The Effect of Motivational Interviewing and Clinician Centered Interviewing Based Cardiac Rehabilitation on Core Outcomes

By

Darby J Winkler

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Approved by

Danielle W. Wadsworth, Chair, Associate Professor of Kinesiology
James McDonald, Associate Clinical Professor of Kinesiology
C. Brooks Mobley, Assistant Professor of Kinesiology
Jan Kavookjian, Associate Professor of Health Outcomes Research and Policy

Abstract

BACKGROUND: Cardiovascular disease (CVD) is the leading cause of death globally and affects almost 50% of the American population over the age of 20 years old. Following cardiac events patients are encouraged to participate in Cardiac Rehabilitation. Cardiac Rehabilitation has been proven to reduce all-cause mortality and prevent secondary cardiac events[1]. Despite the clear benefits between 12%-56% of patients' dropout [2]. The purpose of this randomized clinical trial is to examine the impact of a motivational interviewing as well as a clinician centered interviews on adherence to OPCR and OPCR outcomes. METHODS: 88 Cardiac Rehabilitation patients were randomized into the control (30), CCP (30) or MI (28) group. All groups received a 10–15-minute interview every other week over the duration of their program. Core component measures were collected pre and post intervention. RESULTS: A group by time effect was found for the Rate Your Plate between the control and CCP group. Time interactions were found for the PHQ-9, Dartmouth, and walk test distance. CONCLUSION: Structured communication demonstrates a positive effect on eating behaviors and weight managements. Face-to-face communication overall was beneficial for depression, quality of life, walking test distance and adherence to programs.

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LIST OF ABBREVIATIONS

CVD - Cardiovascular Disease

HTN – Hypertension

PCI – Percutaneous Intervention

CABG – Coronary Artery Bypass Graft

WHO – World Health Organization

OPCR – Outpatient Cardiac Rehabilitation

ECG – Electrocardiogram

MI- Motivational Interviewing

SDT – Self-Determination Theory

AMI – Acute Myocardial Infarction

DM – Diabetes Mellitus

HDL- High-Density Lipoproteins

BMI- Body Mass Index

LDL- Low Density Lipoproteins

RCT- Randomized Control Trials

MVPA – Moderate-Vigorous Physical Activity

AACVPR –

CCP- Clinician Centered Perspective

RYP – Rate Your Plate

MITI - Motivational Interviewing Treatment Integrity

PHQ-9 – Patient Health Questionnaire

PNSS- Psychological Needs Satisfaction Scale

CDC – Center for Disease Control and Prevention

IRB- Institutional Review Board

MIA- MI Adherent

MINA- MI Non- Adherent

R:Q – Reflection to Question Ratio

%CR – Complex Reflection

I. INTRODUCTION

Introduction

Cardiovascular Disease (CVD) is the leading cause of death worldwide [3]. CVD is defined as a condition that involves the narrowing or blockage of blood vessels, leading to chest pain, AMI, or stroke. Heart failure, heart valve issues, and rhythm disorders are also considered heart disease [4]. CVD is responsible for approximately 17.3 million deaths per year [5] and is predicted to rise to over 23.6 million by 2030. In the United States, one in every four deaths is due to CVD [6], which equates to 2,200 deaths per day, one life every 40 seconds [7]. In 2016, 48% of adults > 20 years of age in the United States had diagnosed CVD [8]. Furthermore, 47% of Americans suffer from one of the three main risk factors for CVD, including hypertension (HTN), hyperlipidemia (HLD), and tobacco use [8, 9].

African Americans have the highest rates of CVD with 60% of all African American men and 57% of African American women with some form of CVD compared to 50.6% and 43.4% Non-Hispanic (NH) white males and females, 49.0% and 42.6% Hispanic males and females, and 47.4% and 37.2% NH Asian males and females [6, 8]. Men have higher death rates due to CVD than women [10], although African American males and females have the highest death rates due to CVD complications [11].

High rates of CVD place an economic burden on the health care system as well as individuals. According to the American College of Cardiology, between 2014-2015, it was estimated at $351.2 billion total costs of CVD in the United States alone. Broken down by standard procedures done: a cardiac catheterization on average costs $57,494, and in 2014, over 1 million were performed; a percutaneous coronary intervention (PCI) costs $84,813, and

480,000 were performed, and coronary artery bypass graft (CABG) on average is $168,541, and 371,000 procedures were performed [6].

As CVD occurrence is high, it is crucial to identify risk factors for CVD. Risk factors for CVD are categorized as non-modifiable or modifiable. Non-modifiable risk factors or factors that cannot be controlled include a family history of CVD and age. Modifiable risk factors, or factors that can be changed, include stress level, physical inactivity, obesity, tobacco use, hypertension, hyperlipidemia, and diabetes mellitus [12]. The modifiable risk factors are of particular interest to behavior change programs as they can be altered to decrease CVD rates. Individuals with multiple risk factors further exacerbate the risk for developing CVD and suffering from a cardiac event [9]. Although risk factor profiles vary, males typically have a higher risk profile than women [13]. If these risk factors go undiagnosed, ignored, or not well-maintained, it may result in a cardiac event. Incidents that could damage heart muscles [14]. According to the CDC, Cardiac Rehabilitation is an essential part of recovery following a cardiac event.

Levine and Lown were the early pioneers in the development of Cardiac Rehabilitation in the 1960s. Cardiac Rehabilitation was defined by the World Health Organization (WHO) in 1993 as the sum of activities needed to impact the underlying cause of disease positively, as well as to guarantee the patient the best possible physical, mental, and social conditions, so that they may return to a typical or improved quality of life [15]. Cardiac Rehabilitation is associated with many benefits, including strengthening the heart and body after a AMI through physical activity, helping build healthier habits, improving energy, mood, and preventing future heart problems [16].

Cardiac Rehabilitation involves Phases I-III. Phase I Cardiac Rehabilitation takes place during hospital admission. It is primarily an education-based session discussing the cardiac event bringing individuals to the hospital and relevant risk factor-specific education to prevent a secondary event. In addition to education, phase I cardiac rehabilitation determines eligibility for phase II cardiac rehabilitation. The closest cardiac rehabilitation facility will receive referrals for eligible patients. Following phase I Cardiac Rehabilitation is Outpatient Cardiac Rehabilitation (OPCR). OPCR is considered Phase II Cardiac Rehabilitation and is required to be medically supervised with electrocardiographic monitoring beginning 1-3 weeks after a cardiac event. To meet the Medicare-based guidelines, a program must meet the duration, component, facility, and staff requirements. OPCR typically consists of up to 36 sessions covered by insurance, 2-3 sessions per week for an average of 12-18 weeks. The program's components are medical evaluation, modification of cardiac risk factors (nutrition), prescribed exercise, education, and counseling. The facility must have the necessary cardiopulmonary, emergency (rapid response team), diagnostic (ECG), and lifesaving equipment (defibrillator) readily available for immediate use. The staff must be able to conduct the program safely and effectively, trained in both basic and advanced life support and exercise therapy for coronary disease, and the program is required to be under the direct supervision of a physician [17]. Phase III Cardiac Rehabilitation is long-term outpatient Cardiac Rehabilitation that provides preventative and rehabilitative services in the outpatient setting over a longer duration [18].

Participating in OPCR is associated with improved health outcomes. For example, the mortality rate for non-attendees of OPCR is 58% higher than attenders. Morality rates were two times greater in participants that attended <25% of the sessions when compared to participants attending > 75% of sessions [19]. Furthermore, data between 1995-2012 showed one year after

an initial AMI, 3% and 5% of NH white males and females 45 to 64-year-old, and 9% and 10% of black males and females, who did not participate in OPCR died [8]. Within five years, the same age group's mortality increased to 11% and 17% for NH- white males and females and 16% and 28% for black males and females, respectively. Additionally, 11% and 15% of NH white males and females and 22% and 32% of black males and females will have a second AMI within five years of their first AMI without participating in OPCR [8]. Despite these benefits, adherence to Cardiac Rehabilitation programs is low [20], with some studies showing 22% of those who enroll in OPCR will drop out in the first two weeks [21], and between 25%-50% drop out at some point in the program [22]. Due to CVD rates, coupled with the benefits of Cardiac Rehabilitation, further research is needed to address how to increase adherence rates to OPCR. Although multiple approaches have attempted to improve adherence to OPCR, emerging evidence show Motivational Interviewing (MI) as a potential effective and sustainable solution.

Motivational Interviewing has been used to initiate and sustain healthy behaviors beginning in the 1980s by Rollnick and Miller. MI is a person-centered communication approach that uses the patient's own motivation to change behavior long term. MI is a collaborative approach between the interviewer and patient by respecting autonomy, evoking their values and views to enhance their own internal motivation [23]. MI, when appropriately trained and applied, has been shown to increase decision-making towards adherence with the desired health behavior while also helping the practitioner to resist the urge to "fix" the individual, understanding and exploring their motivations while actively listening and eliciting change talk [23]. In comparison, a provider-centered approach is focused on fixing the patient and dictating to the patient that changes are needed. Table 1 provides examples of MI compared to a provider-centered approach.

Table 1. Patient vs. Clinician Centered

Patient-Centered	Clinician Centered
Adherence	Compliance
Help facilitate patient to save self	"Save" the patient
Evaluate motivation	Motivate the patient
Servant	Authoritarian
Confront	Argue
Information exchange	Information giving
Understanding, accepting	Persuade, manipulate
Respect is earned	Respect expected
Resistance is information	Resistance is bad

Patient autonomy is a significant aspect of MI, and research suggests that autonomy is one of the most significant physiological needs a person requires for behavior change [24]. MI relies on respecting a patient's autonomy and strives not to violate autonomy in the behavior change process. In addition to autonomy, relatedness and competence have been reported to increase behavior change [25]. Autonomy, relatedness, and competence are the three psychological needs that must be satisfied to motivate individuals to change their behavior intrinsically [26]. While MI has been effective in increasing adherence to OPCR, these three components of the Self- Determination Theory (SDT) have also been shown to improve adherence and successful change behavior but have not been explored in OPCR [27]. Furthermore, current MI literature does not determine if relatedness and competence are underlying mechanisms of change.

Statement of the Problem

Although Cardiac Rehabilitation has clear benefits, utilization is low. Dropout rates among patients who attend Cardiac Rehabilitation are extremely high, with 50% of patients enrolling in Cardiac Rehabilitation completing their program [28-30]. Between 2005 and 2015 < 40% of eligible patients self-reported participation in OPCR [8]. OPCR focuses on increasing

physical activity, medication adherence, improving blood lipid levels, dietary education, improving quality of life, decreasing depressive symptoms, improving blood pressure and blood glucose, and smoking cessation when applicable. These components can be achieved within the appropriate climate to encourage long-term behavior change, reduce the risk of a second cardiac event, and improve overall health.

Prior research shows that MI interventions have increased OPCR adherence [31, 32], increased physical activity during OPCR [33], and promoted behavior changes to reduce secondary events [34, 35]. MI has also been used in OPCR to increase medication adherence [34], HbA1c control [36], and depressive symptoms [37], however, other outcomes in OPCR have not been investigated.

Based on prior research, it appears that interaction with others and being included in their care plan, in addition to education, could be a practical addition to OPCR adherence, although research is minimal [38]. While MI studies effectively increase adherence to OPCR programs and increase physical activity, current research lacks consistent MI delivery. Therefore, a different approach to this question is needed. A thorough examination of MI research within OPCR patients showed tremendous success when patients collaborated with the interventionist regarding the care plan compared to the control groups [32, 39]. Patients assigned to the MI group perceived the importance of OPCR to a greater extent than the control group resulting in more exercise classes attended [39]. In addition, when clinicians spent more time talking with their patients, even if not following the MI structure, adherence to OPCR programs also increased [40]. This identifies a gap in the literature regarding the interaction itself or a specific communication type such as MI that influences change.

MI has been linked to SDT through autonomy support, which, along with relatedness and competence, are the basic human needs that promote optimal well-being [41]. Autonomy is the ability to direct an individual's behavior [26]. Autonomy-focused interventions have been more successful in producing behavior changes than clinician-centered approaches or low autonomy [42]. Relatedness has been reported as a basic need for behavior change and is the need for relationships and a sense of security [43, 44]. Competence is supported when clinicians provide skills and tools to change and experience mastery [45]. Clinicians can provide an environment that can facilitate autonomy, relatedness, and competence to aid in Cardiac Rehabilitation attendance [43]. However, research has not thoroughly examined if autonomy alone through MI or relatedness and competence are the successful components that lead to increases in adherence among OPCR patients.

Furthermore, research has not evaluated if MI or clinician-centered counseling (low autonomy) compared to traditional Cardiac Rehabilitation is more effective in eliciting positive outcomes from OPCR. While MI's addition to OPCR appears to be directly related to adherence to the program [32, 33, 38, 39, 46], research cannot determine that MI specifically and not face-to-face communication and continuous engagement that is directly related to adherence. This is a clear gap in the theoretical underpinnings of MI. Furthermore, research has not indicated how MI affects relevant risk factors associated with CVD. Therefore, the purpose of this randomized clinical trial is to examine the impact of a motivational interviewing intervention as well as a clinician center interview on adherence to OPCR and OPCR outcomes.

Statement of Purpose and Study Objectives

The mixed findings from MI research within OPCR and the lack of data regarding mechanisms of change calls for further investigation. This study aimed to examine the effect of

motivational interviewing and clinician-centered interviews on OPCR program adherence and core component outcomes (e.g., walk test distance, blood pressure, rate your plate, Patient Health Questionnaire, and Dartmouth COOP) for OPCR patients. This study will also assess whether autonomy, relatedness, and competence are underlying factors to changes within an OPCR sample compared to a clinician-centered approach. This study will inform a wide range of clinicians working with this population to provide effective evidence-based behavior change modalities and ideally decrease the prevalence of hospitalizations and increase quality of life.

Primary Objective: Determine the effect of Motivational Interviewing on cardiac patient's adherence to OPCR programs and OPCR health outcomes.

Secondary Objective: Determine if autonomy support is the main component in cardiac patient's adherence to programs.

Research Questions and Hypotheses

1. Does motivational interviewing, compared to a clinician-centered perspective (CCP) and control, affect core component outcomes in OPCR to a greater extent?
    a. Hypothesis 1.a: OPCR with MI will increase participation in physical activity more than the CCP and Control group measured by a 6-minute-walk test and exercise outside of Cardiac Rehabilitation as measured by self-reported exercise logs.
    b. Hypothesis 1.b: Patients in the MI group will have a more heart-healthy diet as measured by the "Rate Your Plate" at the end of OPCR compared to the CCP and Control group.
    c. Hypothesis 1.c: Both the MI and CCP groups will not have a significant decrease in weight, compared to the control group.

d. Hypothesis 1.d: The CCP and MI groups will experience fewer depressive symptoms as measured by the PHQ-9, compared to the control group.
e. Hypothesis 1.e: The MI and CCP groups will report increased quality of life, measured by the Dartmouth COOP, compared to the control.
f. Hypothesis 1.f: The MI group will have greater blood pressure control compared to the CCP and control groups.
g. Hypothesis 1.g: The MI and CCP groups will have more adherence to the OPCR program measured by the number of sessions completed out of 36.

2. Does one group report more perceived autonomy, relatedness, and competence than the other?
    a. Hypothesis 2: The MI group will experience/report more perceived autonomy and relatedness as measured by the Psychological Need Satisfaction Scale and IMI than the CCP and control groups.

Significance of the Study

The interventions in this field regarding cardiac patients in OPCR have demonstrated mixed results in program benefits. Overall, the literature reports positive changes during an OPCR program with the addition of MI to standard OPCR. By implementing this intervention into standard OPCR programs, this study aims to positively impact OPCR outcomes and decrease secondary events and hospital readmissions. Exploration within the interviews will help clinicians bring to light topics that patients may or may not have known they considered necessary, in addition to understanding the implications their behaviors have on their health.

This study will help determine if the MI is responsible for successful adherence to OCPR. This can help improve clinician interviews regarding behavior change. Based on the following

literature review, a clinician-led OPCR program with the options of standard OPCR, OPCR with a MI, or OPCR with a clinician-centered approach (low autonomy) was the most appropriate intervention to examine adherence to OPCR and increase behavior changes for cardiac patients.

Limitations

The limitations associated with this study include:

1. The intervention was done at one Outpatient Cardiac Rehabilitation clinic in Alabama and so results may not be generalizable to other settings.
2. Self-report on physical activity outside of OPCR may be limited by social desirability or recall bias.
3. There is minimal control over how case managers interact with the participants. Each clinical staff member is responsible for overseeing the treatment plan for certain patients. Staff members will be blinded to the group assignment to interact with each patient as they usually would. One member of the clinical staff will conduct all of the study intervention interviews.

Delimitations

The following delimitation of this study should be noted:

Participants of this study were cardiac patients at only one outpatient Cardiac Rehabilitation clinic located in the Southeast of the United States; additional sites were not included.

Summary

This chapter summarized the background, a statement identifying the problem, the objectives of this study and purpose, the research questions and hypotheses, the significance of the study, and the limitations and delimitations. Chapter two includes a review of relevant literature regarding modifiable risk factors, outpatient Cardiac Rehabilitation, motivational

interviewing, and interventions. Chapter three outlines the proposed methods for this study, including the approval for human subjects, participants and setting, power analysis, procedures, the design of the intervention, measures, and the statistical analysis.

II. Literature Review

Overview of CVD

Cardiovascular disease is the leading cause of death in the United States [47]. CVD affects approximately 18.2 million adults over the age of 20 in the United States [8], and every 40 seconds, one person in the United States suffers from a acute myocardial infarction (AMI [9]. It is estimated that in 2021 alone, 200,000 people will experience a second AMI. Furthermore, every 36 seconds, one person dies from CVD, and about 655,000 will die from heart disease each year [8].

Risk Factors

Healthy behaviors such as increased physical activity, medication adherence for controlled blood pressure and cholesterol levels, and smoking cessation can decrease CVD risk. These behaviors are associated with a lower prevalence and incidence of CVD events, heart failure, and atrial fibrillation [48]. It is recommended after CVD diagnoses to change relevant behaviors associated with the progression of the disease and minimize complications [49]. The WHO has broken down risk factors for CVD into two initial subgroups, non-modifiable and modifiable. There are two non-modifiable risk factors and seven modifiable risk factors that are associated with CVD.

The non-modifiable risk factors that cannot be controlled or changed are family history of CVD and age. Family history of CVD is defined as having a first-degree relative (male age 55, female 65) undergo revascularization, sudden cardiac death, or an acute myocardial infarction (AMI). Age-related risk for CVD starts at 55 years of age for females and 45 years of age for males. Although age is a risk factor for CVD, two in ten deaths from CVD occur in adults less than 65 years of age [6], and 62% of adults with CVD are younger than 65 [50].

The modifiable risk factors, factors that can be controlled or changed, are known as "Life's Simple 7" [8]. These risk factors include obesity, physical inactivity, tobacco use, stress, HTN, hyperlipidemia, and diabetes mellitus (DM). WHO further breaks down the modifiable risk factors into three main groups: behavioral, metabolic, and other risk factors [51]. Behavioral interventions can change behavioral and metabolic risk factors.

Behavioral risk factors include tobacco use and physical inactivity. Tobacco use, smoking, specifically, is the most preventable risk factor for CVD [49] and is the second leading cause of death worldwide at 8.1 million deaths in 2017 [8]. However, the rates of smoking in adults have decreased from 33.5% in 1980 to 15.1% in 2010 [3]. Not only does smoking cause an increase in blood pressure, but it also increases triglycerides, lowers heart-healthy cholesterol levels of high density lipoproteins, thickens blood making it more likely to clot, damages blood vessels, and increases the buildup of plaque in blood vessels [52]. Current smokers have a 2-4 times higher chances of having a stroke than non-smokers and double the risk for fatal and non-fatal CVD events [53, 54]. Although e-cigarettes are associated lung injury and death [55], thus far no data links e-cigarettes with CVD.

Physical inactivity is a significant predictor of CVD mortality. Physical activity recommendations include 150 minutes (about 2 and a half hours) of moderate-intensity exercise per week or 75 minutes of vigorous-intensity exercise per week or a combination of both [56-58]. A variety of moderate-to-vigorous intensity is encouraged, as well as two or more days a week of resistance exercises [57, 59]. In 2017, approximately 24% of adults met the guidelines for aerobic and muscle-strengthening exercises [60]. Physical activity decreases with age, about 10% every ten years after age 65 [61]. In addition, sedentary behavior, any behavior while awake that is 1.5 metabolic equivalents or less [62], increases CVD risk. Previous data show that

individuals whom self-reported >23 hours/week of sedentary behaviors are at 64% higher risk of CVD mortality than those who reported <11 hours/ week of sedentary behaviors [63]. At this time, a recommendation for sedentary behavior per day has not been determined [57].

Metabolic risk factors for CVD include obesity, hypertension, dyslipidemia, and diabetes. Obesity is defined by an individual's body mass index (BMI), which is weight in kilograms (kg) divided by height in meters squared (m^2). In 2008, 10% of males and 14% of females worldwide were obese compared to 1980 when 5% of males and 8% of females were obese [3]. A study by the American Heart Association reported that between 1987 and 1989 only 33% of adults meet the "ideal" weight status [64]. Between 2015-2018 73.2% of males and 66.9% of females over the age of 20, were classified as overweight or obese [8]. Being obese increases the risk of developing CVD due to the negative impact on the body's hemodynamics as well as altering the heart's structure [65]. Furthermore, obesity is associated with an increased risk for all-cause mortality, hypertension, hyperlipidemia, type II diabetes mellites, CVD, and stroke [65, 66].

Diabetes, both type I and II, denotes a fasting plasma glucose of ≥126 mg/dL or a HbA1c of ≥ 6.5%. An HbA1c is the average blood glucose over the previous three months [67]. Patients living with Type I DM are at an increased risk of developing CVD [8]. According to NHANES 2013, 26 million adults have DM, 9.4 million have undiagnosed DM, and 91.8 million adults have prediabetes [8]. In addition, 20.9% of adults between 2013 to 2016 have treated and controlled diabetes, 45.2% had treated but uncontrolled diabetes, 9.2% were aware they had DM but were not treated, and 24.7% were undiagnosed and not treated [8]. The prevalence of DM is as follows: 9.4% white males and 7.3% white females, 12.8% Asian males and 9.9% Asian females, 14.7% black males and 13.4% black females, and 15.1% Hispanic males and 14.4% Hispanic females [68]. As blood sugar continues to rise, the blood vessels and nerves associated

with the heart are damaged [68]. Furthermore, individuals with diabetes are more likely to suffer from hyperlipidemia and hypertension [68].

Hypertension is defined as a systolic blood pressure > 130 mmHg, a diastolic blood pressure of > 80 mmHg or being on an anti-hypertension medication and is the most common risk factor for CVD [50]. Since 1980, the number of individuals with HTN increased from 600 million to a billion in 2008 [3]. In 2015, 55.1% of adults aged 20 to 49 identified as having untreated HTN. Between 2013 – 2016, 59.2% of adults aged 22-44 had HTN, 59.2% among 45-64, and 78.2% for those > 65 years or older [9]. The Cardiovascular lifetime, Risk Pooling Project found the lifetime risk of hypertension for black males as 86.1%, 85.7 for black females, 83.8% for white males, and 69.3% for white females [8]. HTN is also significantly associated with smoking and sedentary behavior and an increased risk for a AMI, stroke, heart failure, vision loss, chest pain, and peripheral artery disease of the legs [69, 70]. The relationship between CVD and HTN is related to the continuous strain on the blood vessels due to increased pressure, which causes damages and stiffens the arteries surrounding the heart, allowing for plaque to build up [69].

Hyperlipidemia or high cholesterol is a condition in which low-density lipoproteins (LDL), also referred to as “bad cholesterol” is elevated in the blood. The recommended levels for the types of cholesterol include > 200 mg/dl total cholesterol and >120 mg/dl low-density lipoproteins. As cholesterol levels exceed the recommendations, the risk of developing CVD increases. Hyperlipidemia can be due to genetics, diet via increased saturated fat intake, or a combination of both as well as smoking, physical inactivity, obesity, age, and diabetes [70, 71]. Between 2013 to 2016, 92.8 million adults in the US had a total cholesterol of > 200 mg/dl putting them at an increased risk for CVD. Females had a higher prevalence of high total

cholesterol compared to men [72]. In addition to total cholesterol, LDL are associated with CVD development [73]. LDL are fatty acids that can result in plaque in the blood vessels, leading to an AMI. Twenty-nine percent of the US population between 2015-2016 was classified as having high LDL cholesterol (≥130 mg/dL) [74]. Furthermore, reports show that lowering LDL cholesterol levels reduced major vascular events [8]; whereas, untreated increased the risk of AMI and stroke by plaque buildup in arteries [75].

If modifiable risk factors go undiagnosed, ignored, or not well-maintained, it may result in a cardiac event. A cardiac event is defined as an incident that could damage heart muscles [14]. According to the CDC, Cardiac Rehabilitation is an integral part of recovery following a cardiac event. Cardiac Rehabilitation is associated with many benefits, including strengthening the heart and body after a AMI through physical activity, helping build healthier habits, improved energy, mood, and prevention of future heart problems [16]. After a cardiac event, modifying risk factors are encouraged to decrease the risk of a secondary event, and participating in Cardiac Rehabilitation is an option.

Overview of OPCR

OPCR or Phase II Cardiac Rehabilitation is a multidisciplinary medically supervised exercise-based program designed to assist cardiac patients during recovery from cardiac events. OPCR follows inpatient Cardiac Rehabilitation (Phase 1), which is education-based only. Standard OPCR programs consist of exercise and education sessions that cannot exceed 36-weeks. The exercise sessions' goal is to increase aerobic fitness, muscular strength, endurance, balance, flexibility, improve functional movement, and return to activity. Before and after each exercise session, blood pressure is monitored. Education is provided on heart-healthy nutrition and disease management as well as methods to stay physically active [76]. To determine if

additional actions are required, psychosocial assessments are completed. Patients are re-evaluated every 30 days based on their treatment plan to assess if goals were met and what adjustments need to be made to their treatment.

Benefits of OPCR

Following a cardiac event, the American Heart Association reported that participation in OPCR is effective in strengthen and repairing the heart [77]. OPCR is utilized to prevent a secondary event from occurring and provide behavior modification for a better overall quality of life. In addition to lowering the risk of a secondary event, OPCR has been shown to promote weight loss, improve nutrition habits, allow patients to return to work, and participate in activities they could not before [78]. There is a significant (p <0.001) impact on mortality rates based on the number of OPCR sessions completed, with mortality rates highest among patients who attended less than 12 sessions [78]. The same trend can be seen regarding subsequent AMI rates. Patients who attended less than 12 sessions had the highest AMI rate and, for every 6 OPCR sessions attended, a 6% reduction in risk of an AMI occurred. Furthermore, death's risk was significantly lower in patients who participated in 36 sessions [78]. An analysis of 34 RCTs showed that patients in the OPCR groups had lower risks of reinfarctions, cardiac mortality, and all-cause mortality [79]. Another review reported lower systolic blood pressures and a greater reduction in total cholesterol and triglyceride levels for participants that attended OPCR [80].

OPCR Considerations

Though there are clear benefits of OPCR, these programs are tremendously underutilized. Of the patients referred, only 13.9% and 31% of patients hospitalized with an AMI or underwent a coronary bypass graft surgery enrolled in OPCR, respectively [81]. Additionally, only between 10% to 20% of the 2 million eligible patients participate in OPCR [82]. Of the patients that enroll

in OPCR programs, adherence varies between 36.7% to 84.6% [83], with dropout rates between 12% and 56% [2]. Intrapersonal (self-reported health, self-reported mental health, and health beliefs), interpersonal (family caregiver role, work conflicts), logistical concerns (transport, distance), Cardiac Rehabilitation program characteristics (perceptions of the objective of OPCR programs, exercise component, inconvenient timing, OPCR equipment), and health system variables (financial assistance for transportation, long weight list) have reported influencing dropout in OPCR patients [84].

Limited research has examined methods to promote adherence within OPCR programs. Of the published literature regarding increasing adherence to OPCR programs, autonomy and autonomy support were common themes. Motivational Interviewing is a high autonomy patient-centered approach that may provide a high autonomy climate suited for sustained behavior change in OPCR.

Motivational Interviewing

MI was initially developed in the 1980s to assist inpatient rehabilitation from addiction [85]. It was soon discovered that this counseling style could be beneficial in various healthcare fields focusing on behavior [86]. Utilization of MI in health care contexts emerged in the literature in the 1990s, with recent additions demonstrating that motivational interviewing has shown positive changes in modifiable risk factors and specifically within the Cardiac Rehabilitation setting [87]. MI is a style of counseling used to promote behavior changes from within the patient [23, 86]. MI is defined as a direct, patient-centered approach to elicit behavior change by encouraging exploration and resolution of barriers. The "spirit" of MI, the relational dimension of MI, has been described as a collaborative process between patient and clinician, evoking the patient's motivation and ability to change while respecting and supporting the

patient's autonomy. A clinician's awareness of the fluctuation and variability of readiness to change allows the patient and clinician to sync during each session. While avoiding explaining why some behaviors are problematic, MI's nonjudgmental approach allows the patient to explore and express their concerns and desires for change in their own words. Together, these components comprise the spirit of MI and can effectively facilitate patient decision-making for behavior change [85]. In addition to the spirit of MI, there are three critical aspects of MI: MI principles, MI communication skills, and facets of MI.

Principles of MI must be followed to provide sufficient skills and have effective communication. Principles of MI include agenda setting, asking open-ended questions, and asking permission. Agenda setting provides options of conversation topics which the patient can choose. Open-ended questions allow the patient more opportunity to respond. Asking permission allows the patient active involvement in their care. MI relies on the patient's autonomy to thoroughly guide behavior change and is essential for MI to be effective. These aspects of MI are necessary because they offer suggestions of care plan options and allow for the patient's desired choices. Understanding desired choices are helpful because it instructs the clinician on appropriate interventions that would be most successful for each patient [88].

In addition to MI principles, clinicians need specific communication skills, including assessing readiness, expressing empathy, establishing risk, and supporting self-efficacy. Assessing readiness tells the clinician about what the patient views as a motivation and how influential that motivation is in the moment in deciding whether or not to engage in the target behavior. Expressing empathy lets the patient know that the clinician is listening to their concerns and feelings and helps him/her feel understood and supported. Establishing risk helps clinicians determine what the patient knows and understands about the situation and where

additional information may be needed. Supporting self-efficacy enhances the patient's personal beliefs of their ability and confidence to engage in the specific target behavior. Within each interview, the clinician must support opportunities for the patient to decide on their own behavior change plan. These aspects allow the clinician to understand and address potential concerns regarding behavior changes, build rapport during the change process, support autonomy, and strengthen effort for change [89].

Facets of MI consist of developing discrepancy, evoking change talk, incremental change, and rolling with resistance. Developing discrepancy allows the patient to recognize the importance of change. The larger the discrepancy becomes; the more important change becomes for the individuals. Evoking change talk enables the clinician to present the case for change. Incremental changes are small changes that are realistic and doable for the patient to succeed in their behavior change. Rolling with resistance is a way to avoid arguing and avoids the patient feeling as if they are being attacked. The resistance must be overcome to properly assist in behavior change.

Implementing the spirit, principles, and facets of MI provide an autonomy-supportive environment to encourage sustained behavior change in OPCR. The following paragraphs describe MI interventions conducted in OPCR.

Motivational Interviewing in OPCR

A systematic review of the literature, using a modified Cochrane method of systematic review, was conducted for the period of 1990 through 2020. Overall, 9 studies were retained that met inclusion criteria and have utilized MI to improve adherence to OPCR and positive outcomes associated with OPCR [32, 34, 37-39, 90-93]. Ter Hoeve et al. examined MI in addition to OPCR in various clinics throughout the Netherlands [33]. Participants were

randomized into three groups, two experimental and one control group. The experimental groups consisted of traditional OPCR with either face-to-face MI or telephone-delivered MI. The OPCR + face-to-face MI was delivered in a group setting, three 75-minute sessions throughout the intervention and led by a physical therapist previously trained in MI. The MI sessions included information about health behaviors, self-monitoring strategies, goal setting, feedback, barrier identification, and relapse prevention. Following the initial 3-month program, participants assigned to this group had a 9-month after-care program consisting of three face-to-face MI group sessions. These sessions were led by a physical therapist, a social worker, or a dietician, all previously trained in MI. The MI telephone group participated in the traditional OPCR for the first 3-month program and then had five to six individual telephone interviews. Specialized nurses previously trained in MI conducted these interviews. Topics discussed in these sessions included information regarding risk factors and how to measure their coronary risk, as well as psychosocial problems. Physical activity was measured via an accelerometer at four different time points throughout each stage of the intervention for all three groups[33].

Variables of interest included moderate-to-vigorous physical activity (MVPA), step count, prolonged physical activity, and prolonged sedentary behavior. Prolonged physical activity was defined by periods of 10 minutes or more of physical activity, and prolonged sedentary behavior was characterized by 30 minutes or more. This intervention showed that compared to standard OPCR, face-to-face MI significantly increased overall step count per minute ($p = 0.035$). During the initial 3-month program, a significantly higher number of steps were taken per minute of wear time, measured by a tri-axial accelerometer, in the face-to-face group compared to the control ($p = 0.021$). There were no differences between the two MI experimental groups[33].

The face-to-face MI group was significantly more likely to reach the step count goal per day overall ($p = 0.004$). However, there were no significant differences in MVPA, sedentary behavior, prolonged sedentary behavior, or achieving 150 minutes of prolonged MVPA per week between the MI group and control. There were no significant differences between the telephone MI group and the standard OPCR control group for any variable. No significant differences were found between the face-to-face MI group and the telephone MI group for any variable. At 12-months, the face-to-face MI group participated in significantly more MVPA than the control group ($p = 0.033$) [33].

This intervention demonstrated that during the 3-month program, face-to-face MI was more effective in promoting increases in steps per minute compared to the standard program and the telephone MI sessions. Face-to-face MI was also effective in promoting prolonged MVPA after the traditional 3-month program. For this study, the telephone MI group did not experience the same benefits from the MI as the face-to-face group did. Therefore, it is difficult to determine if the MI communication style influenced change or face-to-face interactions, as the author did not report MI fidelity assessment[33].

Rouleau et al. examined MI in addition to OPCR in a single clinic in Canada. Participants were randomized into two groups, an experimental MI group or the control group. The MI group consisted of traditional OPCR and a single MI session lasting between 30 to 60 minutes. This session could occur at the OPCR center, at the university-based office, or as a home visit. This session's content included rapport development, identifying the importance of the education, encouraging confidence and problem-solving OPCR barriers, and summarizing the session. A clinical psychology Ph.D. student previously trained in MI conducted the session. This

intervention's primary outcome was to determine the influence MI has regarding intention to attend and adhere to OPCR[39].

The results of this intervention demonstrated participants within the MI group had a greater perceived necessity for OPCR and positive beliefs about participation/enrollment. In addition, adherence to the OPCR program was significantly higher for the MI group than for the control group ($p = 0.008$), as reported by attending on average 5 more sessions. Rouleau et al. did not report a preferred location for the interview and if the interview location influenced adherence outcomes[39].

Beckie et al. (2010) examined the effects of MI in addition to OPCR in the United States to predict adherence to OPCR programs. Participants were randomized into either the MI group or the control group. Participants in the intervention group engaged in two sessions of MI, each six weeks apart. There was a significant difference in the number of exercise sessions attended ($p < 0.001$) between groups, with the traditional group attending 28 ± 12 and the MI group attending 32 ± 9 sessions[91].

McGrady et al. examined MI in addition to OPCR in the United States. Researchers randomly assigned participants to either the MI group or control group. The MI group consisted of traditional OPCR and four 30-minute group sessions with 15 minutes focused on MI remaining in the group setting. These sessions' content included patients' personal goals, optimistic views of the benefits of OPCR, limiting negative self-talk, and overcoming barriers to adhere to the program. It was not reported who provided the intervention interviews or if they were previously trained in MI. Adherence was measured by counting the number of sessions of OPCR were attended, and no significant difference was reported in adherence to OPCR.

However, significantly more participants in the control group did not complete OPCR than the intervention group ($p < 0.001$)[38].

Chair et al. (2012) examined the short-term effects of MI in addition to traditional OPCR in Hong Kong. Researchers randomly assigned participants to either the intervention group or control group. The intervention group consisted of traditional OPCR and four 30–45-minute MI sessions. Two mental health nurses previously trained in MI led these sessions. During these sessions, the nurse discussed the participant's knowledge of the conditions, and participants were invited to consider their behaviors involved in the progression of their cardiac conditions. Variables examined included blood pressure, body mass index, cholesterol, and medication adherence. No variable outcomes were significantly different between groups from pre- to post-intervention[92].

Chair et al. (2013) examined the long-term effects of MI in addition to traditional OPCR in Hong Kong. Researchers randomly assigned participants to either the MI group or control group. In addition to the four MI sessions participants received during OPCR, they received nine more MI sessions after completing the program. The first four were two weeks apart, followed by four sessions one month apart, and the last two being three months apart. Two mental health nurses previously trained in MI led the sessions. These sessions used MI to strengthen the commitment to behavior change and reflect on their roles in managing their health. Physiological variables examined in this study includes depression, anxiety, and quality of life. Clinical variables examined included blood pressure and blood glucose. There were no significant group-by-time interactions for any of the outcome variables[34].

Pietrabissa et al. examined the effect of MI in addition to traditional OPCR in Italy. Participants were randomized into either the intervention or control group. The intervention

group consisted of traditional OPCR and three MI sessions. These sessions were face-to-face and lasted between 30-45 minutes, with 15 minutes dedicated to MI. A psychotherapist led the sessions, but the publication did not report previous MI training. Examined variables included LDL cholesterol, BMI, and systolic blood pressure. This intervention reported a significant improvement in systolic blood pressure ($p = 0.036$) in the MI group. No other variables were significantly different. Like the McGrady et al. study, it cannot be confirmed that these participants received MI-consistent approach and communication in the intervention encounters. Furthermore, dietary habit changes blood pressure, and lipid profiles were not examined[93].

Beckie et al. (2011) examined the effect of MI in addition to OPCR in the United States. Participants were randomized into two groups, the intervention or control group. Participants in the intervention group participated in three sessions of MI, each six weeks apart. A clinical psychologist or nurse previously trained in MI led sessions for approximately 60 minutes. Researchers did not report the content nor MI-consistency of these interviews. This intervention reported that women participating in OPCR with MI attended significantly more OPCR sessions ($p = 0.007$)[32]. In addition, researchers examined depressive symptoms in women following MI's effect in OPCR in the United States. Participants were randomized into either the MI intervention or control group. Participants in the MI intervention group engaged in three sessions of MI, each six weeks apart. A clinical psychologist or nurse previously trained in MI let these sessions which lasted approximately 60 minutes each. These sessions aimed to reinforce statements of reasoning from the participants and the need for change. A significant group-by-time interaction for depressive symptoms was reported ($p = 0.013$). The MI group had fewer depressive symptoms than the control group at post-OPCR and the 6-month follow-up. It is important to note that this study only examined OPCR adherence in women[37].

In summary, these studies' combined results demonstrate mixed findings regarding MI's impact on adherence to OPCR and key OPCR outcomes. Although several studies reported increases in adherence to OPCR sessions [37-39, 94, 95], another showed no difference [33]. Several studies lacked clear MI guidelines and implementation [33, 34, 37-39, 92, 94, 95]. Pietrabissa et al. was the only study that reported evaluation of MI sessions for intervention efficacy [31]. Finally, the literature has not thoroughly examined changes in other target OPCR outcomes, including meeting physical activity recommendations, reporting improved quality of life, reporting decreased depressive symptoms, increasing blood glucose monitoring, and no studies examined changes in dietary behaviors.

Further Research

Although MI has shown some success in improving adherence to OPCR, underlying mechanisms of change have yet to be explored. Self-determination theory proposes that for motivation to persist, the psychological needs of relatedness, autonomy, and competence must be met [41]. Relatedness is defined as the perceived sense of a connection and sense of belonging, autonomy is the belief of choosing a behavior volitionally, and competence is the mastery of different tasks and skills [96].

Although not MI-specific, research has provided evidence that autonomy is important in factors related to OPCR. Though not much has been reported regarding increasing adherence to OPCR programs, a commonality appears to be patient autonomy. D'Angelo et al. reported that autonomy was an essential factor in long-term adherence to physical activity in the cardiac population following recent hospitalizations [97]. Results reported that patients were moderately and consistently self-motivated to adhere to a Cardiac Rehabilitation walking program [98]. A qualitative study reported that patients in OPCR were more likely to adhere to their program if

clinicians considered their personal preferences. Recommendations that were disliked ultimately made it difficult to adhere to the Cardiac Rehabilitation program [99].

In addition, high perceived autonomy support was reported after patients could select the modalities during clinic-based rehabilitation [100]. Rahman et al. stated a lack of research exists in OPCR settings examining psychological needs in relation to adherence to programs [101]. Eynon et al. found limited evidence that autonomy alone can significantly increase adherence to exercise but found strong evidence for the satisfaction of autonomy, relatedness, and competence [102]. In addition, there are apparent gaps in MI literature identifying mechanisms of change, such as autonomy, within MI interventions.

Summary of the Literature

CVD is the leading cause of death in the United States, and individuals with CVD are at a higher risk for a secondary event without intervention. Unhealthy behaviors such as physical inactivity, unhealthy eating, negative stress, tobacco use, along with conditions like obesity, uncontrolled hypertension, hyperlipidemia, and diabetes mellitus, are associated with increased CVD risks. While the addition of MI to OPCR appears to be directly related to adherence to the program [32, 33, 38, 39, 46], in many studies, it cannot be determined that it is specifically MI and not a face-to-face communication mode that is directly related to adherence. Furthermore, research has not indicated how MI affects relevant risk factors associated with CVD. Finally, there are clear gaps in the theoretical underpinnings of MI. Therefore, the purpose of this randomized clinical trial is to examine the impact of a motivational interviewing intervention compared to a clinician center interview and control group on adherence to OPCR and OPCR outcomes.

III. METHODOLOGY

Human Subject Approval

Before recruiting participants for this intervention, a full-board research protocol application was submitted to the East Alabama Medical Center (EAMC) Institutional Review Board for Research Involving Human Subjects (IRB). Following EAMC's IRB approval (Appendix A), this protocol was submitted to the Auburn University IRB. This study protocol was approved for use from 11/10/2020 to 11/09/2021 under protocol number 20-512 EP 2011 (Appendix B). This study was registered at clincicaltrials.gov under the number NCT04899752.

Participants and setting

Participants were recruited from an American Association of Cardiovascular and Pulmonary Rehab (AACVPR) certified outpatient Cardiac Rehabilitation (OPCR) clinic in Opelika, Alabama. Participants were included in the study if they met the following criteria:

1. Obtained a written order from their cardiologist to enroll in OPCR at EAMC in Opelika, Alabama.
2. Agreed to complete a 36-session phase II Cardiac Rehabilitation program.
3. Able to fill out the admission paperwork independently.

Study Protocol

This study utilized a blinded RCT. Researchers informed eligible patients that if they participated, they would be randomly assigned to one of three groups which aimed to understand how interview procedures can assist in core outcomes in OPCR. The three experimental groups included 1) OPCR+ MI, 2) OPCR + clinician centered perspective (CCP) and 3) traditional OPCR (control). The 12-week intervention consisted of 36 sessions, three times per week (Monday, Wednesday, and Thursday/ Friday). Participants completed pre-test assessments prior

to the intervention, and post-assessments immediately followed the 12-week intervention. Assessments included: anthropometrics, blood pressure, aerobic fitness, dietary intake, and questionnaires to assess psychological needs, depression, quality of life, and intervention perception. In addition, logs gathered physical activity outside of the OPCR sessions at pre-test, 6 weeks, and post-testing. Each session began with resting blood pressure and was followed by an individualized exercise prescription. Once per week, participants engaged in a 15-minute interview scheduled at a time of their convenience based on their assigned group. Fifteen minutes for the interviews were selected to allow time for conversation and respect the participant's time and ability to synthesize information. The total interview potential dose was 90 minutes. See Figure 1 for detailed procedures.

Measures

Anthropometrics

Weight was measured to the nearest tenth of a pound using a Scale-Tronix Portable Scale (Welch Allyn, Skaneateles Falls, NY). Patients were instructed to remove their shoes before weighing at initial pre and post-test. Height was only assessed at the pre-test and measured with shoes off to the nearest 0.25 inch using the ST Scale-Tronix Portable Scale.

Blood Pressure

Blood pressure was measured manually before and after each session, primarily on the left arm as it was the arm closest to the heart. After the patient had been sitting for five minutes, the blood pressure cuff was placed on the left arm on the cuff's artery line in line with the radial artery. The sphygmomanometer was inflated up to 180 mmHg and slowly released to obtain blood pressure. Blood pressure was monitored throughout the study as a precautionary measure during OPCR. The blood pressure obtained at the pre-test walk test on the left arm was used as

the initial visit value, and blood pressure obtained on the left arm during the discharge walk was used for the post-test value.

Aerobic Fitness

The 6-minute-walk test determined aerobic fitness, a submaximal hallway walking test commonly used in cardiac and pulmonary patients to evaluate exercise capacity [103]. This test represents the patient's actual ability to perform activities of daily living [104]. The 6-minute-walk test has demonstrated validity supported by the linear relation to maximum METs ($r = 0.687$, $p < 0.001$) [105, 106] and test-retest reliability with an intraclass correlation = 0.97 [106]. Before the test began, patients were instructed to walk at a pace that the participant could maintain for 6-minutes. Participants completed the 6-minute walk test indoors on a tiled floor which was premeasured to 100 ft from the starting point to the end of the hallway. Every turn in the hall was marked at the end of the 6-minutes. Marks determine the distance traveled in 6-minutes. With the COVID-19 guidelines, patients were required to wear masks while performing this test. The test was performed at pre and post-test and supervised by one of the clinicians. The outcome from this assessment was distance walked in feet.

Dietary Recall

Clinicians provided each participant a "rate your plate" (RYP) to fill out in their admission packet and graduation packet. The "rate your plate" measured how heart-healthy the participants' diet was. The questionnaire utilized 24 questions focused on fat and sodium intake. The questionnaire broke down scores into three categories. Scoring between 24 to 40 indicates, "there are many ways you can make your eating habits healthier," 41 to 57 "there are some ways you can make your eating habits healthier," and 58 to 72 "you are making healthy choices." The higher the score, the more heart-healthy the diet. Previous research established validity (ICCs

were 0.788 for energy intake and 0.905 for protein) and reliability (ICC for energy and protein were 0.904) [107].

Psychological Need Satisfaction Scale

To assess the basic psychological need satisfaction, a 21-item measure was used, which evaluated the satisfaction of autonomy (e.g., "I feel I am free to decide for myself how to live my life"), relatedness (e.g. "I get along with people I come in contact with"), and competence (e.g., "Most days I feel a sense of accomplishment from what I do"). Items were rated on a 7-point Likert scale ranging from 1 (*not true at all*) to 7 (*very true*). The reliabilities of autonomy, competence, and relatedness scales were .81, .85, and .82, respectively [108].

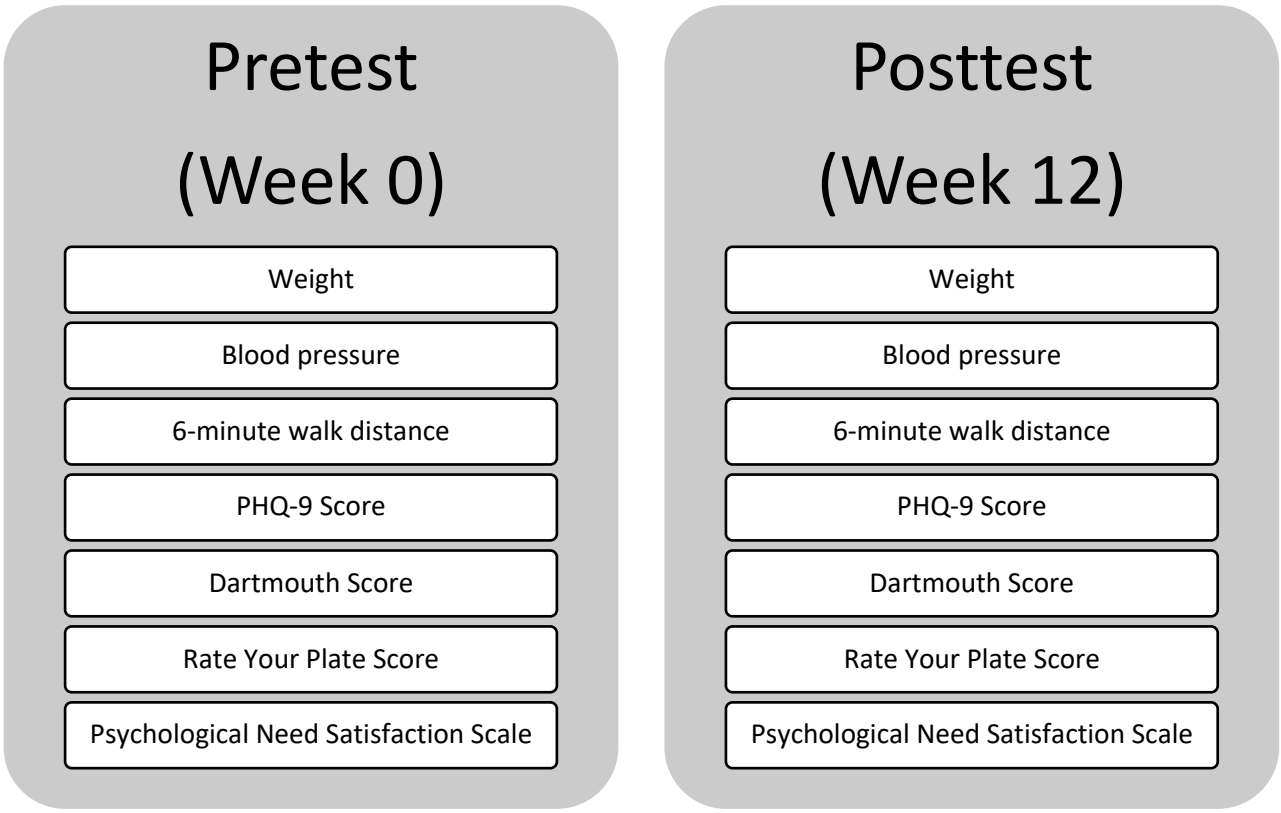
Patient Health Questionnaire

Depressive symptoms were assessed using a 9-item measure that evaluated the severity of depressive symptoms of the last two weeks. Scores for this survey range from 0 to 27. Each of the 9 items can be scored from 0 (*not at all)* to 3 *(nearly every day)*. Previous research showed the internal reliability of the PHQ-9 with a Cronbach's alpha of 0.89 [109].

Dartmouth Cooperative Functional Assessment Charts

Quality of life was assessed using a 9-item measure which evaluated physical function, daily activities, pain, social activities, social support, feel, overall health, change in health, and quality of life. Scores range from 9 to 45 scored by a five-point ordinal scale ranging from 1 to 5 (1 = optimal). Previous research showed the test- retest reliability ranged from 0.93 to 0.99 [110]. Validity was reported that the mean convergent validity correlation was 0.60 and discriminant validity correlation was 0.16 [111].

Figure 1. Data collection time points



Intervention

All participants participated in standard OPCR in line with the guidelines required by AACVPR as a certified OPCR clinic [112]. The sessions consisted of two or three 30 minutes exercise sessions per week up to 36 sessions. These sessions consisted of aerobic activities such as walking, bike riding, and resistance exercises when appropriate, balance, and functional training exercises. All exercises were prescribed by a clinical staff made up of exercise physiologists and cardiac nurses. Additionally, every Monday, the clinician provided education about physical activity and exercise. On Wednesdays, a registered dietitian came to talk to the groups about different topics, and Fridays, the education focused on psychosocial aspects

Participants were randomized into one of three communication styles. Randomization occurred by sequentially numbered sealed envelopes. The envelopes were prepared by another researcher who used a computer-based random number generator. Patients were randomized into one of the following groups:

1) *Traditional OPCR (control)*: Approximately 6 face-to-face interview sessions lasting 10-15 minutes took place every other week (total potential dose = 60- 90 minutes). These interview sessions were structured to answer questions regarding education that week. Goals and goal setting were not discussed, nor were participants given goal sheets. The purpose of this style was to blind participants from differentiating group assignments. Each session was audio recorded for fidelity checks and took place in the OPCR clinic setting. A physical activity log was provided at each interview session and asked to return at the following interview.
2) *OPCR+MI*: participants attended a standard OPCR program as described above. In addition, participants assigned to this group participated in motivational interviews once every other week for approximately 15 minutes (total potential dose = 90 minutes). A clinical exercise physiologist (EP) previously trained in motivational interviewing and facilitated MI training sessions conducted all MI interviews. The interview sessions' content included medication adherence, physical activity/exercise, or nutrition. The EP facilitated and encouraged self-motivated goal setting while providing feedback. Each MI session was audio-recorded and took place in the OPCR clinic setting. The audio recordings were used to determine intervention fidelity. In each session, goal forms were filled out and provided to remind participants of what was discussed in the session and their goals for that week (Appendix D). A physical activity log was provided at each interview session and asked to return at the following interview.

3) *OPCR- CCP*: Patients participated in the standard OPCR program as described above. In addition, participants assigned to this group participated in clinician-centered interviews once every other week for approximately 15 minutes (total potential dose = 90 minutes). The interviews discussed medication adherence, physical activity/exercise, nutrition, and how these topics impact their risk factors (cholesterol, blood pressure, diabetes management, and weight). The EP predetermined the topic, and the EP determined a realistic goal for the patient. During the interviews, the researcher and participant discussed the importance of the goal, how it would help their behavior change, and how their current behavior influenced their health (i.e., salt intake increasing blood pressure). The researcher provided the same goal form utilized in the MI sessions; however, it was pre-filled out, and participants were instructed to sign and acknowledge they accepted the goal. These discussions eliminated the participants' autonomy and collaborative process. The researcher provided a physical activity log at each interview session, and participants were instructed to return the form at the following interview. The purpose of this group was the minimize autonomy while providing face-to-face interactions. Each interview was audio recorded for intervention fidelity checks and took place in the OPCR clinic setting.

See Table 2 for the MI criteria and Table 3 for interview session details.

Table 2. Motivational Interviewing Skills and Examples

Motivational Interviewing Skill	Description	Example
Agenda Setting	A guide to finding out where the person wants the conversation to go.	Today we can discuss medication adherence, nutritional habits, or physical activity. Which would you prefer to discuss first?
Assessing Readiness	Used to tell clinician about motivation but also elicits change talk.	On a scale of 1 to 10, with 1 being not at all ready and 10 being extremely ready, how would you rate your readiness to cut back on your smoking?
Ask Open-Ended Questions	These questions allow more room for the patient to respond.	What questions do you have for me about tobacco cessation?
Ask permission to give information.	Honors patient autonomy and active involvement in their care.	Do you mind if I share with you some information regarding tobacco uses on blood pressure?
Developing Discrepancy	Allows for the patient to recognize the importance of change.	On the one hand, you understand the importance of tobacco cessation, but your current stress level is interfering with the goal of quitting?
Evoking Change Talk	The clinician asks questions to elicit change talk from the patient; the patient hearing him/herself express change talk predicts taking action.	If you could, imagine successfully cutting back on smoking, stress management, and increasing physical activity. What benefits do you see, and how does that make you feel?
Expressing Empathy	Allows the patient to feel that they are being understood and respected.	It sounds like this event has been a very stressful time in your life and impacted your tobacco use.
Establishing Understanding of Risk/Susceptibility	Determine what the patient knows/understands about the situation.	Tell me what you have been told about tobacco use and how it affects your health.
Incremental Change	Small changes are more successful in behavior changes.	In what ways have you thought about slowly cutting back on the number of cigarettes you smoke each week?
Rolling with Resistance	Avoid arguing and the feeling of attacking the patient.	It is your decision if you want to decrease your tobacco use or not. In the future, if you have any additional questions, I am always available.
Supporting Self- Efficacy	Enhance their personal beliefs of their behavior.	That's great you are down to one pack per day!

Table 3. Intervention Timelines

Time Point	Motivational Interviewing Group		Clinician Centered Perspective Group		Control Group	
	Action	**Duration and Delivery**	**Action**	**Duration and Delivery**	**Action**	**Duration and Delivery**
Week 0	Pre-Testing Variables: Weight, 6-minute walk test, and collection of the admission packet.	60 minutes OPCR Clinic	Pre-Testing Variables: Weight, 6-minute walk test, and collection of the admission packet.	60 minutes OPCR Clinic	Pre-Testing Variables: Weight, 6-minute walk test, and collection of the admission packet.	60 minutes OPCR Clinic
Week 1	Discuss their cardiac event and their thoughts/feelings regarding it.	15 minutes OPCR Clinic	Discuss the cardiac event which brought them to OPCR	15 minutes OPCR Clinic	Discuss the cardiac event which brought them to OPCR.	10 minutes OPCR Clinic
Week 3	Discus their choice for modifiable risk factors and set PA goals.	15 minutes OPCR Clinic	Provide a predetermined goal for behavior.	15 minutes OPCR Clinic	Discuss education and answer any additional questions.	10 minutes OPCR Clinic
Week 5	Discuss their choice of modifiable risk factors.	15 minutes OPCR Clinic	Provide predetermined goals for behavior.	15 minutes OPCR Clinic	Discuss education and answer any additional questions.	10 minutes OPCR Clinic
Week 7	Progress update regarding weight, blood pressure, and MET levels.	15 minutes OPCR Clinic	Obesity-related issues and behaviors to promote weight loss.	15 minutes OPCR Clinic	Discuss education and answer any additional questions.	10 minutes OPCR Clinic
Week9	Discus their goal from the previous week and barriers if applicable.	15 minutes OPCR Clinic	Provide a predetermined goal for behavior.	15 minutes OPCR Clinic	Discuss education and answer any additional questions.	10 minutes OPCR Clinic
Week 11	Discuss their goal from the previous week and barriers, if applicable.	15 minutes OPCR Clinic	Provide a predetermined goal for behavior.	15 minutes OPCR Clinic	Discuss education and answer any additional questions.	10 minutes OPCR Clinic
Week 12	Post-Testing Variables: HCCQ, Weight, Blood pressure, 6-minute walk test, and collection of graduation packet and discuss results of discharge assessments.	60 minutes OPCR Clinic	Post-Testing Variables: HCCQ, Weight, Blood pressure, 6-minute walk test, and collection of graduation packet discuss results of discharge assessments.	60 minutes OPCR Clinic	Post-Testing Variables: HCCQ, Weight, Blood pressure, 6-minute walk test, and collection of graduation packet discuss results of discharge assessments.	60 minutes OPCR Clinic

Motivational Interviewing Training

For interventionists in this study, MI training included the equivalent of a two-day interactive overview and skills development training in a small group and continued follow-up exposures to MI applications over 12 weeks. This training time has been described as adequate for base-level skills uptake and feasibility [86, 113, 114]. The training included at least two rounds of case-based role play with MI expert facilitation and feedback/coaching, which MI originator William Miller asserts is a key strategy in effective MI training [86]. The small group role play allowed two turns to practice, get feedback and coaching, and reinforce MI skills development. Training also included two turns serving as the patient, helping to develop a person-centered perspective. The small roleplay group also gave immediate feedback to their peer, which helps to reinforce skills development for the observer/evaluator trainee in a roleplay turn.

At post-training, MI skills competence was assessed using the validated Motivational Interviewing Treatment Integrity (MITI) instrument, validated for the specific MI training model applied for the study interventionist [115]. The MITI was used to assess intervention fidelity in the study implementation phase by evaluating a random sample of the audio recordings of actual patient encounters.

Intervention Fidelity

All interviews were audio-recorded and screened to ensure that each interview contained content related to their randomized group. Fidelity was determined by selecting 10% of recordings at random to ensure quality. An expert in the field using the MITI assessed the quality of MI's principles across the relational and technical dimensions of MI. Reliability and validity

for the MITI were established through previous research and reported as internal consistency, which was 0.78 [116].

Data Analyses

A chart describing research questions, variable measurements, and appropriate statistical analyses can be found in Figure 2. A power analysis was completed a priori to determine sample size using G* Power 3.1. A minimum of 66 total participants, 22 participants per group, were necessary to achieve a power of 0.818 and effect size of f = 0.40 with a significant level set to 0.05 [117].

Data analyses were conducted using SPSS (Statistical Package or the Social Sciences, version 27, IBM). Descriptive statistics were used to describe participants' characteristics. All data were screened for assumption violation. Levene's test was produced to determine homogeneity of variance. Cronbach's alpha was determined for survey data.

An ANOVA was used to determine if a difference between groups at the initial visit were present. A Mixed ANOVA was used to determine if a difference in 6-minute walk test distances (ft), rate your plate scores (28-72), weight (lbs.), PHQ-9 scores (0-28), Dartmouth scores (9-45), blood pressure (mmHg) were different between groups and within groups. Group assignment (control, MI, CCP) served as the between factor, and time [pre-test and post-test] served as the within factor. 6-minute walk test distance, Blood pressure, Rate Your Plate, PHQ-9, and Dartmouth scores were all measured from the admission packet, and graduation packet gathered at pre-test and post-test. Minutes of physical activity per week were measured with the self-report logs provided to participants to fill out while not at OPCR. Following the intervention, an ANOVA determined score differences in autonomy support by group measured by the PNSS and was used to determine if group allocation influenced program adherence. Though not a random sample, participants were randomly assigned to one of the three groups.

Figure 2. Research questions, variables, and analyses

Research Questions	Variable Measured	Statistical Analysis
1. Does motivational interviewing, compared to a clinician-centered perspective and control, affect outcomes in OPCR patients?		
a. Rate Your Plate	Rate your plate score; pre and post	Mixed ANOVA – rate your plate scores at post-intervention
b. Weight	Weight pre and post	Mixed ANOVA – weight post-intervention
c. PHQ-9 Score	PHQ-9 score; pre- and post-intervention.	Mixed ANOVA - PHQ-9 score post-intervention
d. Dartmouth	Dartmouth score; pre- and post-intervention	Mixed ANOVA – Dartmouth score post-intervention
e. Blood pressure	Blood pressure; pre- and post-intervention.	Mixed ANOVA - Blood pressure post-intervention
f. Physical Activity	Physical activity- minutes of physical activity and 6-minute walk test.	Mixed ANOVA –minutes of physical activity per week and 6-minute walk test distance at discharge
g. Program Adherence	Number of sessions completed	ANOVA: number of sessions completed out of 36
2. Does one group experience more perceived autonomy than the other?	Psychological Need Satisfaction Scale	ANOVA: groups scores after intervention.

V. RESULTS

The effect of Motivational Interviewing and Clinician Centered Interviewing on Cardiac Rehab Core Component Outcomes: A Randomized Controlled Trial

Keywords: Motivational Interviewing; Cardiac Rehab; Core Components

Introduction

Participation in outpatient Cardiac Rehabilitation (OPCR) following cardiac events is beneficial for multiple outcome variables. However utilization of the program has been low with only 24-50% of the patients enrolled in Cardiac Rehabilitation completing the recommended 36 sessions [118]. Reported reasons for dropout have included: low perception of health and ability [119, 120], schedule conflicts [119], transportation and distance to clinic [119-121], depression [120], lack of social support [120] and other co-morbidities [121]. Recent studies have reported that the addition of Motivational Interviewing (MI) to Cardiac Rehabilitation programs increases adherence, positively affects other core component outcomes, and mediates some of the common causes of dropout [39].

MI focuses on the patient's values, respects their autonomy and opinions to motivate their behavior change, as well as being a person-centered communication technique [86]. Previous clinic trials in OPCR show the MI group reported an increase in physical activity [33], weight reduction [31], increase in 6-minute walk test distance [38], depressive symptoms reduction [37, 38], and improvement in the perception of quality of life [32, 38, 92]. Furthermore, MI research in OPCR patients reported greater success when participants were included in their care plan compared to control groups [32, 39]. Although these finding are promising there are research gaps concerning MI as a method to enhance OPCR outcomes such as the effect of MI on dietary intake which is a key behavioral focus of OPCR. Furthermore, research has also reported when

patients spend more time talking to clinicians, without a specific interview/ communication technique, similar benefits were found [31, 40]. Indeed, Lynggaard et al. and Pietrabissa et al, had similar outcomes with differing communication techniques. Lynggaard et al, assigned his participants to standard OPCR and standard OPCR + additional education which focused on learning about heart disease and coping strategies to promote living with heart disease [40]. Pietrabissa et al, randomly assigned participants into two groups, standard OPCR + MI and standard OPCR, both groups were interviewed once per week for 30 to 45 minutes[93]. Both studies found increased adherence and reductions in weight and depressive symptoms for the experimental groups with additional clinician communication. Therefore, it is unclear if it is the interaction between patient and clinician alone, or a specific communication technique such as MI influences changes in OPCR outcomes. Therefore, the purpose of this clinical trial was to examine the impact of MI as well as a clinician centered interviewing on changes in core components of OPCR. As understanding adherence is a goal of our study, we also examined differences in baseline core component scores between those who adhered to OPCR and those who dropped out, as well as, differences in dropouts between experimental groups.

Methods

Participants were recruited from one Cardiac Rehabilitation center that served local and rural areas of East Alabama. A total of 89 patients out of 90 were eligible to participate in the study. One patient declined to participate. Eligibility for this study included an order for OPCR signed by a cardiologist, sufficient literacy skills to fill out paperwork and a willingness to participate. See Consort diagram for details (Figure 1).

A full-board research protocol application was submitted to the East Alabama Medical Center (EAMC) Institutional Review Board for Research Involving Human Subjects (IRB). Following the approval of EAMC's IRB, this protocol was submitted to the Auburn University IRB and approved under the protocol number 20-512 EP 2011. This study was registered at clincicaltrials.gov as NCT04899752.

This study utilized a blinded RCT design. Eligible patients (n=89) were informed that if they participated, they would be randomly assigned to one of three groups which aimed to understand how communication styles can assist in core outcomes in OPCR. The 12-week intervention consisted of 36 sessions, 3 times per week (Monday, Wednesday, and Thursday/ Friday). Pre-test assessments were completed prior to the intervention and post assessments immediately followed the 12-week intervention. Assessments included: anthropometrics, blood pressure, aerobic fitness, dietary intake, depression, and quality of life. Each session began with a resting blood pressure and was followed by an individualized exercise prescription. Once every other week each participant engaged in a 15-minute interview scheduled at a time of their convenience based on their assigned group. Fifteen minutes for the interviews was selected to allow time for conversation but also respected the participants' time and ability to synthesize information. Total interview potential dose was 90 minutes across the 12 weeks for all three treatment groups.

Measures

Anthropometrics

Weight was measured to the nearest tenth of a pound using a Scale-Tronix Portable Scale (Welch Allyn, Skaneateles Falls, NY). Patients were instructed to remove their shoes prior to

weighing at initial pre and post-test. Height was only assessed at the pretest and measured with shoes off to the nearest 0.25 inch using the ST Scale-Tronix Portable Scale.

Blood Pressure

Blood pressure was measured manually before and after each session primarily on the left arm as it was the arm closest to the heart. After the patient had been sitting for five minutes, the blood pressure cuff was placed on the left arm on the artery line on the cuff in line with the radial artery. The sphygmomanometer was inflated up to 180 mmHg and slowly released to obtain blood pressure. Blood pressure was monitored throughout the study as a precautionary measure during OPCR. The blood pressure obtained at the pretest on the left arm was used as the initial visit value and the blood pressure obtained on the left arm during the discharge was used for the posttest value.

Aerobic Fitness

Aerobic fitness was determined by the 6-minute-walk test, a submaximal hallway walking test, commonly used in cardiac and pulmonary patients to evaluate exercise capacity [103].This test represents the patient's actual ability to perform activities of daily living [104]. The 6-minute- walk test has demonstrated validity supported by the linear relation to maximum METs ($r = 0.687$, $p < 0.001$) [105, 106] and test-retest reliability with an intraclass correlation = 0.97 [106]. Before the test began patients were instructed to walk at a pace that could be maintained for 6-minutes. The 6-minute walk test was completed indoors on a tiled floor, premeasured to 100 ft from the starting point to the end of the hallway. Each turn in the hall was marked and at the end of the 6-minutes the marks totaled to determine distance traveled in the 6-minutes. With the COVID-19 guidelines, patients were required to wear masks while performing

this test. The test was performed at pre and posttest and supervised by one of the clinicians. The outcome from this assessment was distance walked in feet.

Dietary Recall

Each participant was provided a "rate your plate" to fill out in their admission packet and graduation packet. The "rate your plate" measured how heart healthy the participants' diet was. The questionnaire utilized 24 questions that focused on fat and sodium intake and designed to be useful for counseling and education. The higher the score, the more heart healthy the diet. Scores were broken down into three categories. Scoring 24 to 40 indicates, "There are many ways you can make your eating habits healthier", 41 to 57 "there are some ways you can make your eating habits healthier", and 58 to 72 "You are making healthy choices". Previous research established validity (ICCs were 0.788 for energy intake and 0.905 for protein) and reliability (ICC for energy and protein were 0.904) [107].

Patient Health Questionnaire

The Patient Health Questionnaire (PHQ-9) is a 9-item measure designed to measure depressive symptoms of the last two weeks. The score ranged from 0 to 27 as each of the 9 items can be scored from 0 (*not at all)* to 3 *(nearly every day)*. The internal reliability of the PHQ-9 had a Cronbach's α of 0.89 [109].

Dartmouth Cooperative Functional Assessment Charts

Quality of life was assessed using a 9-item survey that evaluates physical function, daily activities, pain, social activities, social support, feels, overall health, change in health and quality of life. Scores range from 9 to 45 scored by a five-point ordinal scale ranging from 1 to 5 (1 = optimal). The internal reliability of this samples Dartmouth had a Cronbach's α 0.736. The returning correlation coefficients range from 0.93 to 0.99 [111].

Intervention

All participants participated in standard OPCR in line with the guidelines required by AACVPR as a certified OPCR clinic [112]. The sessions consisted of two or three 30 minutes exercises sessions per week up to 36 sessions. These sessions consisted of aerobic activities such as walking, and bike riding as well as resistance exercises when appropriate, balance, and functional training exercises. All exercises were prescribed by clinical staff made up of exercise physiologists and cardiac nurses. Additionally, every Monday education was provided about physical activity and exercise, on Wednesdays, a registered dietitian came to talk to the groups about different topics, such as eating healthy on a budget, incorporating more fruits and vegetables into the diet, and label reading, and Fridays, the education focused on psychosocial aspects.

Participants were randomized into one of three communication styles by sequentially numbered sealed envelopes. A researcher who did not have contact with the participants and used a computer based random number generator prepared the envelopes. Patients were randomized into one of the following groups:

4) *Traditional OPCR (control)*: Approximately 12 face-to-face interview sessions lasting 10-15 minutes which took place once every other each week (total potential dose = 90 minutes). These interview sessions were structured to answer questions regarding education that week. Goals and goal setting were not discussed nor were participants given goal sheets. The purpose of this style was to blind participants from differentiating group assignment. Each session was audio recorded for fidelity checks and took place in the OPCR clinic setting.

5) *OPCR+MI*: participants attended a standard OPCR program as described above. In addition, participants assigned to this group participated in interviews based on Milner's motivational interviewing techniques [86] each week for approximately 15 minutes (total potential dose = 90 minutes). The interview sessions were facilitated by a clinical exercise physiologist previously trained in motivational interviewing, who has also facilitated role play feedback and coaching in MI trainings. The content of the interview sessions was based on medication adherence, physical activity/exercise, or nutrition. The exercise physiologist facilitated and encouraged self-motivated goal setting while providing feedback. Each MI session was audio recorded and took place in the OPCR clinic setting. The audio recordings were used to determine intervention fidelity (Table 4). In each session, a goal form was filled out and provided to the patient as a reminder of what was discussed in the session and their goal for that week. A physical activity log was provided at each interview session and asked to return at the following interview.
6) *OPCR- CCP*: Patients participated in the standard OPCR program as described above. In addition, participants assigned to this group participated in clinician centered interviews once every other week for approximately 15 minutes (total potential dose = 90 minutes). The interviews discussed medication adherence, physical activity/exercise, or nutrition and how these topics impact their risk factors (cholesterol, blood pressure, diabetes management, and weight). The topic and goals were pre-determined by the exercise physiologist. During the interviews the importance of the goal and how it would help participants' behavior changes as well as going over how current behavior was influencing health (i.e., salt intake increasing blood pressure) was discussed. The same goal form utilized in the MI sessions was provided however, it was pre-filled out and participants were instructed to sign and acknowledge they

accepted the goal. These discussions eliminated the participants' autonomy and collaborative process. A physical activity log was provided at each interview session and participants were instructed to return the form at the following interview. The purpose of this group was to minimize autonomy, while providing face-to-face interactions. Each interview was audio recorded for intervention fidelity checks and took place in the OPCR clinic setting.

Motivational Interviewing Training

MI training for interventionists in this study included the equivalent of a two-day interactive overview and skills development training in a small group and continued follow-up exposures to MI applications over a 12-week period. This amount of training time has been described as adequate for base-level skills uptake and feasibility [86, 113, 114]. The training included at least two rounds of case-based role play with MI expert facilitation and feedback/coaching which MI originator, William Miller, asserts is a key strategy in effective MI training [86]. The small group role play allowed for two turns to practice, get feedback and coaching, and while reinforcing MI skills development. Training also included two turns serving as the patient, helping to develop a person-centered perspective. In addition, the small role play group participated in giving immediate feedback to their peer, which helps to reinforce skills development for the observer/evaluator trainee in a role play turn.

MI skills competence was assessed at post training using the validated, Motivational Interviewing Treatment Integrity Code (MITI) instrument, which was validated for the specific MI training model applied for the study interventionist [115]. The MITI was also used to assess intervention fidelity in the study implementation phase by using it to assess audio recordings of a random sample of actual patient encounters.

Intervention Fidelity

Fidelity measures during the intervention were employed to support claims for MI-adherent implementation. During the intervention, all participant encounters were audio recorded and about 10% were randomly selected between the three treatment groups for fidelity assessment by trained, MI experts using the Motivational Interviewing Treatment Integrity Code MITI 4.1.2[122]. Reliability and validity for the MITI were established through previous research and reported as internal consistency which was ranged from 0.60 -1.0 [115]. This fidelity measure was included because it has been previously used with the cardiac population [31].

The MITI 4.2.1 is a behavioral coding system used to monitor fidelity to MI and has two components: global scores and behavior counts. A global score entails the coder to assign a single number from a five-point scale to characterize an entire interaction. Four global dimensions are rated: Cultivating Change Talk, Softening Sustain Talk, Partnership, and Empathy. A behavior count requires the coder to tally instances of interviewer behaviors. The various behavior counts included: giving information, persuading, persuading with information, question, simple reflection, complex reflection, affirm, seeking collaboration, emphasizing autonomy, and confront.

Data Analyses

Descriptive statistics were used to describe participants' characteristics. A power analysis was completed a priori to determine sample size using G* Power 3.1. A minimum of 66 total participants, 22 participants per group, were necessary to achieve a power of 0.818 and effect size of $F = 0.40$ with a significant level set to 0.05 [117].

Data analysis was conducted using SPSS (Statistical Package or the Social Sciences,) (Statistical Package or the Social Sciences, version 27, IBM). A one-way ANOVA was

completed to examine the baseline variables of age, number of risk factors, PHQ-9, Dartmouth, RYP, BMI, WC, SBP, DBP, and 6 MW distance between those who dropped out and completed the program. A Mixed ANOVA examined the effects of the intervention on the following variables: 6-minute walk test distances (ft), rate your plate scores (range = 28-72), weight (lbs.), PHQ-9 scores (range = 0-28), Dartmouth scores (range = 9-45), and blood pressure (mmHg). Group assignment (control, MI, CCP) served as the between factor and time (pretest and posttest) served as the within factor. Alpha level was set at .05 a priori. The 6-minute walk test distance, Blood pressure, Rate Your Plate, PHQ-9, and Dartmouth scores were all measured from the admission packet and graduation packet gathered at pretest and posttest. Follow up testing included LSD post-hoc analysis. Levene's test determined homogeneity of variance. The box test was not significant indicating the use of Wilks Lambda.

Results

A total of 88 patients were randomly assigned to one of the three groups. Ages of participants ranged from 28 to 87 years old (63.15 ± 10.82). Seventy-three percent (n= 64) of the participants were male, 90.9% were white (n = 80), and the most common diagnosis of 47.7% was a CABG (n= 42) followed by PCI/STENT (n = 23), STEMI/ NSTEMI (N= 11), HFrEF (N= 4), TAVR (n= 4), and other consisting of Heart and Bilateral lung transplant and STEMI or NSTEMI leading to CABG (n = 4). Both the control (n = 30) and the CCP group (n = 30) made up 34.1% of the participant distribution and the MI group (n= 28) was 31.8%. Forty participants dropped out of the study prior to completion made up of 36.6% (n =11) from the control group, 40% (n=12) of the CCP group, and 61% (n=17) of the MI group. The main reason provided was returning to work (n = 8) followed by not interested in Cardiac Rehabilitation (n=7), COVID-19 (n=7), decline in health (n=7), family commitments (n=4), insurance issues (n=4), and distance

to clinic (n=3). Forty-eight participants remained at the end of the study. There was not a significant difference between the number of dropouts by group. Baseline comparisons by ANOVA between mean responses for dropouts and completers showed dropout participants weighed significantly more (p = .044), had a higher BMI (p = .027), and higher DBP (p = .046). See **Table 1** for between group differences.

Table 1. Core Component Characteristics by Group

	Pre	Post	95% CI Lower Bound	95% CI Upper Bound	% Change
Control					
PHQ-9	4.29 (3.29) *	2.41 (3.67) *	0.343	3.323	- 43.8%
Dartmouth	21.76 (6.04) *	16.41 (3.65) *	2.871	7.018	- 24.6%
Rate Your Plate	49.47 (6.44)	50.47 (5.94) †	-3.170	0.948	2.0%
SBP	115.76(16.01)	113.18(13.46)	-6.505	8.283	-2.2%
DBP	62.47 (8.35)	61.29 (5.83)	-4.251	5.362	-1.8%
Distance	1324.41(225.1) *	1639.64(307.86) *	-442.575	-188.014	23.8%
Weight	193.04 (39.66) *	198.05 (43.52) *	-9.518	-0.030	2.6%
CCP					
PHQ-9	3.38 (3.89)	2.44 (2.85)	-0.134	2.766	- 36.2%
Dartmouth	19.72 (4.25) *	16.50 (4.81) *	1.034	5.071	- 16.0%
Rate Your Plate	52.61 (7.71) *	57.44 (7.94) *†	-6.689	-2.680	9.2%
SBP	112.00(19.48)	111.78 (15.45)	-7.171	7.616	0%
DBP	66.22(12.15)	64.44(6.60)	-3.028	6.584	-2.7%
Distance	1477.22(343.45) *	1744.17(394.22) *	-390.639	-143.250	18.1%
Weight	198.21 (34.29)	198.19 (32.57)	-4.712	4.745	0%
MI					
PHQ-9	3.842 (3.97)	1.92 (2.11)	-0.325	3.325	-43.9%
Dartmouth	20.08 (6.186) *	16.17 (3.46) *	1.377	6.456	-19.5%
Rate Your Plate	48.5 (9.00) *	55.17 (7.59) *	-9.189	-4.145	13.7%
SBP	124.17(16.74)	121.50 14.04)	-6.389	11.722	-2.14%
DBP	66.17 (9.24)	64.50 (7.19)	-4.220	7.553	-2.5%
Distance	1356.5 (284.32) *	1655.92 (255.98) *	-450.911	-147.923	22%
Weight	186.650 (50.04)	188.15(51.78)	-7.291	4.291	1%

Negative percent change on PHQ-9 and Dartmouth indicate improvement.
* $p \leq .05$ between pre and post
† Statistically significantly different between groups

Table 2: Interactions

	Main effect of time				Time by group interaction			
	F	**p**	**n^2**	**Observed power**	**F**	**p**	**n^2**	**observed power**
PHQ-9	11.445	0.001*	0.199	0.912	0.128	0.880	0.006	0.068
Dartmouth	38.792	0.000*	0.457	1.000	0.867	0.427	0.036	0.190
RYP	43.045	0.000*	0.483	1.000	6.462	0.003*	0.219	0.886
SBP	0.303	0.585	0.007	0.084	0.091	0.913	0.004	0.063
DBP	0.803	0.375	0.018	0.142	0.077	0.926	0.003	0.061
Distance	57.983	0.000*	0.569	1.000	0.156	0.856	0.007	0.073
Weight	2.039	0.160	0.043	0.287	1.083	0.347	0.046	0.228

* denotes significance p<.05.
PHQ-9: Patient Health Questionnaire; RYP: Rate Your Plate; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure.

See Table 2 for interactions and effects of time by test. A significant test by time interaction was present for Rate Your Plate (p = .003), with the control group scoring significantly lower than the CCP group (p = 0.04). Low scores for Rate Your Plate indicates poorer diet. A significant group interaction was present for SBP, with post-hoc showing that CCP had significantly lower SBP than the MI group (p = .046). No significant difference was found between groups for PHQ-9, Dartmouth, 6 minute-walk test distance, or weight. An effect of time was found for PHQ-9 (p = .002), Dartmouth (p <.001), and the 6-minute walk distance (p < .001). The control group experienced a positive effect resulting in a significant decrease in PHQ-9 (p= .017) and Dartmouth scores (p <.001). All groups significantly increased in walk distance (p < .001)).

MI Fidelity

Table 4 presents fidelity to MI as measured by the MITI 4.2.1. Summary scores were utilized to compile the results from all interviews in each experimental group to provide a more concise manner rather than detailing each individual interview [20]. Relational scores are the

sum of both partnership and empathy global scores. Technical scores are the sum of cultivating change talk and sustaining change talk global scores. Percentage of complex reflections (%CR) is the total percentage of behavior counts for reflections that are complex as opposed to simple. Reflection-to-question ratio (R:Q) is the ratio of behavior counts of reflections compared to questions. Total MI-adherent (MIA) is the total sum of behavioral counts of seeking collaboration, affirm, emphasizing autonomy. Total MI Non-Adherent (MINA) is the sum of behavioral counts of confront and persuade. Based on expert opinions from the MITI protocol manual, the MI portion of the intervention was good for relational, technical and R:Q and fair for % CR. No recommended proficiencies are present for MIA and MINA. The control and CCP interviews did not meet the fair criteria for any of the categories. In terms of time, the MI interviews were considerably longer than the control and CCP interviews. Based on these fidelity assessments the MI portion of the interviews was adherent to MI principles.

Table 3. *Motivational interviewing proficiency compared with recommended proficiencies using the MITI 4.2.1*

Table 3. MITI Fidelity Results							
Group	Relational	Technical	%CR	R:Q	MIA	MINA	Time
Control	3.21	2.28	2%	1:0	1.2	.14	5.31
CCP	2.63	2.5	8%	2:.92	1.11	.38	6.86
MI	7.93	7.43	40%	3:2	12.6	.13	14.75

%CR=Complex reflections, R:Q=Reflection-to-question ratio, MIA=Total MI-adherent, MINA=Total MI Non-Adherent

Discussion

This study provides evidence of the effect communication styles have on Cardiac Rehabilitation core component outcomes. Based on the results of the MI fidelity, the interviewer followed the MI criteria adequately indicating MI consistent techniques. Overall structured communication styles appear to impact rate your plate scores, weight, and PHQ-9 scores.

Rate Your Plate scores, the tool used to measure dietary habits, increased across all three groups. The CCP group had significantly higher scores compared to the control group. Increases in RYP scores after Cardiac Rehabilitation is a common outcome in research when diet is being examined [123, 124]. This result indicates that the communication technique influences the behavior change. Based on the results of this study, clinician centered communication styles assists participants in enhancing dietary outcomes.

Weight in the control group increased significantly and remained the same in the CCP and MI group. The utilization of a structured communication technique appears to prevent weight gain but not promote weight loss. Similar studies showed a decrease in weight in the control and intervention group [125, 126]. As, weight measurements do not consider the type of weight gained or lost (i.e., fat mass or lean mass), further research should utilize measures to assess changes in body composition.

PHQ-9 scores decreased across all groups but only significantly in the control group. This finding demonstrates the structured communication does not influence PHQ-9 scores but communication in general does. Individuals experience depression for a wide variety of reasons. This could be due to patients feeling fewer depressive symptoms when they are able to communicate with others in general and not specifically about their depression. The PHQ-9 is an option to provide during Cardiac Rehabilitation to measure depressive symptoms. Minimal research utilizes this questionnaire. Furthermore, differences exist in depressive symptom outcomes, with some research showing no changes in depressive symptoms [92] and some finding decreases in depressive symptoms in women [37]. This could be due to women being more likely to accept social support compared to men after their cardiac events [127].

It appears that communication styles do not impact blood pressure, quality of life scores, and distance walked. Studies with similar methodological interventions did not report a reduction in SBP or DBP [92, 126]. Distance completed during the 6-minute-walk test did not differ significantly between groups. However, all groups increased significantly over time. During Cardiac Rehabilitation all participants were following the same general framework for frequency, intensity and duration for exercise and improvements may be a result of improvements in fitness. The average improvement for 6-minute-walk test distance in previous studies averaged 21% which is similar to our results for all groups with ranges between 18.1 – 23.8% [128].

The Dartmouth COOP quality of life questionnaire decreased significantly across all groups, indicating an improvement in the perception of quality of life. The utilization of structured communication techniques, such as CCP or MI, does not promote a higher perception in quality of life, however, communication in general appears to improve quality of life within a OPCR setting. This may be due to the structure of OPCR setting in that one of the main goals of Cardiac Rehabilitation is the increase the perception of quality of life and tools are provided to all patients via education materials. Within previous research, quality of life questionnaires varies between clinics and outcomes vary between studies. For example, one study that did utilize the Dartmouth COOP reported significantly lower scores after the MI intervention which contradicts this study [129], however, another study found significantly lower scores after the intervention but not between groups [92]. Further research is needed to determine the appropriate intervention within OPCR programs to improve the perception of the quality of life.

After analyzing the variables between dropout and adherence, patients with weight over 210 lbs., BMI over 32 kg/m2 and BDP above 70 mmHg pose a greater risk of dropout. This

information should be used by OPCR staff to identify participants who may be more likely to drop out and provide further intervention. Further research should examine if targeted intervention based on these variables increase adherence in OPCR.

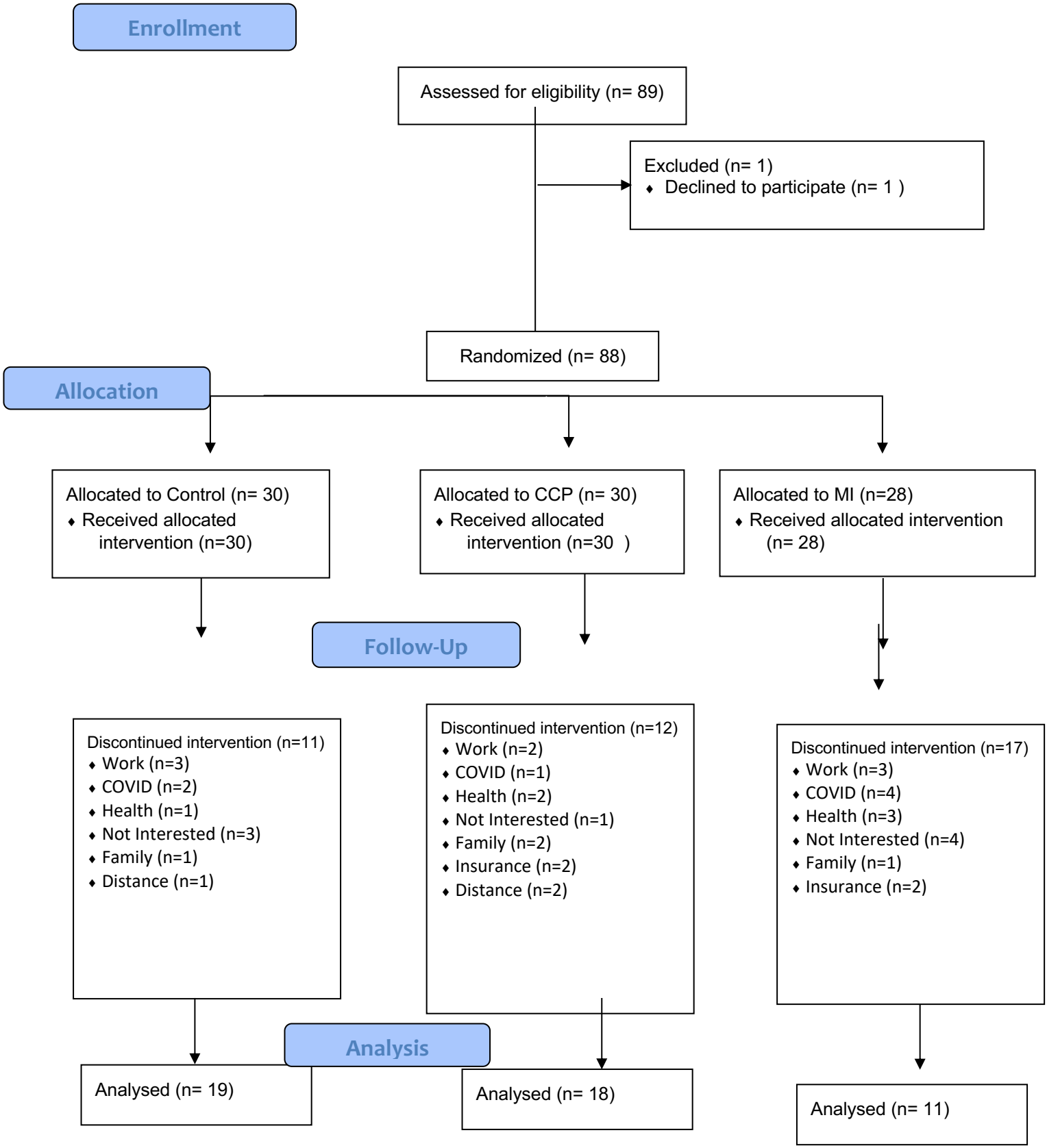
Limitations

One of the primary limitations to this study was the small sample size. Though 88 patients agreed to participate, the post-testing sample size was only 48 which was smaller than the power analysis suggested sample of 66 from G*power. Many participants dropped out not only due to COVID-19 but work commitments, health issues, and cost. The addition of interviews does not appear to overcome the barriers associated with Cardiac Rehabilitation. In addition, due to HIPPA, there was only one interviewer to conduct all the interviews, therefore, three of the participants had two weeks versus every other week between interviews at one point in the intervention, and the one interviewer changed communication style and level of autonomy support across the three study arms to avoid contamination from an MI-trained person in the CCP and control groups.

Conclusion

Based off the results above, the style of communication does not appear to impact all core component outcomes. The CCP group demonstrated favorable outcomes for Rate your Plate scores and the utilization of communication structure did prevent weight gain compared to the control group. Future studies may benefit from the importance of any form of communication with patients to improve clinical outcomes and adherence. Further research should continue examining communication styles and how to overcome barriers to adhering and improving clinical outcomes in cardiac rehabilitation.

Figure 1: Consort Flow Diagram



Determining the Impact of Motivational Interviewing on Patient Adherence with Outpatient Cardiac Rehabilitation

Keywords: Cardiac Rehab, Self-Determination Theory; Adherence

Introduction

Outpatient Cardiac Rehabilitation (OPCR) is an important part of recovery from cardiac events [16] and has clear benefits, however utilization is low with only 25% of eligible Medicare recipients enrolled [130]. Furthermore, only 50% of patients that enroll complete the program [28-30]. As such OPCR programs have investigated methods to increase utilization and adherence of the program.

Motivational Interviewing (MI) is a high autonomy supporting communication technique that has been used in cardiac OPCR to increase program adherence [39] and physical activity during cardiac rehabilitation [33]. MI is a collaborative communication approach between the interviewer and patient to promote long term behavior change by respecting autonomy and evocating values and views important to the patient to enhance motivation [23]. Table 1 shows MI principles associated with effective interviewing techniques. Based on a systematic review [131], MI has been associated with higher attendance compared to the control group following a single session of MI with a 30 – 60-minute duration at the OPCR clinic, university office or a home visit. [39]. In addition, OPCR patients showed greater success when patients were able to collaborate with the interventionist regarding the care plan compared to the control groups [32, 39]. Increases in attendance following MI have been linked to perceptions of autonomy [132], however, minimal research has examined the impact of autonomy on adherence to OPCR.

The self-determination theory (SDT) consists of three sub concepts, autonomy (having a choice), relatedness (sense of belonging with peers), and competence (sense of mastery in

performing a task). MI has been linked to SDT by autonomy which, along with relatedness and competence, are the basic psychological needs that promote optimal well-being and autonomous motivation [41, 133]. In addition, MI's guiding principles (resisting righting reflex, understand and explore patient's motivation, listen to empathetically, and empower the patient) are consistent with supporting the psychological needs outlined in SDT [134]. These concepts are important to consider in OPCR as they have been cited as reasons for dropout [119, 120].

SDT places autonomous motivation towards the intrinsic end of the motivation continuum which focuses on self-determined actions [135]. Psychological need satisfaction pertaining to exercise, and physical activity is positively associated with self-determined motivation, as well as physical activity participation [136]. Research demonstrates that adherence to physical activity is strengthened when needs for autonomy, competence and relatedness are met [137]. These concepts are important to consider when examining adherence to OPCR programs. From a theoretical perspective, when patients have a greater motivation to participate, this will lead to increased adherence and new modalities of physical activity resulting in greater perceived competence [138] as well as support patients' needs and allowing exploration of motivation to promote autonomy and relatedness. Supporting patients' psychological needs in other rehabilitation settings, such as physical therapy and occupational therapy, have shown increased adherence to the program and recommendations provided by clinicians [138].

Both MI and the SDT have been utilized to examine health behaviors by collaborating with the patient compared to coercing patients toward behavior changes [134]. Clinicians have the ability to provide an environment that can facilitate autonomy, relatedness, and competence to aid in OPCR attendance [43]. However, research has not fully examined if autonomy alone

through MI or the addition of relatedness and competence are the successful components which lead to increases in adherence among OPCR patients. Furthermore, research has not evaluated if MI or clinician centered counseling (low autonomy) compared to traditional OPCR is more effective in eliciting adherence to OPCR. For example research has found when clinicians simply spent more time talking with their patients, without following the MI structure, adherence to OPCR programs increased [40]. While the addition of MI to OPCR appears to be directly related to adherence to the program [32, 33, 38, 39, 46], it cannot be determined that it is specifically MI and not face-to-face communication and continuous engagement that is directly related to adherence. Therefore, the purpose of this randomized clinical trial is to examine the impact of a motivational interviewing intervention as well as a clinician center interview on adherence to OPCR and components of SDT.

Methods

Before recruiting participants for this intervention, a full-board research protocol application was submitted to the East Alabama Medical Center (EAMC) Institutional Review Board for Research Involving Human Subjects (IRB). Following the approval of EAMC's IRB, this protocol was submitted to the Auburn University IRB and approved under the protocol number 20-512 EP 2011. This study is registered at clincicaltrials.gov under the number NCT04899752.

A total of 89 patients were informed on the day of the Cardiac Rehabilitation orientation that they were eligible to participate in a research study. One patient declined to participate. See Consort diagram for participant flow through the study (Figure 1).

Procedures

Communication styles

Participants were randomized into one of three communications styles: control group, motivational interviewing or clinician-centered. Randomization occurred by sequentially numbered sealed envelopes. The control group's communication style did not follow any guidelines or provide any specific prompts for behavior change. The discussion was conversational in nature and aimed to provide face-to-face communication. The MI group adhered to MI communication principles outlined in Table 1. Each MI session began with agenda setting to provide autonomy for a patient guided discussion. For example, "Today we can discuss physical activity, nutrition, or medication. Which would you prefer?" The Clinician Centered Perspective (CCP) group participants were told what the topic of the conversation was going to be that day removing their perception of autonomy. The goal of this group was to provide face-to-face communication while limiting patient decision making and provide a clinician center behavior change approach. Further description of the three communications styles can be found in Table 2.

OPCR Environment

All participants participated in standard OPCR in line with the guidelines required by AACVPR as a certified OPCR clinic [105]. The sessions consisted of up to three 30 minutes exercises sessions per week for 36 sessions. These sessions consisted of aerobic activities such as walking, and bike riding as well as resistance exercises when appropriate, balance, and functional training exercises. All exercises were prescribed by clinical staff made up of exercise physiologists and cardiac nurses. Additionally, every Monday education was provided about physical activity and exercise, on Wednesdays, a registered dietitian came to talk to the groups

about different topics, and Fridays discussed psychosocial education. All groups participated in all OPCR activities.

Table 1: MI Principles and Skills

Motivational Interviewing Skill	Description	Example
Agenda Setting	A guide to find out where the person wants the conversation to go.	Today we can discuss medication adherence, nutritional habits, or physical activity, which would you prefer to discuss first?
Assessing Readiness	Used to tell clinician about motivation but also elicits change talk.	On a scale of 1 to 10, with 1 being not at all ready and 10 being extremely ready, how would you rate your readiness to cut back on your smoking?
Ask Open-Ended Questions	These questions allow more room for the patient to respond.	What questions do you have for me about tobacco cessation?
Ask permission to give information	Honors patient autonomy and active involvement in their care.	Do you mind if I share with you some information regarding tobacco uses on blood pressure?
Developing Discrepancy	Allows for the patient to recognize the importance of change.	On one hand you understand the importance of tobacco cessation, but your current stress level is interfering with the goal of quitting?
Evoking Change Talk	Clinician presents the case for change.	If you could, imagine successfully cutting back on smoking, stress management, and increasing physical activity. What benefits do you see and how does that make you feel?
Expressing Empathy	Allows the patient to feel that they are being understood and respected.	It sounds like this event has been a very stressful time in your life and has been impacting your tobacco use.
Establishing Risk	Determine what the patient knows/understands about the situation.	Tell me what you have been told about tobacco use and how it effects your health.
Incremental Change	Small changes are more successful in behavior changes.	In what ways have you thought about slowly cutting back on the number of cigarettes you smoke each week?
Rolling with Resistance	Avoid arguing and the feeling of attacking the patient.	It is your decision if you want to decrease your tobacco use or not. In the future if you have any additional questions, I am always available.

Supporting Self-Efficacy	Enhance their personal beliefs of their behavior.	That's great you are down to one pack per day!

Table 2. Description of experimental groups

	Number of potential interviews	Duration	Potential Dose	Audio Recorded	Topics Discussed	Goal Sheet provided	Goal pre-determined	Overall Description
Control	6	10-15 minutes	60-90 minutes	Yes	Weekly Education	No	N/A	No set structure or topic
CCP	6	10-15 minutes	60-90 minutes	Yes	Relevant Risk factors	Yes	Yes	Set structure and topic
MI	6	10-15 minutes	60-90 minutes	Yes	Patients' choice	Yes	No	Set structure no set topic

Psychological Need Satisfaction Scale

The psychological need satisfaction scale (PNSS) survey was given at the orientation appointment and at the discharge assessment appointment to assess changes in autonomy, relatedness, and competence over the intervention. The survey is a 21-item survey that evaluates the need satisfaction of autonomy ("I feel I am free to decide for myself how to live my life"), relatedness ("I get along with people I come in contact with"), and competence ("Most days I feel a sense of accomplishment from what I do"). Items were rated on a 7-point Likert scale ranging from 1 (*not true at all*) to 7 (*very true*). The minimum and maximum scores for each subscale range based on the number of questions per category. The competence subscale includes 6 questions with scores ranging from 6 to 42. The autonomy subscale includes 7 questions with a range of scores from 7 to 49. The relatedness subscale includes 8 questions with scores ranging from 8 to 56.

The previous reliabilities of autonomy, competence, and relatedness scales were .81, .85, and .82 respectively [102]. Chronbach's alpha values for this study are autonomy α= .64, relatedness α=.85, competence α= .36 and the overall survey α= .845.

Attendance Measures

Attendance to exercise sessions were recorded at each session. It was determined by the number of total completed sessions out of the possible 36 sessions covered.

Motivational Interviewing Training

MI training for interventionists in this study included the equivalent of a two-day interactive overview and skills development training in a small group and continued follow-up exposures to MI applications over a 12-week period. This amount of training time has been described as adequate for base-level skills uptake and feasibility [86, 113, 114].

Intervention Fidelity

All interviews were audio-recorded and screened to ensure that each interview contained content pertaining to their randomized group. To determine fidelity, 10% was selected at random to ensure quality. The quality of MI's principles and approach was assessed by an expert in the field using the Motivational Interviewing Treatment Integrity Code (MITI). Reliability and validity for the MITI were established through previous research and reported as internal consistency which was ranged from 0.60 -1.0 [115]. This fidelity measure was included because it has been previously used with the cardiac population. Summary scores were utilized to compile the results from all interviews in each experimental group to provide a more concise manner rather than detailing each individual interview [20]. Relational scores are the sum of both partnership and empathy global scores. Technical scores are the sum of cultivating change talk and sustaining change talk global scores. Percentage of complex reflections (%CR) is the total

percentage of behavior counts for reflections that are complex as opposed to simple. Reflection-to-question ratio (R:Q) is the ratio of behavior counts of reflections compared to questions. Total MI-adherent (MIA) is the total sum of behavioral counts of seeking collaboration, affirm, emphasizing autonomy. Total MI Non-Adherent (MINA) is the sum of behavioral counts of confront and persuade. Based on expert opinions from the MITI protocol manual, the MI portion of the intervention was good for relational, technical and R:Q and fair for % CR. No recommended proficiencies are present for MIA and MINA. The control and CCP interviews did not meet the fair criteria for any of the categories. In terms of time, the MI interviews were considerably longer than the control and CCP interviews. Based on these fidelity assessments the MI portion of the interviews was adherent to MI principles.

Data Analysis

Data analysis was conducted using SPSS (Statistical Package or the Social Sciences, version 27, IBM). G*power indicated a required sample size of 66, 22 per group [117]. Probability values of $p < 0.05$ were deemed significant. A MANOVA examined the differences in Autonomy, Relatedness, and Competence subcategories of the Physiological Needs Satisfaction Survey between groups post intervention. Following the MANOVA, a stepwise linear regression was completed to determine subcategory scores that predict number of Cardiac Rehabilitation sessions attended.

Results

Of the 88 participants who started the intervention only 17 participants returned the surveys at baseline and 36 post intervention (Table 3). Both the control (n = 30) and the CCP group (n = 30) made up 34.1% of the participant distribution and the MI group was 31.8(n= 28). Forty participants dropped out of the study prior to completion. From the control group 11

dropped out, 40% (n=12) of the CCP group, and 61% (n=17) of the MI group. Due to the limit response at baseline, only post intervention data was analyzed. The MANOVA results did not reveal significant differences among the groups on the dependent variables, PHQ-9, Dartmouth, RYP, SBP, DBP, distance walked and weight (Table 4). A significant difference was not found in the subcategories of the Psychological Needs Satisfaction Scale. The step wise linear regression utilizing post-intervention data indicated that competence was the only subcategory to predict session adherence. Competence subscale scores above 25 decreased the number of predicted sessions attended. Competence explained 14.5% of the variance in sessions attendance. See Table 5 for regression data.

Table 3. Post-intervention subscale results

Pre	Control (n=3)	CCP (n=9)	MI (n=5)	Total (n=17)
Post	Control (n=12)	CCP (n=13)	MI (n=11)	Total (n=36)
Autonomy				
Pre	42.00 (8.88)	36.11 (5.97)	41.4 (4.16)	38.71 (6.33)
Post	39.08 (4.36)	37.00 (5.46)	38.19 (3.17)	38.19 (4.47)
Relatedness				
Pre	44.67 (10.01)	48.22 (8.21)	45.20 (4.44)	46.71 (7.35)
Post	49.50 (3.66)	48.08 (6.56)	48.27 (5.82)	48.61 (5.39)
Competence				
Pre	25.00 (1.73)	28.67 (6.48)	27.40 (3.51)	27.65 (5.14)
Post	29.17 (5.10)	29.77 (5.57)	29.64 (3.61)	29.53 (4.75)

Note: Numbers in parenthesis show differences in the number of pre and post surveys returned

Table 4.

	F	*P*	$\eta_{p\,2}$	Power
Autonomy	.746	.482	.043	.166
Relatedness	.238	.790	.014	.084
Competence	.051	.950	.003	.057

Table 5. Stepwise Linear Regression

	Unstandardized B	Coefficient Std. Error	t	*p*
Constant	45.789	4.798	9.543	<.001
Post-Competence	-.386	.160	-2.406	.022

Discussion

This study aimed to identify differences in autonomy, competence and relatedness as well as identify which of the three psychological needs impacted adherence to OPCR when different communication styles where utilized. Our results show autonomy, competence and relatedness did not differ between communication techniques and that competence was important to OPCR adherence.

Previous research has demonstrated a link between MI and SDT. Both focus on a person-centered structure to promote an optimal climate for behavior change [139]. MI focuses on autonomous aspects of motivation as well as providing an environment to promote relatedness by minimizing judgement and encouraging new knowledge to increase competence [134, 140]. Minimal research examining psychological factors in OPCR as well as other health behaviors following MI based intervention have been conducted. A MI intervention conducted by Boiche et al. aimed to increase psychological needs through face-to-face interviews. Participants in the intervention group were provided face to face interviews that focused on the psychological needs in addition to exercising, whereas the control group met each morning to exercise in a group setting based on fitness level. The results showed both groups perceived increases in autonomy, integrated and intrinsic motivation, as well as reported increases in relatedness for the control group [141].

Another study examining the components of the SDT following a motivation based intervention, not specifically mentioning MI but focusing on autonomy, reported improvements in relatedness and competence compared to the control group [142]. In terms of MI specifically within OPCR settings, the minimal studies utilizing MI report differences in autonomy, which is not consistent with our findings [143]. In fact, for our study the reported perception of autonomy decreased following the intervention in the MI group, although this assessment is limited by the

lack of survey completion at baseline. This may be due to some patients are not given the choice to participate in OPCR but are forced by family members or strongly encouraged by physicians [144, 145]. Therefore, this unmeasured external factor could influence the results diminishing autonomy support regardless of group assignment [146].

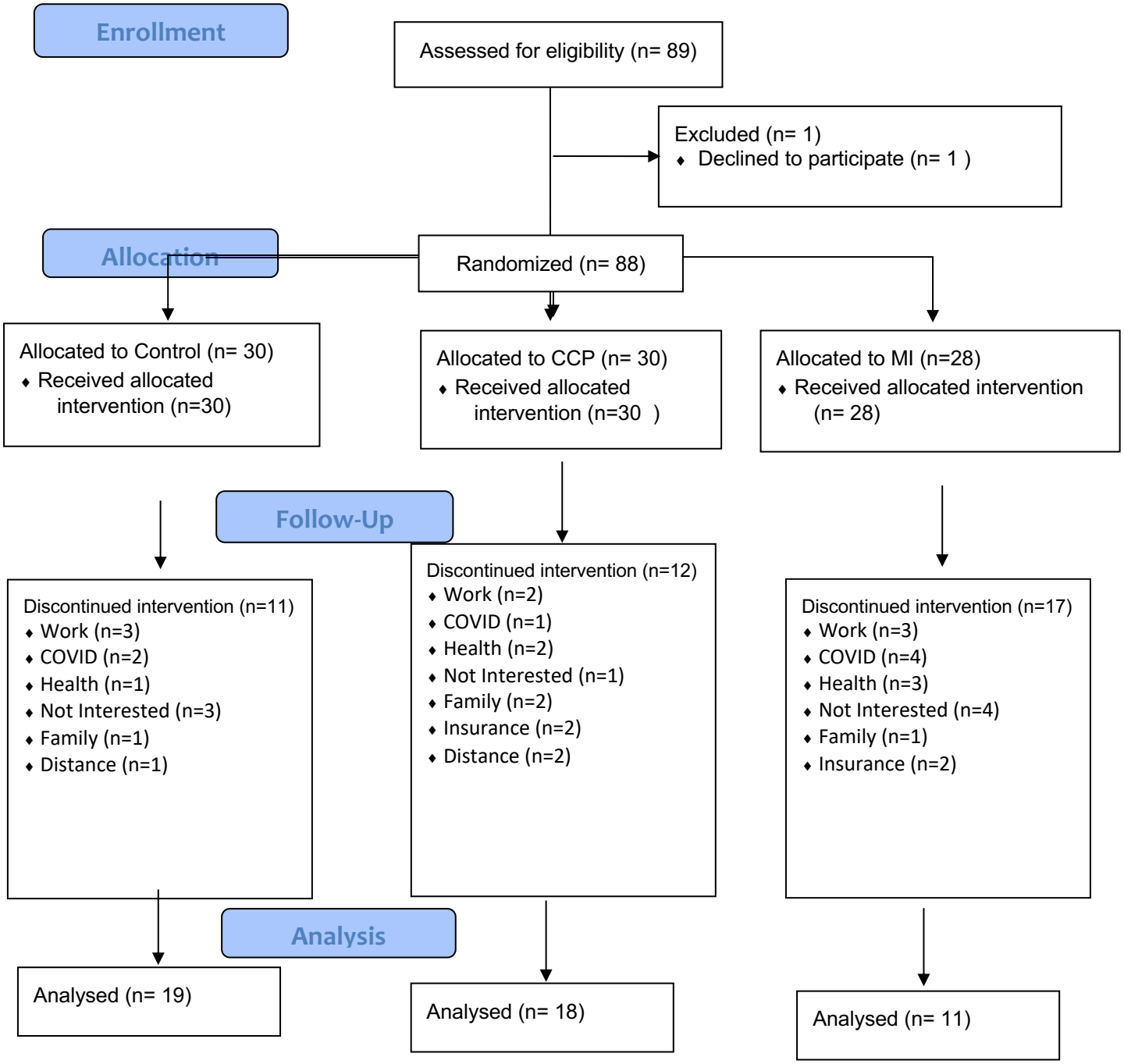
Our method of MI delivery may have also impacted changes in the three psychological needs. In related literature, MI has been provided in a variety of ways including via video chat, telephone sessions and face-to-face interactions. It has been reported that a mix of face-to-face interactions and telephone interviews has been successful for increasing adherence [37, 38, 147]. As this research utilizing only face-to-face interactions, more research in OPCR only utilizing face-to-face MI interviews is needed to understand how MI changes participants' perception of autonomy.

Research is clear that when autonomy, relatedness and competence is perceived it encourages adherence to exercise and physical activity [148, 149]. Competence was the only variable that significantly influenced number of sessions attended and higher competence decreased OPCR adherence. Previous research has shown that need satisfaction for competence and relatedness were important in the adoption phase of physical activity [150]. Cardiac rehabilitation is designed to educate, demonstrate, and reinforce the importance of physical activity and exercise. Individuals with a higher competence towards physical activity and exercise may not view cardiac rehabilitation as a necessity due to their perceived skill level [120]. Though the competence scores only made up a small percentage of variance, clinicians can utilize this information to form an exercise prescription that the patients will view as beneficial and eliminate the potential risk of higher perceived competence that elicits dropout.

Limitations to this study include the use of a convenient sample of cardiac patients from one program recruited over a four-month period. Due to the low response rate an adequate sample was not available. Of the 66 participants required by the a priori power analysis, only 24% responded at baseline and 55% post intervention to complete the survey. Data for this study was collected during the first wave of COVID-19. Due to lack of baseline return pre and post comparisons were unable to be made. Therefore, only post intervention data was used to determine differences between groups.

Many studies have demonstrated some factors that influence adherence in older adults include mobility issues, psychosocial, environmental, routines disruption, and motivation [151, 152]. Determining factors that affect adherence to cardiac rehabilitation programs are necessary due to the low participation and adherence rates [144]. Some of the stated barriers to adherence can be nurtured under one of the three subcategories of the SDT. The results of this study show that competence may be a key factor in continued OPCR participation. Clinical staff should evaluate each patient's perception of their skill level regarding physical activity to promote adherence to OPCR. By doing this, realistic expectations can be made and supported by clinicians. Additional studies with larger populations examining more psychosocial barriers should be conducted. Understanding the factors that promote motivation and adherence within the cardiac population is vital in facilitating adherence to OPCR programs.

Figure 1. Consort Flow Diagram



V. Discussion

Research has demonstrated the influence communication with patients has on adherence to cardiac rehabilitation programs as well as the core components measured during these programs [37, 93, 94]. To our knowledge, there have not been interventions looking at more than one communication technique to improve adherence and core component outcomes in cardiac rehabilitation programs. Most patients receive a clinician centered form of communication, with low autonomy. Previous research utilized one communication style and did not account for face-to-face interactions, nor low autonomy communication styles. Therefore, the comparison of three communication techniques were critical to reduce gaps within the current literature. Since MI requires strict criteria to be followed to be considered MI, the fidelity check deemed the interviewer displayed adequate technique.

Based on previous research, between 30%-50% of patients enrolled in cardiac rehabilitation will complete the program [28, 29]. Research provides evidence for a variety of reasons patients have for not adhering to cardiac rehabilitation [153]. Something to consider with these results as well is the complications from the COVID-19 precautions and required protocols. Most research in this field has been done prior to COVID-19, due to the severity of the consequences and actions required to prevent the spread, the impact of care in the outpatient setting is unknown. This study provides evidence regarding the impact of communication with patients on adherence to cardiac rehabilitation and improvement of core component outcomes during the COVID-19 pandemic.

During March 2020 East Alabama Medical Center shut down the Cardiac Rehabilitation clinic. This shut down was the response of a national emergency caused by the COVID-19 pandemic. Upon re-opening, in May 2020, only 24 patients were allowed to be seen per day, compared to 72 patients per day prior to the COVID-19 shut down. To this day (Sept. 2, 2022),

there are continuous changes being made to prevent the spread of COVID-19. Many health care facilities closed their outpatient services and are unable to open their doors two and a half years after the pandemic began. It is not a surprise that adherence to the programs that are operating are still low even though there was an increase in cardiac related hospitalization during the shutdown. For our study 17.5% of the patients that participated dropped out due to concerns of COVID-19. Future research would benefit from examining the feasibility of home-based cardiac rehabilitation for those that should not be surrounded by others due to being at a high risk of mortality and who fear the potential consequences of COVID-19. Other aspect that are needed to be considered included vaccination status, comorbidities, and exercising in masks.

The results of this study showed that adherence to cardiac rehabilitation did not differ significantly between groups. Previous studies reported the use of MI in RCTs significantly increase adherence and session attendances compared to controls [38, 94, 154]. Comparing this intervention to others is challenging due to the addition of COVID-19 and the impact it plays on high-risk populations. The different communication techniques did not impact session attendance, blood pressure, walk test distance, quality of life scores and depressive symptom reduction. Structured communication was shown to prevent weight gain and encourage positive changes to nutritional habits. A point to note is the core component surveys (Dartmouth and PHQ-9) which assess health related quality of life and depressive symptoms respectively, are focused on feelings which did not differ by group. This result indicates that structured communication techniques do not influence core component survey results. The RYP survey measures eating behavior did differ by group. This indicates that structured communication techniques do influence behavior change. This finding can guide clinicians when to use structured communication techniques and when general conversation is adequate.

In addition to adherence and core components, the Self Determination Theory's three psychological needs of competence, autonomy, and relatedness were examined. The results of this study were surprising as the MI group did not have a higher perception of autonomy compared to other groups. The perception of having the choice to make decision is important for promoting adherence but is not typically a component of OPCR[42, 155]. Lack of changes in autonomy may be due to the driving factors for enrollment, primarily enrollment is due to a medical event that the patient did not specifically choose to happen. Furthermore, it may not be the patient's choice to enroll, or their lack of autonomy, but an influence from medical personnel, family members or friends.

This type of motivation is described as introjected motivation which is a form of extrinsic motivation from SDT that stems from aiming to appease someone or avoiding negative reinforcement. Future research should examine the driving factor for a patient enrollment and better understand the amount of choice each patient has in their care from non-healthcare professionals. The higher competence scores being associated with lower session attendance was not surprising. With a higher perception of skill mastery patients may be less likely to value the need of Cardiac Rehabilitation, therefore dropping out. Relatedness scores did not differ between the groups which was to be expected as each participant had the same amount of one-on-one time and group structure during exercise time. Future research should include determining each patients drive to exercise such as being able to choose the exercise they do, becoming more proficient and confident in the exercise they do, or just being able to interact with others going through the same thing. Based off these results structured communication does not influence the satisfaction of the three psychological needs that lead to adherence.

Based on the results of this study, further efforts are necessary to determine the best intervention for continued adherence to OPCR. The longevity of the COIVD-19 pandemic, restrictions in health care, and uncertain adverse health outcomes still pose an issue. Going forward, regardless of communication approach and skills used, further research is needed to understand the implications COVID-19 has on the health care programs such as cardiac rehabilitation. Research should continue to investigate this topic further.

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Appendix A.

20-02-E

eamc
east alabama medical center

LETTER OF APPROVAL
Institutional Review Board

TO: Darby J. Winkler
Principal Investigator

FROM: Michael J. Lisenby, M.D.
Chairperson, IRB

DATE: June 4, 2020

The research project submitted for Expedited Review and approval entitled, "The Effect of Motivational Interviewing or Non-Autonomy Based Cardiac Rehab on Core Outcomes", was reviewed and approved with the following stipulations:

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable thereof.

B. Investigators must report promptly to the IRB:

(1) Any proposed changes in IRB approved research and acknowledge such research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.
(2) Any unanticipated problems involving risks to human subjects or others.
(3) Any instance of serious or unexpected adverse events arising during the research.

C. The above titled project is approved June 4, 2020 through June 3, 2021.
If the project is to continue beyond the ending date of approval, application for renewal must be made as of April 3, 2021 to be further approved by the IRB.

D. Approval is contingent upon modifications, if any, of the protocol or consent form and approved documentation of such modifications.

Michael J Lisenby MD — IRB Chairperson
6-4-2020 — Date

Please acknowledge your agreement to abide by these stipulations by your signature, keep a copy and return the original to the IRB office.

Darby J Winkler — Principal Investigator
6/12/2020 — Date

2000 Pepperell Parkway | Opelika, Alabama 36801 | (334) 749-3411 | eamc.org

Appendix B

AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS

RESEARCH PROTOCOL REVIEW FORM

FULL BOARD or EXPEDITED

For Information or help contact **THE OFFICE OF RESEARCH COMPLIANCE (ORC)**, 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 **e-mail:** IRBAdmin@auburn.edu **Web Address:** http://www.auburn.edu/research/vpr/ohs/index.htm

Revised 2.26.2020 **Submit completed form to IRBsubmit@auburn.edu.**

***Complete this form using Adobe Acrobat** Writer **(versions 5.0 and greater).** Hand written copies not accepted.*

1. PROPOSED START DATE of STUDY: 01/15/2021 **Today's Date:** 10/20/2020

PROPOSED REVIEW CATEGORY (Check one): ☐ FULL BOARD ☒ EXPEDITED

SUBMISSION STATUS (Check one): ☒ NEW ☐ REVISIONS (to address IRB Review Comments)

2. PROJECT TITLE: The Effect of Motivational Interviewing and Clinician Centered Interviewing Based

3. Danielle Wadsworth	A	SOC	KINE	wadswdd@auburn.edu
PRINCIPAL INVESTIGATOR		TITLE	DEPT	AU E-MAIL
301 Wire Rd			334 844 1836	
MAILING ADDRESS			PHONE	ALTERNATE E-MAIL

4. FUNDING SUPPORT: ☒ N/A ☐ Internal ☐ External Agency: _____ ☐ Pending ☐ Received

For federal funding, list agency and grant number (if available). _____

5a. List any contractors, sub-contractors, other entities associated with this project:

None

b. List any other IRBs associated with this project (including Reviewed, Deferred, Determination, etc.):

None

PROTOCOL PACKET CHECKLIST

All protocols must include the following items:

☒ **Research Protocol Review Form** (All signatures included and all sections completed)
(Examples of appended documents are found on the OHSR website: http://www.auburn.edu/research/vpr/ohs/sample.htm)

☒ **CITI Training Certificates** for all Key Personnel.

☒ **Consent Form or Information Letter** and any Releases (audio, video or photo) that the participant will sign.

☒ **Appendix A**, "Reference List"

☐ **Appendix B** if e-mails, flyers, advertisements, generalized announcements or scripts, etc., are used to recruit participants.

☒ **Appendix C** if data collection sheets, surveys, tests, other recording instruments, interview scripts, etc. will be used for data collection. Be sure to attach them in the order in which they are listed in # 13c.

☐ **Appendix D** if you will be using a debriefing form or include emergency plans/procedures and medical referral lists (A referral list may be attached to the consent document).

☒ **Appendix E** if research is being conducted at sites other than Auburn University or in cooperation with other entities. A **permission letter** from the site / program director must be included indicating their cooperation or involvement in the project. NOTE: If the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of **IRB approval** from each entity is required prior to initiating the project.

☐ **Appendix F** - Written evidence of acceptance by the host country if research is conducted outside the United States.

Version Date (date document created): 10/20/2020

The Auburn University Institutional Review Board has approved this Document for use from 11/10/2020 to 11/09/2021

Protocol # 20-512 EP 2011

page x of y

Appendix C.

Weekly Goals

Date: _____

Participant ID: _____

Time: _____

Today's Topic:

Medication Physical Activity Nutrition

Goal:

Participant Signature: _____

Authorized Person:_____