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Relationship Between Quality of Life and Physical Activity with Diagnosed Myocardial Infarction

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Abstract

Relationship Between Quality of Life and Physical Activity with Diagnosed Myocardial Infarction

The purpose of this research was to determine if physical activity is related to health related quality of life (HRQoL) in older adults who have a history of myocardial infarction. This study included eight older adults with history of myocardial infarction who were enrolled in a medically supervised exercise and education program known as cardiac rehabilitation. Each participant completed the HRQoL survey and wore a FitBit for three consecutive days in order to measure physical activity level. A Pearson's correlation test was run. Results showed that HRQoL and physical activity level did not correlate when the data was run with the outlier present (r = .46, P = .29, P > 0.05) or without the outlier present (r = .14, P = .77, P > 0.05). In conclusion, there was no significant correlation between HRQoL and physical activity level in older adults with history of myocardial infarction. The number of participants in this study was less than expected. There were only 8 participants who agreed to participate in the present research study, which was limited by diagnosis and age. During the data collection process, 19 patients enrolled in cardiac rehabilitation either did not have an MI diagnosis or qualify to participate based on age. Three patients, who did qualify, did not want to participant in the study.

Further research needs to be conducted with a larger sample size and a wider range of heart diagnoses in cardiac rehabilitation in order to get a more reliable and valid result. The research sample should be open to all patients who have been diagnosed with an MI or who have had heart procedures (Stent/PTCA) or open-heart surgery (CABG) in

order to obtain a more reliable measure. The present research study is unique because all patients are post-MI and are enrolled in a medically supervised exercise program in order to educate them on how to exercise and what guidelines to follow. Future research could control for the type of MI each participant has or how many bypasses or stents each participant received and investigate any differences in the results that may appear after analyzing steps per day and HRQoL.

CHAPTER ONE: INTRODUCTION

Significance

Myocardial infarction (MI) events have slowly been on the rise over the years; however, death rates from the heart event have fallen from 46,610 to 23,085 between 2001 and 2012 (Boseley, 2013). According to 2014 Health Disease and Stroke Statistics, an American has an MI every 44 seconds. This equates to over 700,000 MIs every year. Due to a decrease in the number of deaths from an MI, there are more survivors needing care (Boseley, 2013). According to the Centers For Disease Control and Prevention (2015), approximately 15% of people who experience an MI die shortly after the event. Therefore, the other 85% of those people who have an MI are survivors who need the care after the cardiac event. Care includes increased physical activity, stress management, proper nutrition, and cardiac and risk factor patient education in a clinical setting in order to improve physical, psychological, and social functioning (National Heart, Lung, and Blood Institute, 2013). Research shows that physical activity improves physical, psychological, and social functioning, as well as reduced additional risks that could be a factor for an MI (AACVPR, 2015).

Background Information

An MI, or heart attack, is caused when the heart muscle is damaged or dies because of blocked coronary arteries. Research has suggested that positive physical health practices throughout life and emotional well-being could possibly delay this cardiac event (Riiser et al., 2014). Many of the research studies summarized in this research found a significant correlation between physical activity level and health related quality of life (HRQoL) post-MI. There are other studies in which researchers suggested there were decreased HRQoL results post-MI and an improvement when exercise therapy was incorporated. Research studies have suggested that HRQoL is decreased after an MI. Plevier et al. (2001) and Brink, Grankvist, Karlson, & Hallberg (2005) both conducted research on participants with a

history of MI in order to find if HRQoL is affected with an exercise program. While Plevier et al. (2001) did not find an improvement in HRQoL over time in participants with an MI, Brink, Grankvist, Karlson, & Hallberg (2005) did find that HRQoL in participants with an MI improved one year after MI. Other research has looked at the correlation between HRQoL and evidence of coronary artery disease (CAD) and/or history of MI, as well as the correlation between physical activity level and evidence of CAD and/or history of MI. There is also research on HRQoL and patients before they go through coronary artery bypass grafting surgery and six months post surgery, in which the participants had a poor HRQoL pre-operation and a higher HRQoL post-operation. The gap in literature is the correlation between physical activity level and HRQoL in a specific population sample of older adults (age 50 and up). Researching the correlation between these two variables in older adults who have a history of MI can lead to a contribution to the current literature on physical activity and HRQoL because evidence has shown that HRQoL is greater when people exercise more (Fortuno-Godes, Guerra-Balic, & Cabedo-Sanroma, 2013). The present research study is unique because all patients are post-MI and enrolled in a medically supervised exercise program in order to educate them on how to exercise and what guidelines to follow. There were patients of all exercise levels, some sedentary and some very active, and the goal of this research was to investigate if HRQoL would be higher in those who are very active. Contrary to other research, the present study looked at a group of people who wanted to start or continue an exercise program post-MI, while most other research includes a variety of post-MI participants whether they want to get better after their event or not.

Statement of the Problem

The purpose of this research was to determine if physical activity is related to HRQoL in older adults, age 50 and older, who have a history of MI. This study included

only older adults, age 50 or older. Limited literature exists on the relationship between physical activity and HRQoL regarding those at that age who have history of MI.

Hypothesis

It was hypothesized that older adults with a history of MI who maintain higher levels of physical activity will have a greater HRQoL than those who are not as physically active. The more physically active someone is, the more likely they are to have a positive outlook on their life. It was hypothesized that physical activity level and HRQoL were significantly and positively correlated.

Operational Definitions

- Physical activity is any of type movement that requires energy and expends such energy to produce a movement, including daily living activities, walking, jogging, swimming, dancing, and gardening (National Heart, Lung, & Blood Institute, 2011). For this study, a FitBit Ultra™ was used to measure physical activity. Physical activity was measured in each participant by the total number of steps each participant took for three days.
- Activities of Daily Living (ADLs) are normal daily tasks that people perform including self-care such as feeding, bathing, dressing, and grooming. Additionally, this includes homemaking and leisurely things, as well as shopping (Jekel et al., 2015).
- HRQoL is a concept of self-reported physical and mental health measures. The 36-item Health Survey (SF-36) is an instrument that was used to measure the HRQoL of each patient (Centers for Disease Control and Prevention, 2012).
- An MI is a heart attack. The term “myocardial” refers to the heart muscle and “infarction” refers to tissue death caused by oxygen deprivation due to blocking of the arteries. This cardiac event occurs when there is a sudden deprivation of

circulating blood and causes necrosis of the heart tissue (Centers for Disease Control and Prevention, 2013).

- Older Adult is defined as any individual 65 years or older and any other individual between the ages of 50-64 years with physical limitations or clinically significant conditions that affect physical activity, physical fitness, or movement (Skinner, 2005).

Strengths and Limitations

The strength of this study was the unique contribution to current literature by measuring the physical activity level of older adults who have a history of MI. The study measured physical activity level with a FitBit™ by observing the amount of steps taken over a three-day period. This method of measuring physical activity level removes the errors of participants in self-reporting their amount of physical activity as well as accurately representing the participant's typical physical activity levels by measuring steps for multiple days. Noah, Spierer, Gu, and Bronner (2013) studied the validity and reliability in the FitBit™. The researchers concluded that, monitoring step counts and measuring energy expenditure while walking, the FitBit™ is valid and reliable (r = 0.81-0.83, $P < 0.05$). The accuracy of the FitBit™ is also taken into consideration. A study by Diaz, et al. (2016) measured step count activity at the same attachment site as the participants in the present study. In a 1500-step treadmill walking trial, the researchers manually counted steps from a video recording of the participants and compared the step count recorded from the FitBit™. The FitBit™ had a mean step count of 1,497± 10.7 steps with a 0.2 ± 0.7 % error. The researchers concluded that the FitBit™ is accurate when walking.

Limitations to the present study included the sample size and sampling method because the research was based on volunteers from one specific facility, and the number of participants that were recruited for the study limited it. Another limitation included self-reported information. Each participant completed the HRQoL survey form, which is a self-

reported measure. The correlation in the present study does not completely explain the cause of HRQoL because there is no control for the baseline HRQoL value and there are multiple other factors other than physical activity that influence one's HRQoL. Another limitation included adherence to wearing the FitBit™. Since the participants were not monitored 24/7, it was not possible to know if every participant adhered to wearing the device the entire time.

Delimitations

The present study was restricted to a specific age population of older adults who were 50 and older with a history of MI simply because of the gap in literature with this specific population. The sampling method was not random because participants were recruited from a specific cardiac rehabilitation facility.

Summary

Not much research has been completed on evaluating the relationship between HRQoL and physical activity levels in older adults with a history of MI. The HRQoL of older adults who have a history of MI was used to examine the relationship between that and their physical activity levels. The present study is just a snapshot of how active the participants were during the first part of cardiac rehabilitation. The present study appends other completed research studies on HRQoL and physical activity level for other groups. The present study also helps to understand older adults with history of MI and current physical activity levels.

CHAPTER TWO: LITERATURE REVIEW

According to the 2014 Health Disease and Stroke Statistics, an American has a myocardial infarction (MI) every 44 seconds (Alan et al., 2014). Research has shown that physical activity and health related quality of life (HRQoL) are key factors in a heart healthy life. The purpose of this research review was to study HRQoL and its relation to physical activity level in older adults who have a history of MI. Several articles discussed in the literature review are about HRQoL and physical activity level in patients who have had an MI. Other articles in this literature review included: other age populations, different cardiac events, different modes of exercise, and other variables that may impact the outcome of physical activity level and HRQoL in older adults who have history of MI.

Health Related Quality of Life and Coronary Artery Disease

Some researchers investigated coronary artery disease (CAD) and HRQoL. Research included the change in HRQoL over time before and after the event or at certain times after the event had passed. Other research included gender differences and weight classification differences in people with CAD or MI and the affect on HRQoL.

In a recent study, researchers suggested that HRQoL was lower in individuals with a history of MI (Plevier et al., 2001). The researchers of this study tested two different groups: those with a history of MI and those without a history of MI. The purpose of the study was to evaluate changes in emotional functioning in people who do and do not have a history of MI in order to find out if HRQoL recuperated after an acute cardiac event. There were ninety-nine subjects that were in the MI group, and 101 subjects were in the non-MI group: a total of 200 subjects. Each participant was tested at one and three-year intervals. Emotional functioning was measured using the hospital anxiety and depression scale (HAD) and the heart patient's psychological questionnaire (HPPQ). The researchers found that MI survivors have impaired emotional functioning such as anxiety, depression, feeling disabled, and displeasure when compared with their unaffected peers. No improvement over time was

found in the subjects with a history of MI. A similar study assessed HRQoL in men and women one week, five months, and one year after an acute MI (Brink, Grankvist, Karlson, & Hallberg, 2005). The purpose of the study was to detect any changes in HRQoL at one-year post-MI compared to measures assessed at one week and five months post-MI. The study included 134 subjects who completed the HRQoL SF-36. It was suggested that the HRQoL in both men and women improved one year after the acute MI. While both genders overall HRQoL scores increased, the categories of improvement differed between men and women. Men's scores increased in the physical health category, while mental health scores were increased in women ($P < 0.01$). In conclusion, early assessment of fatigue and depression (HAD) indicated a decreased HRQoL in patients one-year after the cardiac event. Both studies assessed HRQoL on patients after an MI. The difference between the two studies was that the study by Plevier, et al. (2001) had an MI group and a control group of people who have not had an MI tested over time, while the study by Brink, Grankvis, Karlson, & Hallberg (2005) compared men and women over a long period of time to see if HRQoL changed as time passed since the cardiac event. Another comparable study compared HRQoL scores 1, 7, 13, and 25 months after an acute MI to study the results over time and respective differences between patients and partners (Eriksson, Asplund, Hochwalder, & Svedlund, 2012). This study was also modeled the same way as the two previous studies, except this study contained only 13 subjects. The results were similar to the Brink, Grankvist, Karlson, & Hallberg, (2005) study, as HRQoL scores improved over time. Additionally, mental and physical health significantly improved. The researchers suggested that patients strive to adapt to their situation, which could be one reason why people's HRQoL improved over time post-MI.

A recent research study had 3109 patients with history of MI, stroke, or both that were compared to patients with other diagnoses using the HRQoL survey (Bach et al., 2010). The lowest HRQoL results were seen in patients with a history of stroke only, while

MI was second lowest. This study was similar to others, but it was not an experiment studied over a time period to see if HRQoL would begin to improve long after the event. However, it ties into similar studies of patients who have had an MI and their self-rating of HRQoL because it shows that people who have had other personal medical events also have a lower HRQoL.

A study by van Tol, Huijsmans, Kroon, Schothorst, and Kwakkel (2006) was similar in that the researchers studied HRQoL, but the participants were patients who were diagnosed with Chronic Heart Failure (CHF), this population frequently suffers from diminished exercise capacity, fatigue, dyspnea, and poor quality of life. The purpose of the study was to perform a meta-analysis to determine the effect of a training program on the exercise capacity, HRQoL, and cardiac performance in CHF patients. In this meta-analysis, two reviewers selected the studies that were analyzed. Randomized cross-over trials, patients with CHF in the control and intervention group, groups with and without exercise training, and outcome measures were evaluated from different studies. The researchers found that diastolic blood pressure and end-diastolic volume had a significant summary effect size (SES) at rest, which means that these variables had improved after a period of training. Also noted at maximal exercise, systolic blood pressure, heart rate, cardiac output, peak oxygen uptake, anaerobic threshold, and the 6-minute walk test suggested significant SESs because these variables also improved over a period of training. Not only were the SESs significant, but The Minnesota Living with Heart Failure Questionnaire (MLWHFQ) also improved an average of 9.70 points for those CHF patients who exercised. In conclusion, researchers found that clinical effects on exercise capacity and MLWHFQ may be due to exercise training over a period of time. Cardiac performance during exercise bouts may also have small positive clinical effects. People who exercise with diagnosed CHF are more likely to have a small positive improvement on heart performance during exercise,

higher overall HRQoL, and a greater exercise capacity than people with CHF who do not exercise.

Other researchers suggested that patients with a lower HRQoL are correlated with greater CAD severity, depression/anxiety, poor social effort, and symptoms of mental distress (Staniute, Bunevicius, Brozaitiene, & Bunevicius, 2014). Researchers suggested that a higher exercise capacity is an important indicator of treatment of CAD and delaying onsets of MI. The purpose was to compare exercise capacity and fatigue with HRQoL in patients who have been diagnosed with CAD. There were 1,072 patients with CAD who participated in this study. The subjects were all part of a cardiac rehabilitation program and evaluated with the medical outcomes short form 36-question questionnaire (SF-36), body mass index, and coronary interventions, symptoms of fatigue and depression, and hypertension. The mean SF-36 score in this research study was 51.20. Researchers found that a lower HRQoL score was associated with higher mental fatigue levels and lower exercise capacity. In conclusion, the researchers suggested that patients in cardiac rehabilitation with CAD are at a greater risk for high levels of fatigue and decreased exercise capacity, which correlates with a low HRQoL. Similarly, a study by Carlsson (1998) studied patients with CAD and measured serum cholesterol, lifestyle such as smoking, exercise, dietary habits, working capacity, and health related quality of life. The purpose of the study was to develop and evaluate a secondary prevention program, as well as examine the ability of the program to reduce high levels of lipids and reduce fat in patients with CAD. There were 263 total patients in this study who had to have a history of MI, coronary artery bypass grafting (CABG), or percutaneous transluminal coronary angioplasty (PTCA) and also be between the ages of 50-70 years of age. The study was a meta-analysis of five studies, which used a prevention program that compared levels of lipids for four weeks after the event, measured HRQoL with a questionnaire at one month and one year in patients, smoking habits, dietary habits, and work capacity. The secondary

prevention program was more effective because it monitored smoking habits, diabetes, hypertension, lipid levels, and body mass index (BMI). Food habits improved, but there was not an effective improvement on smoking habits or physical exercise. There was not a successful intervention for working capacity, but the most effective and successful intervention programs affected lipid levels and food habits. HRQoL was negatively affected after a cardiac event. In conclusion, the researchers suggested that secondary prevention programs are important for assessing multiple variables on patients with MI, CABG, and PTCA history.

In a similar study to the previous one, researchers conducted a study on patients with diabetes mellitus (DM) and CAD to test their HRQoL (Porojan, Poanta, Cerghizan, & Dumitrascu, 2010). DM was more prevalent due to aging, population growth, and obesity, and CAD was major cause of mortality in diabetic patients. The researchers suggested that HRQoL could not be extrapolated from routine clinical variables; therefore, patients with DM need better monitoring to improve outcomes. In conclusion, the researchers suggested that the diabetic patients with CAD scored lower on the physical component of the HRQoL survey. Overall, the results from this study are important for further research review on HRQoL in those at risk for an MI.

Similarly, the purpose of the study by Peric, Borzanovic, Stolic, Jovanovic, & Sovtic (2006) was to investigate the changes in HRQoL in patients prior to heart surgery and six months after CABG surgery. There were 243 patients who underwent CABG due to their severe angina who also participated in the study. The survey was distributed twice, once before surgery and once six months after surgery. Of the patients who participated, 226 completed both pre and post surveys. Variables that were measured in this study included: sex, age, type of job, marital status, and job status. Researchers noted that patients who underwent CABG and were in a higher angina classification, as estimated by the Canadian Cardiovascular Society, had a significantly worse quality of life prior to the operation, but

improved post-operation. Additionally, patients had a greater improvement after the operation in physical mobility, energy, and pain levels due to the relief of unstable angina. In conclusion, the researchers suggested that the higher the severity of angina, the better the improvement of HRQoL post-operation.

An additional study with 205 subjects who were all 60 years of age or older, and the aim of that study was to investigate a mean difference in the SF-36 Physical component summary score between three classes of weight: normal weight, overweight, and obesity (Giuli et al., 2014). The questionnaires that were conducted included: quality of life, physical activity, and socio-psychological domains. The researchers found that the SF-36 Health Survey physical component (PCS-36) reported lower scores in the overweight and obese subjects compared to the normal weight people. Depression, age, years of education, and physical activity were shown to be significant variables to the different weight classifications, but BMI was negatively associated with all physical subscales of the SF-36 questionnaire ($p < 0.05$). In conclusion, the interrelationships among psychological factors that affect well-being offer a valid tool in preventing cardiovascular complications and adverse effects in older adult obese people.

The researchers investigated HRQoL and CAD and MI. The studies were very closely related, and the findings were similar. Participants had a change in HRQoL based on their diagnosis.

Physical Activity and Coronary Artery Disease

Physical activity and a high HRQoL can reduce the risk of associated health problems such as CAD and those of a psychosocial nature (Riiser et al., 2014). Researchers suggested that physical activity is a key factor in preventing overweight and obesity in adolescents (ages 13-15 years). This also contributes to well-being and HRQoL. The purpose of this study was to research the effects of cardiorespiratory fitness (CRF) and HRQoL after a 12-week exercise intervention. The number of subjects in the study was 120.

A 20-meter shuttle run test was used to measure CRF. A Norwegian KIDSCREEN was used to assess HRQoL. The Behavioral Regulation in Exercise Questionnaire-2 was used to determine motivation towards exercise and physical activity. BMI was also calculated. Results showed that the intervention had a moderate effect on HRQoL and a small effect on CRF. BMI increased significantly in the control group, which yielded a moderate preventive effect in the intervention group. In conclusion, the physical activity counseling on CRF, HRQoL, and BMI among adolescents who are overweight had a beneficial short-term effect from the intervention. This study differs from the other studies due to the sample population including adolescents, but demonstrates exercise can increase HRQoL in just a few weeks. Therefore, it is important to practice a healthy lifestyle incorporating exercise at a young age.

Hawker et al. (2014) mentioned that the risk for (CVD) and death could possibly be increased for people who have OA because typically they avoid activities that exacerbate pain symptoms. Different variables were researched in the study, but each of their variables are linked to physical activity. The study included 2,156 people who were 55+ years of age with moderately severe hip/knee symptoms or disability. The researchers found that walking disability was significantly associated with the CVD composite ($P = 0.01$). The researchers concluded that there was a significant increase not only in all-cause mortality in patients with hip or knee osteoarthritis and severity of osteoarthritis of OA disability, but also a significant increase in serious CVD events.

Health Related Quality of Life and Physical Activity

Other researchers investigated physical activity and the affect on HRQoL. Some researchers aimed to study the amount of physical activity that could change HRQoL, and other researchers studied the type of physical activity that could change HRQoL. Research included participants with history of CAD, peripheral artery disease (PAD), stroke, and people with both cardiovascular disease (CVD) and osteoarthritis (OA).

Brovold, Skelton, and Bergland (2013) studied two different types of exercise programs and the effects on HRQoL, physical fitness, and physical activity in older adults over the age of 70 with chronic disease post hospital discharge. This study used different exercise modalities than those mentioned previously. The purpose of the study was to compare the two different types of exercise programs and what affects those modes of exercise would have on HRQoL and physical activity. The first type was high-intensity aerobic interval exercise (HIA), and the second type was home-based exercise (HB). There were 115 subjects who were recruited to participate in the study, and randomly selected for one particular exercise group after discharge. The SF-36 was used to assess HRQoL. The Senior Fitness Test was used to assess physical fitness. The Physical Activity Scale for the Elderly was used to assess physical activity. The researchers suggested that subjects' HRQoL and level of physical activity was correlated; it improved and increased after three months of activity. It was also suggested that the HIA group had a greater improvement in physical fitness than the HB group. In conclusion, exercise therapy is suggested to be part of a routine for older people who are at risk of functional decline. A study by Fortuno-Godes, Guerra-Balic, and Cabedo-Sanroma (2013) was similar to that above, and the researchers mentioned that evidence shows mortality is delayed by regular physical activity when compared to inactivity. The purpose of the study was to assess HRQoL and medication in elderly people who are physically active and engage in a community-based exercise program. Dissimilar to the previous study mentioned, there was also a sedentary group included in this study in order to see the differences between the physically active and inactive in HRQoL. In conclusion, the researchers suggested that elderly people show a better HRQoL when they participate in regular physical activity. Similarly, Mobily (2014) conducted a research study with 2,592 adults who were age 60 and older. Exercise frequency and compliance in older adults consisted of five exercise events per week. The researcher suggested that health-related characteristics were better in older adults who

exercised regularly compared to older adults who did not exercise regularly. A study by Ishibashi, Fujita, and Yasuda (2012) was also very similar. The researchers looked at number of steps and HRQoL after treatment of percutaneous coronary intervention. Participants were measured for both steps and HRQoL after discharge from the hospital and one-month post treatment. The researchers collected and analyzed the data, and both number of steps and HRQoL increased significantly ($P < 0.00$, $P < 0.05$). Participants who had a higher activity level also had a higher HRQoL, so researchers suggested that exercise training continue.

Comparably, Parmenter, Dieberg, Phipps, and Smart (2015) investigated whether or not people with PAD had an improvement in HRQoL with exercise training. The researchers conducted a systemic research with randomized controlled trials (RCTs) only. The researchers discussed 15 RCTs that included a total of 1,257 subjects. The different groups either exercised with or without supervision, and some subjects did resistance training. Each study concluded that when compared to a controlled trial, the exercise group improved the speed of their Walking Impairment Questionnaire (WIQ) and Short-Form Physical Component Summary (SF-PCS) score. When compared to the control group, the exercise group did not improve on the Mental Component Summary (SF-MCS) score. Other studies about physical activity and HRQoL in people with history of MI can be compared to this study because the variables that are examined.

Other researchers investigated the mode of group exercise and the affect on HRQoL (McGrath, O'Malley, & Hendrix, 2010). The aim of the study was to compare different modes and find out which mode of group fitness was chosen by subjects based on their demographic characteristics. In the general population, researchers have suggested that HRQoL is improved by regular exercise. Little research has studied which mode of exercise impacts HRQoL the most. There were 143 subjects in this study separated into three groups who met on a regular basis at a fitness facility. The SF-36 was used to measure HRQoL.

Subjects chose one of the three group fitness classes: Pilates, strength training, or step aerobics to attend, and they each answered the SF-36 either before or after the exercise. The researchers found that there was a significant association between the amount of time subjects exercised and the mode of exercise that the subjects chose. They also found that between the strength training and Pilate's modes of exercises, there was a significant difference in energy and fatigue report on the SF-36. The strength-training group scored higher on the energy and fatigue report than the Pilates group. In conclusion, the researchers suggested that modes of exercise do affect HRQoL domains. This study differs due to the mode of exercise being any type of formal exercise and not just physical activity, which includes activities of daily living. It is important to motivate people who are inactive with a mode of exercise that they enjoy in order to achieve a better quality of life. In the present study, participants were allowed to perform whatever type of physical activity they liked, and it was simply recorded by the FitBit™. Holmgren, Gosman-Hedstrom, Lindstrom, & Wester (2010) investigated the impact of a high-intensive exercise program and group discussions about falls in stroke patients at risk of falls. Similarly to the study above, the exercise program was a type of formal exercise. The patients who were tested did have a history of a stroke. There were 391 patients that were screened at a stroke unit during their rehabilitation. Due to the inclusion criteria, there were 34 stroke patients that participated in the study. All stroke patients had to be 55 years of age or older, at risk for falls, ability to understand and comply with Swedish instructions, and the ability to walk without a walking device for 10 minutes. The SF-36 was used to assess HRQoL. During the 3-6 month study, there was an improvement in the both the strength training and Pilates groups at the Physical Component Scale on the SF-36. Differences were not shown between the intervention and control groups. In conclusion, patients should be educated about exercise after a stroke event in order to have a favorable impact on HRQoL.

There were a few research studies that researchers looked at number of steps taken and HRQoL. The three studies that are discussed included older adult men and women, two studies with healthy participant and the other study included participants with chronic obstructive pulmonary disease (COPD). Each of these studies included statistical measures that looked at the relationship or association between daily steps and HRQoL. Aoyagi, Park, H., Park, S., and Shephard (2010) studied the amount and the intensity of activity on HRQoL in both older adult males and females ages 65-85. The subjects were healthy and of Japanese decent. The researchers studied step counts and physical activity intensity in metabolic equivalents (METs) with pedometers and accelerometers continuously for a year's time. After data was collected for physical activity, a final HRQoL was assessed using the SF-36. The researchers used linear and quadratic regressions to assess daily step count and daily duration of physical activity. The results showed relatively close associations between the two measurements of daily step counts and duration of physical activity of >3 METs ($P < 0.05$), which translates to those participants who took more steps were more likely to spend more time in moderately vigorous activity. The researchers also found that a higher HRQoL was associated with participants who spent more time in moderately vigorous activity (> 3 METs) compared to those participants who were less active during the overall day. Vallance, Eurich, Lavallee, and Johnson (2012) also looked at daily steps and HRQoL. There were 385 men age 55 years and older who participated in this study. HRQoL was measured and assessed using the RAND-12 Health Status Inventory survey, and, like the present study, steps were measured using a pedometer over a three-day period. Unlike the present study, the researchers explored all three adjusted models for HRQoL (physical, mental, and global health), and they found a significant linear trend with daily steps. Daily steps were classified in quartiles 1, 2, 3, and 4 based on the number of steps per day the participants took. In quartiles 3 and 4, the researchers found a higher physical, mental, and global health when compared with quartiles 1 and 2. Overall,

researchers found that HRQoL, across all three models, was significantly associated with a higher number of steps per day. In conclusion, researchers suggested that participants in the higher quartiles of steps per day reported less symptoms of depression when compared with participants in the lowest quartile. Durr, et al. (2014) aimed to examine the independent association of HRQoL with physical activity level as well as functional capacity in patients with COPD. There were 87 diagnosed COPD patients who participated in this study. Each participant took a COPD assessment test in order to measure HRQoL. To measure functional capacity, participants also performed a six-minute walk test and a pulmonary function test. Participants wore a SenseWear Mini Armband for seven days in a row to measure physical activity level. Researchers performed a multiple linear regression analysis and analyzed the data. The researchers found that age, six-minute walk distance, and average daily steps were independent of the COPD assessment score. Researchers also found no significant association between physical activity duration and forced expiratory volume in one second ($P = 0.364$). Researchers suggested that functional capacity and average daily steps are independent determinants of HRQoL. The researchers revealed that physical activity and functional capacity is associated with a higher HRQoL in COPD patients. These results highlight the importance to continue being active and move throughout the day.

In summary, these research studies include many relevant themes to this proposed research topic such as: physical activity, HRQoL, heart disease that leads to cardiac events, such as MI, and the effects that any of those may have on older adults. Other populations and variables in various research studies were examined due to the limited research on the topic. Upon reviewing the literature, it was stated that physical activity could improve HRQoL in other populations. Many articles reviewed found that HRQoL and physical activity are related; when someone is more physically active they have a higher HRQoL.

Further research is analyzed for a significant relationship on HRQoL and physical activity level in older adults with a history of MI.

CHAPTER THREE: METHODOLOGY

Participants

Eight patients (seven male, one female) from cardiac rehabilitation participated in this study. The participants were older adults with a mean age of 70±14 years and had a history of myocardial infarction (MI). All participants were enrolled in outpatient cardiac rehabilitation within 12 months of the event. Based on a power analysis, the number of participants needed was 22. That number is based on the correlation coefficient effect size (*r*) of a correlational study. The *r* is aimed to contrast two continuous variables (Vincent & Weir, 2012). This comes from looking at past research and strong correlations between different variables (van Tol, et al., 2006; Aoyagi, et al., 2010).

Patients were a mix of both deconditioned novices and individuals experienced in exercise. Informed consent was obtained from each participant in order to participate in this research study. Three people who were eligible to participate chose not to in the present study. There were 19 patients enrolled in cardiac rehabilitation who did not qualify for participation in the present study due to diagnosis and age stipulations.

Inclusion criterion included participant's age over 50, medical history of an MI, and active participation in cardiac rehabilitation. Volunteer recruitment was used for this research study. Each participant was asked to participate in the research study during week two of their cardiac rehabilitation program. The reason participants were asked to participate during week two of their program is due to them getting into a routine their first week at the facility, then each person agreed to participate in this extra task. Once they agreed to participate, they signed a consent form before getting started with the survey and tracking their physical activity level.

Instruments

The HRQoL Medical Outcomes Study 36-item Short Form Survey Questionnaire (SF-36) and the number of steps recorded by the FitBit™ were used to collect the data from each participant. Both variables are scale data.

Health Related Quality of Life. Each participant completed the HRQoL survey known as the Medical Outcomes Survey or Short Form (SF)-36. Evidence was provided by psychometric analyses that the SF-36 is a valid and reliable measure for multiple populations (Yu, Coons, Draugalis, Ren, & Hays, 2003). It is a questionnaire with 36 items grouped into different subscales, which include: physical functioning (PF), role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and mental health (MH). For this study, the total score was used. The range of scores is scaled from 0 as worst health to 100 rated as best health.

Physical Activity Level. Physical activity was measured in each participant by the use of a FitBit Ultra™ that records steps. For recording number of steps while walking, the FitBit™ is valid and reliable (Noah, Spierer, Gu, & Bronner, 2013). Participants wore the device for three days. Of those three days, two of the days were weekdays, and the other a weekend day. Participants continued their own exercise program, activities of daily living, nutritional intake, and lifestyle. Once the FitBit™ was returned, the data on the total number of steps taken for the three days was recorded.

Procedures

Each participant volunteered to participate at the cardiac rehabilitation center. Once the informed consent was signed, the participant completed the HRQoL SF-36 survey and was assigned a FitBit™. Participants were shown how and where to wear the FitBit™ for best measurement of steps. Each participant wore the FitBit™ around their waist just above the hips, and took the FitBit™ off before showering. Each participant put the FitBit™ back

on after showering but before continuing with his or her daily activities. Participants continued their normal lifestyle while the FitBit™ measured physical activity. After the three days were up, each participant returned the FitBit™ in order to collect the data. The data showed the total number of steps each person took in the three-day period. If a participant would have failed to be compliant wearing the FitBit™ throughout the three days, then that participant's data would have been removed from the research. All participants were compliant with wearing the FitBit™.

Research Design and Statistical Analysis

The research design of this study was non-experimental. The participants' HRQoL and number of steps taken over multiple days were observed. Descriptive statistics were used to determine the mean and standard deviations of the data that is collected. Because the variables are scale, a Pearson's Product Moment correlation was used for the statistical analysis of this research in order to find a possible relationship between physical activity level and HRQoL. The purpose of this research was to determine if physical activity is related to HRQoL in older adults who have a history of MI.

CHAPTER FOUR: RESULTS

The objective of this research was to investigate if HRQoL correlated with physical activity in older adult patients who have had a myocardial infarction (MI). Eight participants, all with history of MI, from cardiac rehabilitation were recruited to voluntarily participate in this research study. There were seven male and one female with a mean age of 70±14 years. Each subject was asked to complete the SF-36 version of HRQoL and wear a FitBit™ for three consecutive days following survey completion. The total number of steps in three days was collected from each participant using The FitBit™.

Descriptive statistics were used to determine the mean and standard deviations of both the number of steps and SF-36 results (Table 1). Skewness Standard Error was 0.75 for both steps and SF-36 results. Kurtosis Standard Error was 1.48 for both steps and SF-36 (Table 2). When the descriptive statistics were run, an outlier was found.

Table 1

Descriptive Statistics for FitBit™ Steps and SF-36 Survey

	N	Range	Minimum	Maximum	Mean	SD
Steps	8	22,316	2,530	24,846	11,026.88	6,689.70
SF-36	8	38.33	33.75	72.08	53.42	12.95

Table 2

Skewness and Kurtosis for FitBit™ Steps and SF-36 Survey

	Skewness	Skewness SE	Kurtosis Statistic	Kurtosis SE
Steps	1.20	0.75	2.40	1.48
SF-36	-0.38	0.75	-0.62	1.48

A Pearson's Product Moment correlation was the statistical analysis used in this research to find if HRQoL and physical activity were correlated. Pearson's correlation (2-tailed) resulted in $r = .43$, $P = .29$, $P > 0.05$ between number of steps and SF-36. Based on the results of the Pearson's correlation, there is no significant correlation between physical activity and HRQoL (Table 3). Figure 1 shows the scatterplot between number of steps and HRQoL score.

Table 3

Pearson's Correlation Between FitBit™ Steps and SF-36 Survey

		SF-36
Steps	N	8
	Pearson Correlation	.43
	Sig. (2-tailed)	.29

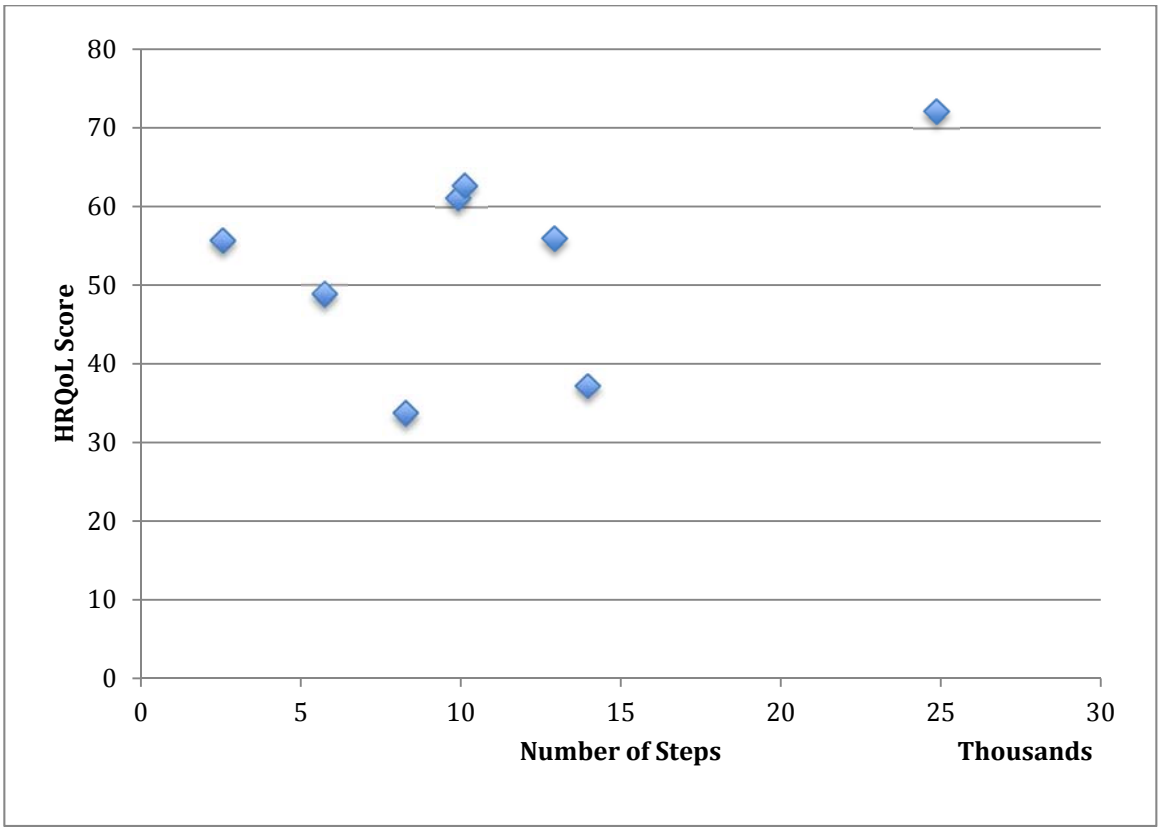

Figure 1. Scatterplot for FitBit™ Steps and SF-36 Survey.

Within this research study, there was an outlier found for number of steps. Descriptive statistics were used to determine the mean and standard deviations of both the number of steps and SF-36 results when the outlier was removed (Table 4).

Table 4

Descriptive Statistics for FitBit™ Steps and SF-36 Survey with Outlier Removed

	N	Range	Minimum	Maximum	Mean	SD
Steps	7	11,419	2,530	13,949	9,052.71	3,979.44
SF-36	7	28.89	33.75	62.64	50.75	11.37

A Pearson's correlation was used for the statistical analysis of this research to find if HRQoL and physical activity level are correlated. Pearson's correlation (2-tailed) resulted in $r = .14$, $P = .77$, $P > 0.05$ between number of steps and SF-36. Based on the results of the

Pearson's correlation, there is no significant correlation between physical activity level and HRQoL when the outlier is removed (Table 5). Figure 2 shows the scatterplot between number of steps and HRQoL score with the outlier removed.

Table 5

Pearson's Correlation Between FitBit™ Steps and SF-36 Survey with Outlier Removed

		SF-36
Steps	N	7
	Pearson Correlation	-.14
	Sig. (2-tailed)	.77

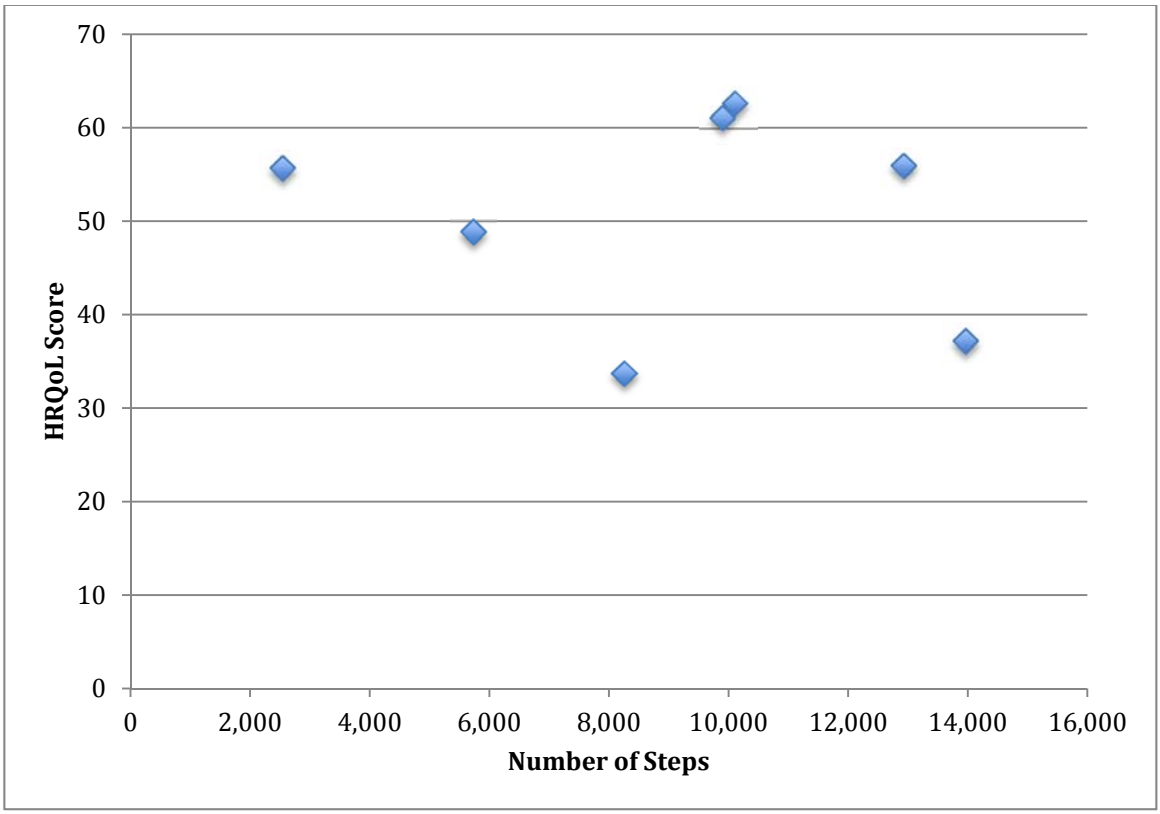

Figure 2. Scatterplot for FitBit™ Steps and SF-36 Survey with Outlier Removed.

Although not significant, the results reported with the outlier showed a positive correlation in the scatterplot (Figure 1). Once the outlier was removed, the scatterplot (Figure 2) depicted a very weak, negative correlation.

CHAPTER FIVE: DISCUSSION

Review of Results

The intention of this research was to determine if health related quality of life (HRQoL) and physical activity level were correlated in older adults who have had a myocardial infarction (MI). Physical activity was measured in each participant by the total number of steps each participant took over three days.

There were eight male and female participants in this study. The participants were older adults with history of an MI who were all enrolled in outpatient cardiac rehabilitation. Based on the results of the Pearson's correlation, there was no significant correlation between physical activity level, measured by steps, and the HRQoL short form 36-question questionnaire (SF-36).

The mean SF-36 results of this study can be compared to a study which yielded a non-significant correlation by Staniute, Bunevicius, Brozaitiene, & Bunevicius (2014). In the study, the mean SF-36 score was 51.20, similar to a mean score of 53.41 with the outlier and 50.75 with the outlier removed in the present study. However Staniute et al. (2014), researchers got a different result in the comparison of HRQoL and activity. HRQoL was found to be lower in those participants with lower exercise capacity, whereas this study did not find a significant correlation between HRQoL and number of steps. Staniute et al. (2014), had participants in which were diagnosed with CAD, whereas the present study had participants who were diagnosed with an MI. When the outlier was removed from the mean HRQoL score in my study, the value was less than that of the mean HRQoL score in the study by Staniute et al. (2014). Due to these differences, more research studies need to be conducted on larger sample sizes and population samples of both CAD and MI on HRQoL.

The mean total number of steps taken for the three days was 11,027 with the outlier and 9,053 with the outlier removed. The results included the exercise completed on one cardiac rehabilitation day, all participants walked for 15 minutes on the treadmill. The

recommended number of steps per day for adults to be considered active is 10,000 steps. Older adults with certain health conditions may not be able to or need to reach as many as 10,000 steps per day (Davis, 2016). Since the mean number of steps is lower in the descriptive statistics with the outlier removed, this may relate to the lower mean HRQoL value when compared with the particular study by Staniute et al. (2014). In the present study, the total number of steps over a three-day period was recorded, which computes to an average of 3,000 steps per day. Based on the results, all participants are substantially under the recommended number of steps per day for adults.

The participant who was recognized as an outlier had a step count of 24,846 steps over the three-day period, a daily average of 8,282. This was the only participant to have an average step count close to the recommendation. This particular participant mentioned having a very physical job, in which the participant walks many flights of stairs and up and down the hallways throughout the workday. The other participants in the present study are retired or have a job in which they are not as physically active and stated that they adhered to wearing the FitBit™ throughout all three days. This is why the participants step count is so high compared to other participants.

Although not significant, the scatterplot with the outlier removed (Figure 2) depicted a negative correlation. The non-significant result means that there is a possibility that physical activity level and HRQoL are not related. In a future study, the relationships among the eight different domains of the SF-36 and physical activity could also be examined. There is a possibility that particular aspects of HRQoL could be more strongly related to physical activity than others or that some relationships are positive while others are negative, cancelling each other out in the total. Each domain can be investigated for which is least and most related to number of steps per day. On the other hand, due to the size of the sample in the present study, analyzing all eight domains, as opposed to the overall HRQoL of each participant, would increase type I error. Additionally this is one of the first studies to

examine number of steps and HRQoL in this population, so a more general approach was taken.

The present research study is unique because all patients are post-MI and are enrolled in a medically supervised exercise program in order to educate them on how to exercise and what guidelines to follow. The research has helped encourage patients at cardiac rehabilitation to exercise more at home, including walking more throughout the day to become or remain physically active. The present study could help adapt cardiac rehabilitation protocols for tracking home exercise in all patients enrolled in the program.

Limitations

The number of participants in this study was less than expected. There were only 8 participants who agreed to participate in the present research study, which was limited by diagnosis and age. During the data collection process, 19 patients enrolled in cardiac rehabilitation either did not have an MI diagnosis or did not qualify to participate based on age. Three patients, who did qualify, did not want to participant in the study.

There was a wide range in steps taken by participants. One of the participants stated spending all of one day sitting in a car due to unexpected travel. This limited the number of steps taken by the participant, which possibly skews the data in this small sample. There was also no pre-test information collected on participants, so differences between participants, such as exact walking mobility, are not accounted for. The correlation in the present study also does not completely explain HRQoL because there is no control for the baseline HRQoL value.

There was only one facility that was used to recruit participants. If there were participants from multiple facilities, that would give a more diverse sample. There would have also more likely been many more participants in the study.

Another limitation to the present study was the diagnosis of MI. The severity level of each participant MI was not included. This research was interested in the general cardiac

rehabilitation patients with MI, so there was no control for the type of MI. Future research could control for the type of MI and investigate any differences.

Future Direction

In future research, a larger population sample should be used, such as a larger cardiac rehabilitation facility or numerous smaller facilities. The research sample should be open to all patients who have been diagnosed with an MI or who have had heart procedures (Stent/PTCA) or open-heart surgery (CABG) in order to obtain a more reliable measure. Future research could control for the type of MI each participant has or how many bypasses or stents each participant received and investigate any differences in the results that may appear after analyzing steps per day and HRQoL. There are patients of all exercise levels, some sedentary and some very active, and the goal of this research is to investigate if HRQoL would be higher in those who are very active. Further research could be developed on finding how many steps per day a person with chronic disease should be taking in order to be considered physically active. If a researcher in the future is interested in how monitoring physical activity impacts daily activity, data would need to be collected numerous times throughout the course of treatment at cardiac rehabilitation. This could enhance research in heart patients, and help people understand how many steps to take per day in order to maintain health benefits.

Conclusion

In conclusion, there was not a significant correlation between physical activity and SF-36. Although there was not a significant correlation between the two variables, this information is pertinent for opening the door for further research concerning physical activity and HRQoL in cardiac rehabilitation patients. This research will append other completed research studies on HRQoL and physical activity for other groups. The present study is just a snapshot of how active the participants were during the first part of cardiac rehabilitation, but it is one of the first studies to actually measure daily number of steps in a

group of individuals with MI. If a future researcher is interested in how monitoring physical activity impacts daily activity, data would need to be collected numerous times throughout the course of treatment at cardiac rehabilitation. More research needs to be conducted with more participants and a broader range of diagnoses.

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Appendix A

Completed IRB Application

INSTITUTIONAL REVIEW BOARD
APPLICATION FOR REVIEW OF HUMAN SUBJECTS RESEARCH
(Pursuant to Title 45-Code of Federal Regulations-Part 46)

Date: 11/1/15
Title of Project: Relationship Between Quality of Life and Physical Activity with Diagnosed Myocardial Infarction

Principal Investigator(s): Meagan Wilson

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Specify Type and Source of Funding: RCSA Grant

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1. **Describe the purpose/hypothesis of the project or the research problem in enough detail that we can ascertain what the project is about. Describe why it is being done and the importance of the knowledge expected to result.**

   Explain how the project/study fits with and extends current knowledge.
   According to the 2014 CDC statistic, a myocardial infarction occurs in approximately 735,000 Americans every year, which is caused when the heart muscle is damaged or dies because of lack of blood flow. People's physical health and well-being is suggested to prevent or delay this cardiac event. The purpose of this research project is to determine if health related quality of life is related to physical activity levels in older adults who have a history of myocardial infarction. This topic is of high interest, and it will be great to research physical activity and HRQoL in patients with history of myocardial infarction. The gap in literature to be filled is the correlation of physical activity to Health Related Quality of Life (HRQoL) in this specific population sample, which, with research, can lead to a contribution to the current literature on physical activity and HRQoL. The process of cardiac rehabilitation is fully explained in the cardiac rehab initial assessment with the patient. During one of the first three exercise sessions, the patient will be asked to participant in this voluntary research study. This research study is

separate from cardiac rehabilitation, and it will not impact their exercise program. It will be emphasized to the participant that the research study is completely voluntary and that their information will be kept private.

2. **Describe the subjects needed for this project and, at a minimum, provide the following information:**
   a. **The type of individuals needed as subjects:**

   ☐ Any UCO Student
   ☐ Students in investigator(s) class
   ☒ Other (describe below)

   Admitted Patients in cardiac rehabilitation

   b. **The procedures used to recruit subjects:**

   X Advertisement (flyer)
   ☐ Email blast
   ☐ Direct/targeted email
   ☐ Online posting
   ☐ In-class announcement
   ☒ Other (describe below)

   Word of mouth.

   c. **Where will the recruitment of subjects occur?**
   Cardiac Rehabilitation at Total Health. 1810 N. Perkins Road, Stillwater, Oklahoma 74074

   d. **Do you plan to recruit subjects from outside businesses or other organizations?**

   Yes - X No

   If "yes," attach a copy of the required written permission (email or letter) from the appropriate person authorized to grant such permission.

   e. **Do you plan to recruit from specific classes?**

   Yes ☐ **No** ☒

   If "yes", attach a copy of the required written permission (email or letter) from the course instructor.

If recruitment occurs in the classroom, describe measures to minimize undue influence or coercion during recruitment:

f. Do you plan to recruit subjects via email or conduct any of your research via the Internet?

Yes ☐ **No** ☒

If "yes", indicate which of the following you will use:

☐ SONA
☐ Survey Monkey
☐ Survey Share
☐ Qualtrics
☐ Other
☐ None

Please enter an explanation if "Other" is chosen.

You must give a copy of your IRB application to the UCO Office of Information Technology for authorization. This may be done simultaneous to ORC submission.

g. Do you intend to use an oral or written script or any materials (flyer, letter, email, advertisement, announcements) as part of the recruitment of research subjects?

Yes X **No**

If "yes", attach a copy of these scripts/documents.

3.

a. What is the maximum number of subjects you expect to participate?

25

Provide an explanation for that number.

Looking at scholarly sources and the statistical power of r, this number of subjects will be needed to find a possible relationship between physical activity level and HRQoL.

b. Will you be specifically including or targeting any of the following groups for research subjects? (Select all that apply)

☐ Minors (<18 years old)
☐ Cognitively Impaired
☐ Pregnant Women
☐ Prisoners
☐ Native Americans
☒ Older Adults (65+ OR 50+ w/ cardiac, pulmonary, metabolic diseases)
☐ None of the above

If any were selected, please explain the additional safeguards used to protect the welfare of these vulnerable groups.

There are concerns with the privacy of patient information and coercion with the older adult population. A safeguard used to protect the privacy of the participant's information will be to keep all patient information stored securely in Dr. Olson's office. This study is voluntary; therefore, patients will only participate if they agree to.

4.

a. Describe the methods to be used in the study, including study design, measurements or observations of subjects, and what subjects will experience. Provide the estimated total time to complete surveys/questionnaires, etc.)

Participants will be patients who have undergone a heart procedure, some being previously active and others being previously inactive. Physical activity level will be assessed with a FitBit™, which will be worn for three days, and HRQoL data will be gathered with the SF-36 prior to assessing physical activity level. The FitBit™ will assess how much the participants move on an average daily basis and it will be compared to how high each participant's HRQoL is The HRQoL survey should take about ten minutes on average. Participants will fill it out while at the study location.

b. Will you be using questionnaires, surveys, tests, or other written instruments?

Yes ☒ **No** ☐

If "yes", attach a copy of these scripts/documents.
Attached

c. Where will data actually be collected (i.e. room number, place)?

The data will be collected at Total Health in Stillwater Oklahoma. 1810 N Perkins Road, Stillwater, Oklahoma 74074. When a new cardiac rehab

patient goes through orientation, the research study will be explained after all other information about rehab. It will be emphasized that participating in the study is voluntary and will not impact their cardiac rehab experience at all. The PI typically conducts these orientations as part of her normal job duties. If the patient agrees to participate and signs an informed consent, they will be asked to complete the HRQoL survey. They will also be given a FitBit™ and asked to wear it for the 3 days of data collection. After the three days of data collection, the subject will return the FitBit™ to the PI.

d. Will you be using existing data?

Yes ☐ **No** ☒

If "yes", are data de-identified?

Yes **No**

If "yes", is database available to the public?

Yes **No**

e. Will tissue or blood samples be collected for data?

Yes ☐ **No** ☒

If "yes", explain the procedures for disposal.

f. Projected start date :

☒ Upon IRB Approval
☐ Other (specify)

g. Projected end date: One Year

5. **Will medical clearance be necessary for subjects to participate because of tissue or blood sampling, or administration of food or drugs, or physical exercise conditioning?**

Yes ☐ **No** ☒

If "yes", explain how the medical clearance will be obtained.

6. **Does the research involve any of the following? (select all that apply)**

☐ Physical stress including exercise or exertion
☐ Psychological or social stress
☐ Exposure to radiation
☐ Legal risk
☐ Economic risk
☐ Exposure to infectious disease
☒ Personal or sensitive information about subject or family
☐ Offensive, threatening, or degrading materials
☐ Use of confidential records (medical or educational)
☐ None of the above
☐ Other (explain below)

For each type of risk selected fill out a-c below:

a. Describe the amount of risk or harm anticipated.

The amount of risk anticipated is minimal.

b. Justify why the risk is necessary.

The risk is necessary because sensitive information will be collected from the patient, such as HRQoL.

c. Explain how the risk will be minimized.

The risk will be minimized by keeping the personal or sensitive information locked up securely.

7.

a) **Will the subjects be deceived or misled in any way?**

Yes ☐ **No** ☒

b) **Describe the deception or omission, justify the necessity, and explain how and when subjects will be debriefed (attach debriefing script).**

8. **Will any inducements be offered to the subjects for their participation?**

Yes ☐ **No** ☒

a. If "yes", please describe the inducements.
☐ Course Credit (complete b. below)
☐ Extra Credit (complete b. below)
☐ Money (specify amount)
☐ Other (specify below)

b. If course credit or extra credit is offered, what alternative means of obtaining additional credit are available to those students who do not wish to participate in research project?

9.

a. How will consent be obtained?

Select all that apply:

☒ Subject will sign consent form
☐ Subject will be given online consent*
☐ Subject will be given an information sheet*
☐ Subject will give verbal consent*
☐ Other or no consent (explain below how voluntary participation will be secured)

*****Submit a Waiver of Documentation (available at our website) with your application if there is no signed consent form.***

Attach a copy of the consent form or information sheet (see Informed Consent Form guidelines at http://www.uco.edu/academic-affairs/research-compliance/).

b. Who will be consented? (select all that apply)

☒ Participant
☐ Child (<18)
☐ Parent/Legal Guardian

c. Specify where consenting will occur:

Consent will occur where the data will be collected, which will be at Total Health in Stillwater Oklahoma in an assessment room.

d. Is a Waiver of Consent requested? (If approved, informed consent will not be obtained.)

Yes ☐ **No** ☒

e. Do you have or will you obtain a Certificate of Confidentiality?

Yes ☐ **No** ☒

If "yes", please provide a copy once obtained.

10.

a. Will any aspect of the data be made a part of a record that can be identified with the subject?

Yes ☐ **No** ☒

If "yes", describe and justify the necessity. Explain when the data will be de-identified.

b. Will a master code sheet be kept for purposes of identity security?

Yes X **No**

If "yes", explain where the code sheet will be stored and when it will be destroyed.

Stored securely in Dr. Olson's office separate from the rest of the data for one year until destroyed.

c. Does this study involve?

☐ Audio taping of the subjects
☐ Video taping of the subjects
☐ Taking photographs of the subjects
☐ Digital imaging of the subjects
☒ None of the above

If "yes", explain necessity and attach a copy of release or permission

form. Describe the storage, disposition, and security provisions taken to protect recordings/photos.

d. Will subjects be identifiable in these recordings?

Yes ☐ **No** ☒

If "yes", explain why this is necessary.

11. Please describe the steps you will take to ensure the privacy and confidentiality of the data you collect by answering the following questions:

a. How will the data be reported or disseminated?

☒ Group/aggregate
☐ Single subject/case study
☐ Other (describe below)

b. Where (specify office #) and how will the data be securely stored?

The data will be locked up in a filing cabinet in Dr. Olson's office, CTL 226. Will be stored one year at UCO.

c. Who will have access to the data and/or password?

PI
Co-PI
X Both
Other (describe below)

d. Who will be responsible for secure storage?

PI
Co-PI
X Both

Other (describe below)

e. What will the length of time each of the following will be kept?

Paper data documents: 1 year
Electronic data documents: 1 year
Signed Informed Consent Forms (Federal regulations require a minimum of 3 years): 3 years

f. Who will be responsible for destruction of the data?

The Primary Investigator and Co-PI

g. When and how will the data be destroyed? Be sure to specify for electronic data, paper data, and code sheets (as relevant).

The data will be destroyed one year after the study. The data will be removed from electronic data by doing a memory wipe. Any paper data will be shred upon disposal.

12. Will the fact that a subject did or did not participate in a specific experiment or study be made a part of any record available to supervisor, teacher, or employer?

Yes ☐ **No** ☒

If "yes", describe and justify the necessity.

13. Describe the benefits of participation for subjects (if any). [If there is none, say so].

Benefits to the participants include knowing their level of physical activity and how they compare to normal recommendations for older adults with cardiovascular disease.

14. Describe the benefits of your study to society.

Benefits to society include more information on HRQoL and physical activity and whether or not there is a relationship between the two in people who have had a heart attack. This is beneficial to society in order to show them if they need to be more physically active or not.

REQUIRED AUTHORIZATION SIGNATURES
SIGNATURE/AFFIRMATION/REPRESENTATION OF PRINCIPAL INVESTIGATOR(S):
(Primary PI must read and initial by hand at each of the below.)

1. _____This application represents an accurate and complete description of my proposed research project.

2. _____I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human subjects are properly protected.

3. _____I agree to comply fully with any requirements made by the UCO IRB.

4. _____The human contact portion of my (our) research will not begin until the UCO IRB has given its written approval.

5. _____Any additions or changes after the project has been approved will be submitted to the IRB for approval prior to implementation.

_____ _____
Signature of Primary Principal Investigator Date

_____ _____
Date
Signature of Co-Primary Principal Investigator

If additional Co-PIs are associated with this project, please attach an additional sheet with name, signature, and date.

I have reviewed this Application for Review of Human Subjects Research, and, subject to approval by the UCO Institutional Board, authorize the Principal Investigator(s) to conduct this research. My signature acknowledges that I am aware of this project.

Name of Department Chair : _____
Department : _____

_____ _____
Signature of Department Chair Date

Name of College Dean :_____
College : _____

Signature of College Dean Date

UCO Office of Information Technology (for all e-based research)

Name of UCO IT Representative: _____

Signature of UCO IT Representative Date

CHECKLIST FOR IRB APPLICATION SUBMISSION
Please mark which documents you have attached to your IRB Application:

	Attached	Not Applicable
Research Proposal (i.e. thesis proposal, RCSA application, grant proposal)	☒	☐
Recruitment Script/documents	X	
Informed Consent Form (or Waiver)	☒	☐
Measurement instrument(s) (questionnaires, surveys, etc.)	☒	☐
Written authorization--professors, organizations, etc.	X	
Protecting Human Research Participants (PHRP) Training Certificate(s)	X	
Have you submitted your application to the Office of Information Technology for approval?	☐ Yes	☒

CONTACT INFORMATION FOR QUESTIONS OR CONCERNS:

Office of Research Compliance, Academic Affairs
405-974-5497
irb@uco.edu

Submit one hard copy of your application, with all required signatures to:
UCO-IRB Office
NUC 341, Campus Box 132
Edmond, OK 73034
405-974-5497
405-974-3818 (fax)

AND
Submit one electronic file without signatures to irb@uco.edu.

Please note your application will not be processed until the original application with all required signatures is received.

List all study personnel and indicate how they are involved

Research Staff (Last, First)	**Highest Degree Earned (i.e. Ph.D, M.A., BA., etc.)**	**Affiliation (UCO or other)**	**Role in this research (PI, Co-PI,Data Collection, Data Entry, Interviews, etc.)**	**PHRP* Certificate Date**	**UCO Email Address**
Wilson, Meagan	B.S.	UCO	PI	8/25/14	Mwilson68@uco.edu
Olson, Jacilyn	PhD	UCO	Co-PI	8/11/14	Jolson3@uco.edu

*Protecting Human Research Participants (PHRP) is a National Institutes of Health on-line training course required by the Department of Health and Human Services regulations. Visit http://phrp.nihtraining.com/users/login.php. Copies of Certificates of Completion should be attached to the application. Recertification is required every two years and CITI certification can be substituted.

PHRP certification is required of all study personnel.

Study personnel who are not a PI or Co-PI must complete, sign, and submit an IRB Personnel Agreement Form.

Required for Student Investigators

Purpose of this project:

Student qualification to conduct research: (select all that apply)

Currently in or completed research methods course	☒
Current or prior experience as an independent or supervised Research Assistant	☐
None (If None, Faculty Mentor assumes additional responsibility of training)	☐

Faculty Oversight Agreement

I have reviewed and approved this application and I agree to ensure that all UCO IRB regulations will be complied with.

Name of Faculty Member: _____

Signature of Faculty Member:	Date:

*See Student Research Guidelines on our website: www.uco.edu/academic-affairs/researchcompliance.

Appendix B

Informed Consent Form

UNIVERSITY OF CENTRAL OKLAHOMA

INFORMED CONSENT FORM

Research Project Title: Health Related Quality of Life and Physical Activity in Older Adults with Medical History of Myocardial Infarction

Researcher (s): Meagan Wilson

A. **Purpose of this research:** The purpose of this research project is to determine if health related quality of life is related to physical activity level in older adults who have a history of myocardial infarction. This research will be separate from the exercise program for participants in cardiac rehabilitation. This research study is voluntary, so if the patients wish to participate, information will be keep securely locked up in a private area. This will not have any affect or impact on their time or outcomes at cardiac rehabilitation. This research study is completely separate from cardiac rehabilitation.
B. **Procedures/treatments involved:** This research will assess if a higher physical activity level is related to a higher quality of life. The health related quality of life survey (SF-36) will be distributed to you and completed before physical activity is measured. The accelerometer will be worn for 3 consecutive days in order to measure physical activity level.
C. **Expected length of participation:** You will participate in the study for an expected length of three days during physical activity level data collection. The survey will take about ten minutes to complete prior to getting a FitBit to use to assess your physical activity level.
D. **Potential benefits:** The benefits include advancement in knowledge on how physically active you are after an acute myocardial infarction as well as your self- measured quality of life. Additional benefits include knowing the physical activity level in comparison with the normal standards
E. **Potential risks or discomforts:** Potential risks involve the privacy of patient information and coercion with the older population. During the recruitment process the PI will emphasize that participation in the study is completely voluntary and will in no way impact the participant's cardiac rehab process. There are no incentives for participating or punishments for not participating (see Script).
F. **Medical/mental health contact information (if required):** Total Health 405-533-4348
G. **Contact information for researchers:** Meagan Wilson, BS Email: mwilson68@uco.edu Cell: (325) 356-6141
H. **Contact information for UCO IRB:** UCO-IRB Office NUC 341, Campus Box 132 Edmond, OK 73034

405-974-5497
405-974-3818 (fax)

I. **Explanation of confidentiality and privacy:** The results observed from the data that is collected will not be released to anyone outside of the research team including insurance companies. A code number will be assigned to your results to be used as they are analyzed in order to make conclusions needed of the research study.

J. **Assurance of voluntary participation:** This research is by volunteer only. Therefore, there are not negative consequences due to participation in this study because it is by choice in order to participate. I have been given an opportunity to ask questions as to the procedures of this research study. Further understand that there are also risks that may be associated with this program. Despite the fact that a complete accounting of all these risks in not entirely possible. I am satisfied with the review of these risks, which was provided to me, and it is still my desire to participate. I acknowledge that I have read this document in its entirety, or that it has been read to me if I have been unable to read the same consent to the rendition of all services and procedures as explained herein by all program personnel

AFFIRMATION BY RESEARCH SUBJECT

I hereby voluntarily agree to participate in the above listed research project and further understand the above listed explanations and descriptions of the research project. I also understand that there is no penalty for refusal to participate, and that I am free to withdraw my consent and participation in this project at any time without penalty. I acknowledge that I am at least 18 years old. I have read and fully understand this Informed Consent Form. I sign it freely and voluntarily. I acknowledge that a copy of this Informed Consent Form has been given to me to keep.

Research Subject's Name: _____

Signature:
Date:

Appendix C

SF-36 Survey Instrument

Medical Outcomes Study: 36-Item Short Form Survey Instrument

RAND 36-Item Health Survey 1.0 Questionnaire Items

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. **Compared to one year ago**, how would your rate your health in general **now**?	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing **several** flights of stairs	[1]	[2]	[3]
7. Climbing **one** flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking **more than a mile**	[1]	[2]	[3]
10. Walking **several blocks**	[1]	[2]	[3]
11. Walking **one block**	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?
(Circle One Number on Each Line)

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2

14. **Accomplished less** than you would like	1	2
15. Were limited in the **kind** of work or other activities	1	2
16. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
(Circle One Number on Each Line)

	Yes	No
17. Cut down the **amount of time** you spent on work or other activities	1	2
18. **Accomplished less** than you would like	1	2
19. Didn't do work or other activities as **carefully** as usual	1	2

20. During the **past 4 weeks,** to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
(Circle One Number)
Not at all 1
Slightly 2
Moderately 3
Quite a bit 4
Extremely 5
21. How much **bodily** pain have you had during the **past 4 weeks**?
(Circle One Number)
None 1
Very mild 2
Mild 3
Moderate 4
Severe 5
Very severe 6
22. During the **past 4 weeks,** how much did **pain** interfere with your normal work (including both work outside the home and housework)?
(Circle One Number)
Not at all 1

A little bit 2
Moderately 3
Quite a bit 4
Extremely 5
These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.
How much of the time during the **past 4 weeks** . . .
(Circle One Number on Each Line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6
25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6

29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks,** how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?
(Circle One Number)
All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
None of the time 5

How TRUE or FALSE is each of the following statements for you.
(Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

Appendix D

SF-36 Scoring

Item numbers	**Change original response category:**	**To recoded value of:**
1, 2, 20, 22, 34, 36	1 →	100
	2 →	75
	3 →	50
	4 →	25
	5 →	0
3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1 →	0
	2 →	50
	3 →	100
13, 14, 15, 16, 17, 18, 19	1 →	0
	2 →	100
21, 23, 26, 27, 30	1 →	100
	2 →	80
	3 →	60
	4 →	40
	5 →	20
	6 →	0
24, 25, 28, 29, 31	1 →	0
	2 →	20
	3 →	40
	4 →	60
	5 →	80
	6 →	100
32, 33, 35	1 →	0
	2 →	25
	3 →	50
	4 →	75
	5 →	100

Appendix E

Script

The process of cardiac rehabilitation is fully explained in the cardiac rehab initial assessment with the patient. During one of the first three exercise sessions, the patient will be asked to participant in this voluntary research study. This research study is separate from cardiac rehabilitation, and it will not impact their exercise program. It will be emphasized to the participant that the research study is completely voluntary and that their information will be kept private.

"For the study, I am measuring your physical activity level and health related quality of life.

You will complete a health related quality of life survey before measuring physical activity level.

You will wear this Fit Bit in order to track your activity level for three days.

The ultimate goal is to see if there is a relationship between quality of life and physical activity level.

This research study is voluntary, so if you wish to participate, your information will be keep securely locked up in a private area. This will not have any affect or impact on your time or outcomes at cardiac rehabilitation. This research study is completely separate from cardiac rehabilitation."

Appendix F

Written Authorization

From: Weichbrodt, Blake
Sent: Thursday, January 07, 2016 9:04 AM
To: Wilson, Meagan
Subject: FW: Research Thesis

Meagan,

Based upon your submission and the subsequent approval from the Stillwater Medical Center Compliance Committee on October 8th, 2015; you have been approved to continue your research within the cardiac rehab department

Thank you,
Blake Weichbrodt, PT/DPT
Director of Rehabilitation and Medical Fitness
Stillwater Medical Center
Total Health
(405)533-4348

-----Original Message-----
From: Wilson, Meagan
Sent: Monday, August 31, 2015 1:34 PM
To: Weichbrodt, Blake
Subject: RE: Research Thesis

Blake,

I really appreciate you checking on this.
I will send you my research proposal this week, which includes the questionnaire and equipment. There are a couple of edits that I need to make, and will be able to make those on Wednesday evening. For my research, I cannot have any type of participant identifiers, if that helps with taking data outside Total Health, etc. If needed (and if possible) I could work on my thesis here (off the clock from CR) when I need to look at patient data.

Thanks,
Meagan

From: Weichbrodt, Blake
Sent: Monday, August 31, 2015 11:57 AM
To: Wilson, Meagan
Subject: FW: Research Thesis

Meagan,

This is our step for the research. Our privacy officer will need to run by Compliance

committee for approval, the next meeting is October 8th. Since we are not a research facility, this has been our formal approval mechanism and I like to have the discussion in the minutes.

We need to get the patient to sign an authorization form to override any previous restrictions. We need to review the tools and questionnaires you are going to use, especially if you are taking data outside the building for patient identifiers.

Lastly, she will need to review the paper before submission as a precautionary measure.

Thank you,
Blake

From: Weichbrodt, Blake
Sent: Monday, August 31, 2015 10:57 AM
To: Wilson, Shelly
Subject: FW: Research Thesis

Shelly,

I have read through the HIPAA and Research policy but wanted to run this by you too. Is it OK for our employee to conduct this study with our CR patients? It is my understanding that there will be no PHI documented, rather just results of their testing. I would have her still have the patients sign the authorization. Anything else we need to consider?

Thank you,
Blake

From: Wilson, Meagan
Sent: Friday, August 28, 2015 1:59 PM
To: Weichbrodt, Blake
Subject: Research Thesis

Hello,

Here is the document that is a summary of my research thesis, and what I would like to accomplish.
I have been working on at school along with a separate research proposal that is about ready to submit to the UCO IRB after approval through SMC.

Also, I won't need anything supply wise through the CR program.

I will have my own FitBit™ devices to let the patients borrow for measuring PA level and I am going to use the SF-36 to measure Quality of Life.
Let me know if you need any other info.

Thanks for your help,

Meagan Wilson