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To the Graduate Council:

I am submitting herewith a dissertation written by Michael Shipe entitled "The Effects of a Pedometer Intervention on The Physical Activity Patterns of Cardiac Rehabilitation Participants." I have examined the final electronic copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Exercise and Sport Sciences.

David R. Bassett, Major Professor

We have read this dissertation and recommend its acceptance:

Edward T. Howley, Dixie L. Thompson, Naima Moustaid-Moussa

Accepted for the Council:

Dixie L. Thompson

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

To the Graduate Council:

I am submitting herewith a dissertation written by Michael F. Shipe entitled “The effects of a pedometer intervention on the physical activity patterns of cardiac rehabilitation participants.” I have examined the electronic copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Exercise and Sport Sciences.

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We have read this dissertation
and recommend its acceptance:

Edward T. Howley

Dixie L. Thompson

Naima Moustaid-Moussa

Accepted for the Council:

Carolyn R. Hodges
Vice Provost and Dean of the Graduate School

**THE EFFECTS OF A PEDOMETER INTERVENTION ON THE PHYSICAL
ACTIVITY PATTERNS OF CARDIAC REHABILITATION PARTICIPANTS**

A Dissertation

Presented for the

Doctor of Philosophy

Degree

The University of Tennessee

Michael F. Shipe

August 2009

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As always, my family has been integral to any success I have enjoyed professionally or academically. Their support has been a pillar I have relied upon throughout my academic pursuits. And to my wife Stephanie, who has undoubtedly sacrificed the most yet provided her unerring love and support throughout my doctoral studies, she is owed the greatest gratitude of all.

ABSTRACT

Purpose: To assess whether the provision of a pedometer and exercise diary could significantly increase the activity levels of phase II cardiac rehabilitation program patients on the days they did not attend the program. **Methods:** Seventy patients (53 males, 17 females, age of 68 plus/minus 9 yrs, BMI 29.0 plus/minus 6.1 kg/m²) participated in the study. During their first visit to a phase II CRP, patients were assigned to one of two groups. Control patients were given a blinded pedometer (n = 34), while experimental subjects received a pedometer that they could view (n = 36) as well as an exercise diary to record their daily step counts. Control patients wore the pedometer during all of their waking hours throughout phase II CRP enrollment and were encouraged to increase their overall activity levels in accordance with standard level of care. The baseline activity patterns of were determined during their first week of phase II CRP enrollment. Patients in the experimental group were encouraged to gradually increase their step counts on the days (Tuesday, Thursday, Saturday and Sunday; i.e., non-CRP days) they did not attend phase II CRP gradually until they were accumulating 2,000 steps/day above their baseline levels. Two sample t-tests were used to compare the baseline physical characteristics between genders as well as the control and experimental groups. Mean weekly step counts for both groups were compared based on overall and aerobic steps counts accumulated on CRP and non-CRP days using 2 times 7 repeated-measures ANOVAs. **Results:** At baseline, men took more overall steps than women and all patients took more steps on days they attended the phase II CRP, versus days they did not. There was a significant effect ($p < 0.0001$) of group assignment and time for overall and aerobic step counts on non-CRP days; as the experimental patients took significantly more steps and increased their step counts at a faster rate than the control patients. There was no significant interaction on CRP days as both groups significantly increased their overall and aerobic steps counts. **Conclusion:** Phase II CRP patients who used a pedometer and exercise diary significantly increased their overall and aerobic steps counts on CRP and non-CRP days, to a greater extent than patients who received usual care. Thus, pedometers can be used to increase the physical activity levels of phase II CRP patients.

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CHAPTER I: INTRODUCTION

Healthy People 2010 identified physical activity as one of the ten leading health indicators for American adults (186). In 2008, the federal government issued its initial physical activity guidelines for Americans. Specifically, it was recommended that healthy individuals accumulate at least 150 minutes per week of moderate intensity physical activity to obtain the majority of health benefits from exercise. Older adults with chronic conditions, who cannot meet this activity level, should be as physically active as their personal functional capacity and health conditions permit (124).

Physical inactivity is associated with an increased incidence of various chronic conditions including cardiovascular, metabolic, orthopedic and mental diseases and results in approximately 250,000 premature deaths each year (10). There are numerous cross sectional, prospective and clinically randomized trials that indicate that regular physical activity is associated with positive health related outcomes (11). Yet an estimated 74% of U.S. adults do not perform 30 minutes of moderate leisure time physical activity on most days of the week, and about 27% are completely sedentary. Age demonstrates an inverse relationship with the percentage of individuals attaining the physical activity recommendations, with those 65 years and older demonstrating the least activity (125). This trend is sustained whether activity levels are self-reported or objectively monitored (e.g., subjects' activity levels are assessed with accelerometers or pedometers) (100, 148, 176).

Coronary heart disease (CHD) is one of the most common cardiovascular diseases, especially among seniors, as it currently affects 16 million Americans. Furthermore, it is the leading cause of death for adult males and females, contributing to over 600,000 fatalities annually. More than

1.2 million acute myocardial infarctions (MI) occur annually and it is estimated that approximately 15 years of life are lost due to the typical MI (132).

Research over the past 55 years has shown that regular physical activity reduces the occurrence of CHD. In 1952, Morris et al. (108) reported that the rate of CHD was lower in more active bus conductors versus sedentary bus drivers. Subsequent epidemiological studies noted an inverse relationship between caloric expenditure and heart attack risk as well as cardiorespiratory fitness (CRF), an outcome of physical activity, and the prevalence of CHD (118, 194). The results of these studies helped support the American Heart Association's re-classification of physical inactivity from a secondary to a primary risk factor for CHD in 1992 (12). Leisure-time physical activity (LTPA), as well as changes in LTPA, has also been shown to be independently related to the risk of all-cause mortality and myocardial re-infarctions for individuals with known CHD (71, 89, 154, 188).

The exact physiological mechanisms by which increased physical activity levels mediate CHD risk are unknown. Higher physical activity levels are associated with the effective management of the modifiable risk factors while improving cardiorespiratory fitness (CRF), an independent predictor of all-cause and cardiovascular mortality (25, 60). Specifically, individuals who are more active demonstrate better lipoprotein profiles, lower blood pressure, blood sugar and body weights and are less likely to smoke than their sedentary counterparts (60). Thus, effective physical activity interventions for individuals with established CHD should enhance their risk factor management and minimize the occurrence of recurrent coronary events.

Individuals who have had a recent MI or index cardiac surgery (e.g., coronary artery bypass graft, percutaneous transluminal coronary angioplasty or valve replacement) are eligible to

participate in a cardiac rehabilitation program (CRP). A traditional CRP involves a supervised exercise program three times a week for 45-60 minutes (10). The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American College of Cardiology (ACC), American Heart Association (AHA) and the American College of Sports Medicine (ACSM) recommend that patients with CHD perform a minimum of 30 to 60 minutes of moderate intensity activity at least 5 times/week, coupled with an increase in daily lifestyle activities (11, 16, 71, 153). These recommendations are based on the dose-response relationship between overall activity levels and CHD (11, 12, 90, 188).

A typical CRP exercise session lasts 45-60 minutes and usually involves a series of 5-15 minute exercise bouts on various exercise machines (e.g., treadmill, cycle ergometer, NuStep®, etc.) as well as strength training. Research indicates that approximately 75% of phase II CRP participants do not perform an adequate amount of physical activity on the days they attend a CRP, when caloric expenditure is used to measure physical activity (136, 139). Furthermore, individuals enrolled in a phase II CRP are sedentary on the days they do not attend the program (133, 138). These facts may be attributable to the average age (e.g., > 55 years) of participants in phase II CRPs, the likelihood that they have multiple risk factors, as well the low maximal CRF exhibited in men and women (5 and 4 METS, respectively) in this population (5, 15, 138). Each of these variables has been associated with low leisure-time activity levels (55, 138, 177).

Another indication that the typical phase II CRP participant is likely not exercising on the days they do not attend the program is provided by Meijer et al. (102). These researchers examined older adults (e.g., 57 years) whose exercise program mirrored the one commonly employed in phase II CRPs (e.g., 2 exercise sessions a week for 12 weeks). Using an

accelerometer, the authors reported that subjects demonstrated significantly higher levels of physical activity on exercise training days, but their overall activity level did not change. In essence, the subjects compensated for their structured exercise activity by decreasing their activity on non-exercise training days (102). These results underline the necessity to determine effective strategies to enhance the physical activity levels of individuals enrolled in phase II CRP, especially on non-CRP days, so that they may enjoy more exercise-related positive health outcomes.

Exercise prescriptions commonly specify four variables: frequency, intensity, duration and type (12). Given that most individuals entering a phase II CRP are older with a remarkably low CRF, low and moderate intensity exercise bouts for short durations are recommended at the beginning of the program (10, 16, 153). The AHA standards for exercise training of CRP patients state that the overall daily activity, including the performance of regular moderate intensity exercise, is more important for health than the performance of high intensity exercise. The authors cited that although regular high intensity may provide greater benefits, this intensity is also associated with less compliance as well as more adverse cardiac events and orthopedic injuries (153). Therefore, it is imperative to find practical and effective strategies to increase the total volume of low and moderate intensity leisure time physical activities performed by phase II CRP participants.

Several methods have been utilized to assess physical activity including questionnaires, heart rate monitors, doubly labeled water, and motion sensors (e.g., accelerometers and pedometers). Each of these activity assessment tools entails benefits as well as limitations (172). Pedometers may be the most effective of these given they provide a relatively inexpensive, objective, reliable

and valid manner in which to measure ambulation, the most frequently performed activity of adults, including seniors (19, 125, 180). In addition, pedometers appear to motivate sedentary individuals to increase their physical activity levels by providing immediate feedback and by serving as an environmental cue (175). Pedometers are often used in conjunction with individualized steps goals and exercise diaries, which increases their effectiveness (39, 175). A recent meta-analysis of subjects in 26 pedometer-based interventions demonstrated that they significantly increased daily step counts in sedentary adults by 2,491 (a 26.9% increase) over baseline (30).

There is scientific consensus that individuals with established CHD should accumulate 30 minutes of moderate intensity at least five days a week (16, 71, 153). Yet it appears that the exercise monitoring and counseling strategies currently employed in phase II CRPs results in the vast majority of its participants not attaining these activity levels. Thus, it is necessary to determine if pedometers can serve as an effective tool to increase the daily activity levels in this population.

Statement of problem

The AACVPR, AHA, ACA and ACSM recommend that a minimum of 30 to 60 minutes of moderate intensity physical activity be performed on most, preferably all, days of the week for individuals with CHD. Individuals who only exercise during phase II CRP (e.g., 30-45 minutes, 3 days/week) cannot meet these activity goals and thus must exercise on their own as well. The recommended core components of CRPs include optimizing primary risk factor reduction, coupled with the adoption and maintenance of regular physical activity. Yet CRPs do not provide

sufficient counseling or monitoring strategies to ensure its participants are accumulating adequate physical activity.

Statement of purpose

The purpose of this study is to determine whether providing a pedometer and exercise diary to phase II CRP patients along with individualized step goals on non-CRP days results in an increase in physical activity compared to those receiving typical treatment. The use of pedometers in this study will also provide evidence concerning the daily activity patterns of phase II CRP participants.

Significance of the study

To date, the overall physical activity patterns of individuals with CHD have not been well established. The study will help to establish the baseline step count values for individuals who initially enroll in a phase II CRP. The results will determine whether the use of a pedometer and step counts goals leads to significant changes in their leisure-time activity levels on the days they do not participate in a phase II CRP (e.g., non-CRP days). The Omron HJ 720 ITC pedometer can delineate whether changes in leisure time physical activity are accomplished through either fragmented bouts (e.g., increased activities of daily life) or continuous activity (e.g., structured exercise). This information can be used by allied health professionals who work in phase II CRPs to provide practical, specific step count recommendations to help ensure their participants are attaining their recommended physical activity levels.

CHAPTER II: REVIEW OF THE LITERATURE

CHD prevalence and its attendant healthcare costs

In 2009, the AHA reported that coronary heart disease (CHD) affected over 16 million adults in the United States and contributed to over 600,000 fatalities. CHD is the single leading cause of death for adults and is also a major cause of physical disability, especially in the ever-increasing senior population. More than 1.2 million acute myocardial infarctions (MI) occur annually and it is estimated that 15 years of life are lost due to the typical MI. Depending on their gender and clinical outcome, people who survive the acute stage of a heart attack have a chance of illness and death that is 2.5 to 15 times higher than that of the general population and two-thirds never make a complete recovery. Almost 40% of people who experience a MI in a given year will die from it. In 2008, the estimated combined direct and indirect cost of CHD was \$156.4 billion (132). These statistics highlight the necessity of developing cardiac rehabilitation programs (CRPs) that minimize the chance of recurrent coronary events in patients with CHD by effectively managing their primary risk factors while improving their cardiorespiratory fitness (CRF). CRF has been shown to be an independent predictor of all-cause and cardiovascular mortality (25, 85).

Cardiac rehabilitation: overview

CRPs have historically included four components. The initial phase consists of hospital-based in-patient education and daily ambulation following an index CHD event (e.g., MI) or surgery (e.g., coronary artery bypass graft (CABG)). Phase II CR includes 4-12 weeks of electrocardiograph (ECG) monitored exercise three times a week for 45-60 minute in an out-patient hospital setting or wellness program (10). Phase II CR typically begins within 3-6 months after an index CHD event or surgery. During this time, participants' exercise regimens are

continually progressed to increase their functional capacity (e.g., VO_{2max}). Common aerobic exercise modalities utilized in this program include treadmills as well as arm, cycle, rowing and seated stepper ergometers (10). After 4-6 weeks of regular exercise participation, participants may pursue a strength training regimen as well. Phase III CR is considered a maintenance program without ECG monitoring, but includes clinical supervision in which individuals exercise independently. Phase IV provides no ECG monitoring, but entails supervision by health professionals (70, 163). Third party insurance providers cover the first and second phases of the CRP process, while the later two are self-pay. Individuals eligible for a CRP include those diagnosed with CHD and who have had either a myocardial infarction (MI), coronary artery bypass graft (CABG), percutaneous transluminal coronary angioplasty (PTCA), or angina. Based on their insurance provider coverage, some individuals with advanced congestive heart failure may also participate (157, 163).

One of the core components of CRPs is to provide a monitored and structured exercise environment, combined with education sessions that teach participants how to effectively self-manage their primary risk factors for CHD, which reduce disability and promote long-term adherence to healthy behaviors (3, 16, 135, 152). Phase II lasts 4-12 weeks based on the participants' insurance provider(s) and their CRF. Individuals with higher CRF capacities may only complete 4-6 weeks of CR. Participants typically attend an exercise class for 30-60 minutes, three times a week and perform a combination of aerobic and strength training activities during which they are continuously ECG monitored. Each week, the duration and/or the intensity of the aerobic sessions are increased in order to increase the individual's endurance and cardio-

respiratory capacity. In addition, participants attend a 30 minute educational session led by various healthcare professionals once a week (3, 163).

CRPs as effective secondary prevention programs: current challenges

Several meta-analyses examining randomized clinical trials have concluded that individuals who participate in CRPs show improvement in their primary risk factors (e.g., enhanced CRF, lower systolic blood pressure, and better lipoprotein profiles) (35, 113, 160). These primary risk factors are closely linked to subsequent lower cardiac and all-cause mortality rates (3, 57, 59, 163). Ford et al. (57) reported that half of the decline in the U.S. death rates from CHD during the last 20 years is attributable to better primary risk factor management. Total physical activities, as well as leisure time physical activity, is inversely related to cardiovascular risk factors in men and women (63).

Individuals with established CHD who complete a phase II CRP have a 20-25% decrease in cardiac and all-cause mortality rate, but they do not have reduced non-fatal recurrent MIs (35, 160). Interestingly, some clinical trials report that CR participants' exhibit modest or no improvement in primary risk factors, specifically weight loss and blood glucose management (31, 41, 135). This outcome has been attributed to the low mean caloric expenditure (e.g., approximately 270 calories per exercise session) observed during CR participation (139).

The role of phase II CRPs in secondary prevention of CHD continues to increase (3, 163). Fatalities from acute MI have continued to decline, increasing the number of individuals eligible for CRP (162). Hospital stays after MI, CABG and PTCA procedures have declined, which reduces the opportunity for in-hospital risk factor interventions (190). Although the number of individuals eligible for phase II CRPs has increased, referral rates and enrollment have remained

remarkably low. In 2001, approximately 10-20% of the two million individuals eligible for CRP participated in the program, a participation rate that has not changed appreciably in the last twenty years (41, 92). Contributors to the low CR participation rate include: low patient referral rates, inadequate third party reimbursement, poor patient motivation and excessive driving time to program sites (92).

In 2007, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American College of Cardiology (ACC) and American Heart Association (AHA) published position stands outlining the performance measures for CRPs regarding referral and delivery of phase II CRP secondary prevention services. The focus of these position stands is based on research indicating that the provision of early out-patient services is the most well-established strategy in reducing CHD mortality among CRP participants. These new guidelines suggest that all hospitalized patients with a qualifying CHD event should be referred to a phase II CRP prior to hospital discharge. In addition, all out-patients with a qualifying diagnosis within the past year that have not been enrolled in a phase II CRP by their health care provider should be referred as well (163). As progressively more individuals are referred to CRPs, these programs will be expected to provide better outcome measures regarding their core components, including the promotion and adoption of long-term exercise adherence (16, 152).

After individuals enroll in a phase II CRP, attrition rates average 25-50% over the three month course of the program (16, 106, 136). Thereafter, patients may participate in phase III CR maintenance programs, fitness facilities or home-based programs to continue their exercise program (26). Only 30-60% of subjects who complete a phase II CRP are still physically active 3 to 6 months later (52). And one year after completing phase II CRP, the rate of exercise

compliance is less than 40% (3). These poor exercise adherence outcomes contribute to the finding that 90% of patients who have a CABG procedure revert to unhealthy lifestyles that exacerbate their CHD (62). CHD, like many chronic diseases, is more prevalent among individuals of low socioeconomic status and minorities. Both of these populations participate in CRP at an even lower rate than the national average. Clinicians must consider how they can provide the beneficial aspects of CRPs to indigent and minority populations in a safe and affordable manner that is consistent with hospital and wellness center based programs (3).

Ades et al. (5) reported that the average VO_{2peak} for 2,896 participants entering a phase II CRP was 5.53 and 4.14 METs in men and women, respectively. In contrast, 77 participants who had regularly participated in a phase II CRP for 4 years demonstrated a VO_{2peak} of 9.1 ± 2.8 METs (gender disparities not reported) (13). These results underline the importance of identifying effective exercise monitoring and counseling strategies so that phase II CRP participants will adopt and maintain exercise patterns that improves their functional capacity (35, 113).

In 2007, the AACVPR, ACC and AHA outlined the requisite core components of phase II CRPs including: optimizing cardiovascular risk reduction, cultivating long-term adoption of healthy lifestyle choices, reduction of disability, and promotion of an active lifestyle. Phase II CRPs are encouraged to assess baseline physical activity levels using either a questionnaire or a pedometer and its participants are expected to demonstrate increased domestic, occupational and recreational activity levels (16). Given that questionnaires are subject to recall error and have been shown to provide invalid measurements of time spent in moderate intensity physical activities, especially walking, pedometers may offer the most practical and accurate means to attain the aforementioned assessment and outcome measurements (7, 20, 148).

Pedometers offer an objective, accurate, valid and reliable method to measure ambulatory activity with minimal participant burden (19, 142, 171). These inexpensive devices permit self-monitoring and instant feedback on ambulatory activity. Pedometers may improve self-efficacy and motivate individuals to increase their activity levels with minimal counseling (9, 30, 34, 77). Given that walking is the most prevalent form of leisure time physical activity for seniors (e.g., \geq 65 years), who comprise a large portion of CRP participants, pedometers provide an accurate indication of their overall activity levels (14).

The Omron HJ-720 ITC pedometer has the ability to provide time and day-stamped, hour-by-hour step-count data (delineated between aerobic and non-aerobic steps) which permits researchers the ability to discern whether subjects are accumulating steps through fragmented or continuous physical activity (115).

Pedometers may be part of the solution to increase the number of individuals with CHD who meet clinical exercise guidelines and would likely exhibit improved CRF levels and risk factor management. The use of pedometers and step-count goals can complement traditional CRP counseling to provide a novel strategy for self-monitoring of activity levels. These devices have been proven to enhance patient motivation and adherence to physical activity goals, which would allow participants with CHD to realize the sustained benefits of regular exercise (172).

AACVPR, AHA, ACC and ACSM physical activity recommendations for individuals with CHD

The AACVPR, AHA, ACC and the American College of Sports Medicine (ACSM) each recognize that the promotion and adoption of regular physical activity is imperative for long-term effective primary risk factor management. Their physical activity recommendations for

participants in phase II CRPs is to accumulate 30-60 minutes of moderate intensity physical activity ≥ 5 days/week. Activities that entail low orthopedic demands (e.g., walking) should be pursued and the activity goal may be accomplished through additional structured activities (e.g., 10 minutes walking bouts) or increased activities of daily life (ADLS; e.g., gardening, household work). Furthermore, the volume of activity of should be gradually increased over time (16, 152).

The physical activity recommendations for individuals with CHD regarding the frequency, intensity and duration of activity to be performed are similar for each organization. Each concur that the physical activity can be intermittent (e.g., a minimum of 10 consecutive minutes) or continuous in nature. This recommendation is supported by research findings that suggest that three short bouts (e.g., 10 minutes) of brisk walking accumulated throughout the day effectively reduces primary risk factors as well as one continuous exercise bout of equal duration (110, 111) Furthermore, these recommendations are not appreciably different from those advocated by the ACSM for healthy adults (71). Each organization also states that novel approaches which effectively deliver CR services and promote adherence to its core components should be addressed in future research (16, 152).

Minimal adherence to the physical activity guidelines for individuals with CHD would yield an energy expenditure of about 1,000 calories/week, which has been associated with a significant 20-30% reduction in risk of all-cause mortality in the general population (90). Yet individuals with established CHD who perform this amount of physical activity have been documented, via arteriograms, to experience progression of the coronary artery lesions, whereas a total weekly volume of physical activity equal to 1,500-2,100 kcal is associated with coronary artery disease stability and/or regression (67, 69, 112). Thus, some researchers have concluded that phase II

CRP participants must pursue physical activity outside of their supervised exercise sessions in order to maximize their CHD management (13).

Research supporting the exercise recommendations for individuals with CHD

The aforementioned activity guidelines for individuals with CHD are based upon epidemiological and clinical research demonstrating a positive dose-response relationship between physical activity and reductions in cardiac and all-cause mortality (90, 118). For instance, Paffenbarger et al. (118) demonstrated that versus the least active group of subjects, individuals who expended 71-143 kcal/day had a 22% reduction in all-cause mortality compared to their inactive peers. Individuals who expended 143-214 kcal/day demonstrated a 27% reduction in all-cause mortality; mortality rates continued to decrease up to a caloric expenditure of 300 kcal/day.

Recently, researchers have examined whether the dose-response relationship is consistent in elderly individuals with CHD, who constitute the majority of CRP participants (90). Using sedentary subjects as the referent group, the risk of mortality was reduced in a curvilinear fashion with each 550 kcal/week increase in activity up to 4,000 kcal/week. The intensity of physical activity had no effect on mortality risk after consideration of weekly EE. Interestingly, the authors also noted that a caloric expenditure of 1,500 kcal/week represented the point at which relative risk was reduced by approximately 50% of the maximal reduction (e.g., 4,000 kcal). These results were independent of sex, age, smoking, adiposity, number of co-morbid conditions and type of CHD (81).

Numerous studies have reported that participants in phase II CRPs improve their cardiorespiratory fitness (CRF) approximately 20% (1, 27, 31). This outcome is important since

an inverse dose-response relationship has been documented between CRF and mortality for individuals diagnosed with CHD (88, 97, 187). This relationship also holds true for individuals with CHD who pursue contemporary preventive treatments such as statins or primary PTCA. Specifically, Keteyian et al. (85) reported that in 2,812 patients with CHD every 1 ml/kg · min⁻¹ increase in peak VO₂ is associated with a 15% decrease in all-cause mortality (85). Additional research demonstrates that the magnitude of exercise training induced increases in CRF has been shown to independently predict a decrease in cardiovascular mortality for individuals with CHD (185).

CRF has also been identified as an independent predictor of recurrent cardiac episodes and duration of re-hospitalizations for individuals with established CHD (192). Kavanaugh et al. (84) examined over 12,000 men who had either had an MI or CABG procedure for an average of 8 years. VO_{2peak} levels of < 15, 15 to 22 and > 22 ml/kg · min⁻¹ produced adjusted hazard ratios of 1.00, 0.62 and 0.39 for cardiac mortality and 1.00, 0.66, and 0.45 for all-cause mortality. Additional research indicates that a high exercise capacity (> 10 METs) is associated with excellent prognosis even for individuals with three-vessel CHD (92). In a population of 5,000 individuals with CHD, each 3.5 ml/kg · min⁻¹ increase in CRF decreased all-cause mortality by 17%. Thus, as in the general population, low CRF is a predictor of higher all-cause mortality in individuals with CHD (25).

Several clinical studies have used quantitative angiographic measures to determine the effect of regular PA on coronary lesions. Niebauer et al. (112) has suggested that LTPA independently contributes to enhanced primary risk factor management and prevents the progression of coronary lesions. The authors examined variables that contribute to the progression of CHD in

113 men over a six year period. The intervention group was asked to exercise for 30 minutes each day and attend two 60 minute group exercise training sessions, both at an exercise intensity of 75% HR_{max} each week. There was only a 33% compliance rate to the group sessions over 6 years. During the first year of study, individuals expending 1,500 kcal/week demonstrated no changes in coronary stenoses while patients who accumulated 2,200 kcal/wk experienced lesion regression. Subsequently, during the six-year follow-up period, regression of CHD lesions occurred in subjects who expended an average of 1,785 kcal/week in LTPA. Multivariate regression analysis identified only CRF as independently contributing to angiographic changes (111). This result coincides with Schuler et al. (146, 147) who noted that coronary lesion regression was only related to improvements in CRF (23% increase) in a group of 18 men who performed three hours of moderate intensity exercise per week for one year. These authors also noted that improvement of myocardial perfusion may be achieved independently from regression of coronary lesions.

Hambrecht et al. (67) attempted to identify the effect of different levels of LTPA on CRF and progression of coronary atherosclerotic lesions for 62 individuals with CHD. Subjects were prospectively randomized either to an intervention group participating in regular physical exercise on their own or to a control group receiving usual care. After one year, an analysis of all participants revealed the lowest level of LTPA associated with CHD progression was $1,022 \pm 142$ kcal/week as opposed to patients who experienced no change ($1,533 \pm 122$ kcal/week) or regression in their coronary lesions ($2,204 \pm 237$ kcal/week). Interestingly, subjects had to expend approximately 1,400 kcal/week during LTPA to significantly improve their CRF (67). This amount of activity appears to have no effect on coronary lesions for individuals with

established CHD, yet is associated with a decrease in cardiac and all-cause mortality (81, 90, 118).

Additional evidence indicates that exercise training may be superior to angioplasty. Hambrecht et al. (69) observed the angiographic changes over 12 months in 94 men with established CHD and stable angina who were randomized to exercise training or angioplasty with stent placement. Exercise training consisted of 10-minute cycle ergometry sessions 6 times daily at 70% HR_{max} for 2 weeks, followed by a year of unsupervised 20 minute daily home exercise sessions plus a weekly supervised 60-minute session. At 12 months, VO_{2max} increased significantly (16%) in the exercise group with no change (2%) in the group receiving angioplasty. The target lesion did not change in the exercise group, while 15% of the angioplasty subjects developed re-stenosis (e.g., a luminal narrowing of > 50%). Overall CHD progression was only significantly reduced in the exercise-trained group. Six patients in the exercise training group and 15 patients in the angioplasty group experienced a major cardiovascular event, including nonfatal MI, stroke, a revascularization procedure, or hospitalization for angina, giving a significantly higher event-free survival in the exercise subjects (88% versus 70%) (69).

Ornish et al. (116, 117) used angiographic documentation to show that 28 individuals with CHD who adopted and sustained extensive lifestyle changes had a significant reduction in coronary lesions at one and five years. It is difficult to determine the extent that regular physical activity contributed to these results due to dietary intervention employed in the study. Participants averaged 35 minutes of moderate intensity activity each day. They also reduced their dietary fat intake to 14 grams/day and cholesterol intake to 12 mg/day, which likely made a considerable contribution to lesion regression (116, 117).

The results from Hambrecht et al. (67) and Niebauer et al. (112) suggest that high volumes of physical activity, completed at moderate to high intensities, corresponding to approximately 1,500 and 2,200 kcal/week are associated with no change and regression of coronary lesions, respectively. Therefore, it appears that a significant amount of moderate and high intensity physical activity is required to effectively manage coronary lesions.

In order to attain the energy expenditure levels associated with management and regression of coronary lesions, an individual who weighs 85 kg would have to walk at a pace of 3 mph for approximately 5 hours per week or accumulate 15 miles to expend 1,500 calories, and accumulate approximately 22.5 miles (e.g., walking for 7.5 hours) to attain a 2,200 caloric expenditure, respectively. This estimation is supported by research which utilized a questionnaire to assess the relationship between the effects of LTPA on mortality rates in 5,934 older men (63 years) with established CHD. Over a 5 year period, individuals who performed regular walking 40 or more minutes/day exhibited a significant reduction in cardiac (RR = 0.39) and all-cause mortality (RR = 0.48) even after adjustment for age, smoking, obesity, stroke, diabetes and history of MI. Individuals who participated in physical activity at light, moderate or moderate/vigorous levels demonstrated a RR of 0.42, 0.47 and 0.63 for all-cause mortality versus their sedentary counterparts. A similar relationship was evident for cardiovascular mortality (188).

Previous research indicates these calorie goals cannot be feasibly attained through exercise in phase II or III CRPs alone, given the typical caloric expenditure (e.g., 270-300 kcal) documented during these exercise sessions (137, 139). Therefore, a significant amount of additional moderate intensity LTPA would have to be pursued as a complement to regular phase II CRP exercise

session participation in order to attain the activity level that maximizes the benefits of regular physical activity regarding the maintenance or minimal regression of pre-existing coronary artery lesions.

Energy expenditure during phase II and III CRP participation

CRP programs are designed to increase physical activity levels of its patients so that they can increase their functional capacity to more readily perform the activities of daily life and effectively manage their primary risk factors. The present research indicates the majority of participants in CRPs do not meet the activity recommendations for individuals with CHD.

Savage et al. (136) examined 120 phase II CRP participants (63 years, BMI of 29 kg/m²) who expended about 270 kcal per exercise session during a 12 week period. Participants exercised three times a week for 45 minutes at 70-85% HR_{max}. Using open-circuit spirometry, men and women less than 65 years expended significantly more (men; 323 kcal versus 266 kcal, women; 230 kcal versus 171 kcal) calories per session than individuals older than 65. Subjects did not favorably improve body weight, cholesterol and other risk factors for CHD. Overall, 73% of participants did not achieve a 1,000 calorie weekly energy expenditure, which is the minimum volume of activity suggested for this population.

Scharier et al. (139) measured the caloric expenditure by open circuit spirometry in 30 phase III CRP participants (64 years, BMI of 28.8 kg/m²). The average caloric expenditure of participants who had been enrolled in phase III CRP for 19 months was 250 calories/session. Participants exercised three times a week for an average of 47 minutes at 60-80% HR_{max}. Surprisingly, 83% of patients did not expend 300 kcal/session and 40% did not even expend 200 kcal/session. A 300 calorie energy expenditure (EE) is considered necessary to attain significant

improvements in cardiovascular health (31). The results of the two prior studies are limited by the fact that exercise was not quantified outside of CRP participation and patients may have fulfilled their weekly exercise requirement with home-based physical activity (135).

In another study of 77 phase III CR participants (68 years, BMI of 27.0 kg/m²), an accelerometer was used to document their total weekly amount of activity as well as the amount of physical activity performed on days individuals attended the CRP versus days they did not. Overall EE averaged 1,597 ± 846 kcal/week with subjects spending approximately 376 and 125 minutes in light and moderate intensity activity, respectively. Vigorous activity participation was negligible. Activity levels were significantly higher on CRP days than on non-CRP days; 299 ± 161 versus 177 ± 113 kcal/day, respectively. Subjects also spent significantly more time in low and moderate intensity activities on CRP versus non-CRP days (low intensity; 59.7 ± 19.8 versus 49.3 ± 19.3 minutes, moderate activity; 26.4 ± 20.4 versus 10.5 ± 14.6 minutes) (13).

These results concur with prior research that neither phase II nor III CRP participants perform an adequate volume of exercise during structured exercise alone to achieve the suggested activity levels for individuals with CHD. Furthermore, their overall volume of activity is insufficient to maximize the possibility of coronary artery lesion stability or regression. These results indicate that the amount of physical activity was generally adequate on CRP days, but failed to reach target levels on non-CRP days. Thus, CRP participants should be encouraged to incorporate lifestyle physical activity, additional exercise, or both on non-CRP days to supplement their structured activity and attain the recommended activity levels. Regarding exercise modality and intensity recommendations for this population, it is important to note that subjects in Scharier et

al. study (139) self-selected low and moderate intensity activities (predominantly walking) and that they may consider vigorous exercise too demanding.

Effectiveness of phase II CRPs in mitigating cardiac and all-cause mortality

National and international clinical guidelines indicate that exercise therapy is of central importance to phase II CRPs (135) since physical inactivity has been identified as a primary risk factor for CHD (3). The relative risk of CHD associated with physical inactivity ranges from 1.5–2.4, an increase in risk comparable to that observed for high blood cholesterol, hypertension or cigarette smoking (160). A substantial body of evidence indicates that phase II CRP participants experience a significant decrease in all-cause and cardiac mortality (approximately 20-30% for both) versus individuals who receive usual care after an index cardiac event (35, 70, 113, 160). Today, an array of new drug therapies coupled with efficacious less invasive surgical procedures are employed in the routine management of cardiac patients. Yet contemporary meta-analyses report the benefits of phase II CRPs regarding all-cause and cardiac mortality are similar for recent as well as older clinical trials (161, 166).

Taylor et al. (161) conducted a recent meta-analysis of risk factor outcomes for CHD patients enrolled in a phase II CRP. Forty-eight clinical trials were reviewed which included 8,940 patients randomly assigned to exercise-based cardiac rehabilitation or usual care. The study population was required to have a follow-up of at least 6 months (up to 69 months) in a supervised or unsupervised exercise programs. Subjects averaged 2.7 exercise sessions of 53 minutes per week and exercised at 76% VO_{2max} . In agreement with prior meta-analyses of similar populations, total mortality and cardiac mortality were decreased by 20% and 26%, respectively, in phase II CRP participants versus individuals with CHD who received usual care (114). CRF

levels increased 20% and participants demonstrated a significant reduction in total cholesterol (-14.3 mg/dL), triglycerides (-20.4 mg/dL) and systolic blood pressure (-4.2 mmHg) and a lower proportion of patients reported smoking versus usual care. In contrast, there was no significant difference between the groups regarding low density lipoprotein (LDL), high density lipoprotein (HDL), or diastolic blood pressure (161). Although anthropometric results were not reported, most research indicates participants in traditional phase II CRPs do not lose weight which is likely due to the low average number of calories expended per session and the short duration of CRPs (3, 31 135). The authors concluded that the improved mortality outcomes may be attributable to the improvements in CRF levels, primary risk factor management, reduced ventricular fibrillation, or improved MI survival secondary to exercise-induced ischemic preconditioning (161).

Recent clinical trials have reported that participation in phase II CRPs yields favorable effects as well for non-traditional risk factors implicated in the progression of CHD. Significant improvements in endothelial function, C reactive protein, fibrinolysis, left ventricle function, autonomic tone and heart rate variability have each been noted (3, 23, 54, 68, 92). The significant improvement in endothelial function with CRP participation may be the most important of these variables since it is an independent predictor of cardiac events (47, 54).

Higher volume exercise programs have proven to be more efficacious regarding primary risk factors for CRP participants. Using primarily walking as the exercise modality, Savage et al. (137) supervised 15 subjects (62.5 years, BMI of 31.1 kg/m²) who walked 60-90 minutes 5-7 days/week at 50-60% VO_{2peak} for four months within a CRP. Subjects were counseled to expend > 1,500 kcal/week, an activity level associated with mitigating coronary artery lesion progression

and substantially higher than the caloric expenditures reported in traditional phase II CRPs (14, 111, 135). Subjects exhibited a body weight loss of 4.6 kg and a fat loss of 3.6 kg while maintaining fat free mass. Furthermore, triglycerides (-20.4 mg/dL; 23.7% reduction), TC/HDL-C ratio (-1.2; 14.5% reduction) and fasting insulin (-2.9; 22.3% reduction) also decreased significantly, while VO_{2peak} increased by 21.2%. In agreement with the meta-analysis of phase II CRPs conducted by Taylor et al. (161), there was no significant changes in LDL (-8.7 mg/dL) or HDL (2.3 mg/dL) levels. Subjects wore a Caltrac accelerometer for 7 days to estimate activity-related energy expenditure (AREE) at the 2nd and 16th week of the intervention. AREE increased 71% from $2,726 \pm 1,089$ kcal/day to $4,673 \pm 1,703$ kcal/day and there was a significant relationship between AREE and fat loss ($r = 0.69$). No adverse cardiac events were reported during the study.

These results indicate that participation in traditional CRPs leads to moderate improvements in modifiable primary risk factors while significantly reducing cardiac and all-cause mortality (3, 15, 35, 59). Phase II CRPs can enhance their ability to monitor and improve the daily physical activity patterns of their participants using pedometers. Therefore, participants may be able to increase their weekly energy expenditure to a level that is associated with more pronounced favorable changes in primary risk factors.

Phase II CRPs: structured versus unstructured programs

Home-based exercise programs using occasional contact by healthcare professionals have been proven to be as effective as center-based programs regarding non-fatal MI re-infarctions, CRF improvement as well as cardiac and all-cause mortality outcomes (26, 32, 63). Gordon et al. (63) compared the results of 142 patients (75% men, 61 years, BMI of 29.8 kg/m^2) who were

enrolled for 12 weeks in (1) a traditional phase II CRP, (2) a physician-supervised nurse case management program or (3) a community-based exercise program monitored by exercise physiologists. All participants were given a report outlining their current CHD risk factors, the goal level for each risk factor and an individualized action plan for achieving these goals. Home-based patients were encouraged to perform 30-60 minutes of aerobic exercise at 60-85% peak HR and/or at a RPE of 11-13 at least 3 days per week for 12 weeks. All three interventions significantly improved CRF, systolic and diastolic blood pressure, total cholesterol, and low density lipoproteins with no statistical differences between the three groups (63).

Recent technological advancements have allowed healthcare professionals to effectively monitor individuals' exercise progress and provide appropriate feedback while they are at home. Southard et al. (155) utilized an Internet-based program that permits nurse case managers to provide risk factor management training, risk factor education and monitoring services to patients with CHD. The Internet program entailed electronic discussion groups, online assessments and interactive education modules and separate interfaces for other health care providers. Patients were required to log in once a week for 30 minutes, communicate with their case manager via e-mail, complete assigned education modules and report their daily blood pressure and minutes of exercise. Compared to usual care subjects over a six-month period, participants in the Internet based intervention had less cardiovascular events (3.1% versus 15.7%) and enjoyed more weight loss (-3.68 versus 0.48 pounds). There was no significant difference between the two groups regarding blood pressure, lipid levels, depression scores, minutes of exercise or dietary habits. The authors noted that the program could be more effective with the integration of Internet-enabled devices for monitoring progress in clinical measurements

such as blood pressure, blood glucose, weight and exercise (e.g., pedometers) that could send information to case managers and physicians in real time (155).

The promise of using pedometers to measure the amount of activity associated with positive health outcomes for home-based CRPs is supported by preliminary results from Houle et al. (76). In this study, a clinical nurse specialist (CNS) contacted CRP-eligible participants intermittently who were given a pedometer and exercise log upon hospital discharge. The CNS provided them with individualized exercise goals based upon their reported activity patterns (e.g., step count results). The control group received typical care and wore a blinded pedometer. At 6 months, the experimental subjects averaged 2,400 steps/day more than the controls while demonstrating significantly lower LDL levels, systolic blood pressure, and waist circumference versus controls (76).

Part of the reason home-based exercise programs have documented success commensurate with hospital-based programs may be due to the efficacy of walking in eliciting health outcomes. Brisk walking, the most commonly performed exercise in the aforementioned studies, has been demonstrated to confer favorable outcomes in regards to cardiac and all-cause mortality in middle aged and elderly men and women (96, 97, 160). It is also important to note these results are attained without additional risk of adverse cardiovascular events and can be easily implemented for individuals who do not have the financial resources, time or logistical ability to participate in a traditional center-based phase II CRPs. These findings support the use of pedometers to complement center-based phase II CR exercise sessions in order to improve activity levels on non-CRP day levels, which can increase the number of individuals attaining the activity goals for individuals with CHD during CRP participation. By doing so, the health

outcomes of phase II CR participants will be enhanced in a practical, cost effective manner that can readily complement the current CRP model.

Measuring habitual physical activity: pedometers versus physical activity questionnaires

Phase II CRPs are encouraged to assess baseline physical activity levels using either a questionnaire or a pedometer (16). Although physical activity questionnaires (PAQs) have been used for decades to quantify activity levels, they have several shortcomings which limit their reliability and validity. Individuals commonly misrepresent the total volume of daily physical activity level they perform due to misclassification of the frequency, intensity and/or duration of physical activities (7, 105, 148). In addition, many researchers use metabolic standards that overestimate the energy expenditure for certain activities and populations (especially middle aged and senior populations) (7, 18, 105). These limitations may lead to errors in physical activity estimation. There is also a lack of standardization for PAQs regarding the syntax utilized, methods of analysis and subsequent interpretation (148).

Pedometer measurements of physical activity are only moderately correlated with PAQs (r range = 0.33-0.48) (20, 148). These disparities have been attributed to study populations that were mostly sedentary or whose activities were limited by chronic disease (e.g., chronic obstructive peripheral disease, peripheral vascular disease) as well as the shortcomings of PAQs previously mentioned (148, 169).

Pedometers have several advantages for researchers who wish to assess physical activity. First, they can accurately determine an individual's cumulative daily walking levels and are likely to reflect LTPA levels since walking is the most common performed of LTPA performed by adult Americans (150). These devices are relatively inexpensive, easy to use, and lightweight

(18, 182). Pedometers provide an absolute value (e.g., steps) which can be used to estimate the distance an individual walks. Step counts are readily understood by the general population and are widely used for prescribing exercise. Step counts can also provide comparisons across different studies (142).

Methodological considerations for using pedometers: step counts and monitoring time frame

Pedometers provide a variable (e.g., steps) which researchers can use to assess physical activity patterns and determine their association with various health outcomes in the general and special populations (173). These results can be used to provide simple, uniform exercise recommendations for the general public. Pedometers are increasingly being used in clinical and intervention research trials. In order to facilitate the interpretation and comparison of results from these studies, researchers should address a series of methodological considerations.

Prior research has demonstrated that pedometer-determined data are highly variable. The variability is partially attributable to the day of the week monitored, attendance at work, participation in aerobic exercise, sports activities, the weather, season, injury status or sickness (17, 148, 171, 180). These factors contribute to the high standard deviation relative to mean daily step counts that has been consistently reported in healthy and special populations (9, 103, 142). In order to account for these possible variations, researchers have sought to establish the requisite number of days that provide a reliable and accurate estimation of an individual's habitual activity patterns.

The intra-class correlation (ICC) is a statistical technique that measures the internal consistency for a data set. Regarding the assessment of pedometer-based ambulatory activity, the

ICC estimates the consistency of step counts collected over multiple days, providing a measure of intra-individual variability (38). For instance, if the ICC for a single day of pedometer monitored activity in a group of subjects was 0.60, then approximately 60% of the variance in their daily ambulatory activity could be accounted for by any single given day of data collection. A monitoring time frame which provides an ICC of 0.80 has been noted to accurately reflect an individual's habitual activity patterns, since higher values do not provide significant greater explanations of intra-individual variability (17).

In order to establish the number of days required to estimate weekly mean pedometer-determined steps/day in free-living conditions, Tudor-Locke et al. (183) assessed the physical activity patterns of 90 subjects (63% females, 49.1 years, BMI of 27.1 kg/m²) for seven consecutive days using a pedometer. The criterion was the mean steps/day for the observation period and the average steps count for the cohort was 6,838 ± 3,643 steps/day. The authors concluded that a minimum of three days of monitoring were necessary to obtain an acceptable ICC reliability level of at least 0.80 (range 0.86-0.91) to estimate weekly activity levels.

Recently, Clemes et al. (38) examined the physical patterns of 212 adults (64% female; 38.3 yrs; BMI of 27.9 kg/m²) who wore a Yamax SW-200 for 28 consecutive days to determine the number of days of monitoring required to estimate monthly activity. The mean step counts during the 28 day period served as the criterion. Approximately 76% of the subjects were allocated to a reliability group and the remainder served as a confirmation group. The average daily step count for the cohort was 9,090 ± 2,829. ICCs were computed for the one, two, three and four week periods as well as for different combinations of any two, three, four, five, six or seven days. The ICC in the reliability group for any single given day was 0.41. All combinations

of six days or more had ICCs above 0.80, while a seven day period had an ICC of 0.86.

Importantly, there was a significant relationship between mean step counts calculated from the initial week of monitoring and the criterion ($r^2 = 0.91$, $p < 0.001$). The authors recommended that researchers collect pedometer-based step count data over a 7-day period to accurately and reliably estimate monthly activity. This is based on previous studies indicating that step counts are consistently significantly lower on Sundays and if one day of data is missed then the resultant ICC (e.g., > 0.80) will remain sufficiently high to reliably estimate mean monthly activity.

Togo et al. (169) stated that intra-individual variations in physical activity may be of a greater magnitude in the elderly population compared to younger adults because their daily schedules are not governed by academic requirements or full-time employment. The typical phase II CRP participant is typically older (e.g., 57 years) and is likely to no longer work full-time (15). Preliminary research assessing factors affecting the baseline activity patterns (e.g., first week of enrollment) for phase II CRP participants report an inverse relationship ($r^2 = 0.09$, $p < 0.002$) for the number of days since their index cardiac event, but a positive correlation with their functional capacity (e.g., $r^2 = 0.24$, $p < 0.0001$) (25). Furthermore, this population's activity levels are lower on the days they do not participate in a phase II CRP versus days that they do (13, 14, 26, 138). These unique circumstances warrant an initial monitoring time frame of at least 7 days to establish an accurate indication of phase II CRP participants' baseline weekly or monthly physical activity levels.

Pedometer reactivity

When assessing physical activity patterns, researchers must attempt to minimize reactivity. Reactivity occurs when an individual changes his/her behavior due to awareness that they are

being monitored. Given that pedometers provide instant feedback on ambulatory activity, this may motivate individuals to increase their activity levels (e.g., pedometer reactivity). If this occurs it may increase intra-individual variability, change the baseline physical activity level and make it more difficult to detect inter-individual differences over time. Any of these developments would compromise the validity of pedometer-assessed activity (36, 37, 169).

Several studies have used a randomized controlled crossover study design to determine if pedometer reactivity occurs (9, 53, 99). This study design provides increased sensitivity, less variability and requires a small sample size. Matevey et al. (99) noted the absence of reactivity when examining 28 middle aged adult subjects (57% female, 47 years, BMI of 25.1 kg/m²). Half of the subjects wore a sealed pedometer for one week during which their results were monitored by a research staff. The following two weeks they did not wear a pedometer (e.g., washout period) and then they wore an unsealed pedometer for one week while recording their daily step counts. The other participants followed the same protocol in reverse order. Subjects were not given instructions regarding their activity levels. The cohort averaged 7,760 ± 3,194 steps/day during the two weeks of pedometer-assessed activity. Regardless of sealed or unsealed assessment, gender or order of pedometer assignment, there were no significant differences in mean step counts. Also, steps per day did not significantly increase during the first few days of monitoring. Subjects took 419 more steps/day (7,969 versus 7,550) when the pedometer was unsealed, a 5.55% relative difference. The ICC for mean steps per day between the two pedometer conditions was 0.84, an indication of strong repeatability.

Alison (9) examined 103 older subjects (63% women, BMI of 25.4 kg/m²) over a two week time period. The participants had higher steps counts on days when they wore an unsealed

pedometer and recorded their weekly step counts (e.g., 408 steps/day, $p = 0.02$). This disparity amounted to a 5% relative increase in the participants' average daily step counts (i.e., 8,400 to 8,808 steps/day), when wearing an unsealed versus sealed pedometer, similar to the absolute and relative differences in step counts observed by Matevey et al. (99). Conversely, there were no differences regarding gender or order of pedometer assignment. Thus, the authors concluded that although pedometer reactivity may have occurred, the disparity in activity levels attributable to it should not be considered clinically significant.

Lastly, Marshall (98) attempted to discern if pedometer reactivity occurred in 103 older adults (60 years, BMI of 25.5 kg/m²) while wearing a pedometer for two weeks. Half of the subjects monitored and recorded their step counts for a week and the following week the pedometer was sealed. The remaining subjects completed the protocol in reverse order. Subjects accumulated significantly more steps per day (e.g., 400) when monitoring their step counts versus the sealed pedometer protocol (8,767 versus 8,360 steps/day). This disparity is 4.9%, which is similar to results in previous studies.

Presently, several authors have concluded that if pedometer reactivity exists it is minimal, it dissipates quickly (e.g., less than three weeks) and it only affects certain types of individuals (9, 53, 98, 99).

Clemes et al. (37) noted that in the above study protocols, the subjects were all aware they were wearing pedometers which may engender its own reactivity. In order to control for this possible confounding variable, 50 subjects (26 years, BMI of 23 kg/m²) were asked to wear what they thought was a sealed body posture monitor for a week. After this time, their results were recorded and then they were informed they had been wearing a pedometer and asked to wear it

for another week and to record their daily step counts. Mean daily steps counts increased significantly ($9,541 \pm 3,186$ versus $11,385 \pm 3,763$) for the sealed and unsealed conditions, a 19.3% relative difference. Thus, the authors concluded that pedometer reactivity exists and that it has implications for short-term studies (e.g., less than a week).

Recently, Clemes et al. (39) expanded the aforementioned study protocol. Sixty three subjects (23.6 years, BMI of 22.7 kg/m^2) wore what they thought was a sealed body posture monitor (e.g. covert method) for one week, and subsequently wore the pedometer for another week under the following three conditions: blinded, unsealed and unsealed with an activity log for an additional week. There was a significant overall effect ($p < 0.001$) of condition as the covert method results were $8,362 \pm 2,600$ steps per day; blinded pedometer $8,832 \pm 2,845$ steps per day; unsealed condition $9,176 \pm 3299$ steps per day; unsealed pedometer and diary condition $9,635 \pm 2,709$ steps per day (a 15.2% relative increase). Post hoc analyses identified that mean step counts were significantly higher in the diary condition than those reported during both the covert and sealed conditions (both $p < 0.003$).

Given that researchers have stated that up to a 10% level of error is acceptable in free-living conditions, the amount of measurement error reported examining the effects of pedometer reactivity (excluding Clemes et al. (36, 39) on daily step counts is acceptable and does not indicate that pedometer reactivity leads to measurement bias (181). Furthermore, these results suggest that if pedometer reactivity does exist, it will be more pronounced in the initial monitoring period and will diminish over time. Thus, results of studies assessing pedometer-based activity over a substantial time duration (e.g., greater than 3 weeks) are unlikely to be adversely affected by pedometer reactivity.

Validity and reliability of pedometers: an objective measurement of physical activity

Pedometers are simple, lightweight devices that measure the number of steps and estimate distance walked. In the 1960s, gear-driven mechanical pedometers were used in Japan to monitor an individual's daily physical activity (73). Unfortunately, mechanical pedometers had questionable accuracy and reliability at walking speeds of 54-107 m/min (2.0 - 4.0 mph) and thus were deemed invalid as research tools (142). In the 1990s, electrical pedometers were developed as a more accurate means to measure ambulatory activity. An electronic pedometer has an internal horizontal spring-suspended lever arm that moves up and down with normal walking movements. With each step, an electrical circuit closes and one event is recorded (18). A pedometer cannot accurately measure the intensity of ambulatory movement, nor can it measure activities such as recumbent cycling, arm ergometry or resistance exercise. It does provide the means to objectively quantify an individual's amount of daily walking activity, which accounts for the majority of calories expended by most adult Americans (150). Significant construct and convergent evidence continues to accumulate indicating that pedometers provide a valid measure of physical activity.

The convergent validity of pedometers indicates the extent to which its ability to quantify physical activity, via steps/day, is associated with other means designed to measure physical activity. Tudor-Locke et al. (172) reported that pedometers demonstrated a strong correlation with a series of accelerometers ($r = 0.86$), time spent in observed activity ($r = 0.82$) and observed steps during running and walking (r range of 0.80-0.97) at typical ambulatory speeds in the adult population. Researchers have noted that pedometers display reduced accuracy during slow walking speeds of 54 m/min (e.g. 2 mph) or less. This is due to the fact that the sensitivity

threshold of pedometers is designed to identify the vertical accelerations of normal walking. The magnitude of vertical acceleration needed to trigger a step is 0.50gs or more, which means that shuffling or very slow walking are unlikely to be detected (18). Further, 2 mph is a walking speed much slower than the self-selected average walking speed for healthy adults during free-living activity (174).

The “gold standard” for measuring of total energy expenditure (EE) is the doubly labeled water technique (DLW) (21, 105). Few research studies have compared the estimated EE obtained by pedometers with DLW. One study demonstrated a strong relationship ($r = 0.61$) between the two measurement techniques in subjects with peripheral vascular disease (PVD) (175). Another study reported that a foot-ground pedometer was highly correlated to DLW ($r = 0.86$) and provided accurate EE estimates up to 3,000 kcal/day in young male and females adults confined to a ship (161). In contrast, two studies examining middle aged, overweight and young healthy adult women reported that pedometers underestimated physical activity related EE by anywhere from 25-46% compared to DLW (93). Additional measures of EE, including heart rate (r range 0.46 to 0.88) estimated EE and indirect calorimetry ($r = 0.49$ to 0.81) have demonstrated moderate to strong correlations with pedometers.

The construct validity of pedometers can be evaluated by determining if their output (steps/day) coincides positively or inversely with other measures of theoretically-related parameters (e.g., age, anthropometric measures, fitness, metabolic values) (173). Tudor-Locke et al. (173) reported an inverse relationship with age ($r = -0.021$), BMI ($r = -0.027$) and overweight ($r = -0.22$) and pedometer-based physical activity. Depending upon the fitness assessment protocol, the association between pedometer-determined physical activity and CRF range from

weak to moderate (r range 0.22-0.69) (0). Additional research is warranted regarding the examination of the relationship between steps/day and health outcomes (e.g., blood pressure, cholesterol, etc.) in special populations. The results of these studies are likely to strengthen the construct validity of pedometers. To date, there is sufficient evidence concerning the construct and convergent validity of pedometers to warrant their use for research, evaluation and intervention purposes.

The validity and accuracy of the Omron HJ series pedometer

The Omron HJ-720ITC contains two piezo-electric accelerometers oriented perpendicular to each other. Ambulation generates a sinusoidal curve of vertical acceleration versus time and whenever the curve crosses the zero line a step is recorded (142). The dual-axis accelerometer design permits steps to be counted accurately regardless of its orientation (91, 130). It can be worn in several positions (e.g., shirt, belt, pants pocket) (49). This pedometer trait is beneficial for researchers and subjects. Subjects cannot be continuously monitored and will spend most of their time unsupervised. Thus, daily pedometer placement cannot be monitored by the researcher. With the Omron pedometer, individuals can readily place the pedometer in their pocket and do not have to be concerned about wearing it on a particular location to ensure its accuracy. Participant burden is further minimized by the pedometer's internal clock which reverts to 0 each day at 12:00 a.m. and thus it does not have to be reset.

The mechanism and algorithm used to measure overall and aerobic steps in this Omron pedometer have been validated and proved to be reliable for younger and older populations, in laboratory settings at designated treadmill speeds (2.0-4.0 mph), flat surfaces in free-living environments at self-selected speeds (e.g., slow, normal, and fast) (48, 91, 131), and when worn

in various positions (49, 131). Also, it has provided valid steps counts for stair climbing at a typical pace (e.g., 80 steps/minute) (14). This device has greater accuracy than the widely used Yamax SW-200 pedometer which records all steps taken within 1% under controlled conditions and has shown a strong relationship ($r = 0.80-0.93$) with accelerometers (20, 176).

Doyle et al. (49) assessed the validity and reliability of the Omron HJ-700IT pedometer in a laboratory setting for twenty young adults (35.0 years, BMI of 23.1 kg/m²) who completed two trials of treadmill walking in which they averaged 3,305.8 \pm 198.7 steps. Each trial was for 15 minutes at walking speeds of either 2.5 or 3.0 mph. The criterion measure was manually counted steps. The Omron pedometer was carried in three different locations (e.g., shirt pocket, belt clip at the hip, and pants pocket) in random order while the Yamax Digi-Walker SW-200 pedometer was worn only on the belt at the right hip. There were no significant differences in total steps counted by the Omron pedometer and the criterion measure. However, there was a significant difference in steps counted by the Yamax pedometer ($p < 0.001$) and the criterion measure. The Pearson's correlation coefficient of manually counted steps compared to the Omron pedometer was 0.991, 0.998, and 0.958 for the shirt, belt and pants pocket, respectively, while the Yamax was 0.725. Percent error for the Omron pedometer was 0.04, 0.15, and 0.67%, respectively, for the three locations compared to -4.21% for the Yamax SW-200. Thus, the Omron pedometer proved to be a highly accurate and reliable in measuring continuous walking activity in a laboratory setting (49).

In order to assess the effects of age and obesity on pedometer accuracy Melanson et al. (103) examined 259 subjects who walked at self-selected speeds on a treadmill using a Yamax SW-200 pedometer. The researchers also evaluated the accuracy of two spring-levered pedometers (e.g.,

Walk-4-Life LS-2500 and Step Keeper HSB-SKM) compared to a piezoelectric pedometer (e.g., Omron HJ-100) at slow walking speeds (e.g., 1.0-2.6 mph) on a treadmill using 32 subjects. Regarding the Yamax SW-200, self-selected walking speed and pedometer accuracy demonstrated an inverse relationship with increasing age, weight and BMI. Crouter et al. (45) also reported an inverse relationship between BMI and pedometer accuracy with the same pedometer. In agreement with prior research, which has studied generally healthy and special populations (18, 109, 131), Melanson et al. (103) noted the slowest self-selected walking speeds (2.0 mph and below) were associated with the lowest pedometer (e.g., Yamax SW-200) accuracy. Specifically, the magnitude of this pedometer's step count error increased with age, from 3% in 18-30-year-old subjects (average speed of 2.9 mph) to 19% in the subjects 61-70 years who walked at an average speed of 2.3 mph. Given that older adults demonstrate the slowest self-selected walking speeds, it is not surprising that increasing age was the best predictor of decreased pedometer accuracy. The Omron HJ-100 pedometer was superior to both spring-levered pedometers at all walking speeds tested (e.g., 1.0-2.6 mph). For example, at 1.8 mph the Omron recorded $97.8 \pm 9.6\%$ of counted steps, which was significantly greater than the Walk-4-Life ($52.1 \pm 38.7\%$) or Step Keeper ($73.4 \pm 36.7\%$) pedometers, respectively (103).

Doyle et al. (50) compared the validity and reliability of the Omron HJ-700IT to the Yamax Digi-Walker SW-200 pedometer when worn by 60 young adults (31.7 years, BMI of 23.7 kg/m^2) who walked at a self-selected pace for 30 minutes on an indoor track. The subjects averaged $3,450.2 \pm 311.4$ steps at an average speed of 3.3 ± 0.6 mph. The criterion measure was manually counted steps. The Omron pedometer was carried in three different locations (e.g., shirt pocket, belt clip at the hip, and pants pocket) in random order while the Yamax Digi-Walker SW-200

pedometer was worn only on the belt at the right hip. There were no differences between both pedometers and manually counted steps. The Pearson's correlation coefficient of manually counted steps compared to the Omron pedometer was 0.995, 0.992, and 0.968 for the shirt, belt and pants pocket, respectively, while the Yamax was 0.786. Percent error for the Omron pedometer was -0.04, 0.18, and 0.43%, respectively, for the three locations compared to - 3.11% for the Yamax. This study demonstrates the accuracy of the Omron pedometer, when worn in various positions, in measuring step counts that reflect the physical activity recommendations of the ACSM (50).

Recently, Holbrook et al. (74) examined the validity and reliability of the HJ-720ITC pedometer at prescribed and self-selected walking speeds in 47 young, healthy adults (24 years, BMI of 25 kg/m²) on a walking course. The walking course required subjects to stop at road crossings, perform up and downhill walking on grass as well stair climbing. Subjects walked for 100 meters at three speeds (e.g., slow, moderate or brisk) and walked 1 mile at a self-selected pace. The pedometer was clipped and worn at the right and left hip, the mid-back, as well as the right and left pockets. Validity was assessed by having a subset of 31 subjects complete the 1 mile walking course twice and reliability was ascertained by allowing subjects to randomly select different pedometers for each trial they completed. Aside from the backpack position, the Omron HJ-720ITC demonstrated an absolute percent error of less 3.0% regarding pedometer wear sites and a coefficient of variation of less than 3.3% at any designated or self-selected walking speed (74).

These results indicate that piezo-electric pedometers provide superior validity and reliability when compared to popular spring-levered mechanisms (e.g., Yamax Digi-Walker SW-200). This

holds true at slower speeds (common in the elderly population) (103, 109), during self-selected speeds (49, 103) and when the pedometer is tilted at an angle, which may be the case for individuals who are overweight and obese (45, 65). Given that elderly individuals self-select slower walking speeds than younger adults, piezo-electric pedometers are recommended for the older population (46, 65, 103). Furthermore, piezo-electric pedometers should be utilized in CRP whose participants are typically overweight or obese (e.g., 88.4%) and older (e.g., 57 ± 11 years) (15).

Omron HJ 720-ITC: a novel pedometer with enhanced data collection

The Omron HJ-720 ITC pedometer provides time and date-stamped, hour-by-hour step-count data (delineated between aerobic and non-aerobic steps). This permits researchers to readily assess inter-day step variations and with a concise questionnaire, researchers can determine whether steps are accumulated via occupational, domestic or leisure time activities. This pedometer can distinguish whether subjects are accumulating steps through fragmented or continuous bouts at a pace of ≥ 60 steps/minute continuously for 10 minutes (e.g., aerobic steps) (115). These measurements could be used to ascertain if a given amount of total or continuous physical activity is needed for disease prevention, health, weight loss, or effective risk factor management. The pedometer also has an activity flag that indicates that if the user has pursued any movement for a given hour it is worn. This activity flag allows researchers to determine how compliant subjects are regarding the number of hours the pedometer is worn each day. In order to reduce non-step artifacts, the pedometer does not record movement of less than 4 seconds of duration (115).

The subject's ambulatory activity information can be downloaded, via a supplied USB cable, using the accompanying Omron B₁ software to any computer using either the Windows XP or Millennium operating systems. The software program presents step counts in a bar graph format that is delineated between aerobic and non-aerobic steps (see Figure 1). Activity patterns can be displayed in this manner on a daily, weekly, monthly or yearly basis. In addition, users can enter daily goals for each of the aforementioned step count parameters and the software program provides feedback regarding the percentage achievement level attained. The pedometer data displayed includes: overall steps, aerobic steps and aerobic walking time on an hour-by-hour basis. All of this information can be readily converted to an Excel spreadsheet or PDF format for statistical analysis. Each time the activity record is downloaded, it is seamlessly integrated with prior records in order to provide a continuous overview of step counts. As long as the data are downloaded before 42 consecutive days have elapsed, a given individual's detailed ambulation activity could be monitored continuously for as long as they are willing to wear the pedometer.



Figure 1: shot of an individual's daily steps counts using the Omron B1-link software

Overall, the Omron HJ -720 ITC pedometer demonstrates exceptional accuracy, validity and unprecedented detailed step count data allowing researchers to more readily assess an individual's inter and intra-day activity patterns. Three studies have shown the ability of this pedometer to assess and increase step counts for individual who were obese, diagnosed with Type 2 diabetes or have intellectual disabilities (123, 128).

Step indices for the general population and phase II CRP participants

In 2001, Tudor-Locke and Myers (171) reviewed 32 studies which involved cross-sectional, prospective cohort and intervention study designs. The authors noted that daily step count for healthy younger adults varied between 7,000-13,000 steps/day. Healthy older adults accumulate 6,000-8,500 steps/day while individuals with disability and chronic illnesses accumulated 3,500-5,000 steps/day. The inverse relationship between daily step counts and age has been confirmed by other researchers (33, 101).

Recently, Tudor-Locke and Bassett (181) designated the initial daily step indices for healthy adults using the following five classifications: (1) $< 5,000$; sedentary, (2) 5,000-7,499; low active, (3) 7,500-9,999; somewhat active, (4) $\geq 10,000$; active and (5) $\geq 12,500$; highly active. The authors noted that a minimum of a 2,500 steps/day increase (e.g., improving one activity designation) is required to alter health outcomes favorably. Interestingly, this increment in step counts corresponds with the results from a recent meta-analysis of studies which used pedometers to enhance habitual activity levels and quantified that the typical increase in daily step counts is 2,491 for pedometer users versus control subjects (30).

The popular daily step count recommendation of 10,000 has been advocated to provide significant health benefits, such as weight loss and blood pressure improvements (78, 141). The amount of physical activity required to accumulate 10,000 steps does not require 30 minutes of continuous physical activity during which individuals walk 3-4,000 steps (173). Prior research using pedometers has shown that 3-4,000 steps should be accumulated to meet the ACSM activity guidelines in the context of the following parameters: they are of at least moderate intensity (e.g., > 100 steps/minute), accumulated in at least 10 minutes bouts and in addition to

steps taken to perform the activities of daily life (e.g., approximately 5-6,000 steps/day) (176, 183, 184). This step count range combined with the sedentary designation of 5,000 steps would necessitate 8-9,000 steps/day and is associated with meeting the current ACSM activity guidelines (94, 171). This step count goal may be more practical for older populations and those with chronic diseases than 10,000 steps/day.

The step indices proposed by Tudor-Locke and Bassett are not applicable to healthy children or individuals with chronic diseases (181). Additional research has examined the average daily steps for several special populations, including individuals with peripheral vascular disease (4,100-5,300 steps/day), chronic obstructive pulmonary disease (3,800 steps/day), diabetes (6,600 steps/day), congestive heart failure (4,900 steps/day) and the elderly (6,500 steps/day) (1, 144, 145, 173). Furthermore, several pedometer based studies have noted an inverse relationship between daily step counts and increasing age which is associated with an increased prevalence of the aforementioned chronic diseases (28, 33, 145, 181).

Seniors comprise the majority of the phase II CRP population, which has a high prevalence of multiple chronic diseases and exhibits a sedentary lifestyle (1, 15, 26). Thus, as opposed to encouraging them to attain an 8-10,000 daily step count, which would require them to almost double their daily activity level, a more reasonable physical activity goal would be to increase their daily activity levels significantly (e.g., 2-2,500 steps/day) versus their baseline activity level (173). CRP participants could accomplish this activity goal through increased activities of daily life or short bouts of moderate intensity walking. This would indicate that they had increased their activity designation (e.g., from sedentary to low active). This recommendation would concur with the AHA exercise training recommendations for CRP participants, which states that

“the total amount of activity is more important for health than the performance of high intensity exercise” (56). This statement is supported by research demonstrating a dose-response relationship between overall activity and reductions in CHD mortality (16, 25, 71, 90). The preliminary results from a pedometer-based intervention study indicate that individuals with CHD may be capable of sustaining the “somewhat active” designation regarding daily step counts for a prolonged period of time (76).

Although several studies have used pedometers to assess the average daily step counts for participants in phase III CRP, only two published studies have examined phase II CRP participants. Savage et al. (138) examined 107 individuals (76% men, 63 years, BMI of 29 kg/m²) for seven days after their initial phase II CR exercise training session. Subjects demonstrated significantly higher step counts on CRP versus non-CRP days (7,387 ± 3,387 versus 5,315 ± 3,336 steps/day; p < 0.0001). The authors noted the results for non-CRP days are likely indicative of these individuals’ typical activity patterns and categorizing their activity levels using the aforementioned step indices would indicate that 57% were sedentary, 21% low active, 10% somewhat active, 7% active and 5% highly active. These activity patterns do not compare favorably with the results of 23 healthy adults (70% women, 38 years and BMI 27.7 kg/m²) who wore a pedometer for a year during which 45% of the cohort was classified as active or highly active (38). The phase II CRP participants’ sedentary activity designation on non-CRP days warrants additional exercise counseling and monitoring to enhance their activity levels on these days to enhance the effectiveness of regular exercise on cardiac and all-cause mortality outcomes (138).

The typical individual participating in a phase II CRP is sedentary and counseling them to increase their activity levels all the way up to the “active” category (e.g., 10,000 steps/day) appears to be impractical, since this would essentially require them to double their daily step counts. Instead, a more pragmatic activity objective for this population may be the upper range of “low active” or the lower range of the “somewhat active” designation (e.g., 7-8,000 steps/day) by the end of their phase II CRP enrollment. This would require an increase in daily step counts of 2-3,000, which has been demonstrated to be achievable in individual with chronic conditions and is associated with improvements in primary risk factors for CHD (8, 76, 107, 143, 174).

Walking as a means to improve CRF levels of phase II CRP participants

Walking is the most commonly performed leisure activity by middle age and older adults in the United States (61, 150). It is readily accessible, requires no special clothing or equipment to perform and can be accurately quantified with pedometers (20, 61, 171). Walking can be performed in domestic, occupational or recreational settings at a frequency, intensity and duration that is self-determined (73). In the healthy population as well as in individuals with CHD, walking has been shown to have a favorable effect on primary risk factors for CHD which reduces the risk of cardiovascular events (61, 107, 143). Ahlbom et al. (6) reported that walking approximately 30 minutes 4-5 times/week is associated with a decreased incidence of heart attacks in healthy populations as well as individuals with known CHD. Furthermore, walking pace has been associated with significantly lower CHD risk in men and women in age-adjusted and multivariate models (97, 160)

The AACVPR, AHA, ACC and ACSM recommend walking as an appropriate activity for CRP participants to perform in an unsupervised capacity at low to moderate exercise intensities

(e.g., 2.0-3.5 mph walking pace) (16, 152). Walking at a self-selected pace has not been associated with a greater incidence of myocardial infarctions for individuals with CHD (190). Walking is an exercise modality that is feasible for individuals who participate in CRPs given their especially low cardiorespiratory fitness (CRF) levels. Ades et al. (4) reported on the VO_{2peak} in 2,896 patients entering phase II CR. Men demonstrated a significantly higher VO_{2peak} values of $19.4 \pm 6.1 \text{ ml/kg}^{-1} \cdot \text{min}^{-1}$ versus $14.5 \pm 3.9 \text{ ml/kg}^{-1} \cdot \text{min}^{-1}$ for women. Low CRF levels demonstrate an independent, linear increase in risk for MI, unstable angina, coronary revascularization and all-cause mortality (25, 121). The low CRF level of the phase II CR population indicates that many activities of daily life that may be generally considered low intensity activity would require a high percentage of their functional capacity. Since a typical walking speed of 3.0 mph requires an oxygen consumption of $11.5 \text{ ml/kg}^{-1} \cdot \text{min}^{-1}$, this would require 60% and 80% of the maximal aerobic capacity for the average male and female, respectively, entering a phase II CRP. Given their low baseline CRF levels, walking speeds of 2.0-3.0 mph should be sufficient to engender improvements in CRF levels for individuals with CHD. A recent meta-analysis of randomized clinical trials using walking at self-selected speeds as the sole activity intervention noted an improvement in CRF levels of approximately 10% (111). The importance of improving the CRF of this population is underlined by the results from Yu et al. (197) reported that CR patients who failed to achieve an exercise capacity > 4 METs had a relative risk (RR) of 16.5 for cardiac mortality, regardless of whether the patient had experienced an MI prior to CRP participation.

Regular walking is an appropriate form of routine exercise for individuals with CHD to pursue in an unsupervised capacity given its practicality, suitability for various functional

capacities and ability to increase CRF levels, while not posing any increased cardiac event risk when performed at low to moderate intensities (61).

Pedometer-based walking programs result in improvements of the primary risk factors for CHD

Primary risk factors for coronary heart disease are considered clinical designations or lifestyle characteristics that independently expedite the CHD process. The primary risk factors for CHD include: physical inactivity, type 2 diabetes, hyperlipidemia, hypertension, obesity, smoking and a family history of CHD (11, 132). Approximately 90% of individuals with CHD have at least one of the following primary risk factors: hypertension, hyperlipidemia, current smoker or diabetes (64, 87). Ades et al. (5) noted that in 2,896 patients entering phase II CR the prevalence of HTN was 62%, obesity 40%, smoking 19.4%, and diabetes 24%. Cholesterol results were not reported. Given the low CRF level in this population (e.g., approximately $17 \text{ ml/kg}^{-1} \cdot \text{min}^{-1}$) it is reasonable to assume the majority of subjects were sedentary. Interestingly, studies have demonstrated there is an inverse relationship between daily step counts and an individual's number of primary risk factors (33, 55). For example, Farmer et al. (55) noted that individuals with 0 or 1 primary risk factor had a baseline activity level approximately 1,700 steps higher than subjects with 2 or 3 or more risk factors.

Currently there is insufficient evidence to indicate that a given step count is associated with reductions in cardiac or all-cause mortality. However, a significant amount of research has been performed using pedometers to measure the average daily steps associated with improvements in primary risk factors for CHD. The research to date indicates that increases of at least 2,500

steps/day are required to favorably alter health outcomes (181). This would be equivalent to walking an additional 1.5 miles/day (190).

Hypertension is clinically defined as resting systolic blood pressure of at least 140 mmHg, or a diastolic blood pressure of at least 90 mmHg, or currently taking anti-hypertensive medication, and is considered a risk factor for CHD as well as stroke (11). Moreau et al. (107) studied 15 postmenopausal women (53 years, BMI of 29.5 kg/m²) who were provided with incrementally greater target step counts above their baseline activity level periodically until they achieved a 3 kilometer increase in daily walking. They also recorded their daily step counts on a log sheet. Subjects increased their daily step counts by 4,300 to 9,700 and demonstrated a significant reduction in their systolic blood pressure at 6 weeks (e.g., 5 mmHg) and even further at 24 weeks (e.g., 11 mmHg). The blood pressure lowering effects of exercise were sustained for individuals' already taking anti-hypertensive medications and were especially profound for individuals classified with mild hypertension (107).

Additional research in Japan examined 30 hypertensive men (48.5 years, BMI of 24.6 kg/m²) who were encouraged to walk at least 10,000 steps a day over a 12 week period. Subjects were not taking anti-hypertensive medication. During the study, subjects averaged 13,510 ± 837 steps/day (baseline activity levels were not reported) and their systolic and diastolic pressures decreased 10 and 8 mmHg, respectively. In addition, sympathetic nerve activity was reduced significantly in experimental group, while their VO_{2max} increased significantly from 26.1 to 29.5 ml/kg⁻¹ · min⁻¹ (p < 0.05). Seventeen control subjects (48.7 years, BMI of 25.2 ± 0.9 kg/m²) walked 5,790 ± 458 steps/day and demonstrated no changes in either of the aforementioned

variables. Neither systolic nor diastolic blood pressure changes were correlated with daily step counts (78).

Hyperlipidemia is considered a primary risk factor for CHD and stroke (132). Total cholesterol (TC) levels > 200 mg/dl, a TC/HDL-C ratio ≥ 5.0 or a LDL/HDL ≥ 3.0 constitutes hyperlipidemia (11). Sugiura et al. (158) reported that 14 sedentary women (49 years, BMI of 22.3 kg/m^2) who sustained an increase in their daily steps of approximately 2,400 (e.g., 6,500 to 8,900 steps/day) over a 24 month period had significant improvements in their HDL-C (3.7 mg/dL), coupled with a significant decrease in TC (25 mg/dL) while demonstrating a non-significant 1 kg weight loss. LDL values decreased 19 mg/dL, although the change was not significant. A control group of 13 women (48 years, BMI of 22.6 kg/m^2) did not alter their daily step counts during the study and demonstrated no changes in any lipoprotein sub-fraction. Multiple regression analysis revealed that although no relationship existed at baseline, at 24 months daily step counts were inversely related to TC and the TC/HDL-C ratio and positively related to HDL-C. The authors noted that the changes in the subjects' lipoprotein profiles were attributable, in part, to changes in daily steps taken.

Type 2 diabetes is clinically diagnosed when an individual's fasting blood glucose levels are equal to or greater than 126 mg/dl on two separate occasions and is considered a CHD equivalent (11). Impaired fasting glucose (IFG) requires a fasting blood sugar level greater than 100 but less than 125 mg/dl on two separate occasions and is considered a precursor to Type 2 diabetes and a risk factor for CHD. Swartz et al. (159) examined a group of 18 sedentary, obese women (53 years, $35.0 \text{ BMI of kg/m}^2$) with impaired glucose tolerance. After they increased their daily step count from 4,952 to 9,200 steps per day over an 8 week period, they exhibited significant

improvements in glucose tolerance as well as systolic and diastolic pressure (e.g., decreased 6 mmHg). These outcomes occurred independently of changes in body mass, BMI, body fat, waist circumference, waist/hip ratio.

An individual is considered obese with a BMI ≥ 30 kg/m², if men and women have a waist/hip circumference ratio $\geq .95$ and $\geq .86$ or a waist circumference ≥ 40 inches and ≥ 35 inches, respectively (11). Pedometer based studies have consistently demonstrated an inverse correlation between daily step counts and the prevalence of overweight or obesity (33, 75, 165), as well as various indices of adiposity including BMI, percentage body fat, waist circumference and waist/hip circumference ratio (33, 75, 77, 172). For instance, Thompson et al. (167) observed that 80 female subjects (50 years, BMI of 26.0 kg/m²) who wore a pedometer for one week exhibited an inverse relationship between steps/day and percentage body fat ($r = - 0.713$), BMI ($r = - 0.417$), waist ($r = - 0.616$) and hip ($r = - 0.278$) circumference and waist/hip ratio ($r = - 0.652$). Prior research has suggested that 50% of the variance in percentage body fat can be explained by differences in pedometer-based physical activity (165).

Schneider et al. (143) reported that sedentary, overweight or obese adults (47 years, BMI of 33.5 kg/m²) who adhered to a 36-week exercise intervention program increased their daily step from 5,115 to 10,390. Their body weight (4.5 kg), BMI (1.6 kg/m²), percentage body fat (3.2), fat mass (4.7 kg), waist circumference (3.1 cm) and hip circumference (2.9 cm) decreased significantly.

The results of these pedometer-based studies indicate that increases in walking positively affects each modifiable risk factor for CHD, which are especially prevalent for individuals participating in phase II CRPs (1). Preliminary results of the daily step counts for seniors (i.e., >

65 years, 3,500 steps/day) and individuals entering a phase II CRP participants (5,000 steps/day) indicate these individuals are sedentary (138, 178). A prior pedometer-based intervention for seniors with no and up to three chronic diseases (e.g., CHD, HTN, type 2 diabetes, etc.) indicate they increase their absolute activity levels approximately 20% (range of 600-2,000 steps/day) versus baseline over 24 weeks (55). There is a paucity of research involving seniors with multiple chronic diseases and it has yet to be determined if the reported increase in steps/day required to alter risk factors favorably (e.g., 2,500), which would represent at least a 50% absolute increase in activity levels, is feasible for this population.

The use of motion sensors in phase II and II CRPs

To date, only two studies have used pedometers to examine the physical activity patterns of participants in Phase II CRPs (133, 138). Rosneck et al. (133) evaluated the activity patterns of 98 subjects in phase II CR who were randomly assigned to wear an open or closed Yamax SW-200 pedometer. Individuals assigned to wear the open pedometer, self-recorded their step counts each day. Subjects had to participate in the CR for a minimum of 7 weeks. Both groups were asked to gradually increase their activity level on non-CRP days but were not given individual step counts goals. The mean daily steps during phase II CR enrollment were similar between the open and closed groups, 6,340 versus 5,694, respectively. Although baseline step counts were not reported, it appears that regular participation in phase II CR does not meet the activity guidelines advocated by the AACVPR, AHA, ACC and ACSM for individuals with CHD (16, 71, 152)

Savage et al. (138) assessed the physical activity levels of 107 individuals (76% men, 63 years, BMI of 29 kg/m²) for seven days using a Walk4Life pedometer after their initial phase II

CR exercise training session. Subjects had significantly higher step counts on CR versus non-CRP days ($7,387 \pm 3,387$ versus $5,315 \pm 3,336$ steps/day; $p < 0.0001$) with no differences based on gender. Given that non-CRP days are probably indicative of these individual's typical activity patterns, this variable was used for primary analysis. A stepwise linear multiple regression revealed that the variable showing the strongest correlation with total daily step counts on non-CRP days was VO_{2peak} ($r = 0.49$, $p < 0.0001$). There was also a significant inverse relationship between non-CRP day step counts and the following: diabetes mellitus, waist circumference, BMI, age, glucose, total co-morbidity score, weight and resting systolic blood pressure. HDL-C was positively correlated with step counts on non-CRP days. Using stepwise multivariate analysis, VO_{2peak} , HDL-C and diabetes mellitus each correlated with average daily step counts. These results indicate that higher daily step counts were associated with a more favorable CHD risk profile (138). Using the step indices proposed by Tudor-Locke and Bassett (181), participant step counts on non-CRP days indicated that 57% were sedentary, 21% low active, 10% somewhat active, 7% active and 5% highly active. The authors noted the results for non-CRP days are likely indicative of these individuals' typical activity patterns and that their sedentary classification warrants additional exercise counseling and monitoring to enhance their activity levels on these days (138).

Several studies have employed motion sensors to assess the activity levels of phase III CRP participants. Jones et al. (83) assessed the physical activity levels of 25 men (60 years, BMI of 29.6 kg/m^2) using an Actigraph GT1M accelerometer. Subjects wore the accelerometer for seven days and recorded the duration, intensity and mode of any exercise activity they completed in an exercise log. Overall, the subjects averaged $6,907 \pm 510$ steps/day while expending 466 ± 38

kcal/day via physical activity. Step counts were significantly higher on CRP versus non-CRP days (e.g., $10,087 \pm 631$ vs. $5,287 \pm 520$). The step counts on non-CRP days were very similar to the activity levels of participants in phase II CR on non-CRP days (e.g., $5,315 \pm 3,336$ steps/day) (138). Individuals who performed home exercise as well as CRP exhibited significantly higher step counts than CRP-only exercisers (e.g., $7,933 \pm 604$ vs. $5,277 \pm 623$). Lastly, individuals who were employed accumulated significantly more steps on CR days than those who were retired (e.g., $6,271 \pm 701$ vs. $3,938 \pm 537$).

Izawa et al. (79) examined exercise maintenance and LTPA six months after 109 participants (64 years, BMI of 23.2 kg/m^2) completed a 5-month supervised phase II CRP. All participants had sustained a previous MI. Over 83% of patients continued to exercise for more than 6 months after completing phase II CRP. The remaining subjects who did not were considered the control group. LTPA was assessed by having each subject wear a Kenz Lifecorder pedometer for one week, which estimated daily EE. The exercise group walked significantly more steps per day than the non-exercise group ($9,252 \pm 3,047$ versus $4,246 \pm 2,025$ steps/day) and expended more than twice as many calories ($1,940$ versus 875 kcal/day). The frequency, intensity and duration of activity were not documented in the exercise group nor were step counts compared for phase III CRP versus non-CRP days. Each group increased $\text{VO}_{2\text{peak}}$ significantly (experimental; $4.6 \text{ ml/kg} \cdot \text{min}^{-1}$, controls; $3.7 \text{ ml/kg} \cdot \text{min}^{-1}$) but there was no difference between groups (8).

Izawa et al. (80) conducted the only randomized clinical trial using pedometers forty-five patients (64 years, BMI of 22.4 kg/m^2) who had just completed six months of supervised exercise in a Japanese-based phase II CRP were randomly assigned to a self-monitoring approach (SMA) group or a control group. Baseline daily step count values were $6,564 \pm 1,115$

for the SMA versus $6,282 \pm 1,986$ for the control group. During the next six months, the SMA group monitored their activity levels using a Lifecorder pedometer and recorded them in an exercise log. Both groups regularly participated in phase III CR exercise sessions three times a week. At the conclusion of the study, the SMA group's mean daily step counts were $10,458 \pm 3,310$ versus $6,922 \pm 3,192$ in the control group (80). These results show that pedometers can enhance activity levels for prolonged periods of time for individuals with CHD.

It is important to note that both of the aforementioned studies by Izawa et al. (79, 80) were conducted in Japan and used different phase II CRP protocols than those used in the United States. For instance, the patients' exercise intensity was maintained "at an anaerobic threshold heart rate" which is likely higher than the 60-75% HR_{max} prescribed in the U.S. Furthermore, exercise maintenance after completing a phase II CRP is remarkably higher in Japan than in the U.S. (83 vs. 50%) (70, 79). This may result from the fact that CRP participation is covered by Japanese national health insurance for six months versus the United States where it may be covered for only 6 to 36 visits (79). Thus, the financial hurdle for CR participation is considerably less for the Japanese populace. Also, the average body mass index (BMI) values of the participants in this study were considerably lower than that of CRP participants in the U.S (e.g., 23 versus 28 kg/m^2). The average steps/day in the exercise group was close to 10,000 which researchers have reported is equivalent to expending 332, 383 and 432 kilocalories while walking at approximately 2.6, 3.2 and 3.9 mph for an individual weighing 55 kg (80). Furthermore, this level of EE meets the upper range of physical activity recommended by national clinical guidelines and is associated with coronary lesion regression (14, 112). Although the study did

not provide specific details for how the exercise group attained their exercise volume, it does indicate this level of physical activity is safe and attainable for Japanese individuals with CHD.

Ayabe et al. (13) examined 77 subjects (69% men, 68 years, BMI of 27.0 kg/m²) enrolled in a phase III CRP. The amount of time they spent in light (< 3 METs), moderate (3-6 METs) and vigorous (> 6 METs) physical activity was determined by a uni-axial accelerometer (Lifecorder). Subjects had been participating in the program for an average of 5.4 years and walking was the only form of physical activity pursued during the phase III CRP. The weekly amount of physical activity EE was 1,597 ± 846 kcal/week, indicating significant between-subject variability. Weekly EE was significantly higher in men (e.g., 1,778 kcal) versus women (e.g., 1,197 kcal) but after adjustment for weight, the gender difference disappeared. Activity levels were significantly higher on CRP days than on non-CRP days; 299 ± 161 versus 177 ± 113 kcal/day. These values are substantially lower than reported by Jones et al. (83) which could be due to the use of a different accelerometer. Subjects also spent significantly more time in low and moderate intensity activities on CRP versus non-CRP days (low intensity; 59.7 ± 19.8 versus 49.3 ± 19.3 minutes, moderate activity; 26.4 ± 20.4 versus 10.5 ± 14.6 minutes). These caloric expenditures are comparable to prior studies that assessed EE during phase II and III CRPs (136, 139). These results confirm that these participants are not meeting the exercise recommendations for individuals with CHD (11, 16, 152). During the remainder of the day when subjects were not participating in a CRP, they did not have a significant difference in physical activity levels on CRP or non-CRP days (13). Less than half of participants surpassed 1,500 kcal/week and only 16% exceeded 2,220 kcal/week; activity levels believed to be associated with arresting coronary artery progression and minimal regression, respectively (14, 112). The average daily energy

expenditure for this population could have been elevated to 2,200 kcal if subjects consistently walked at 3.0 mph for 30 minutes on days they did not attend the CRP.

Recently, a follow-up analysis of this cohort was used to discern the daily steps counts required for secondary prevention of CHD (14). Overall, average daily step counts were $6,752 \pm 2,659$, with $8,499 \pm 3,173$ steps accumulated on phase III CRP days and $5,491 \pm 2,805$ steps on non-phase III CRP days. The latter value is very similar to the activity levels of participants on non-CRP days in phase II CR (e.g., $5,315 \pm 3,336$ steps/day) (138). The number of daily step counts was strongly related to total physical activity energy expenditure ($r = 0.92$, $p < 0.001$) and time spent in moderate to vigorous intensity physical activity ($r = 0.85$, $p < 0.001$). These results indicate that walking is the most commonly performed activity for leisure time as well as structured exercise activity. The average daily step counts which corresponded to 144, 214 and 314 kcal/day (reflective of weekly values of 1,000, 1,500 and 2,200 kcal, respectively), were 5,046, 6,470 and 8,496 steps/day, respectively. Therefore, the authors concluded that daily step counts of 6,500 and 8,500 correspond to the physical activity level associated with arresting coronary artery lesion progression and minimal reversal (14, 112).

The majority of studies to date indicate that the average physical activity level of phase II or phase III CRP participants is appreciably less than recommended for individuals with CHD (13,83, 136). This result appears to be attributable to low physical activity levels on days when patients do not attend a structured exercise program. Many authors have commented on this and suggested that CRPs should encourage participants to accumulate additional physical activity on days they do not attend the program (13, 83, 136). Presently, no research study on phase II CRP participants has used pedometers to examine whether they can increase LTPA on non-CRP days.

Integrating pedometers into CRPs

A model for how pedometers may be used by allied health professionals to enhance their ability to provide effective physical activity monitoring and counseling exists in the form of telephone counseling. The basis of this counseling method involves an allied health professional who periodically contacts a patient, via the telephone, to assess their progress in managing a given chronic disease. A typical conversation may entail the case manager inquiring if the patient is regularly taking their prescribed medications, eating the recommended diet and monitoring the symptoms of the given disease. The case manager provides positive feedback and reinforces the lifestyle strategies the patient can pursue to self-manage their condition(s) (76, 130). For example, telephone counseling has proven to be effective in counseling patients with congestive heart failure (CHF) regarding management of their body weight. The program involves a case manager who provides patients with CHF a body weight scale and a daily log to record their weight after being discharged from the hospital. Once a week for 12 successive weeks, a case manager calls the patient who reports their present body weight. If body weight has increased by three pounds or more, the case manager asks directed questions to determine the cause of the weight gain and provides advice to prevent further weight gain or schedule a physician visit, if necessary. A typical call lasts approximately 5-10 minutes. This program has been proven to significantly decrease hospital re-admissions, heart failure hospital days and in-patient heart failure costs were 45% lower for individuals with CHF undergoing telephone case-management care versus typical care (130).

Pedometers have been used in a similar manner with physicians or cardiologists providing a pedometer to their patients classified as low or moderate risk. This population has shown a

similar reduction in adverse cardiac events or mortality whether they have participated in a home or center-based exercise program (82). Stovitz et al. (156) observed 21 subjects who received a pedometer after brief physician endorsement (e.g., 1 minute) during which they were asked to incrementally increase their average daily steps counts by 400 each week for 9 weeks. Subjects received three follow-up phone calls from a health educator and significantly increased (by 2,089 steps/day) their mean daily step counts from a baseline level of $6,779 \pm 4,690$ steps/day.

Preliminary results indicate that pedometers can be used in a manner similar to telephone counseling to increase activity levels. Houle et al. (76) studied 32 subjects who received a pedometer and an exercise log book upon discharge from a hospital after suffering a CHD event. In the experimental (E) group, a certified nurse specialist (CNS) contacted patients intermittently to assess their activity goals and gradually encouraged them to increase their activity levels. Control (C) subjects received usual care and were asked to record their daily exercise activity while wearing a blinded pedometer. Baseline step counts were similar (E; $6,116 \pm 2,985$ versus C; $6,020 \pm 3,325$ steps/day; $p = 0.767$) between the two groups. Three months after hospitalization, the two groups significantly increased their daily step counts (E; $9,285 \pm 3,359$ versus C; $8,447 \pm 3,974$ steps/day). At 6 months after hospitalization, the experimental group further increased their average daily step counts by 109 steps/day compared to a 1,501 steps/day decrease in the control subjects (76). These are preliminary results as the study is designed to last 1 year.

Combined, these studies show the promise of using pedometers coupled with practical monitoring and counseling strategies to enhance physical activity levels. Pedometers can provide an objective, cost effective tool that can be readily be integrated into the behavior counseling

strategies utilized in traditional CRPs with minimal participant burden. These devices can complement pre-existing counseling strategies to positively influence the physical activity levels of phase II CRP participants.

Summary

The vast majority of individuals eligible for a CRP do not enroll in one. Individuals who regularly participate in a phase II CRP do not perform the recommend volume of physical activity recommended by the AACVPR, AHA, ACC and ACSM. Yet research consistently demonstrates favorable cardiac and all-cause mortality outcomes in this population.

Activity guidelines for this population indicate home based exercise programs are appropriate for low and moderate risk individuals with CHD (16, 152). Research indicates that home based programs are as efficacious as center-based CRP for the management of risk factor and mortality outcomes (82, 153). Regarding individuals with CHD, walking is the most common physical activity (14). It expends a significant amount of calories, requires no special equipment and it is convenient to perform. Further, epidemiological studies confirm its effectiveness in reducing cardiac and all-cause mortalities (84, 85, 97). The integration of pedometers could provide CR clinicians with a cost-effective, valid assessment of their patient's physical activity patterns. In addition, pedometers provide individuals with easy to understand activity recommendations and motivate them to increase their activity levels. Therefore, future research should determine whether the addition of pedometers to phase II CRPs can increase physical activity levels, especially on non-CRP days. Higher activity levels in this population would likely lead to improved primary risk factor management, decreased cardiac events and reduced cardiac and all-cause mortality.

**CHAPTER III: THE EFFECTS OF A PEDOMETER INTERVENTION ON THE
ACTIVITY PATTERNS OF PHASE II CRP PARTICIPANTS**

Introduction

Individuals with coronary heart disease (CHD) who participate in phase II cardiac rehabilitation program (CRPs) demonstrate reduced cardiac and total mortality (26, 92, 189, 195). This may be due to the fact that regular aerobic exercise provides a number of physiological and psychological benefits related to effective CHD management (23, 58, 59, 60, 69, 67, 112, 159). Only 10-20% of eligible patients enroll in a phase II CRP due to logistical and financial challenges coupled with poor referral rates by physicians (157, 161). Furthermore, about one-half of patients who enroll no longer exercise on a regular basis 1 year after completing a phase II CRP (3, 26, 159). These shortcomings results in avoidable mortality, morbidities and healthcare expenditures (67, 113, 159).

Phase II CRPs offer patients with CHD the opportunity to pursue an appropriate exercise program, coupled with education, to effectively manage their primary risk factors (121, 135). The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American College of Cardiology (ACC), American Heart Association (AHA) and the American College of Sports Medicine (ACSM) recommend that patients with CHD perform a minimum of 30 to 60 minutes of moderate intensity activity at least 5 times/week, coupled with an increase in daily lifestyle activities (11, 16, 71, 153). These recommendations are based on the dose-response relationship between overall activity levels and CHD (3, 67, 118). A typical phase II CRP entails 30-60 minutes of moderate intensity physical activity 3 times a week and thus participants cannot meet the aforementioned physical activity recommendations if this is the only time they exercise. Thus, additional unsupervised exercise is required on the days these

individuals do not attend a phase II CRP (e.g., non-CRP days) in order to meet the physical activity levels recommended for this population (5, 16, 92).

Research indicates that approximately 75% of phase II CRP participants do not perform an adequate amount of physical activity on the days they attend a CRP when caloric expenditures are used to measure physical activity (27, 31). This observation may explain why some clinical studies have reported that phase II CRP participation results in modest or no improvements in risk factor modification (31, 126, 159).

A core component of phase II CRPs is to pursue effective counseling strategies that permit their patients to meet the physical activity guidelines and maintain them after completing the program (3, 26, 165). Attaining this activity objective should help reduce physician visits due to heart complications, lead to better management of risk factors, reduce the likelihood of future cardiac events and enhance functional capacity (3, 54, 70, 113, 119). Presently, the counseling methods and exercise component used in traditional phase II CRPs to enhance and monitor the short and long-term activity patterns of its participants are insufficient.

Pedometers offer an objective, accurate, valid and reliable means to measure ambulatory activity with minimal participant burden (18, 19, 20, 141, 174, 176). They permit self-monitoring and instant feedback on ambulatory activity, which may improve self-efficacy and motivate individuals to increase their activity levels (30, 34, 42, 77, 143, 156). Walking is the most prevalent form of leisure time physical activity among seniors and thus pedometers should provide an accurate indication of their overall activity levels (151).

Researchers have established that increased daily step counts are inversely related to adiposity (e.g., body mass index, percentage body fat), body weight and waist/hip circumference (36, 37,

51, 75, 165). Increased daily step counts have been reported to improve blood glucose management (158, 195), blood lipid profiles (145, 157) and lower systolic blood pressure values (107, 145, 170). These results indicate that higher physical activity levels can help individuals more effectively manage the modifiable risk factors for CHD (15, 157). Although the majority of these studies were conducted with healthy young to middle-aged adults, pedometer programs designed to improve activity levels are also effective in older adults (55, 129).

Recently, pedometers using a piezo-electric mechanism have been developed. Specifically, the Omron HJ-720ITC pedometer contains a dual-axis accelerometer that accurately records step counts whether it is upside-down, slanted or perpendicular to the ground (91, 131). This pedometer is valid and reliable in younger and older individuals (49), in laboratory settings at designated treadmill speeds (e.g., 2.0-4.0 mph) and on flat surfaces at self-selected speeds (e.g., slow, normal, and fast) (48, 49, 74). This device is more accurate than the Yamax SW-200 pedometer, which has a spring levered mechanism and is widely used in research (19, 174). In addition, the accuracy of the Yamax SW-200 decreases with increasing BMI and waist circumference, whereas the accuracy of the Omron does not (45). The Omron HJ-720ITC pedometer provides time and day-stamped, hour-by-hour step-count data, which can differentiate between aerobic (i.e., steps taken at a pace of 60 per minute for at least 10 minutes consecutively) and non-aerobic steps (115).

The purpose of this study was to determine if the use of a pedometer coupled with an exercise diary and step goals will change the physical activity patterns of adults who participate in a phase II CRP on their non-scheduled CRP days compared to those receiving typical treatment.

Methods

Patients

Seventy male and twenty female adults between the ages of 46 and 86 years volunteered to participate in the study. Inclusion criteria for the study were: enrollment in a Mercy Health Partners cardiac rehabilitation program (CRP), the ability to follow the study protocol, (i.e., no presence of dementia), and the ability to walk at a speed of at least 2.0 mph. The latter requirement is due to the fact that pedometers display poor accuracy at slower walking speeds (i.e., < 2.0 mph) (22, 46, 103). All patients recently had at least one of the following cardiac events or procedures performed: myocardial infarction (n = 26), percutaneous transluminal coronary angioplasty (PTCA) (n = 44), coronary artery bypass surgery (CABG) (n = 34), implantable cardioverter defibrillator (n = 2), and/or valve replacement (n = 7). The aforementioned diagnoses were not mutually exclusive. Additional inclusion criteria were a risk stratification of low or moderate risk (according to AACVPR guidelines), and the ability to perform continuous walking (no cardiovascular or orthopedic contraindications to aerobic exercise training).

Patients were excluded from the study if they: 1) were classified as high risk (according to AACVPR guidelines), 2) had a documented history of dementia that could preclude them from following the study protocol, 3) demonstrated unusually high step counts (e.g., > 8,000 steps/day) at baseline (138), or 4) required an assistive walking device. Patients must have received clearance for at least 20 supervised phase II CR visits from their insurance provider so that their activity patterns could be monitored for a sufficient period of time.

The phase II CRP began with an orientation in which a registered nurse and/or an exercise physiologist documents each patient's medical history, medication regimen and physical activity

patterns before he/she begins supervised exercise participation, including electrocardiogram observation. During the orientation, a registered nurse informed eligible patients about the voluntary nature of the study and its requirements and potential risks (see Appendix A). Next, they were given an informed consent form (see Appendix B). After the patient had read and signed the informed consent form, they were given a copy for their personal use. The original informed consent was kept in the patient's medical history file and a copy was maintained by the principal investigator in a locked file cabinet in the CRP's main office. The informed consent form as well as the study protocol was reviewed and approved by the Institutional Review Boards (IRBs) at the University of Tennessee and Mercy Health Partners, Inc., respectively. During the orientation, all patients were encouraged to accumulate additional physical activity on the days they did not attend the phase II CRP.

Study design

Phase II CRP enrollment typically entails 4-12 weeks of supervised exercise and education (e.g., cardiovascular risk factor reduction and lifestyle modification) for approximately one hour three times a week (Monday, Wednesday, Friday). Phase II CRP participants usually exercise three days a week and attend a 30-60 minute education session (consisting of seven different topics) once a week. The minimum length of time a patient was enrolled in the study protocol was 20 CRP sessions, or approximately seven weeks. This time period allowed them the opportunity to attend each education session. The maximum length of time a participant was enrolled in the study was 36 phase II CRP sessions, or approximately 12 weeks. The length of phase II CRP enrollment is dependent on several factors including: the patient's medical

diagnosis, functional progress and insurance provider coverage. The exercise sessions were offered in the morning and afternoon with patients choosing to participate in one or the other.

During the first six months of data collection, subjects who chose to participate in the afternoon exercise sessions were assigned to the control group and given a blinded pedometer. Conversely, patients who elected to participate in the morning session were designated as the experimental group. This design was reversed for the last six months of data collection. This design was chosen so as to minimize the chance that patients in the control group (i.e., those with the blinded pedometer) would interact with experimental patients, who could read their pedometer display.

Subjects assigned to the experimental group were given a step count log (see Appendix C) and were instructed to record the total number of steps they accumulated at the end of each day. Control patients were informed that they would not be able to view their step counts but they would be given a report that explained their activity levels at the end of their CRP enrollment (See Appendix D).

At the end of the phase II CRP orientation, each patient was given an Omron HJ-720 ITC pedometer (Omron, Inc., Dalian City, China). The beginning of phase II CRP participation was chosen for the onset of the study since patients had received medical clearance from their cardiologist and the registered nurse had verified they were capable of resuming their typical daily activities. Each patient was informed that the pedometer was capable of measuring the number of steps they take on a daily basis and that an objective of the study was to monitor their physical activity patterns throughout their participation in the CRP. Patients were given instructions regarding how the pedometer was to be carried (e.g., in either the left or right front

pocket) or worn (e.g., placed in the supplied pedometer holder and attached to the belt or top of their pants at the mid-thigh).

The Omron HJ-720 ITC pedometer contains a microchip with enough memory to store 42 days of time and date-stamped, hour-by-hour step count data. This pedometer discriminates between aerobic and non-aerobic steps and includes a software program which displays and archives the activity information. Aerobic steps are recorded whenever a subject walks for at least ten consecutive minutes at a pace of at least 60 steps/minute. The pedometer allows researchers to monitor how compliant subjects are by displaying the number of hours the pedometer is worn each day. For a given day, the initial hour a subject began wearing the pedometer was determined if they registered at least 50 steps for that hour. The last hour they wore the pedometer for a given day was noted when they registered less than 50 steps for a particular hour. In order to reduce non-step related step artifacts, the pedometer does not record any movements that last less than 4 seconds in duration. Therefore, minor movements that occur in isolation are not recorded (115).

The Omron HJ-720 ITC pedometer has been validated for younger and older populations (46, 48), in laboratory settings at designated treadmill speeds (e.g., 2.0 - 4.0 mph) (65, 72), and on flat surfaces in free-living environments at self-selected speeds (e.g., slow, normal, and fast) (48, 11, 15, 16). It also provides valid steps counts for stair climbing at a typical pace (e.g., 80 steps/minute) (14). It provides equal accuracy in step counts among normal weight, overweight and obese individuals (131) and when worn in various positions (e.g., in either front pocket or in a designated clip at the midline of either thigh) (16, 17, 131). This device is more accurate than the widely used Yamax SW-200 pedometer, which uses a spring-lever design.

Patients were instructed to designate a standard area (e.g., nightstand or vanity) where they would place the pedometer immediately before they went to bed to increase the likelihood they would be visibly prompted to wear the pedometer each day. Patients in the experimental group were instructed to keep their step diary in the same area. The pedometer was programmed with the appropriate time, the patient's weight and stride length. Stride length was determined as recommended by Omron Inc. (115). Specifically, patients walked 10 steps using their typical gait; the total distance covered during the walk was divided by 10 to determine stride length. During the baseline period, pedometer accuracy (acceptance criteria: ± 2 steps) was verified by having each patient take 20 steps in a straight line in a designated area in the CRP facility (171). Patients in the experimental group were encouraged to repeat this test on their own and advised to report inaccurate pedometer readings.

Patients were instructed to wear the pedometer during all waking hours except showering or participating in water-based activities. They were also instructed not to change their typical leisure-time physical activities during their initial week of participation in the phase II CRP. Previous research has indicated that middle aged adults (e.g., 47 years) need to wear a pedometer for three days to achieve an intra-class correlation (ICC) reliability coefficient of 0.80 for weekly step counts (177). Togo et al. has noted that the elderly population (e.g., > 65 years) may require additional days of monitoring to reliably estimate their annual activity since intra-individual variations may be greater than in younger populations due to more flexible daily schedules in retirement (169). These researchers monitored the physical activity patterns of older subjects, average age of 71 ± 4 years, for a year and noted that if the season and day of the week were accounted for, an ICC of 0.80 could be attained with periods of 8 and 4 consecutive days of

observation for men and women, respectively (169). Thus, the initial seven days of phase II CRP enrollment was used to attain an accurate baseline measurement of the patients enrolled in the study.

Protocol

After patients had completed the baseline period, their pedometer data were downloaded to establish a digital record of their overall and aerobic step counts during their first week of phase II CRP enrollment (i.e., baseline step counts). For the experimental group, overall step counts were compared with the values recorded in their step count log each week to verify that they were keeping accurate records of their activity patterns. For both groups, pedometer wear time was noted to ensure that each patient was wearing the pedometer at least 12-14 hours/day. Those who did not consistently wear the pedometer for this time period (n=11) were eliminated from the study.

Pedometer data for all patients were downloaded each week. All patients were asked each week if they experienced any untoward cardiac events outside of the CRP and if they felt their stamina was improving. All patients were informed each week that the physical activity recommendations for individuals with CHD is to accumulate 30-60 minutes of moderate intensity activity five or more days of the week and thus they needed to perform additional exercise on the days they did not attend the phase II CRP (16, 71, 153). Overall and aerobic steps counts were averaged for CRP days (e.g., M, W and F) and non-CRP days (T, R, Sa. and Su.).

Patients had to attend at least two exercise sessions per week to maintain their eligibility for the study. If they did not, they were eliminated from the study (n = 11). An exception was made regarding this eligibility criteria if the patient went on vacation, had to undergo a non-cardiac

related procedure (e.g., cataract surgery) and for weeks that involved a holiday during which the phase II CRP was closed. When patients missed a phase II CRP exercise session, that session (e.g., CRP day) and the following day (e.g., non-CRP day) were omitted from their step count data collection. Data collection was resumed when they attended their next exercise phase II CRP session. Collecting data in this manner allowed for an equal number of monitored days between patients who never or rarely missed a phase II CRP session versus those who did. When patients failed to wear a pedometer for a weekday, the missing data were replaced by using the mean of the remaining weekdays. Missing weekend days were replaced with the alternate weekend day (86).

Patients in the experimental group were given individualized step count goals, which have been shown to result in positive health outcomes (30, 181). After baseline step counts were established, these patients were encouraged to increase their average overall step counts by 5-10% on non-CRP days during the next week. This increment in step counts has been proven to be attainable and safe in senior populations (e.g., > 70 years of age) (55). They could accomplish the goal via increased activities of daily life (e.g., performing additional housework, parking further away when performing errands, etc.) or short continuous walks of 5-10 minutes, which have been demonstrated to increase daily walking time (193). This protocol, which gradually increases the volume of exercise over time, follows the AACVPR and AHA recommendations for this population (3). Specifically, the AHA states that the amount of physical activity performed is more important than the exercise intensity for health improvements in this population, although moderate intensity activities should be pursued (56). Patients were asked if

the step count goals were reasonable and if so, how they planned to attain it. The step count goal was written on their exercise log for the appropriate upcoming seven day period.

If the patients reached their step count goal, then they were encouraged to repeat it for the next week. The following week, they were encouraged to increase their step counts by 5-10% and this process continued until patients had increased their average step counts on non-CRP days by approximately 2,000 to 2,500 steps per day, compared to their baseline value.

Thereafter, they were asked to maintain this increase in activity level on non-CRP days for the remainder of their enrollment in the phase II CRP. This incremental improvement in daily step counts has been suggested as a minimum requirement to favorably alter health outcomes (181). When patients did not attain their step count goal, they were asked if the goal was reasonable, in order to help determine why they did not reach the goal. Then, additional strategies were employed in an attempt to meet the goal during the next week.

Patients in the control group were reminded each week what the activity recommendations were for individuals with CHD. Specifically, they were informed that a minimum of 30 to 60 minutes of moderate intensity physical activity should be performed at least five, preferably all, days of the week for individuals with CHD (16, 71, 153). Thus, they were consistently instructed that they should regularly perform additional exercise on the days they did not attend the phase II CRP.

Medical history

Primary risk factors for coronary heart disease (CHD) were determined by self-report and the patient's medical history. These included hypertension, high cholesterol, type 2 diabetes, family history, smoking, obesity and a sedentary lifestyle. The standards for each primary risk factor

were based on the AHA guidelines (11). Type 2 diabetes was ascertained by self-report or if the patient was prescribed blood sugar management medications. Obesity was defined as a body mass index (BMI) ≥ 30 kg/m², based on the direct measurement of height and weight. Physical activity status was ascertained through self reported activity levels. Medications were documented by the registered nurse or exercise physiologist during the orientation (each patient was required to bring their prescription medication to the orientation). Working status, cardiac events, cardiac procedures and the number of days from hospital discharge until phase II CRP entry were determined from in-patient hospital records.

Data analysis

Statistical analyses were performed using SAS 9.2 software for Windows (Cary, NC) and SPSS 14.0 (Chicago, IL) and an alpha of < 0.05 was used to denote statistical significance. Values are presented as mean \pm standard deviation for the patient physical characteristics, step counts and baseline data (see Tables 1 and 2). Two sample t-tests were used to compare the baseline physical characteristics between genders as well as the control and experimental groups. Normality was tested by the Kolmogorov-Smirnov test and the Satterthwaite estimation was employed to account for non-homogeneity of variance.

The patients' daily overall and aerobic step counts were averaged each week for CRP (e.g., M, W and F) and non-CRP days (e.g., T, R, Sa. and Su.). Two sample t-tests were used to assess differences between genders and groups regarding baseline step counts for CRP and non-CRP days. Baseline step counts for CRP and non-CRP days were compared based on the presence of each risk factor with the exception of sedentary behavior.

The study protocol required that patients enrolled in a phase II CRP for a minimum of seven and maximum of twelve weeks. 70 patients completed seven weeks of the phase II CRP. Seven subjects completed between seven and twelve weeks. A total of 55 subjects completed 12 weeks of the phase II CRP. Thus, two separate statistical analyses were performed to account for CRP enrollment differences.

Step count results for the first seven weeks of phase II CRP enrollment were analyzed using a 2 x 7 repeated measures ANOVA (with group as the between factor and time as the within factor) to assess differences between groups and time and their interaction regarding changes in overall and aerobic step counts on CRP and non-CRP days. If there was a significant interaction effect, the groups were analyzed separately using a one-way repeated measures ANOVA. This permitted the identification of significant differences between designated points in time (e.g., week 2 versus baseline, week 3 versus baseline, etc.) for overall or aerobic step counts. Next, each time point (e.g., week 1, week 2, etc.) was analyzed separately to determine if there were significant differences between the control and experimental groups. In the event of a significant effect for any variable, a Bonferroni corrected post hoc comparison was performed.

In order to account for the variations in the number of weeks of enrollment in the phase II CRP, each patient's last week of enrollment was designated as their "completion" variable. A repeated measures ANOVA was used analyzing only baseline and "completion" time points. Thus, if a patient was enrolled for 8 weeks in the phase II CRP, their step count values for week 8 were compared to their baseline values. This statistical analysis revealed the effects of the intervention, regardless of how long patients were enrolled in the phase II CRP.

Results

Patient participation

Ninety four patients met the inclusion criteria and voluntarily agreed to participate in the study. One patient withdrew from the study after being assigned to the control group. Three subjects reported adverse cardiac episodes (e.g., unstable angina) and were eliminated from participation in the study. A total of five pedometers malfunctioned and would not permit step count data to be retrieved resulting in those patients being discontinued from study participation. Four patients lost their pedometer. Eleven patients were excluded because they did not wear the pedometer consistently. The remaining subjects (n = 70) completed seven weeks of the phase II CRP. Between weeks seven and twelve of phase II CRP participation, three subjects resumed full-time work and elected to discontinue the program, two subjects passed away and 10 subjects either decided they had progressed sufficiently physically to graduate from the program and chose to exercise independently or pursue the phase III CRP. Therefore, 55 patients completed 12 weeks of the phase II CRP. Figure 2 displays the flow of patients in the study. Participants wore the pedometer for $14.1 \pm .9$ hours throughout the study. They consistently wore it as only 20 person-days of missing data were noted.

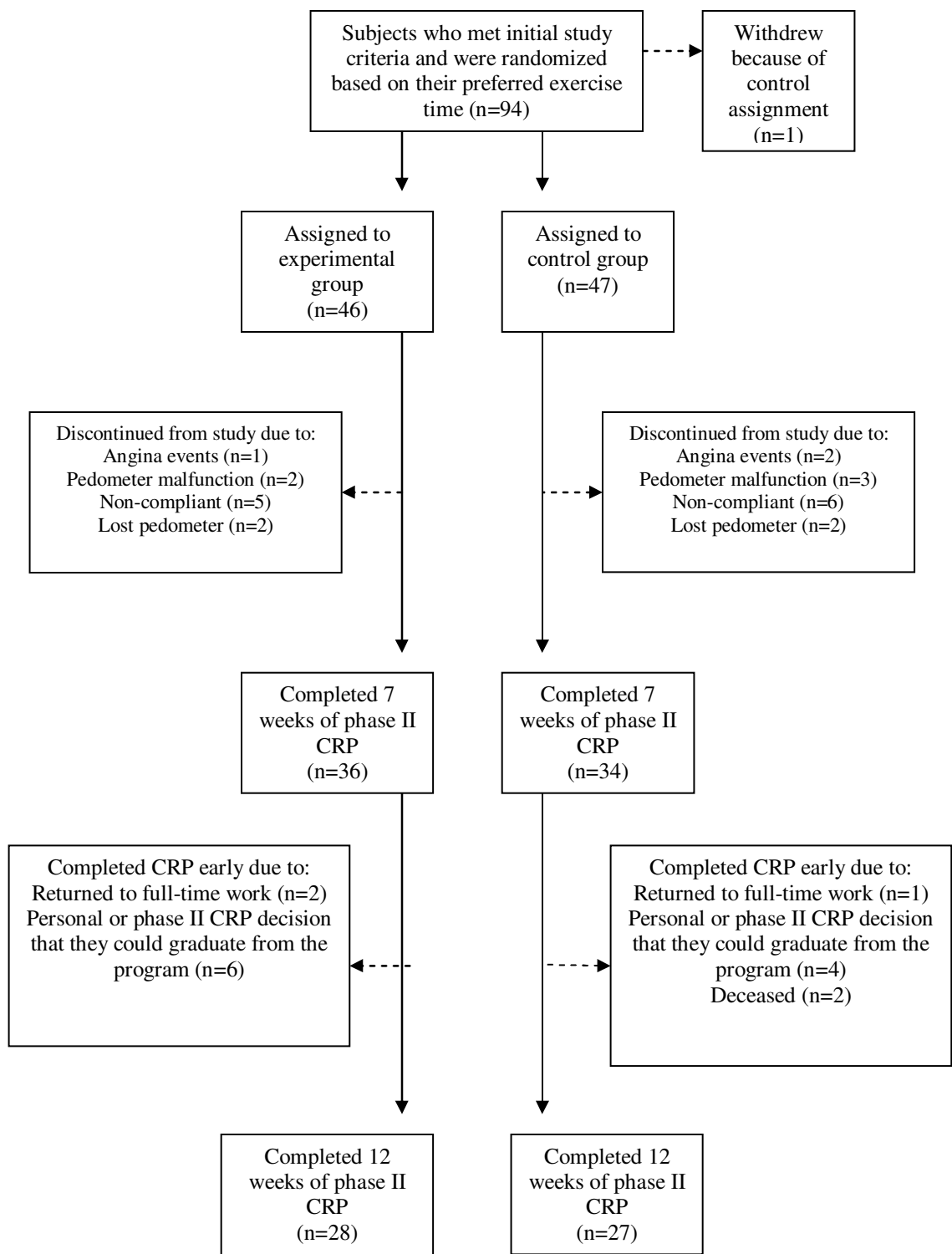


Figure 2: Flow of patients through the study

Baseline characteristics

The patients' baseline characteristics categorized by gender and study group designation are presented in Table 1. Patients were predominantly male (76%) with a mean age of 69 ± 9 years (range, 46 to 86 years). Patients typically enrolled in the phase II CRP about 5 weeks after they were discharged from the hospital. Significant baseline differences were noted between men and women for height and weight. There were no differences in any other physical characteristic between genders, or between the experimental and control groups. Patients were taking a mean of seven medications, with beta-blockers (85%) and statins (92%), being the most prevalent (data not shown). There were no differences in prescription medication usage between genders or groups. Approximately 71% percent of the patients were retired.

Both genders and groups had an average of four primary risk factors, with hypertension, high cholesterol and sedentary behavior being the most prevalent. The presence of primary risk factors for the overall group was similar to previous results regarding the phase II CRP population (15). However, 81% of the subjects in the present study were hypertensive versus 60% noted in previous studies; this may be due to the fact that the present population was approximately 10 years older (5, 15). Women and experimental patients were more likely to have undergone percutaneous transluminal coronary angioplasty (PTCA) while more men underwent coronary artery bypass graft (CABG) surgery. The proportion of subjects undergoing the aforementioned procedures is similar to previous results of patients entering a phase II CRP (5).

Table 1. Physical and medical history characteristics of participants

Characteristic	Men (n = 53)	Women (n = 17)	Exp. (n = 36)	Controls (n = 34)	All subjects (n = 70)
Age (yr)	67.2 ± 9.7	70.5 ± 7.3	68.1 ± 9.0	67.8 ± 9.5	67.8 ± 9.1
Height (m)	1.78 ± 0.1	1.61 ± 0.06*	1.73 ± 0.09	1.75 ± 0.09	1.74 ± 0.10
Weight (kg)	91.5 ± 20.9	75.9 ± 15.0*	86.0 ± 20.8	89.2 ± 20.7	87.7 ± 20.6
BMI (kg * m ²)	28.8 ± 6.5	29.1 ± 5.0	28.5 ± 5.6	29.3 ± 6.6	29.0 ± 6.1
Ejection fraction (%)	49 ± 10	55 ± 9	52 ± 10	48 ± 10	50 ± 9
Days from hospital discharge to CR enrollment	39 ± 25	34 ± 17	36 ± 24	41 ± 23	38 ± 23
Retired	66%	89%	73%	71%	71%
Primary risk factors	3.9 ± 1.1	3.9 ± 1.2	3.8 ± 1.1	4.0 ± 1.3	3.9 ± 1.2
Obesity	40%	39%	43%	39%	41%
Hypertension	82%	78%	81%	81%	81%
High cholesterol	84%	78%	81%	83%	82%
Sedentary	82%	100%	85%	85%	85%
Smoking	20%	28%	16%	22%	23%
Type 2 diabetes	29%	22%	23%	33%	29%
Family history	33%	44%	30%	36%	36%
Cardiac procedure					
CABG	44%	24%	39%	38%	39%
PTCA	43%	65%	56%	41%	49%
Other	13%	11%	5%	21%	12%

Data reported as mean ± standard deviation

* Significant difference between men and women (p < 0.05)

Other surgical procedures included implantable cardioverter defibrillator or valve procedure

Baseline activity levels

Baseline physical activity patterns are depicted in Table 2. Overall daily average step counts were 3,797 ± 1,755 with 355 ± 694 aerobic steps. Subjects averaged 105 steps per minute when accumulating aerobic steps and there were no differences in this value between genders or groups. Men took significantly more overall steps per day than women (p < 0.01), but similar aerobic steps. This pattern was sustained for overall steps counts on CRP (p < 0.05) as well as non-CRP days (p < 0.05). At baseline, participants demonstrated a significantly higher overall step counts on CRP versus non-CRP days (p < 0.01), but similar aerobic steps. This pattern was sustained regardless of gender or group assignment.

Table 2: Baseline physical activity patterns of participants based on gender and group designation

Characteristic	Men (n = 53)	Women (n = 17)	Exp. (n = 36)	Controls (n = 34)	All subjects (n = 70)
Total steps/day	3,996 ± 1,764*	3,136 ± 1,455	4,071 ± 1,781	3,508 ± 1,551	3,797 ± 1,755
Aerobic steps/day	438 ± 652	351 ± 836	488 ± 766	327 ± 440	355 ± 694
Total steps/day on CRP days	4,435 ± 1,572*†	3,561 ± 1,424†	4,515 ± 1,661†	3,962 ± 1,434†	4,247 ± 1,573†
Aerobic steps/day on CRP days	428 ± 622	302 ± 646	483 ± 722	275 ± 427	398 ± 626
Total steps/day on non-CRP days	3,667 ± 1,679*	2,818 ± 1,205	3,763 ± 1,780	3,175 ± 1,372	3,461 ± 1,611
Aerobic steps/day on non-CRP days	445 ± 701	387 ± 791	491 ± 904	324 ± 457	431 ± 718

Data reported as mean ± standard deviation

* Significant difference between men and women ($p < 0.05$)

† Significant difference between CRP and non-CRP days ($p < 0.01$)

Baseline overall step counts were similar for both groups on CRP and non-CRP days ($p = 0.11$ and $p = 0.145$, respectively). This pattern was also apparent for aerobic steps ($p = 0.23$ and $p = 0.47$, respectively).

Statistical results for non-CRP days

Figure 3 illustrates the changes in overall and aerobic steps on non-CRP days (Tuesday, Thursday, Saturday and Sunday) for the experimental and control groups during phase II CRP. 70 subjects completed seven weeks of the phase II CRP, while 55 completed 12 weeks.

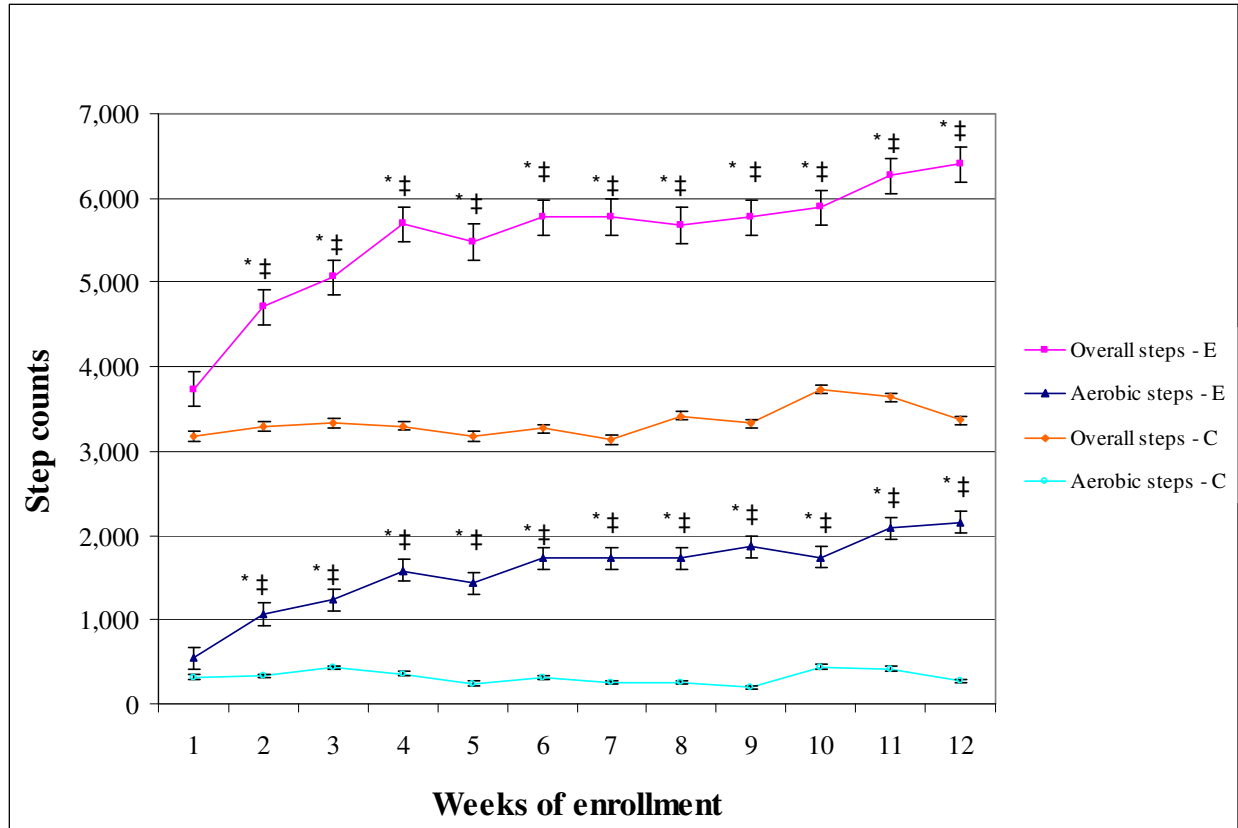


Figure 3: A comparison of changes in weekly overall and aerobic step counts between experimental (E) and control (C) subjects on non-CRP days

* $p < 0.0001$ experimental versus control

‡ $p < 0.0001$ versus baseline experimental step counts (overall or aerobic)

The repeated measures ANOVA of overall step counts on non-CRP days revealed there was a significant ($p < 0.001$) group by time interaction. This indicates that the experimental patients increased their overall steps counts significantly more and at a faster rate on non-CRP days than control subjects. The *post hoc* analysis divided the two groups, which were analyzed with a one-way repeated measures ANOVA. Experimental patients demonstrated significantly ($p < 0.0001$) higher overall and aerobic step counts for weeks 2-7 versus baseline. Interestingly, the experimental patients attained a plateau by week 4 as there were no differences in their step

counts between weeks 4 and 7 (see Figure 1). In contrast, control patients had no change in overall steps throughout weeks 2-7. *Post hoc* analyses compared the groups to one another at each time point. The groups were similar ($p = 0.145$) at baseline but they were significantly different at every other time point ($p < 0.001$).

There was also a significant ($p < 0.001$) group by time interaction for aerobic step counts on non-CRP days. The groups were divided and analyzed using a one-way repeated measures ANOVA. Experimental patients demonstrated a significant ($p < 0.001$) time effect for aerobic steps as each time point was different ($p < 0.05$) from baseline. Conversely, the control group displayed similar ($p = 0.475$) aerobic steps for weeks 2-7.

The 2 by 2 repeated measures analysis comparing the groups' baseline and "completion" values demonstrated that there was a significant group interaction ($p < 0.0001$), indicating that overall step count changes were different between the two groups. There was a significant increase in overall steps on non-CRP days for the experimental patients ($p < .001$) while there was no difference for controls ($p = 0.446$).

There was a significant interaction ($p < 0.0001$) for time concerning aerobic step counts on non-CRP days, indicating the groups did not increase their aerobic step counts at the same rate. Next, the groups were split and compared by time, which revealed that experimental patients increased their aerobic step counts significantly ($p < 0.0001$) and the control patients did not ($p = 0.558$).

The average weekly step counts for overall and aerobic steps on non-CRP days for both groups are depicted in Table 3.

Table 3: Weekly averages for overall and aerobic step counts for non-CRP days

	Experimental		Control	
	Overall steps	Aerobic steps	Overall steps	Aerobic steps
Week 1	3,763 ± 1,780	491 ± 904	3,175 ± 1,372	324 ± 457
Week 2	4,709 ± 2,080 *†	1,063 ± 1,313 *†	3,292 ± 1,900	331 ± 524
Week 3	5,058 ± 2,027 *†	1,233 ± 1,326 *†	3,335 ± 1,409	428 ± 837
Week 4	5,693 ± 2,102 *†	1,585 ± 1,564 *†	3,299 ± 1,423	362 ± 783
Week 5	5,512 ± 1,898 *†	1,435 ± 1,321 *†	3,172 ± 1,475	245 ± 454
Week 6	5,772 ± 2,166 *†	1,726 ± 1,399 *†	3,267 ± 1,688	312 ± 570
Week 7	5,777 ± 2,127 *†	1,726 ± 1,635 *†	3,137 ± 1,661	257 ± 403
Week 8	5,678 ± 2,149 *†	1,726 ± 1,519 *†	3,415 ± 1,773	258 ± 432
Week 9	5,770 ± 2,493 *†	1,868 ± 1,672 *†	3,327 ± 1,707	191 ± 457
Week 10	5,893 ± 2,235 *†	1,740 ± 1,276 *†	3,732 ± 2,160	443 ± 684
Week 11	6,264 ± 2,582 *†	2,087 ± 1,545 *†	3,643 ± 1,922	421 ± 557
Week 12	6,400 ± 2,623 *†	2,158 ± 1,566 *†	3,364 ± 1,960	281 ± 582

Data reported as mean ± standard deviation

* versus control step counts (overall or aerobic) ($p < 0.001$)

† versus baseline experimental step counts (overall or aerobic) ($p < 0.001$)

Statistical results for CRP days

Figure 4 illustrates the changes in overall and aerobic steps on CRP days (Monday, Wednesday and Friday) for the experimental and control groups during the phase II CRP.

The repeated measures ANOVA for overall steps on CRP days indicated that there was not a significant ($p = 0.095$) group by time interaction. There was a significant ($p < 0.001$) time effect, as each week was different from baseline. In terms of a group effect, *post hoc* paired comparisons between the experimental and control groups showed that they were similar at baseline ($p = 0.11$) and that only weeks 3 and 7 were different from one another.

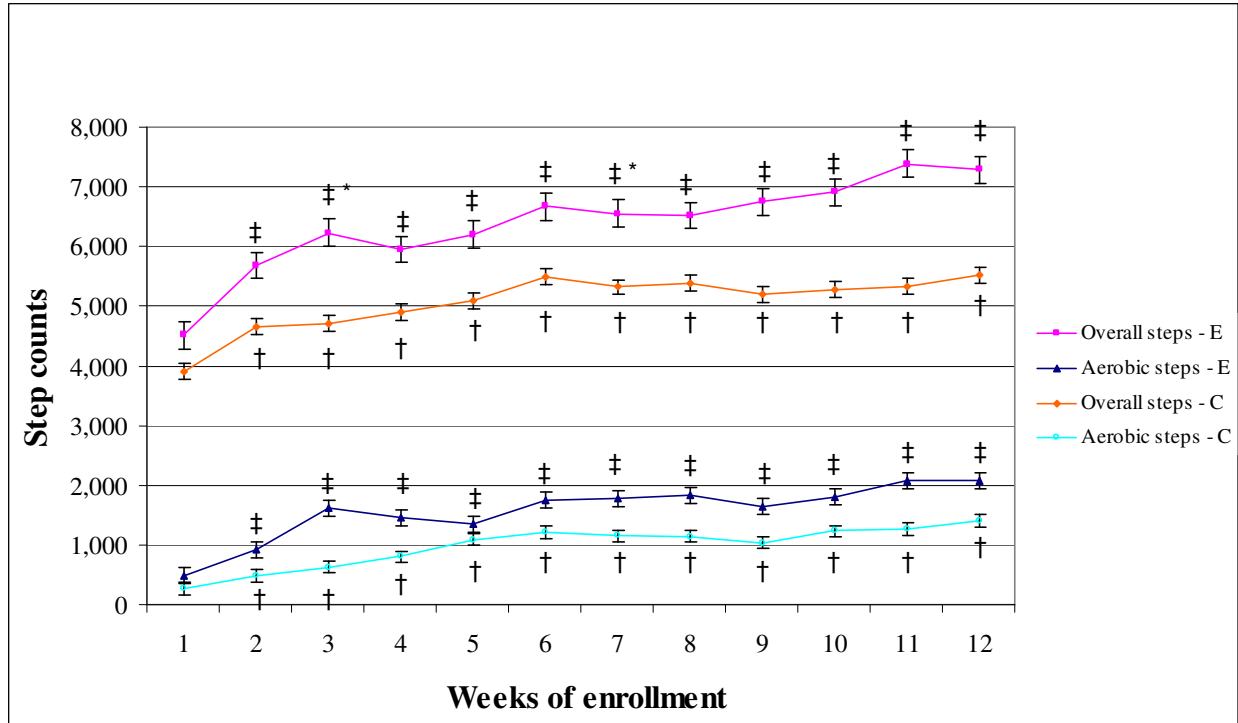


Figure 4: A comparison of changes in weekly overall and aerobic step counts between experimental (E) and control (C) subjects on CRP days

* $p < .05$ experimental versus control (overall)

† $p < .001$ versus baseline control step counts (overall or aerobic)

‡ $p < .001$ versus baseline experimental step counts (overall or aerobic)

The group by time interaction was not significant ($p = 0.312$) for aerobic steps on CRP days.

There was a slight difference ($p = 0.033$) between the groups. There was also a significant ($p < 0.01$) increase over time, as both groups consistently increased their aerobic step counts from baseline until week 7.

The 2 by 2 repeated measures analysis comparing the groups' baseline and "completion" overall step counts for CRP days indicated there was a significant ($p = 0.025$) interaction and thus changes over time were different by group. Next, the groups were split and each of them demonstrated significant ($p < 0.01$) increases over time. The experimental patients increased

their overall step counts on CRP days by 2,516 and the control patients 1,579. As noted, the groups were similar at baseline ($p = 0.11$) but not at phase II CRP completion ($p = 0.007$).

There was no significant group interaction ($p = 0.237$) but there was for time ($p < 0.001$) for both groups concerning aerobic step counts on CRP days. The overall group increased their aerobic step counts on CRP days by 1,250.

The average weekly step counts for overall and aerobic steps on CRP days for both groups are depicted in Table 4.

Table 4: Weekly averages for overall and aerobic step counts on CRP days

	Experimental		Control	
	Overall steps	Aerobic steps	Overall steps	Aerobic steps
Week 1	4,515 ± 1,661	484 ± 722	3,962 ± 1,434	275 ± 427
Week 2	5,684 ± 2,268 †	913 ± 1,322 †	4,637 ± 1,987 *	483 ± 776 *
Week 3	6,232 ± 2,091 †	1,609 ± 1,922 †	4,707 ± 2,072 *	628 ± 1,019 *
Week 4	5,951 ± 2,092 †	1,442 ± 1,584 †	4,895 ± 1,917 *	797 ± 1,015 *
Week 5	6,202 ± 1,923 †	1,339 ± 1,152 †	5,100 ± 1,937 *	1,086 ± 1,181 *
Week 6	6,673 ± 2,253 †	1,763 ± 1,647 †	5,493 ± 2,211 *	1,209 ± 1,224 *
Week 7	6,557 ± 2,148 †	1,769 ± 1,419 †	5,320 ± 1,854 *	1,150 ± 1,069 *
Week 8	6,521 ± 1,994 †	1,823 ± 1,222 †	5,393 ± 2,042 *	1,143 ± 1,008 *
Week 9	6,748 ± 2,266 †	1,655 ± 1,392 †	5,209 ± 2,100 *	1,034 ± 805 *
Week 10	6,917 ± 2,265 †	1,870 ± 1,340 †	5,277 ± 2,347 *	1,230 ± 997 *
Week 11	7,390 ± 2,984 †	2,056 ± 1,527 †	5,344 ± 2,630 *	1,261 ± 910 *
Week 12	7,290 ± 2,738 †	2,071 ± 1,446 †	5,529 ± 2,381 *	1,401 ± 1,107 *

Data reported as mean ± standard deviation

* versus baseline control step counts (overall or aerobic) ($p < 0.01$)

† versus baseline experimental step counts (overall or aerobic) ($p < 0.01$)

Discussion

This is the first study to demonstrate the effectiveness of pedometers in conjunction with step count goals and an exercise diary in patients enrolled in a phase II CRP. The overall increase in daily steps counts (e.g., 2,500) is associated with health benefits for healthy and special

populations. Experimental subjects demonstrated the ability to increase their activity levels on the days they attended a phase II CRP as well as the days they did not, predominantly through an increase in aerobic step counts. The pace of the aerobic stepping (i.e., 112 steps/minute) which falls within the range of 3-6 METs. Thus, it appears that pedometers facilitate phase II CRP participants to increase their overall activity levels versus patients receiving standard care.

Savage et al. (138) contend that step counts on non-CRP days during their first week of enrollment are indicative of an individual's typical activity pattern. They assessed 107 individuals for seven days after their initial phase II CRP exercise training session. Patients demonstrated significantly higher step counts on CRP versus non-CRP days (7,387 versus 5,315 steps/day; $p < 0.0001$). The authors noted that 62% of the patients would be considered sedentary (i.e., they accumulated less than 5,000 steps per day) and that additional exercise counseling and monitoring is warranted to enhance their activity levels on non-CRP days (138). In the present study, patients averaged 3,461 steps per day on non-CRP days at baseline. This non-CRP step count is markedly lower than that reported by Savage et al. (138), which may be attributable to the older age (68 versus 63 years) of the patients in the sample. Alternatively, it could result from a design characteristic of the pedometer used in the present study, which does not record movements that last less than 4 seconds in duration (115). Baseline overall steps were not significantly different between the experimental and control groups (4,071 versus 3,508). This slight difference may be attributable to the fact that experimental patients could view their steps counts and were required to record them in a step count log, which has been noted to significantly increase steps/day versus wearing a blinded pedometer only (39). Overall, 85% of the patients in the present study would be classified as sedentary (i.e., $< 5,000$ steps/day) (181).

These results underline the importance of identifying effective exercise monitoring and counseling strategies so that phase II CRP patients will more readily adopt and maintain exercise patterns that improve their functional capacity and subsequently reduce their risk for cardiac and all-cause mortality (54, 187).

Pedometer based studies in phase II CRP

Pedometers have been used in a limited capacity in phase II (133, 138) and III CRPs (13, 14, 79, 80, 83). Phase II CRPs are insurance-based, electrocardiogram (ECG) monitored exercise and education based programs. Phase II patients exercise at designated time periods for approximately 30-60 minutes, three times a week for 4-12 weeks during which time their exercise program is consistently progressed. Phase III CRPs are self-pay and include patients who have successfully completed 20-36 phase II CRP exercise sessions. Phase III patients are allowed to pursue supervised but non-monitored exercise sessions.

Rosneck et al. (133) evaluated the activity patterns of 98 patients in a phase II CRP who were randomly assigned to wear an open or closed Yamax SW-200 pedometers. Patients assigned to wear an open pedometer self-recorded their step counts each day. Both groups were asked to gradually increase their activity level on non-CRP days but were not given individual step counts goals. Baseline step counts, patient characteristics nor differences between CRP and non-CRP days were reported. The mean daily step counts during phase II CRP enrollment were similar between the open and closed groups, 6,397 versus 5,694, respectively, which was greater than the present study (5,876 versus 4,084, experimental versus control groups, respectively). Prior research using pedometers has shown that 3-4,000 steps/day equates to about 30 minutes of

moderate intensity walking, which is the minimum recommended for healthy adults and those with CHD (13, 22, 153, 192). These steps should be of at least moderate intensity (e.g., > 100 steps/minute) and accumulated in bouts of at least 10 minutes in duration and in addition to steps taken to perform the activities of daily life (e.g., approximately 5-6,000 steps/day) (182, 184). The mean daily step count for experimental subjects who completed the entire phase II CRP was 6,739. Therefore, it appears that even when activity levels at the conclusion of phase II CRP exercise participation is taken into account, the physical activity levels of phase II CRP participants do not meet the activity guidelines advocated for individuals with CHD (11, 71, 153).

The use of pedometers provides a novel approach to complement traditional strategies to monitor and enhance the activity levels of phase II CRP participants. Prior randomized clinical trials have demonstrated that the use of pedometers coupled with daily step count goals leads to significant increases in activity levels (e.g., 2,500 steps/day) in general and in special populations, but this strategy has not been utilized in the phase II CRP population (30, 34, 55, 143, 170).

Activity levels on non-CRP days

In the present study, experimental patients (n =36) demonstrated a significant ($p < 0.001$) increase in their overall and aerobic step counts for weeks 2 through 7 versus the control group (n=34). The majority of the increase in overall steps occurred by week four, and step counts tended to plateau thereafter. This may be attributable to the fact that some experimental patients achieved the designated increase in overall step counts (i.e., 2,000) on non-CRP days early in the program and further increases were not encouraged. In the experimental patients, the average

change in overall and aerobic step counts at the completion of the program on non-CRP days was remarkably similar to CRP days ($2,616 \pm 1,752$ versus, $2,704 \pm 1,644$, respectively). Thus, these patients were willing and able to independently replicate their activity patterns on days they pursue structured, monitored exercise by pursuing leisure time physical activity on non-CRP days. Meijer et al. (102) used a pedometer to study the activity patterns of sedentary seniors who participated in a structured exercise three times a week at a moderate intensity for 12 weeks. Although the training program significantly increased physical fitness, it had no effect on total daily physical activity as the training activity was compensated for by a decrease in activity on non-training days. This outcome was not evident in the present study as experimental patients walked approximately 1.25 more miles per day above baseline levels on CRP and non-CRP days by the conclusion of the phase II CRP. Approximately 60% of this increase was accomplished via aerobic steps and they averaged 14 minutes of continuous walking on non-CRP days. Thus, it appears that experimental patients were pursuing structured continuous activity on a regular basis to enhance their overall activity level on non-CRP days. This result coincides with Richardson et al. (128) who reported that when subjects with Type 2 diabetes were given either overall or aerobic step count goals to increase their daily activity levels, most participants chose to reach their goals by increasing their aerobic steps.

Although pedometers cannot measure exercise intensity, previous research examining phase III CRP patients activity patterns has shown that the number of daily step counts strongly correlated with accelerometer-derived physical activity energy expenditure ($r = 0.92$, $r^2 = 0.846$, $p < 0.001$) and time spent in moderate-to-vigorous intensity physical activity ($r = 0.85$, $r^2 = 0.73$, $p < 0.001$) (14). In addition, Tudor-Locke (182) has reported that a minimal stepping rate of 100

steps per minute is the lower threshold for moderate-intensity walking in adults. This parameter was satisfied by the experimental group, which averaged 109 steps per minute while performing aerobic steps on non-CRP days. Thus, it is likely that the experimental patients were performing additional physical activity at moderate intensity levels and durations commonly associated with improvements in primary risk factors and reductions in cardiac as well as overall mortality (25, 78, 182).

In the experimental group, average daily step counts improved from 4,085 at baseline to 6,739 by the conclusion of the phase II CRP, a 65% absolute increase in daily steps. Thus, they improved from the 'sedentary' designation to the 'low active' designation proposed by Tudor-Locke and Bassett (181). These authors noted that an increase of 2,500 steps/day is associated with favorable health outcomes, which the experimental patients achieved for their average daily step counts (e.g., 2,653). Previous epidemiology studies have reported that increases in physical activity and/or functional capacity decreases the risk of cardiac and all-cause mortality for individuals with established CHD (16, 71, 187). Interestingly, the increase in step counts for the experimental group corresponds with the results of a recent meta-analysis of pedometer based studies. The authors examined the use of pedometers to enhance habitual activity levels and quantified that the average increase in daily step counts is 2,491 for pedometer users versus control subjects (30). In addition, the preliminary results (at 6 months of a 12 month intervention) of a home based CRP program indicate that experimental patients averaged 2,400 steps/day more than the controls while demonstrating significantly lower LDL levels, systolic blood pressure and waist circumference versus controls (76).

Activity levels on CRP days

The experimental and control patients demonstrated a significant increase ($p < 0.01$) in their overall steps and aerobic steps for weeks 2-7 of the phase II CRP versus baseline. This result is to be expected since participants in phase II CRP are encouraged to gradually increase their exercise intensity and duration as they progress through the program (3).

At the conclusion of the phase II CRP, all subjects were averaging 2,135 more steps on CRP days and 65% of this activity increase was due to additional aerobic steps. Aerobic steps were performed at a pace of 114 steps/minute on CRP days. Thus, it appears that patients walked at a similar pace whether supervised or unsupervised (i.e., non-CRP days). It is important to note that although the experimental subjects were averaging approximately 7,200 steps/day on CRP days, this activity level would not meet the activity guidelines for this population (16, 71, 153). This concurs with a previous study which concluded that the majority of phase II CRP patients were not performing adequate activity on days they attend a phase II CRP based on their caloric expenditures (140).

Step counts associated with changes in coronary artery lesions

In the only randomized clinical trial examining the activity patterns of phase III CRP participants, Izawa et al. (80) examined the activity patterns of 50 patients, who had just completed six months in a phase II CRP in Japan. Subjects were assigned to a self-monitoring approach (SMA) or control group. Baseline daily step count values were 6,564 for the SMA versus 6,282 for the control group, respectively. During the next six months, the SMA monitored their activity levels using a LifeCorder pedometer and recorded them in an exercise log. Both groups regularly participated in phase III CR exercise sessions. At the conclusion of the study,

the SMA group's mean daily step counts were $10,458 \pm 3,310$ versus $6,922 \pm 3,192$ in the control group (80). These results may be indicative of the changes in activity levels that could be attained if the experimental patients in the present study who completed the phase II CRP continued to be progressed during the first three months of phase III CRP enrollment.

Previous research on individuals with CHD used arteriograms to establish the amount of physical activity required for effective secondary prevention of CHD. Subjects who expended 1,000 kcal/week experienced progression in their coronary lesions, while those expending 1,500 kcal/week had no changes and patients expending 2,200 kcal/week demonstrated a slight reversal in coronary lesions (69, 112). Recently, Ayabe et al. (14) examined 77 subjects enrolled in a phase III CRP to determine the accelerometer (e.g., Lifecorder) based daily steps counts required to expend 1,000, 1,500 and 2,200 kcal/week. Overall, average daily step counts were 6,752, with 8,499 steps accumulated on phase III CRP days and 5,491 steps on non- phase III CRP days. The average daily step counts which corresponded to 144, 214 and 314 kcal/day (reflective of weekly values of 1,000, 1,500 and 2,200 kcal, respectively), were 5,046, 6,470 and 8,496 steps/day, respectively. Therefore, the authors concluded that daily step counts of 6,500 and 8,500 correspond to the physical activity levels associated with arresting coronary artery lesion progression and reversing it (69, 112).

Experimental patients were averaging 6,739 steps/day at the completion of the phase II CRP, which might indicate they were performing an adequate amount of activity to halt the progression of their coronary lesions. It is also likely that this group improved their cardiorespiratory fitness (CRF) level, a variable that is inversely associated with CHD and all cause mortality (5, 25, 187). Additional support is provided for this inference based on the fitness

levels of CRP participants when they begin a phase II CRP. Although CRF was not measured in the present study, an average VO_{2max} of 15 and 19 $ml \cdot kg^{-1} \cdot min^{-1}$ for women and men, respectively, has been reported for this population (5). Thus, moderately paced walking would be performed at a high percentage of VO_{2max} . For instance, a woman walking at a pace of 2.5 mph is equivalent to 2.9 METs or 10.15 $ml \cdot kg^{-1} \cdot min^{-1}$ which is approximately 70% of her VO_{2max} . Regarding men, a walking speed of 3.5 mph would yield the equivalent relative exercise intensity. The experimental subjects were consistently performing continuous exercise and likely doing so at moderate exercise intensities. This statement is supported by the fact that they averaged 15 minutes of aerobic activity at a step rate of 109 steps/minute, which is considered moderate intensity activity (182). Consistently performing this volume of activity would be likely to improve their VO_{2max} . Previous research has indicated that the magnitude of training-induced increases in peak VO_2 has been shown to independently predict a decrease in cardiovascular mortality as well as coronary lesions (147, 187).

Study limitations

One limitation of this study is the inability of pedometers to measure non-ambulatory activity, such as cycling, arm ergometry and weight lifting. Although walking is the most feasible and popular activity for seniors (151), CRPs commonly employ a series of ergometers (e.g., cycle and seated stepper ergometers) that involve leg movements that are not accurately measured by pedometers (176, 180). During a typical CR exercise session, patients may spend up to 40% of their exercise time on these ergometers which leads to an underestimation of their physical activity on CRP days. A second limitation is that pedometers cannot accurately estimate caloric

expenditure (176, 180). Thus, any discussion of whether proposed step counts are associated with changes in coronary artery occlusion is speculative.

Conclusion

In conclusion, the present study quantified the amount of physical activity performed by patients when they enter a phase II CRP as well as their activity changes during the course of the program. Furthermore, activity levels were divided into intermittent and aerobic designations. The results demonstrated that the use of a pedometer, coupled with a step count diary and individual goals leads to a significant increase of approximately 2,400 steps/day. There were increases in overall and aerobic step counts on non-CRP and CRP days for the experimental group. The use of pedometers and step count goals can complement traditional phase II CRPs to provide a novel strategy for self-monitoring and improving daily activity levels. Future research using pedometers should determine whether changes in risk factors and/or coronary blockages (using arteriograms) are associated with changes in activity patterns. The results could provide more definitive evidence that increasing daily step counts results in significant improvements in CHD management.

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APPENDICES

Appendix A: Script for orientation and the provision of the pedometer

- ▶ At the orientation, please note the following instructions to ensure that the patient is accurately monitoring the number of steps they take in their daily lives.
 - The purpose of the study is to learn the total number of steps that patients take each day they are enrolled in the Mercy CRP.
 - As soon as you wake up each morning, put the pedometer in your pant pocket (without the clip). If they do not have a pant pocket, place the pedometer in the provided belt clip and wear it at your waist at the midline of the thigh. I will demonstrate how the pedometer should be properly worn.
 - The step counter should be worn during all hours, except when bathing or sleeping.
 - Just before you go to bed each night, please remove the pedometer.
 - Repeat these procedures throughout your enrollment in the Mercy CRP

- ▶ After reviewing the informed consent and ensuring that it has been initialed and dated on each page, please note that participation in the study is voluntary and that they should contact their physician if they have any health related problems or Michael F. Shipe (471-3302) if they have any questions about participation in the study. Subjects should be given a copy of the signed consent form.

- ▶ At the orientation, each eligible patient who agrees to participate in the study and has signed an informed consent needs to be given a pedometer. During the first six months of the study, individuals enrolled in the morning sessions should be given a pedometer in which they can view the number of steps they take daily as well as a calendar. They should be encouraged to keep the calendar on their night stand so they are prompted to record their steps each night. The night stand would also be a good place to leave the pedometer at night. If they don't have a night stand, encourage them to designate a place to store it consistently. During the first six months of the study, patients enrolled in the afternoon class will be given a blinded pedometer in which they cannot view their step counts and thus they will not need a calendar. After six months, the experimental and control participants will be switched regarding morning and afternoon CRP participation.

- ▶ If they forget to wear the pedometer, they simply need to note that fact on their calendar. Also, they need to bring their calendar with them each Wednesday, so the principal investigator can note they are recording their steps, during the education class.

- ▶ Subjects in the intervention protocol should only be given the pedometer and a calendar during their first week of enrollment in the study. Thereafter, the principal investigator is responsible for encouraging patients to begin increasing their step count 5-10% above their current daily physical activity levels on non-CRP days for the next two weeks of CRP enrollment. Eventually, if they tolerate the additional exercise well, subjects will be encouraged to increase their daily step counts an additional 5-10% per day on non-CRP days until they average approximately 2,000 more steps day (approximately 1 mile) above their baseline values.

► Each patient will be sent a report detailing their step counts throughout their enrollment in the Mercy CRP. Further, this report will address whether they pursue adequate physical activity that adheres to the CDC/ACSM recommendations. Previous research has shown that these levels of physical activity are associated with significant reductions in morbidity and mortality for individuals with documented coronary heart disease.

Appendix B: Patient Information/Consent Form

The use of pedometers by cardiac rehabilitation program participants to be conducted at

Baptist Hospital of East Tennessee
137 Blount Avenue
Knoxville, TN 37920

St. Mary's Health System, Inc.
900 E. Oak Hill Avenue
Knoxville, TN 37917

Principal Investigator: Michael F. Shipe
Sub-investigator: David Bassett, Jr, Ph.D.

PURPOSE:

The purpose of this study is to use pedometers to examine the physical activity patterns in adults who participate in the cardiac rehabilitation programs (CRP) provided by the Mercy Health partners at either location noted above.

PROCEDURES:

You will be asked to carry a pedometer, which measures the number of steps you take each day, during your enrollment in the CRP. Based on your fitness level and medical history you will be encouraged to walk an additional half mile to 1.5 miles on days you do not attend the CRP, which is standard practice. You may also be required to write down the number of steps you take a day on an exercise log, which will be provided to you.

POSSIBLE RISKS:

It is considered an appropriate activity for CRP participants to engage in unsupervised intermittent and continuous walking at low to moderate exercise intensities (e.g., 2-3 mph) which are not associated with a greater incidence of heart attacks for individuals diagnosed with heart disease. In order to minimize the possibility of adverse heart events during walking, you will be instructed on general precautions to observe while walking on days you do not participate in the CRP. You will be instructed to increase your exercise frequency (e.g., days/week) and duration (e.g., time) gradually.

VOLUNTARY PARTICIPATION:

Participation in this study is voluntary. No compensation for participation will be given. You are free to withdraw your consent to participate in this study at any time without prejudice to your subsequent care. Refusing to participate will involve no penalty or loss of benefits. You are free to seek care from a physician of your choice at any time. If you do not take part in or withdraw from the study, you will continue to receive care.

BENEFITS:

If you agree to take part in this study, there may or may not be direct benefit to you. In general, the benefits of participating in a regular walking program include: lowering your blood pressure, blood sugar as well as better weight management. Further, regular exercise decreases the risk of future of cardiac events, surgeries and additional heart attacks.

ALTERNATIVES:

You may elect not to participate in this study or pursue a regular walking program.

COMPENSATION:

No compensation is available for participating in this study. Also, **no compensation** is available for a physical or psychological injury which might occur as a result of this study. While medical care will be available should an injury occur **you will be billed for the costs** of providing this care.

CONFIDENTIALITY:

Your hospital records, doctors' office records, laboratory, operating room and cardiac rehabilitation records may be reviewed and audited by representatives of the Mercy Health partners and the University of Tennessee. The results of this study may be reported in publication or presentations although your identity will not be disclosed.

PERSONAL HEALTH INFORMATION:

Your medical records will be kept as confidential as possible within the limitations of state and federal law. Federal Privacy Regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the principal investigator, the cardiac rehabilitation staff or the Mercy Health partners. In order to analyze the data collected during this research study, all of the health information generated or collected about you during this study may be inspected by the Office of Human Research Protection (OHRP), the Department of Health and Human Services (DHHS) agencies, the Institutional Review Board of Mercy Health partners or the University of Tennessee. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. Once your personal health information is released it may be re-disclosed, at which point your health information will no longer be protected by federal privacy regulations. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations. By signing this informed consent form, you are authorizing such access to your medical records. This authorization will have no expiration. You can discontinue this authorization in writing to Michael F. Shipe. If you discontinue your authorization, you will also discontinue your participation in this study.

CONTACT PERSON:

If you have any questions about your rights as a participant in this study, about the study itself or if you have any problems or complaints or study related injuries, you may call Mrs. Candy Robertson, the Mercy Health partners Institutional Review Board Coordinator at (865) 549-4150 or Brenda Lawson, Compliance Officer, at the University of Tennessee Office of Research at (865) 974-3466.

PATIENT CONSENT:

I agree to voluntarily participate in the study described above. This consent is given based on the verbal and written information provided to me. The principle investigator has told me that I am medically and physically qualified to participate in this study. I am free to ask questions at any time. I may seek information from any source which might help my understanding of this study. I have the option of refusing to participate or to withdraw from the study at any time without incurring any penalty or loss of benefits otherwise available to me, including medical care at this institution.

Michael F. Shipe or the Office for Human Research Protections (OHRP) may take me off the study if required to guarantee that my best interests will be served. If I encounter medical problems or complications I have been given the telephone number of the East Tennessee Heart Consultants (865) 673-9656 and my physician. If I have any questions about the study, I can contact Michael F. Shipe at 471-3302.

By consenting to participate in this study, I understand that I am responsible for carrying out instructions and that I must relate to Michael F. Shipe or other study personnel any information that might be relative to the study, such as any side effects of a treatment or procedure. Any reluctance I might have to continue in the study must also be reported. Any new information regarding the study and any treatment it involves which might affect my willingness to continue my participation in the study will be related to me in an appropriate way. I will receive a signed and dated copy of this consent form.

Signature of Patient

Date

Signature of Witness

Date

Signature of Investigator

Date

Appendix C: Step count log instruction for experimental subjects

At the end of each day please record the number of total steps you have taken. The pedometer should display the number of steps you have taken for a given day. Please record your step count values for the correct day on the calendar listed below. It may be easier to ensure that you keep an accurate record of your daily steps by keeping your exercise log on your nightstand. If you do so, you will be prompted to record your steps each night before you go to bed. You may also want to designate your nightstand as the area in which you place your pedometer at the end of each evening. Therefore, you have a designated, convenient area to place it when you are not wearing it. By doing so, you will reduce the chance you will lose the pedometer. Also, the pedometer will be visibly present on your nightstand and its appearance can prompt you to wear it at the beginning of each morning. If you are having any type of difficulty with your pedometer, please contact Michael Shipe at 865-471-3302.

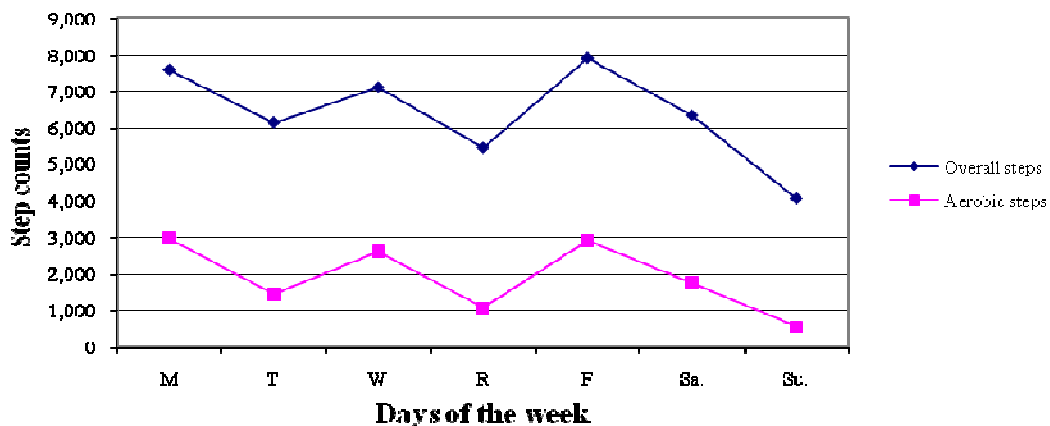
February 2008						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Appendix D: Summary report of participant's step counts

Dear Mr. or Mrs. _____ ,

Initially, I want to thank you for your willingness to participate in my dissertation research. To date, there has never been a research study which has objectively quantified the activity patterns of individuals during their enrollment in Phase II cardiac rehabilitation program (CRP). Thus, the results of my study (e.g., your exercise patterns) will likely be used to help design appropriate exercise prescriptions to improve the clinical outcomes for other cardiac rehabilitation programs. The objective of my research is to determine your activity levels, specifically the number of step counts, on the days you attend cardiac rehabilitation versus the days you do not. The results for your average overall and aerobic steps each day of the week during your 12 week enrollment is presented in the graph below. Please keep in mind that walking approximately 2,000 steps is equivalent to approximately 1 mile. Thus if you walk 5,000 steps in a day, then you would have walked 2.5 miles ($5,000/2,000 = 2.5$). Also, you will see that there is a designation for overall steps, which is the total number of steps you completed in a given day and also a designation for aerobic steps. Aerobic steps are only accumulated when you walk for at least 10 minutes without stopping. Thus, if you walked for 8 minutes consecutively and then stopped for more than a minute then you would have only accumulated overall steps.

Average daily step counts

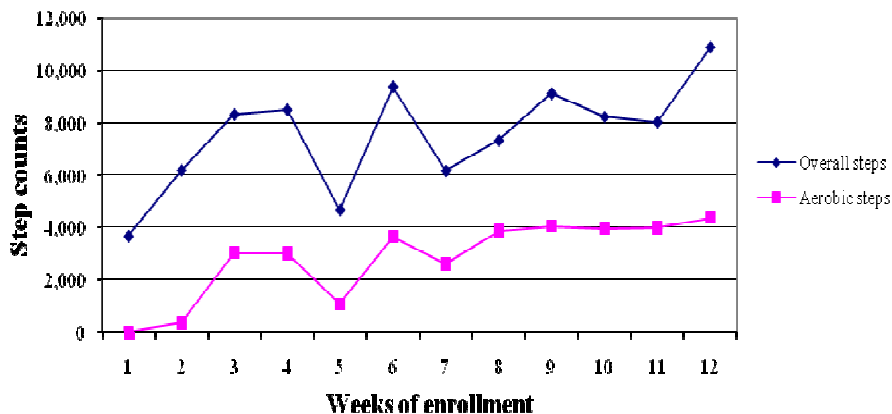


As indicated by the graph, you achieved the highest number of overall and aerobic steps on the days you attended the Mercy CRP (e.g., M, W, F) and averaged approximately 7,500 steps on those days. Friday was the highest day for overall steps, which is not surprising given that is the day you reported that you perform the majority of your yardwork. On Mondays, Wednesdays and Fridays you accumulated the most aerobic steps, approximately 3,000, which is attributable to your regular participation in the Mercy phase II CRP on those days. It is important to note that pedometers are designed to accurately measure the steps you take each day and do not accurately measure the activity you performed using the cycle or seated stepper ergometers (e.g., bicycle or NuStep®). Thus, you could possibly add another 1,000-1,500 steps to your overall and aerobic steps on the days you attended the Mercy phase CRP to account for this shortcoming.

A common pattern in the general population is reflected in your activity patterns on the weekend. Note that although your activity patterns on Saturday are similar to your results during the week, Sunday is a different story. Prior physical activity monitoring research indicates that individuals are markedly less active on Sunday versus any other day of the week and you were as well. Yet if you simply designate and take the time to walk for 10 to 15 minutes each Sunday, you could easily elevate your step counts on this day by 1,000-1,500 steps.

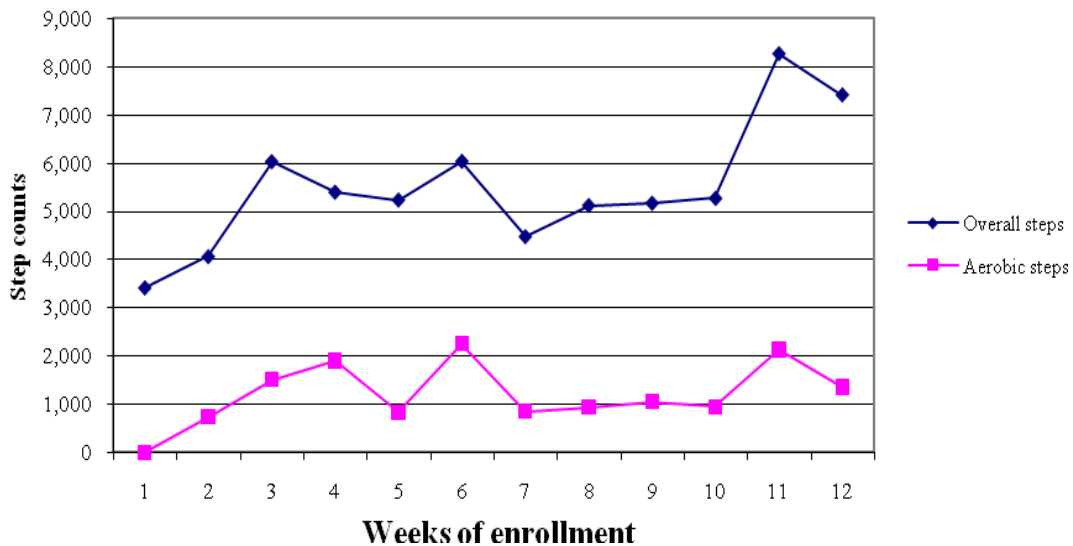
The next graph depicts your average overall and aerobic step counts on the days you attended the Mercy phase II CRP (e.g., M, W and F) during each of your 12 weeks in the program. As before, your steps are divided between overall and aerobic steps.

Average step counts on CRP days



As you can see, you began with averaging 4,000 steps per day on MWF during your first week in the CR program and progressed to averaging over 10,000 steps per day on MWF 12 weeks later! In essence, your physical activity levels improved by approximately 250%; certainly a commendable accomplishment. You may note that there was a significant drop at week 5 which is attributable to the eye surgery you had that week. As you are aware, it is relatively easy to accumulate high step counts when your exercise in a structured environment where you are expected to exercise 45-50 minutes three times a week. Yet what happens when you choose to exercise on your own, with only a pedometer and exercise log to hold you accountable? The last graph answers this question as it demonstrates your average overall and aerobic step counts on the days (T, R, Sa. and Su.) you did not attend the Mercy phase II CRP.

Average step counts on non-CRP days



You began the CRP by averaging 3,400 steps on your non-CRP days per week and improved to 8,000 steps; a 135% improvement! Again, a qualified success in enhancing your physical activity levels. And just think if you are consistently able to improve your steps count on Sundays you would average almost 9,000 steps/day. So, what does all of this mean? First of all, it is important keep in mind that the benefits of exercise mirror the effects of medicine. The more consistent, the greater and the longer you perform regular aerobic exercise, the greater the effect.

Regular aerobic exercise provides a multitude of health benefits that will enhance your ability to manage your coronary heart disease (CHD) effectively. Specifically, regular aerobic exercise is associated with a stronger and more efficient heart, lower blood pressure, an improved lipid profile, better weight management and provides a powerful manner in which to reduce your blood sugar levels.

Your greatest concern may be how to positively effect the blockages you have in your coronary arteries and how much exercise is required to do so. At this time, research indicates that individuals who have established CHD demonstrate increased coronary artery blockages when they expend the energy equivalent of walking on average 5,000 steps/days. In essence, individuals walking this amount experienced more blockages in their coronary arteries. Individuals with established CHD, who expended the energy equivalent of walking on average 6,500 steps/day often demonstrated no change in their coronary artery blockages; they didn't get any better nor did they get any worse. Finally, individuals who expended the energy equivalent of walking on average 8,500 steps/day were likely to exhibit a reduction in the blockages of their coronary arteries. In other words, they were able to minimally reverse the amount of CHD they exhibited! The take home message is that if you want to increase the chances of positively affecting your CHD you will need to accumulate 8,500 steps/day or walk approximately 4.25 miles each day.

The good news is that you were averaging approximately 6,800 steps/day when you completed the Mercy phase II CRP as opposed to 3,200 steps/day when you started. At this level, the research indicates that you may be expending an adequate amount of energy through physical activity to keep your CHD from progressing. The better news is that if you can add a 15-20 minute walk 5 days a week to your present activity patterns then you may enjoy a reduction in the blockages you already have. Please keep in mind that these outcomes are not guaranteed and are based on the fact that you will also pursue a heart healthy dietary regimen as well.

So, where do you go from here? Previous research indicates that the majority of people who complete a CR program and do not join an exercise facility are highly likely to revert back to their previous sedentary habits, which would lead to a progression of the CHD process. If you do

not want to regularly participate in a structured exercise program, then here are some tips to exercising on your own.

1. Develop a positive outlook regarding physical activity. If you consider exercise a chore, drudgery or pain you simply will not continue to do it. A basic principle of psychology is that you repeat behaviors you enjoy. Think of exercise as a means to improve your heart, combat heart disease or to enhance your ability to play with your grandchildren. Think of these things each time you consider skipping an exercise session or quitting exercise altogether. Ultimately you must come to the conclusion that regular exercise is a fundamental part of a healthy existence and without it you will likely have to rely upon medications and surgical procedures to maintain a lower quality of life.
2. Exercise must become a priority in your daily life. Designate a day, time, place and amount of exercise you will perform on the days you plan to be physically active. Treat your physical activity plan as if it is a crucial business meeting you could not afford to miss. If exercise is something you plan to do at the end of the day when you are done with everything else, then guess what? You will never get done with everything else.
3. Set a SMART goal for your physical activity program. A specific, manageable, attainable, realistic, time based goal can assist you in attaining your exercise goals. For instance, your goal is to progress in your exercise capacity until you can walk 3 miles in your neighborhood in 50 minutes five times a week at 7 a.m. in the morning.
4. Social support is a must to keep you exercising. Involving a spouse in your exercise program has been shown to increase long-term exercise compliance by 50% percent. If not your spouse, then ask a friend or another relative to accompany you on your walks so that they become social and more enjoyable. And remember when you enjoy a given activity you are more likely to repeat it.
5. Don't become discouraged if you are unable to reach your exercise goals as quickly as you would have liked. Unforeseen obstacles will arise and you will undoubtedly experience days, if not weeks, when you do not exercise. During these times, it is important to reflect upon why you haven't exercised regularly. Look at the four tips above and make sure you implement each one to increase the chances you will exercise more consistently in the future.

Again Mr. or Mrs. _____, I want to thank you for the time and effort you have contributed to the completion of my dissertation. If you have any questions about this report or I can be of service concerning any questions you may have about your exercise regimen, please contact me at 865- 471-3302.

VITA

Michael F. Shipe was born and raised in Knoxville, Tennessee. He attended the University of Tennessee, where he received his Bachelor of Science degree in Business Administration. Michael then entered the graduate program in Exercise Science at the University of Tennessee where he served as a graduate assistant. He received his Master of Science degree in 1996. Next, he worked as an exercise physiologist in the outpatient physical therapy program at the University of Tennessee Medical Center and became an ACSM registered clinical exercise physiologist. In 1997, he began work as the Fitness Director of the Blount Memorial Hospital Wellness Center. Next, he became the Assistant Director of Cardiopulmonary Rehabilitation at Blount Memorial Hospital in 2001. During this year, he also began his doctoral studies at the University of Tennessee. In 2005, he accepted a position as an assistant professor of Carson Newman College in Jefferson City, Tennessee, where he currently teaches.