FATIGUE TOLERABILITY AND PHYSICAL ACTIVITY POST MYOCARDIAL INFARCTION OR CORONARY ARTERY BYPASS GRAFT SURGERY

By

Karina E. Buchholz, ECU-NS

A Senior Honors Project Presented to the

Honors College

East Carolina University

In Partial Fulfillment of the

Requirements for

Graduation with Honors

By

Karina E. Buchholz, ECU-NS

Greenville, NC

May 2017

Approved by: ___*Patricia Crane*____

Patricia Crane, PhD, RN, FAHA, FNAP

College of Nursing, Associate Dean for Research and Scholarship

Abstract

After a myocardial infarction (MI) or coronary artery bypass graft surgery (CABG), early lifestyle changes coupled with pharmacologic therapies are essential to halt the progression of coronary heart disease and prevent recurrent cardiac events. One of the most effective lifestyle behaviors to affect secondary prevention after an MI or CABG is physical activity (PA), yet 30% of adults do not participate in any leisure time PA. Understanding the amount of fatigue a person can tolerate to participate in cardiac protective PA is essential in developing interventions to mitigate fatigue and increase PA post MI and CABG. The purpose of this project was to develop and test the feasibility of study protocols to examine fatigue tolerance (tolerability) and PA in those persons post MI and CABG. Phase I: All instruments were refined with the research team and piloted with a small sample (*n*=10) of cardiac rehabilitation attendees to assess clarity, utility, and willingness to complete. Phase II: Results were shared with the research team. After modifications to the study protocols, training and reliability tests with the research team was completed. The tools piloted were the demographic health form, the 3-item 100 mm visual analogue scale (VAS) for fatigue tolerability, the Generalized Anxiety Disorder 7-item (GAD-7) scale, Patient Health Questionnaire-9 (PHQ-9), Pain Interference-Short Form 6b, Epworth Sleepiness Scale, accelerometer, and the hand grip strength test using the JAMAR dynamometer.

Key Words: cardiac rehabilitation, tolerance, fatigue, physical activity, myocardial infarction, coronary artery bypass graft surgery

TABLE OF CONTENTS

Fatigue Tolerability and Physical Activity Post Myocardial Infarction or Coronary Artery Bypass Graft Surgery

Literature Review

Coronary heart disease (CHD) is a common health problem in the United States and is the leading cause of annual deaths in both men and women. Approximately 610,000 people die from CHD, which is 25% of all total deaths. In some cases, a myocardial infarction (MI) is the first sign of CHD, but the most common symptom overall is angina. This chronic and progressive disease results primarily from plaque made up of cholesterol and other constituents that build up over time and can either partially or completely block blood flow in the major arteries of the heart resulting in ischemia, injury, and/or MI. A common surgical procedure used to improve blood flow to the heart and reduce chances of MI is a coronary artery bypass grafting (CABG) procedure (National Heart, Lung, and Blood Institute [NHLBI], 2012). Of greater concern is that of the 735,000 people in America who experienced a MI, about 210,000 will experience another MI in their life (Center for Disease Control and Prevention [CDC], 2015).

Many behavioral factors contribute to CHD, including being overweight; having elevated blood pressure, cholesterol, or blood sugars; physical inactivity; unhealthy eating; and smoking tobacco. After a MI or CABG, early lifestyle changes coupled with pharmacologic therapies are essential to halt the progression of CHD and prevent recurrent cardiac events (CDC, 2015). One of the most effective means of incorporating lifestyle changes to affect secondary prevention after an MI or CABG is physical activity (PA). Research indicates many of lifestyle changes are not sustained, especially when it comes to maintaining recommended levels of PA (Urbinati et al., 2015). This lack of adherence to behaviors that halt or prevent the progression of CHD may be due to symptoms, such as fatigue. Over 70% of persons post MI report fatigue 6 to 12 months after MI, and this fatigue prevents participation in PA at levels to provide cardio-protective benefits (Crane, Abel, & McCoy, 2016). Understanding the amount of fatigue a person can tolerate to participate in cardiac protective PA is essential in developing interventions to mitigate fatigue and increase PA post MI and CABG.

Coronary Heart Disease and Cardiac Rehabilitation

The risk of CHD increases with age, with risk significantly increased after age 45 in men and 55 in women (NHLBI, 2012). Exercise based cardiac rehabilitation (CR) programs have been associated with improvements in all domains of PA in adults aged 75 and older. These improvements in PA were seen in older adults after an acute coronary event, such as MI, as well as after a cardiac surgical intervention. The most improvements were seen in those who initially had lower baseline functioning status (Baldasseroni et al., 2016). Based on these findings, CR programs that are started shortly after discharge improves exercise tolerance and muscle strength, and, most importantly, it is safe for patients after a recent acute coronary event.

Physical activity is essential for preventing cardiovascular events, but a large proportion of people post-MI do not engage in even the lowest recommended levels of PA (Crane, Abel, & McCoy, 2016). For example, it has been demonstrated that as many as 51% of women do not meet the recommended levels of PA: 315-840 kcal per week (Crane, 2005). There are a variety of factors that may contribute to persons not adhering to PA, such as increasing symptoms of fatigue and pain. It is essential to examine these factors in the aging population to develop programs to increase PA and thus reduce the progression of the CHD.

Fatigue

The aging population reports fatigue as a common symptom with or without CHD. Research indicates that fatigued men and women, aged 65 and older, have increased disability when performing activities of daily living (ADLs) and physical function tests (Vestergaard et al., 2009). Fatigue is also a prevalent symptom reported with CHD, which has a negative impact on the patients' ability perform ADLs and adhere to exercise based cardiac rehabilitation programs (Crane, Abel, & McCoy, 2016). Therefore, aging adults are at risk for fatigue due to both increasing age and cardiac complications.

Fatigue is frequently reported after MI, which may result from CHD. The prevalence of fatigue reported after MI or CABG ranges from 54 to 67 percent (Alsen & Brink, 2013; Conley et al., 2015; Crane, 2005). This variability may be related to differences in gender representation and various measures of fatigue such as the Revised Piper Fatigue Scale (Crane, Abel, & McCoy, 2016), Multidimensional Fatigue Inventory (MFI) scale (Alsen & Brink, 2013; Alsen et al., 2010, Alsen et al., 2008; Conley et al., 2015; Falk et al., 2006; Fredriksson-Larson et al., 2013), Medical Outcomes Short Form (SF-36) subscales on fatigue (Brink et al., 2005), Functional Assessment of Chronic Illness Therapy- Fatigue (FACIT-F) tool (Mallinson et al., 2006), or specific questions from the Center for Epidemiologic Studies Depression Scale (CES-D) (Vestergaard et al., 2009). The CES-D categorizes people as fatigued if they report that "everything is an effort" and/or "could not get going" on three or more days in the past week. This tool may not be a thorough enough measurement to encompass the complexity of the symptom of fatigue.

Over half of the people who reported fatigue initially after their MI also indicated two years post MI that the fatigue remained, demonstrating how fatigue remains a significant symptom (Alsen & Brink, 2013). Additionally, people who experience an MI are at a 36 to 47% chance of also developing heart failure (HF) (Hellermann et al., 2003; Torabi et al., 2014). The degree of HF depends on the severity of the MI and the ability to remodel/repair the damage to the cardiac tissue. This is important because patients with HF also reported high levels of fatigue in the physical dimension of MFI-20 Scale (Falk, Swedberg, Gaston-Johansson, & Ekman, 2006).

Men and women have been shown to be similarly correlated in prevalence of fatigue, but in some studies women tend to report more severe levels (Alsen & Brink, 2013; Falk, Swedberg, Gaston-Johansson, & Ekman, 2006). Thus, is important to represent both genders equally when studying the effects of fatigue and CR. In the geriatric population (aged 65-102), it was found that a high percentage of those who report fatigue also reported living a mostly sedentary lifestyle (Vestergaard et al., 2009). This finding may be related to fatigue making them more sedentary or the sedentary lifestyle may be precipitating fatigue. Examining this relationship is warranted because increasing PA reduces the chances of CHD and MI in older adults.

Many people report a change in fatigue level after MI. However, very few of them actually attribute it to the recent MI. In fact, they report that the new fatigue is unrelated to activity or exertion. Most patients post MI perceived their feelings of tiredness as being different than before MI with changes in the bodily, cognitive, and emotion sensations involving the whole body. Many patients reported feeling “foggy minded”, listless, sad, heavy, tired, numb in the arms and legs, and dejection after their recent MI (Alsen, Brink, & Persson, 2008). If fatigue is not associated with exertion level, then it may be due to an emotional or psychological factor that is reducing the ability for these patients to remain active and to enhance their quality of life post MI.

Fatigue having a mental component has been explored in other studies. Negative beliefs about control of CHD has been associated with worse experiences of fatigue and lowered perceptions of health related quality of life (Alsen, Brink, Persson, Brandstrom, & Karlson, 2010). All dimensions of fatigue using the MRI-20 are related to illness perception, which means that fatigued patients with a more negative perception of their illness had more severe consequences and decreased perception of control (Alsen et al., 2010). Also, uncertainty about the disease was positively associated with tiredness and reduced functional status (Falk, Swedberg, Gaston-Johansson, & Ekman, 2006). Thus, attitude about the disease and the disease treatment has an impact on perceived level of fatigue and ability to function with ADLs. This mental component is important to incorporate into the structuring of unique CR programs to enhance PA post MI or CABG.

Physical Activity and Function

Physical activity has been linked to positive health outcomes in patients with CHD, and it is an important lifestyle behavior to enhance quality of life. A major factor affecting quality of life is the ability to perform activities of daily living (ADLs) or function well physically. Patients in CR are encouraged to reach at least a minimum level of PA, yet many are not reaching these goals. The 2005 Behavior Risk Surveillance System survey of 297,145 participants contacted over the telephone found that those with

CHD participated in less PA at recommended levels than those without the disease: Only 32% of people with CHD met the recommendations of PA (Zhao, Ford, & Mokdad, 2008). Additionally, Crane, Able, and McCoy (2016) found that 60% of aging women and 35% of aging men post MI did not meet even the lowest recommended level of kilocalories per week.

Those with lower cardiorespiratory fitness have more short term complications after CABG surgery, and people with lower cardiorespiratory fitness before CABG surgery had a higher 30-day mortality after CABG (Smith et al., 2013). The reduction of aerobic activity capacity, or low cardiorespiratory fitness, before CABG may limit physical reserve and decrease ability to respond to the stresses of the procedure (Smith et al., 2013). Clearly, it is known that PA improves health outcomes in patients with CHD. Thus, it is essential to develop interventions to facilitate persons who are post MI and CABG on reaching PA recommendations.

Low adherence to PA recommendations may be due to symptoms, such as fatigue, or decreases in physical function after MI or CABG that is contributing to a more sedentary life. Research indicates that about 70% of patients with the diagnoses of MI who reported fatigue said that their fatigue post MI was different than that before MI, which shows that fatigue may contribute to these decreases in PA post MI for both men and women (Crane et al., 2016). Those post MI in CR report that some perceived barriers to sustained PA are: (a) the difficulty in determining safe exertion levels, (b) fatigue and weakness, (c) preference for informal exercise such as walking, and (d) cultural barriers. Some participants also reported that they were hesitant to exercise in formal gyms or exercise settings due to the fear of being unable to monitor their exertion (Galdas, Oliffe,

& Kang, 2012). While fear of unmanageable fatigue or safe exertion level has led to limited PA, this perceived protective mechanism may ultimately do more harm.

After an MI, persons also struggle with deceased physical function levels which decreases quality of life (QOL). In the first year post MI, 25% of both males and females reported functional decline (Brink, Grankvist, Karlson, & Hallberg, 2005). One possible explanation for this decrease in functional status post MI include the role of fatigue seems to play in both geriatric and younger CHD populations. In Sweden, women reported lower levels of physical function and social functioning 1-year post MI than males, and 13% of total respondents reported possible depression 1-year post MI which can also play a role in fatigue and function level. Additionally, depression and fatigue (vital exhaustion) correlated with health related QOL (Brink et al., 2005). The main consequence of fatigue post MI that was reported was the core theme of "I've lost the person I used to be," which means that they had a reduced ability to manage ADLs. This inability to perform ADLs can be related to reduced PA and functional status (Fredriksson-Larson, Alsen, & Brink, 2013). Older adults who reported fatigue had weaker hand grips, lower function scores on the Short Physical Performance Battery scores, slower walking speed, and higher disability in ADLs than non-fatigued adults (Vestergaard et al., 2009). The greater the severity of perceived fatigue led to a poorer functional fitness, high level of energy expenditure, and lower levels of PA (Barbosa et al., 2015). Older people who report fatigue have a poorer physical function status than those who do not report this symptom, which is essential to understanding the plan of care for patients post-MI experiencing fatigue. Although, pain, fatigue, and depression were associated with deceased physical function in stable HF patients, there was no association with functional capacity as evidenced by the 6 minute walk test. This suggests that symptom such as pain, fatigue, and depression that are associated with HF may limit ADLs and physical function, but do not limit actual potential to perform them (Conley, Feder, & Redeker, 2015). Thus, increasing PA can increase physical function, but increasing physical function may not increase PA.

A cognitive/psychological component may influence the ability to complete ADLs and QOL in patients with the diagnoses of CHD. Alsen and colleagues (2010) found that negative beliefs about control of MI were associated with worse experiences of fatigue and lowered health related quality of life. These findings are similar to another study of those post-MI noting a moderate negative correlation between self-reported fatigue and self-reported physical function level, and self-reported fatigue and physical function related to observable fatigue levels (Mallinson, Cella, Cashy, & Holzner, 2006). These links between perceived fatigue levels and actual function are similar to the fatigue experienced by patients post MI or with the diagnosis of CHD. Thus, perceived levels of maximally tolerable fatigue may be a cognitive component affecting physical function and PA.

Tolerance

One novel approach to understanding fatigue and PA is examining how cognitive processes affect physical effort. According to Tucker (2009), “the overall sensation of exertion measured during exercise is the conscious/verbal manifestation of the integration of (both) psychological and physiological cues” (p. 392). Tolerance, a concept that has been explored in sports psychology to understand physical activity effort and pacing, is defined as the volitional limit to activity/exercise at a constant work load based on a person's rate of perceived exhaustion. Thus, tolerance is the amount of PA that is considered to be maximally tolerated before sustaining injury or unmanageable fatigue (Tucker, 2009). Fatigue tolerance may have a cognitive component that may affect PA in those with CHD.

Pfeifer, Musch, and Mcallister (2001) implemented an animal laboratory quantitative study where they induced a MI to test whether reductions in oxidative enzymes in skeletal muscles coincided with exercise intolerance in rats with HF after MI. They used a run to fatigue (RTF) test to measure exercise tolerance. The RTF times were lower in large MI rats compared to small MI rats and controls. More importantly, they found that exercise intolerance following MI did not coincide with oxidative enzyme activity in skeletal muscles which suggests that there is an underlying cognitive mechanism for the induced intolerance and increased fatigability (Pfiefer, Musch, & Mcallister, 2001). Baden, McLean, Tucker, Noakes, and Gibson (2005) also found that increased rate of perceived exertion was not explained by physiological factors, but rather from an unanticipated increase in duration of exercise leading to a negative emotional response of anger, frustration, distrust, and doubt. These studies support a cognitive component to PA.

Persons may adjust their PA intensity and duration for protection. A study conducted in Brazil with 48 women aged 65 and older detailed how older adults adjust their speed to expend less energy and to maintain a manageable amount of perceived exertion. This perceived maximal exertion level relates to the concept of tolerance that is seen in pacing of athletes (Barbosa et al., 2015). Tolerance of fatigue is sometimes referred to as fatigability, or the tendency to become tired or exhausted quickly or easily and can occur after periods of excessive activity. A correlation exists between severity of perceived fatigability in women and increased demand for oxygen while completing the 6-minute walk test (Barbosa et al., 2015). Understanding the concept of perceived maximal exhaustion/fatigue will be vital in tailoring CR programs to each individual's needs.

Evidence on pacing strategies was collected by using 15 endurance trained cyclists who completed a control trial and additional trials with incorrect distance feedback splits in which they found no differences in finishing times. The power output profiles and finish times were similar despite the incorrect splits which suggest that pacing strategies were unaltered and determined before the exercise began (Albertus et al., 2005). Similarly, Albertus and colleagues (2005) suggest that a subconscious strategy is used to preset pacing during exercise that is based off of preset fatigue tolerability level that affects exercise capacity and physical function. Furthermore, all of the cyclists were able to increase their power outlet, despite incorrect distance feedback, in the last kilometer of the trials, which shows that the athletes held back throughout the trials to prevent developing unmanageable fatigue or fatigue that would impede them from the ability to complete the 20-km test (Albertus et al., 2005). This predetermined safe exercise duration and intensity may be applicable to the performance of people post MI or CABG, and may help in understanding barriers to reaching the recommended PA levels. In fact, persons 4-months post MI reported that they did not want to exercise due to the risk of becoming overwhelmed with fatigue and therefore avoided getting into risky situations that might lead to harm. Thus, patients may adjust their lives to accommodate for fatigue after MI or CABG to avoid a potentially risky activity (Alsen, Brink, and Persson, 2008).

Evidence suggests that expectations, an emotional component, have an influence on perceived symptoms of fatigue that decrease tolerance of PA. As exertion increased the emotional component of pleasure decreased in all of the 16 male running athletes, which indicated that fatigue might actually be a mental construct rather than physical construct (Baden et al., 2005). To further test tolerance as a mental construct, a randomized crossover study was done with 15 untrained, recreationally active students (eight women and seven men) to determine the psychological and physiological effects of cognitive exertion on exercise capacity and perceived physical exertion levels. After cognitively exhausting tasks, participants were unable to tolerate as high of a level of whole-body endurance exercise or reach the same levels of peak power output and oxygen consumption compared to those who did restful tasks prior to exercise, such as watching a documentary. This study demonstrated how there can be a carryover effect: cognitive load that affects physical function and leads participants to rate their perceived exertion higher and withdraw earlier from exercise (Zering, Brown, Graham, & Bray, 2016). Clearly, there exists a psychological/emotional determinant of exercise performance rather than just physiological factors which affects participation in PA. These mechanisms should be explored in exercise based CR settings.

The purpose of this project was to develop and test the feasibility of protocols regarding fatigue tolerance and PA in persons who are post-MI and post-CABG admitted to CR. Objectives were to: a) pilot test the protocols on CR attendees (*n*=10) to assess clarity, utility, and willingness to complete; b) present the findings to the research team;

c) make recommendations to refine the protocols or training for future use with CR attendees; and d) measure inter-rater reliability within the research team.

Context of the Study

Through a windshield survey of Pitt County, it is apparent that the county is lacking in the promotion of healthy lifestyle behaviors, thus promoting unhealthy ones. There is a surplus of fast food options, quick marts, and gas stations that sell fatty foods, junk food items high in sugar, cigarettes, soda, and alcohol. Pitt County has 22.1 restaurants per 10,000 people, which is lower than the national average of 27.3/10,000 (Graphiq, 2017). Based on observation, many of the grocery stores have sales on junk food items and pre-packaged foods, which is what a majority of people purchased. Fatty foods contribute to coronary artery disease and contain high amounts of sodium that aggravate cardiac symptoms, such as increasing blood pressure and fluid retention stressing the heart. There are very few healthy food options in Pitt county that are affordable for the general population. Some healthy food options seen were Muscle Makers Grill, Chipotle, and Clean Eats.

Health benefits identified in Pitt county were the Farmers' Market, the South Tar River greenway, bike routes, recycling center, senior center, ECU North Recreational Complex, City of Greenville Leash off dog park, Vidant Medical Center, Evans Park, the Alice F. Keene District Park, and many other recreational facilities and health services. According to The Pitt County Community Schools and Recreational Department, there are 42 documented and mapped parks/trails. Many of these parks are handicap accessible and available for the public. Although there are many parks in Pitt county, during the windshield survey many of the parks were empty or had only a few children/families outside. Additionally, Pitt County has 31% fewer fitness centers than the North Carolina average and 40% fewer than the average for the United States (Graphiq, 2017). Increasing the percentage of adults getting the recommended amount of physical activity (PA) to 50% is a health priority of Pitt County (Pitt County Community Health Needs Assessment [CHNA], 2015).

In Pitt County the leading cause of total age-adjusted deaths is CHD. From 2009 to 2013, 176.8 deaths per 100,000 people were a result of CHD in Pitt county. In 2008, the United States' rate of death due to CHD was 126 deaths per 100,000 people annually. Although this rate is a 29.6 % decline since 1999-2003, heart disease still remains the leading cause of death in Pitt County (CHNA, 2015). Pitt County places priority in reducing the cardiovascular disease mortality rate by 5% by developing and implementing a hypertension self-management education program (CHNA, 2015).

In North Carolina, 23.2% of adults do not engage in any leisure time PA, which has decreased from the 26.6% in 2013 according to the Behavioral Risk Factor Surveillance System (U.S. Department of Health and Human Services, 2015). Also, in North Carolina, Hispanics are the least likely to participate in leisure time PA (31.5%), followed by non-Hispanic Blacks (29.2%), American Indian/Alaska Native (25.1%), Asians (22.3%), non-Hispanic Whites (20.8%), and then mixed races (16.8%) (CDC, 2015). These secondary statistics demonstrate the health disparities that exist in North Carolina, which play a role in the health of people post MI or CABG. One of the major goals of Healthy People 2020 is to eliminate these health disparities. Other important lifestyle changes after a cardiac event are smoking cessation and healthy eating habits, yet one in four men after a heart attack, stroke, or other major cardiac event do not change their unhealthy behaviors (Kulash, 2013). The prevalence of CHD in east North Carolina, the lack of healthy foods, and decreased PA makes this area ideal for a study on fatigue tolerance and PA in those post MI and CABG attending CR.

Methodology

Study Design

A pilot study was conducted at a Cardiovascular and Pulmonary Rehabilitation (CVPR) center in a metropolitan city in eastern North Carolina. The research team included nursing staff at the CVPR center, nursing faculty, and a doctoral student from the University College of Nursing. The CVPR center provides interdisciplinary services through a large Academic Medical Center to patients in eastern North Carolina. The CVPR center specializes in critical care medicine, pulmonary medicine, and cardiovascular disease with two full time registered nurses and three rotating on-site physicians, making this site an ideal location for sample collection.

Sample

The population in this study are CVPR attendees aged 21 years or older who are either post-MI or post-CABG. The sample included both male and female participants residing in eastern North Carolina from a variety of ethnic backgrounds. Exclusion criteria included persons unable to ambulate, such as those who are wheelchair bound or unable to do the six-minute walk test due to disabilities. To be included, participants must be able to ambulate without the assistance of an additional person, but each may use an assistive device such as a walker with rollers or cane.

Data Collection

A recruitment script was used to invite CR attendees that met the inclusion/exclusion criteria to participate in the pilot. Participation was completely voluntary and each were asked to meet after their CR session on a Tuesday or Thursday. The protocols were tested on the participants, and they were asked to provide feedback throughout the interview on clarity, utility, and willingness to complete. The tools piloted were a demographic health form, the health status survey, the 3-item 100 mm visual analogue scale (VAS) for fatigue tolerability, The Generalized Anxiety Disorder 7-item (GAD-7) scale, Patient Health Questionnaire-9 (PHQ-9), Pain Interference-Short Form 6b, Epworth Sleepiness Scale, accelerometer, and the hand grip strength test using the JAMAR dynamometer.

The demographics tool included information such as date of birth, race, marital status, highest education level, occupation, care giver role, average combined yearly household income, and ability to confide in someone. The health status survey included questions related to if the attendee has been diagnosed with an abnormal heartbeat, diabetes, high blood pressure, and high blood cholesterol as well as detailed history of tobacco and alcohol use. A medication list with dosage was also collected. The participants weight in pounds, height in inches, and blood pressure was measured and recorded. Fatigue tolerability was measured using a three-item 100 mm visual analogue scale (VAS), with 0 mm being not at all fatigued and 100 mm being the worst fatigue possible. The three items included: (a) the highest level of fatigue you can tolerate but still continue to do the things you need/want to do, (b) the level of fatigue that you think slows you down, and (c) the level of fatigue you think is normal for people like you (or similar to you). Each of these items were analyzed separately to determine fatigue tolerance perception. Strength was measured using the hand grip strength test following standardized protocol with the dominant hand using the JAMAR hand dynamometer with the elbow flexed to 90 degrees. Three repetitions will be done, and the average score in pounds was recorded.

The accelerometer, used to record steps, was introduced to the participants, and their feedback was recorded on their willingness to participate in wearing it in future studies. Their perception of wearing the accelerometer for 1-2 weeks, as well as their opinion on the best time to participate in a research study. Lastly, opinions on feelings/willingness about completing the protocols was recorded.

The study questions were:

1. Are the fatigue tolerability and PA protocols clear, functional, well-designed, and are cardiac rehabilitation attendees willing to complete them?
2. What changes should be implemented into the protocols to refine the clarity, utility, and willingness to complete?
3. What is the inter-rater reliability of the research team using the demographic health form, the 3-item 100 mm visual analogue scale (VAS) for fatigue tolerability, The Generalized Anxiety Disorder 7-item (GAD-7) scale, Patient Health Questionnaire-9 (PHQ-9), Pain Interference-Short Form 6b, Epworth Sleepiness Scale, and the hand grip strength test using the JAMAR dynamometer?

Results of these questions will serve as a means to refine project protocols to be used for adults who have experienced an MI or CABG attending CR. The protocols will be used to understand the role of fatigue tolerability on PA in this population.

Limitations

Several limitations to this pilot were identified. First, CR is only scheduled only on Monday, Tuesday, and Thursdays, when physicians are on-site. Also, clinical nursing hours were limited to Tuesdays and Thursdays. Attendees that met the inclusion/exclusion criteria may have been missed due to these time constraints. In addition, some attendees were not able to participate in the study due to prior commitments, appointments, or transportation issues.

Results

Cardiac rehabilitation attendees (*N*=10) completed the interviews and piloted the tools. The average age was 68.3 years (*SD*=10.51). Most were women (70%), married (70%), White (80%), retired (80%), and had at least a high school diploma/GRE (90%). Those post-MI (60%) and post-CABG (40%) were fairly evenly distributed. Table 1 displays demographic data of the population used.

Table 1

Demographic Survey Tool (N=10)

Characteristics	Post-MI (*n*=6)	CABG (*n*=4)
Age (%)		
<70	33	50
70-80	67	25
>80	-	25
Gender (%)		
Male	17	50
Female	83	50
Race (%)		
White	67	100
African American	33	-
High School or greater education (%)	67	75
Married (%)	67	75
Retired (%)	83	75

The average length of time for the interviews was 24.7 minutes with 70% of interviews taking place on Tuesdays and 70% between the hours of 8:30 am and 12:30 pm. Of the 10 participants, 6 people said that they would “for sure” be willing to wear the ankle bracelet accelerometer for 1.5-2 weeks. The others noted that walking wasn't “their primary mode of exercise due to pain” (*n*=1), and three people said they would not want to participate because of a "busy schedule", not wanting to wear it to formal outings, not being used to wearing an anklet, or being afraid of forgetting to wear it (*n*=3). Qualitative feedback resulted in refining 4 questions on the demographic tool and determining that gift cards for groceries and pharmacy are the most desirable form of incentive. Twenty percent of participants reported that they would be willing to participate without any need for gift cards. The second week of CR or later was preferred by 80% of people for the start of a future study. Forty percent of participants reported a negative or stressful experience during the first week of CR, such as experiences of a "pounding heart and anxiety," "feeling so weak that I feel like I am going to float away," "apprehension," or "not knowing what to expect." When asked about clarity of the tools piloted, 30% of people reported wanting additional explanation or guidance on the VAS for fatigue tolerability and more information on the purpose of the handgrip strength test. All other protocols were well understood by the participants.

One mock-participant volunteered to participate in the inter-rater reliability checks with the research team. The tools and protocols for the demographic health form, the 3-item 100 mm visual analogue scale (VAS) for fatigue tolerability, The Generalized Anxiety Disorder 7-item (GAD-7) scale, Patient Health Questionnaire-9 (PHQ-9), Pain Interference-Short Form 6b, Epworth Sleepiness Scale, and the hand grip strength test using the JAMAR dynamometer were completed with the research team. Each team member recorded the volunteer's responses, which were them compared for reliability. Inter-rater reliability was 100% for all instruments and protocols listed above.

Discussion

Based on the findings from this pilot study, it is apparent that four questions on the demographic and health status survey tool needed editing to enhance clarity. The research team are considering adding a cognitive screening tool to be used in the inclusion/exclusion criteria. The research team decided to replace PROMIS version 6b with 8a to better describe the effects of pain on the population in their home setting. It was recommended that a script be developed to use with the accelerometer to ensure the same information is given to all participants. Also, it must be clarified that the hand dynamometer reading should be done with the dominant and/or strongest hand. A script and example for the VAS should also be added to increase understanding of the tool. Instructions should be added to the PROMIS tool that notes if no pain the previous week, then the score is 0 for the tool.

Overall, CR attendees seem interested in the topic of fatigue tolerance and PA, and the vast majority are willing to participate in future studies or think other CR attendees will be interested. Adequate time was provided for the protocols and instruments to be piloted. Most people were interested in knowing more about their current PA level through the use of the accelerometer, and they were excited to be helping increase knowledge on this topic. Participants did not perceive the accelerometer to be troublesome with the understanding that it will not track location, but only information related to motion and PA level. The accelerometer was not piloted, so adherence over time cannot be determined. Inter-rater reliability was strong.

Conclusion

Based on the findings of this pilot study, changes were made to the IRB. The feedback collected from the participants of this pilot was vital in the refining of the tools and protocols to ensure clarity. This pilot provided important information to increase the validity and reliability of study tools and protocols. Without piloting these tools, the progression of the IRB of the future study and research process would not have gone as smoothly. Through completing this project, further studies can be conducted on fatigue tolerability and PA post MI or CABG to develop interventions to increase PA and decrease the effects of coronary heart disease.

References

Albertus, Y., Tucker, R., St Clair Gibson, A., Lambert, E. V., Hampson, D. B., & Noakes, T. D. (2005). Effect of distance feedback on pacing strategy and perceived exertion during cycling. *Medicine & Science in Sports & Medicine, 37*(3), 461-8. doi: 10.1249/01.MSS.0000155700.72702.76

Alsen, P., & Brink, E. (2013). Fatigue after myocardial infarction- a two-year follow-up study. *Journal of Clinical Nursing, 22*, 1647-1652. Doi: 10.1111/jocn.12114

Alsen, P., Brink, E., & Persson, L. (2008). Living with incomprehensible fatigue after recent myocardial infarction. *Journal of Advanced Nursing, 64*(5), 459-468. doi: 10.1111/j.1365-2648.2008.04776.x

Alsen, P., Brink, E., Persson, L., Brandstrom, Y., & Karlson, B. W. (2010). Illness perceptions after myocardial infarction: Relations to fatigue, emotional distress, and health-related quality of life. *Journal of Cardiovascular Nursing, 25*(2), E1-E10. doi: 10.1097/JCN.0b013e3181c6dcfd

Baden, D. A., McLean, T. L., Tucker, R., Noakes, T. D., & St Clair Gibson, A. (2005). Effect of anticipation during unknown or unexpected exercise duration on rating of perceived exertion, affect, and physiological function. *British Journal of Sports Medicine, 39*(7), 742-746. doi: 10.1136/bjsm.2004.016980

Baldasseroni, S., Pratesi, A., Francini, S., Pallante, R., Barucci, R., Orso, F., Burgisser, C., Marchionni, N., & Fattirolli, F. (2016). Cardiac rehabilitation in very old adults: Effects of baseline functional capacity on treatment effectiveness. *The American Geriatrics Society, 64*, 1640-1645. doi: 10.1111/jgs.14239.

Barbosa, J. F., Bruno, S. S., Cruz, N. S. O., de Oliveira, J. S., Ruaro, J. A., & Guerra, R. O. (2015). Perceived fatigability and metabolic and energetic responses to 6-minute walk test in older women. *Physiotherapy, 102*, 294-299. doi: 10.1016/j.physio.2015.08.008.

Brink, E., Grankvist, G., Karlson, B. W., & Hallberg, L. R. (2005). Health-related quality of life in women and men one year after acute myocardial infarction. *Quality of Life Research, 14*(3), 749-757. Retrieved from http://link.springer.com/article/10.1007%2Fs11136-004-0785-z

Centers for Disease Control and Prevention. (2015). *Heart disease: Coronary artery disease (CAD).* Retrieved from http://www.cdc.gov/heartdisease/coronary_ad.htm

Conley, S., Feder, S., & Redeker, N. S. (2015). The relationship between pain, fatigue, depression and functional performance in stable heart failure. *Heart & Lung, 44*, 107-112. doi: 10.1016/j.hrtlng.2014.07.008

Crane, P. B. (2005). Fatigue and physical activity in older women after myocardial infarction. *Heart & Lung*, *34*(1), 30-38. doi: 10.1016/j.hrtlng.2004.08.007

Crane, P. B., Abel, W. M., & McCoy, T. P. (2016). Fatigue and physical activity after myocardial infarction. *Biological Research for Nursing*, *17*(3), 276-284. doi: 10.1177/1099800414541961

Falk, K., Swedberg, K., Gaston-Johansson, F., & Ekman, I. (2006). Fatigue is prevalent and severe symptoms associated with uncertainty and sense of coherence in patients with chronic heart failure. *European Journal of Cardiovascular Nursing, 6,* 99-104. doi: 10.1016/j.ejenurse.2006.05.004

Fredriksson-Larson, U., Alsen, P., & Brink, E. (2013). I've lost the person I used to be: Experiences of the consequences of fatigue following myocardial infarction. *International Journal of Qualitative Studies on Health and Well-being*, *8,* 1-9. doi: 10.3402/qhw.v8i0.20836

Galdas, P. M., Oliffe, J. L., Kang, H. B. K., & Kelly, M.T. (2012). Punjabi sikh patients' perceived barriers to engaging in physical exercise following myocardial infarction. *Public Health Nursing*, *29, 6,* 534-541. doi: 10.1111/j.1525-1446.2012.01009.x

Graphiq (2017). *Pitt County: Count in North Carolina.* Retrieved from http://places.findthehome.com/l/55812/Pitt-County-NC

Hellermann, J. P., Goraya, T. Y., Jacobsen, S. J., Weston, S. A., Reeder, G. S., Gersh, B. J., . . . Roger, V. L. (2003). Incidence of heart failure after myocardial infarction: Is it changing over time? *American Journal of Epidemiology, 157*(12), 1101-1107. doi: 10.1093/aje/kwg078

Kulash, Tara (2013). *25 percent do not change bad health habits after heart attack, stroke.* Retrieved from http://www.stltoday.com/lifestyles/health-med-fit/percent-do-not-change-bad-health-habits-after-heart-attack/article_f30164af-2368-5cf5-8bdc-3f641a7607b8.html

Mallinson, T., Cella, D., Cashy, J., & Holzner, B. (2006). Giving meaning to measure: Linking self-reported fatigue and function to performance of everyday activities. *Journal of Pain and Symptom Management, 31*, 3, 229-241. doi: 10.1016/j.jpainsymman.2005.07.012

National Heart, Lung, and Blood Institute (2012). *What is coronary arterybBypass grafting?.* Retrieved from https://www.nhlbi.nih.gov/health/health-topics/topics/cabg

Pfeifer, P. C., Musch, T. I., & Mcallister, R. M. (2001). Skeletal muscle oxidation capacity and exercise tolerance in rats with heart failure. *Medicine & Science in Sports & Exercise, 33*(4), 542-548. Retrieved from http://journals.lww.com/acsm-msse/pages/articleviewer.aspx?year=2001&issue=04000&article=00006&type=abstract

Pitt County Community Health Needs Assessment (CHNA) (2015). *State of the county health report.* Retrieved from https://www.pittcountync.gov/ArchiveCenter/ViewFile/Item/140

Smith, J. L., Verrill, T. A., Boura, J. A., Sakwa, M. P., Shannon, F. L., & Franklin, B. A. (2013). Effect of cardiorespiratory fitness on short-term morbidity and mortality after coronary artery bypass grafting. *The American Journal of Cardiology, 112,* 1104-1109. doi: 10.1016/j.amjcard.2013.05.057

Torabi, A., Cleland, J., Rigby, A., & Sherwi, N. (2014). Development and course of heart failure after a myocardial infarction in younger and older people. *Journal of Geriatric Cardiology, 11*(1), 1-12. doi: 10.3969/j.issn.1671-5411.2014.01.002

Tucker, R. (2009). The anticipatory regulation of performance: The physiological basis for pacing strategies and the development of a perception-based model for exercise performance. *British Journal of Sports Medicine, 43*, 392-400. doi: 10.1136/bjsm.2008.050799

Urbinati, S., Olivari, Z., Gonzini, L., Savonitto, S., Farina, R., . . . Maggioni, A. (2015). Secondary prevention after acute myocardial infarction: Drug adherence, treatment goals, and predictors of health lifestyle habits. *European Journal of Preventative Cardiology, 22*(12), 1548-1556. doi: 10.1177/2047487314561876

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) (2015). *Nutrition, Physical Activity and Obesity Data, Trends and Maps*. Retrieved from http://www.cdc.gov/nccdphp/ DNPAO/index.html.

Vestergaard, S., Nayfield, S. G., Patel, K. V., Eldadah, B., Cesari, M., Ferrucci, L., Ceresini, G., & Guralnik, J. M. (2009). Fatigue in a representative population of older persons and its association with functional impairment, functional limitation, and disability. *Journal of Gerontology, 64*(1), 76-82. doi: 10.1093/gerona/gln017

Zering, C. J., Brown, D. M. Y., Graham, J. D., & Bray, S. R. (2016). Cognitive control exertion leads to reductions in peak power output and VO2 peak as well as increased perceived exertion on a graded exercise test to exhaustion. *Journal of Sports Science, 1-8*. doi: 10.1080/02640414.2016.1237777

Zhao, G., Ford, E. S., Li, C., & Mokdad, A. H. (2008). Are United States adults with coronary heart disease meeting physical activity recommendations? *The American Journal of Cardiology, 101, 5,* 557-561. doi: 10.1016/j.amjcard.2007.10.015

Appendix A

DEMOGRAPHIC DATA

1. What is your current age? ______________

2. Ethnicity/Race:
   a. White
   b. African-American/Black
   c. Mixed (Ask "Which do you consider most?")

3. Marital status:
   a. Never married
   b. Married
   c. Divorced/separated
   d. Widowed

4. Education (highest level of schooling completed)
   a. 8 years or less
   b. 9-11 years
   c. High school graduate (or GED)
   d. Some technical school
   e. Technical school
   f. Some college
   g. Baccalaureate degree
   h. Some graduate
   i. Graduate degree or higher

5. What is your occupation?
   a. Housewife
   b. Work (volunteer) outside the home ________________________________
   c. Other ____
   d. Retired (If yes, what position before retired?) ________________________

6. Is your work outside the home?
   a. Part time
   b. Full time
   c. Not Applicable

7. Are you responsible for the care of another person? (If No, go to # 10)
   a. Yes
   b. No

8. How many hours a week do you provide care?
   ____

9. Do you have any assistance providing care?
   a. Yes
   b. No

10. Do you feel you have someone to confide in when you need to? (If No go to #12
   a. Yes
   b. No

11. Who do you confide in?
   a. Spouse
   b. Child
   c. Family member
   d. Friend
   e. Other ___________________

12. The last question on this form has to do with finances. I am interested if you had enough money to buy medication and take care of yourself. For that reason, I would like to know your approximate average *combined* yearly household income?
   a. Less than $10,000
   b. $10,000-$19,999
   c. $20,000-$29,999
   d. $30,000-$39,999
   e. $40,000-$49,999
   f. $50,000-$59,999
   g. $60,000-$69,999
   h. $70,000-$79,999
   i. $80,000-$89,999
   j. $90,000-$99,999
   k. Over $100,000
   l. Don't know
   m. Refused
   n. <$30,000
   o. >$30,000

Appendix B

HEALTH STATUS SURVEY

1. Has your doctor or health care provider told you that you have an abnormal heartbeat?
   a. Yes
   b. No

2. Has a doctor or health care provider ever told you that you have high blood pressure?
   a. Yes
   b. No

3. Has a doctor or health care provider ever told you that you have high blood cholesterol?
   a. Yes
   b. No

4. Have you ever smoked more than 5 packs of cigarettes in your life, chewed tobacco or dipped snuff? (If No, go to # 8)
   a. Yes
   b. No

5. How many years did you smoke (dip or chew)?

____________________(years)

6. Do you currently smoke (dip or chew)?
   a. Yes
   b. No

7. How many cigarettes do you presently smoke per day?
   ____

8. Do or did you live around people who smoke(d) every day?
   a. Yes
   b. No

9. Do you have diabetes or need medicine to control your blood sugar?
   a. Yes
   b. No

10. How much alcohol do you drink?
    a. None
    b. 1-3 drinks/month
    c. 1-3 drinks/week
    d. 4-6 drinks/week

e. 6-10 drinks
f. > 11 drinks

11. Weight in pounds?

_________________________(measured by researcher)

12. Height in inches?

_______________________(measured by researcher)

13. Blood Pressure (R or L) ___________________

14. Other than hormones, which of the following types of medications do you take at least daily.

	NO	YES	List Drug and Dosage on your prescription bottle
Antihypertensive (to lower blood pressure)			
Insulin or oral hypoglycemic (to lower blood sugar)			
Cholesterol lowering drug			
Drug to treat angina (chest pain)			
Arthritis			
Sinus or allergy medications			
Water pill			
Thyroid medication			
Vitamins			
Stomach pills			
Aspirin			
Pill for nerves			
Other medication (specify: Ask “any herbal products?)			

11. Dynamometer reading
    a. time 1________________ (denote the dominant arm) R L
    b. time 2 _______________ R L
    c. time 3 ________________ R L

Average______________________

16. What is the highest level of fatigue you can tolerate but still continue to do the things you need/want to do?

0 None 10 Highest

17. What is the level of fatigue that you think slows you down?

0 None 10 Highest

19. What is the level of fatigue you think is normal for people like you (or similar to you)?

0 none 10 Highest