No other use or further disclosure of such information is permitted:

Purpose: Identification of medication utilization behaviors of patients recently discharged from the hospital.

I understand that I may revoke this authorization at any time by contacting Jillian Clark at 816-235-1064, except to the extent that action has been taken in reliance thereon. This consent, unless expressly revoked earlier, shall expire two years after the date signed if I have not provided an expiration date. This information will be released only to the person(s) or agency named above.

READ CAREFULLY: I understand that my medical records are confidential. I understand that by signing this authorization I am allowing the release of any medical information requested to the agency or person specified above. I understand that I do not have to sign this authorization and that my treatment or payment of services will not be denied if I do not sign this authorization. Drug and alcohol abuse information records are specifically protected by federal regulations and by signing this authorization I am allowed the release of any drug and/or alcohol information to the agency or person specified above. Additionally, I understand that information released may include Acquired Immunodeficiency Syndrome (AIDS) or infection with HIV (Human Immunodeficiency Virus)

| | | |
|---|--------------------------|-----------------------|
| _____ Signature of Patient | _____ Date of Consent | |
| _____ Signature of Legally Responsible party | _____ Date of Consent | _____ Relationship |
| _____ Signature of Witness | _____ Date | |

A-3. Randomization Tracking Form

| Randomization Tracking | | | | | | | | |
|---|----------|-----|------|------------|----------------|------|----------|---|
| Assignment Group: 1=Standard of Care (control group; no video) 2=MI-CR + Video (experimental MI-CR group; video) 3=MI-medication (experimental MI-medication group; no video) *If patient is discharged from hospital prior to being approached by CR nurse, patient will be removed as a study participant | | | | | | | | |
| Date Enrolled | Study ID | MRN | Name | Envelope # | Assigned Group | Date | End Time | Comments |
| | | | | | 1 2 3 | | | <input type="checkbox"/> Completed <input type="checkbox"/> Patient discharged prior to approaching <input type="checkbox"/> Other: _____ |
| | | | | | 1 2 3 | | | <input type="checkbox"/> Completed <input type="checkbox"/> Patient discharged prior to approaching <input type="checkbox"/> Other: _____ |


A-4. Study Timeline

| | | SC Group | MI-CR Group | MI-medication Group |
|--|---|-------------------------|--------------------------|--------------------------------|
| | | Standard of Care (n=15) | Video & MI-CR (n=14) | MI-Medication Adherence (n=20) |
| Time | Study Activity | | | |
| Inpatient | | | | |
| ~4pm-7am (next day) | Recruitment & Time 1 Questionnaire (Occurs prior to CR referral) | ✓ | ✓ | ✓ |
| Participant Randomization | | | | |
| ~7am-9am | CR Nurse referral visit (15-20 min) | Standard of Care | Standard of Care + Video | Standard of Care |
| ~8am-10am | Inpatient visit by pharmacist (15-20 min) | ✓ | ✓ | ✓ |
| Post-Discharge | | | | |
| 48-72 hours post-discharge | Pharmacist call about Clopidogrel medication (standard of care) | ✓ | ✓ | ✓ |
| 1-week post-discharge | Pharmacy fill data collected | ✓ | ✓ | ✓ |
| 1-2 weeks post-discharge | Phone call to participant: -Time 2 questionnaire administered (prior to MI session) -Brief MI intervention delivered (4 attempts to reach participants) | ✓ | ✓ (MI-CR) | ✓ (MI-Med) |
| A few days prior to CR orientation appointment | Reminder call from CR nurse | ✓ | ✓ | ✓ |

| | | | | |
|---|--|---|---|---|
| 5 weeks post-discharge/1-month post-orientation appointment | Phone call to participant: -Time 3 questionnaire administered (4 attempts to reach participants) | ✓ | ✓ | ✓ |
| 5 weeks post-discharge | Pharmacy fill data collected | ✓ | ✓ | ✓ |

Appendix B. Intervention Manual (MI-medication Group)

I. HEART MEDICATION ADHERENCE ASSESSMENT:

 *Now, if it is okay with you, I would like to talk about your thoughts and feelings regarding your heart medication.*

Your doctor prescribed heart medications for you, I noticed you haven't yet filled these medications/haven't taken your medications as prescribed (based on survey responses). Tell me how you feel about taking these medications.

- Use reflective listening to generate elaboration and take any opportunity to affirm.
- Identify where participant is on continuum of change. Listen for interest or non-interest and use reflection. If not interested, reflect barriers but also reflect the pros of adhering to heart medications and try to use reflection to direct back to medication adherence if barriers continue to be brought up.
- Provide information as required.
- If they indicate interest in adhering completely to use, use solution-focused approach.

II. ELICIT CHANGE TALK AND DEVELOP DISCREPANCY

TOOLS

- Use eliciting questions as appropriate to **develop discrepancy** and elicit change talk.
 - So if you could wave a wand and take your heart medications as prescribed, would you?
- Use **change talk eliciting questions** such as: What gives you optimism / confidence that you could take your heart medications as your doctor prescribed?
- If appropriate use **values clarification** to develop discrepancy and **elicit change talk**.
 - How do your values relate to taking your heart medication?
 - How would losing your health affect your ability to live out your values?
- **Affirm** strengths and efforts

Three Main Categories of where people are on the Scale

Not a priority to take heart medications

- Use motivation and confidence rulers as appropriate to elicit change talk
 - *On a scale from 0 to 10, with 0 = not at all important/confident and 10 = extremely important/confident, how important is it to you to/confident are you in take (taking) your heart medications as prescribed?*
 - *Following response: You have indicated a ____, so you feel it is at least a little important/a little confidence (1-3)/ somewhat important/somewhat confident (4-7)/ very important/very confident (8-10). Tell me what makes it that important for you/what makes you that confident?*
 - *After reflection of response: What would it take to get your importance level/confidence level up to a ____ or ____?*
- Pros and Cons
 - *What are the pros/cons of filling all of your heart medications/taking your medications as prescribed?*
- Amplified reflections
Remember Action Reflections: “So if you could find a way to [overcome barrier], you would be able to [take your heart medication].”

Express interest in adhering to medication, but hasn't tried or been successful- “On the fence”


- **Solidify** this place: So on one hand, I hear you say you want to take your heart medications as they have been prescribed, and on the other, you are not quite ready to start doing this. Then
- **Explore:** What would it look like for you to take your heart medications as prescribed?

Want to adhere to medications: “Sealing the deal”


- Move participants through continuum of change talk
 1. Disadvantages of status quo
 2. Advantage of change
 3. Optimism for change
 4. Intention to change
 - *How would you like things to be different? OR What's getting in your way?*

CASE CONCEPTUALIZATION








Does this individual primarily lack motivation/desire to take their heart medications as prescribed?

 *I am wondering if you could wave a magic wand and take your heart medications as prescribed, would you?*

If yes, what gets in their way of doing it? (lack confidence or urgency)

 *So what are some things that are getting in the way of you taking your medications?*

If not, why not?

| |
|--|
| <p> <i>Tell me a bit about this decision. Do they doubt health effects? Explore health concerns with eliciting statements such as: What concerns you the most about your heart disease? OR What concerns do you have about your future health? So you're not concerned about health risks? So you have NO reason to take your heart medication? (Activate risk perceptions)</i></p> |
| <p><u>If the person has high motivation and confidence explore inconsistency:</u></p> <p> <i>"You say that your importance/confidence for taking your heart medications as prescribed is high, and you have not really mentioned any barriers to taking your medications. On the other hand, you haven't filled your heart medication (been taking your medications as prescribed). Help me understand this?"</i></p> <p><u>If the person appears to move toward readiness to make a plan to adhere:</u> Summarize, assess readiness and if appropriate proceed to the Barrier Exploration/Problem Solving Module.</p> <p> <i>"It sounds like you might be ready to think about how you might go about taking your heart medications as prescribed"</i></p> <p> <i>"So it really sounds like you'd like to take your heart medications as prescribed"</i></p> <p>SUMMARIZE thoughts about adhering to heart medications, highlighting change talk</p> |
| <p><u>III. BARRIER EXPLORATION/PROBLEM SOLVING:</u></p> |
| <p>E <i>What are some of the obstacles that keep you from filling your heart medication prescription/taking your heart medications as prescribed/continuing to take your heart medications as prescribed?</i></p> <p>E <i>Which of these obstacles do you see as the biggest problem in terms of filling your heart medications/taking your heart medications/continuing to take your heart medications as prescribed?</i></p> <p> <i>What ideas do you have for addressing [barrier] if you should decide to fill your medication/take your heart medications as prescribed/continuing to take your heart medications as prescribed?</i></p> <p>If you have additional ideas, Affirm and Ask permission:</p> <p> <i>Sounds like you are able to come up with some strategies that will work well for you. I am wondering if you are okay with me sharing some additional thoughts.</i></p> <p>E <i>Of the solutions we've listed, which do you like best?</i></p> <p>E <i>What specific actions would you take in order to carry out this solution?</i></p> <ul style="list-style-type: none"> • Utilize reflective listening. |
| <p><u>IV. GLOBAL SUMMARY AND CLARIFY CONTRACT</u></p> |
| <p>Initiate participant's summary of the entire discussion so far.</p> |
| <p> <i>I see that our time is almost up so if it's okay I want to get an idea of what you think about our conversation regarding your heart medication today? Is there anything that</i></p> |

stuck out for you? I think you've given me a really good idea about what you think about taking your medications.

🗣️ *If it is okay may I to add a couple of things?*

Summarize your case conceptualization – as appropriate acknowledge participant's reluctance/obstacles for adhering to medications but end with and highlight change talk including links to values if appropriate. Do NOT summarize entire conversation—mention only those things that seemed most salient to you.

V. CONCLUSION

REINFORCE THEIR EFFORTS AND PARAPHRASE THEIR PROGRESS.

Thank the participant for their time. Let them know that you appreciate their willingness to participate in the counseling with you.

Appendix C. Measures

C-1. Medication Fill Self-Report, Times 2 & 3

How many times have you filled this medication since your discharge from TMC? 0 1 2

C-2. Cardioprotective Medication Information, Times 2 & 3

1. Please describe all the heart medications prescribed to you upon being discharged from TMC:

a. Medication: _____

What is this medication for? _____

What is the dosage? _____

Are there any special instructions? _____

If participant is unable to recall medication name, prompt:

Have you been prescribed _____?

(Then continue to ask above questions)

C-3. Cardioprotective Medication Behavioral Skills, Times 2 & 3

| 1. How confident are you that you can take your heart medicines correctly... | Not confident | Somewhat confident | Very confident |
|---|----------------------|---------------------------|-----------------------|
| a. When you take several different medicines each day? | 1 | 2 | 3 |
| b. When you have a busy day planned? | 1 | 2 | 3 |
| c. When you are away from home? | 1 | 2 | 3 |
| d. When no one reminds you to take the medicine? | 1 | 2 | 3 |
| e. When you take medicines more than once a day? | 1 | 2 | 3 |

C-4. MI-Medication Intervention Acceptability Items, Time 3

| |
|---|
| <p>How did you feel about the length of the heart medication counseling session?</p> <ol style="list-style-type: none">1. Much too short2. A little too short3. Just about right4. A little too long5. Much too long6. Don't know |
| <p>The number of counseling sessions you were offered to talk about your heart medication was...</p> <ol style="list-style-type: none">1. Not enough2. Just about right3. Too much4. Don't know5. Refused |
| <p>What, if anything, would you like to change about the heart medication counseling session?</p> <p>1) _____</p> |
| <p>Would you recommend our heart medication counseling program to your friends or family?</p> <ol style="list-style-type: none">1. No2. Yes3. Don't know4. Refused |
| <p>Overall, how satisfied were you with the heart medication counseling program?</p> <ol style="list-style-type: none">1. Not Satisfied at all2. A little Satisfied3. Somewhat Satisfied4. Very Satisfied |
| <p>Overall, how much has the heart medication counseling program influenced you to take your heart medications as prescribed?</p> <ol style="list-style-type: none">1. No Influence2. A little Influence3. A lot of Influence |

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VITA

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Bennett, K. K., Harry, K. M., Eways, K. R., Wilson, E. J., Clark, J. M. R., Howarter, A. D., & Murdock, T. B. (in press). Stability in cardiac attributions before and after cardiac rehabilitation. *Rehabilitation Nursing*.

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