# HEART-TO-HEART: AN EXERCISE INTERVENTION FOR RURAL WOMEN

By

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#### ABSTRACT

Heart-to-Heart: An Exercise Intervention for Rural Women Walking can reduce the incidence of heart disease in women. There is a paucity of research aimed at increasing exercise in rural women, a high-risk group for heart disease. This pilot study tested Heart-to-Heart (HTH), a multifaceted 12-week-walking program, designed to increase exercise in rural women. Forty-six rural women were randomized to either the HTH program or a control group, which involved brief individual exercise counseling. The primary outcome of cardiorespiratory fitness and the secondary outcomes of self-efficacy and social support were measured pre and posttest. Group differences were analyzed with repeated measures analysis of variance. Women in the HTH group had a greater improvement in cardiorespiratory fitness, (F(1,39) 3.852, p=.057) and experienced a greater increase in social support from friends, (F(1,40)=9.141,p=.004) compared to women in the control group. Women in both groups experienced an increase in social support from family, (F(1,40)=9.304, p=.004); however, they did not experience an increase in self-efficacy for sticking to it, (F (1,40)= .056, p= .814) and self-efficacy for making time for exercise, (F(1,40)= 1.166, p=.287).

HTH appears to be effective in improving cardiorespiratory fitness in a population of rural women; however, further testing is needed.

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## CHAPTER ONE

## INTRODUCTION

#### Introduction

Women's participation in regular exercise is a major factor in preventing heart disease, the leading cause of death in women in the U.S. (Fletcher et al., 1996; Pate et al., 1995; United States Department of Health and Human Services, 1996; 2000, (USDHHS)). Women have higher rates of morbidity and mortality from, and a higher incidence of risk factors for, heart disease than men (American Heart Association, 2005, (AHA)). Physical inactivity is a significant independent risk factor for coronary artery disease (CAD) (AHA, 2005; Fletcher et al., 1996) and contributes to an estimated 30% of coronary events in middle-aged women in the US (Manson et al., 1999). Less than 15% of women reach the recommended level of exercise (USDHHS, 1996; 2000) and the percentage is even lower for rural women (USDHHS, 1996; 2000) in the U.S.

Several published reports indicate that the key determinants of exercise in women include self-efficacy (JF Sallis, Hovell, & Hofstetter, 1992), stage of change (Sherwood & Jeffery, 2000), social support (Neis, Vollman, & Cook, 1998; JF Sallis et al., 1992; Sherwood & Jeffery, 2000), and time for activity (Neis et al., 1998), as well as social interaction during (Sherwood & Jeffery, 2000) and enjoyment (Neis et al., 1998) of the exercise. Rural women, White and Latina, report additional barriers to exercise beyond those experienced by white urban and suburban women, such as a lack of role models (Evenson, Sarmiento, Macon, Tawney, & Amerman, 2002; Wilcox, Castro, King, Housmann, & Brownson, 2000). Thus increasing exercise participation in rural women, both Latina and white, is

particularly challenging, yet holds significant potential to reduce the incidence of CAD in this group.

Heart-to-Heart (HTH) is an innovative, 12-week, multifaceted exercise intervention designed by the investigator to address the determinants of exercise and to increase exercise in rural women at risk of developing CAD. The overall objective of this study is to pilot test HTH in a sample of rural women to determine its feasibility and potential to increase exercise participation. The investigator will incorporate knowledge gained from this pilot study in future studies aimed at exercise promotion and prevention of CAD risk factors in rural women.

### Specific Aims

The specific aims of this study are to:

#### Aim1

Determine the magnitude of change in exercise adherence, cardiorespiratory fitness, and physical activity for rural women engaged in HTH and rural women in the control group and whether this magnitude differs significantly for rural women in HTH and rural women in the control group.

#### Hypothesis

Rural women in HTH will have a greater magnitude of change in exercise adherence, cardiorespiratory fitness, and physical activity than rural women in the control group.

#### Aim 2

Examine the magnitude of the change in self-efficacy and social support for rural women in HTH and rural women in the control group and whether the magnitude of

change differs significantly for rural women in HTH and rural women in the control group.

Hypothesis

Rural women in HTH will have a greater magnitude of change in self-efficacy, and social support than rural women in the control.

#### Aim 3

Examine whether self-efficacy and social support are mediators between HTH and the outcome variables of exercise adherence, cardiorespiratory fitness, and physical activity.

Hypothesis

Self-efficacy and social support mediate the relationship between HTH and the outcome variables of exercise adherence, cardiorespiratory fitness and physical activity.

#### Aim 4

Describe HTH participants' experiences with the intervention to aid in refinement of HTH.

## CHAPTER TWO

## REVIEW OF THE LITERATURE

AND

THEORETICAL FRAMEWORK

Exercise programs tailored to rural women can play a significant role in reducing the incidence of risk factors of heart disease in this population. Physical inactivity is a significant risk factor for heart disease. Physical inactivity was first identified in 1992 by the American Heart Association as a significant independent risk factor for heart disease (Fletcher et al., 2001). The relative risk for CAD due to physical inactivity is similar to the increased risk for CAD associated with high cholesterol, smoking, and hypertension (AHA, 2005). Endurance exercise decreases the risk of heart disease because endurance exercise directly inhibits the physiological mechanisms that can lead to atherosclerosis and reduces risk factors associated with CAD including, obesity, insulin resistance, dyslipemia, and hypertension (Brooks, Fahey, White, & Baldwin, 2000; Fletcher et al., 2001; Shepard & Balady, 1999; Thompson et al., 2003). Exercise interventions that successfully increase exercise participation in women are critical to reducing the risk of CAD in women in the U.S.

Intervention strategies grounded in the social cognitive theory and the transtheoretical model can enhance women's adherence to an exercise program (Dishman & Buckworth, 1996; Kahn et al., 2002; Marcus & Forsyth, 1999) by addressing the key determinants of exercise for women in the U.S. These two behavior change theories explain factors that influence exercise behavior and the process of behavior change. They can guide the development of strategies that encourage a change in exercise behavior in women. Factors that influence a woman's exercise behavior can be categorized into environmental, social, and intrapersonal factors. These factors are expressed differently for different populations of women (Bandura, 1997; National Institutes of Health Consensus Panel of Physical Activity and Cardiovascular Health, 1996; Pate et al., 1995;

USDHHS, 1996). Heart-to-Heart, developed by the investigator, is grounded in an integration of the social cognitive theory and the transtheoretical model that addresses the key factors that influence exercise in rural Latina and white women. It is designed to engage rural women in exercise and promote adherence to regular exercise.

#### Heart Disease in Women

In the last ten years the mortality trend for women with cardiovascular disease has risen, remained flat, and is now declining slightly, whereas, for men it has been sharply declining (AHA, 2005). In 1998 heart disease accounted for 43% of all deaths in women and was twice that of deaths from all types of cancer in women combined (AHA, 2005). One out of every two women will die of cardiovascular disease in the United States (AHA, 2005). The majority of cardiovascular deaths in women are due to coronary artery disease (CAD) and more specifically, from a myocardial infarction (MI) (AHA, 2005). Women have significantly higher rates of complications and mortality from a MI than men, even after adjustment for confounding factors such as age, coexisting illness, and treatment (Chandra et al., 1998; Weaver et al., 1996). The prognosis for women after an MI is worse than men, with 38% dying within one year after experiencing an initial recognized MI and 35% having a second event within six years; in contrast only 25% of men die within one year and 18% have a second event within six years (AHA, 2005). Thus, reducing the risk for CAD results in a reduced risk for an MI and the mortality from an MI.

Several reasons account for the higher rates of morbidity and mortality in women with CAD. Compared to men, women are not evaluated and treated as aggressively (Canto et al., 2002; Chandra et al., 1998; Schulman et al., 1999; Weaver et al., 1996).

Although the majority of men and women experience chest pain with an MI, women are more likely to experience additional non-specific symptoms, such as nausea, that may confuse the diagnostic picture (Devon & Zerwic, 2002). These non-specific symptoms can lead to an acute MI going unrecognized by women and health care providers, thereby delaying treatment. Compared to men, women are less physically active (AHA< 2005; USDHHS, 1996; 2000), have a higher incidence of obesity and being overweight, and after age 55 a higher incidence of hypertension and elevated total cholesterol (AHA, 2005) than men. In addition, Latinas have a higher incidence of obesity, hypertension, diabetes, and physical inactivity (Winkleby, Kraemer, Ahn, & Varady, 1998) and a higher prevalence of CAD than white women (AHA, 2005). Thus, women experience higher rates of morbidity and mortality from and increased incidence of risk factors for CAD compared to men.

#### Rural Women and Heart Disease

Rural women have an increased incidence of risk factors for CAD than urban women (National Center for Health Statistics, 2001). Rural communities are defined as communities that are at least 10 miles from a population center of 30,000 or more (Oregon Health & Science University Oregon Office of Rural Health, 2002). Rural residents are less likely to receive preventive health services (Casey, Call, & Klingner, 2001; Kaiser Commission, 2001) and regular check-ups (Kaiser Commission, 2001) despite having higher rates of chronic conditions (Kaiser Commission, 2001), increasing the severity of chronic disease, such as CAD (National Center for Health Statistics, 2001). Rural dwellers have less education (US Department of Agriculture, 2001a) and a higher rate of poverty (US Department of Agriculture, 2001b) than urban dwellers. Rural

women earn 31% less than rural men (Rogers, 1997). Education level and socioeconomic status (SES) are inversely associated with mortality from CAD and this association is stronger for women (R. Cooper et al., 2000; Lantz et al., 1998). This association is partly explained by a higher incidence of smoking, obesity, and physical inactivity in individuals of low SES (R. Cooper et al., 2000; Lantz et al., 1998). Rural women have the highest incidence of obesity (National Center for Health Statistics, 2001) and are the least physically active (USDHHS, 1996). Therefore, rural women, particularly of low SES, have higher rates of mortality from CAD. Individuals of lower SES are more likely to lack social support which is predictive of morbidity and mortality (Lantz et al., 1998). Women with low social interaction and social support are more likely to have severe CAD (Orth-Gomer et al., 1998). Therefore, rural women, who have low SES, are likely to have low social support and a higher risk of CAD. Thus, rural women are at higher risk for CAD in part due to lower SES and diminished individual and community resources. Therefore, this study is aimed at rural women.

#### Physical Activity and Heart Disease

Endurance Exercise Effects on Atherosclerosis and CAD Risk Factors

Current evidence indicates that endurance exercise inhibits atherosclerosis. One mechanism is through the improvement of endothelial function. (Bowles, Woodman, & Laughlin, 2000; Hambrecht et al., 2003; Hambrecht et al., 2000; Shepard & Balady, 1999; Smith, 2001). Exercise increases blood flow causing a corresponding increase in the frictional force exerted by blood flow on the vessel wall, called shear stress. An increase shear stress stimulates the production of nitric oxide by the endothelium which leads to vasodilation, inhibition of superoxide anion production, and reduced

permeability of the endothelium (Hambrecht et al., 2003; Hambrecht et al., 2000; Malek, Alper, & Azumo, 1999; Ross, 1999; Smith, 2001). In male and female animal models, endurance exercise limits vasoconstriction regulated by endothelin (Bowles et al., 2000). Further research is necessary to determine if endurance exercise produces this response in humans. Arthrosclerotic vessels tend to have a lower shear stress than normal vessles (Smith, 2001). Exercise appears to counter the impairment of nitric oxide production in the endothelium. Thus, those individuals with arthrosclerosis may benefit the most from an increase in shear stress and the subsequent increase in nitric oxide production

In addition, exercise appears to reduce the production of inflammatory mediators thereby, dampening the inflammatory response (Bowles et al., 2000; Hambrecht et al., 2003; Hambrecht et al., 2000; Shepard & Balady, 1999; Smith, 2001). The exercise induced increased shear stress stimulates endothelial phenotypes that protect vessels from atherosclerosis, which are called atheroprotective (Hambrecht et al., 2003; Hambrecht et al., 2000; Malek et al., 1999; Smith, Dykes, Douglas, Kirshnaswamy, & Berk, 1999; Vita & Keane, 2000). Long-term (greater than 6 months) endurance exercise stimulates the production of t-cell phenotypes that are atheroprotective and decreases the production of phenotypes that are atherogenic and promote inflammatory response (Smith, 2001; Smith et al., 1999). Subsequently, theses changes in T-cell and endothelial phenotypes lead to decreased production of cytokines that promote inflammatory response and increased production of cytokines that lessen the inflammatory response (Smith, 2001) Finally, these changes trigger a reduction in the immune and inflammatory responses associated with CAD, such as the proliferation and migration of smooth muscle into the intima. oxidation of LDL cholesterol, production of super oxide anions. These exercise-induced

alterations in the inflammatory process are consistent with the lower levels of C-reactive protein, a marker of inflammation and cardiovascular disease, measured in women who exercise regularly (LaMonte et al., 2002)

Endurance exercise appears to play a role in exerting antithrombotic effects (Bowles et al., 2000; Hambrecht et al., 2003; Hambrecht et al., 2000; Shepard & Balady, 1999; Smith, 2001). It has been found to reduce fibrinogen and favorably affect plasminogen factors (Fletcher et al., 2001). In addition, long term exercise may reduce platelet activity (Fletcher et al., 2001). Reducing platelet activity reduces atherosclerosis because platelet activation contributes to the migration and proliferation of smooth muscle and monocytes to the site of endothelial injury and the formation of the vasoconstricting substance, thromboxane (Ross, 1999).

Endurance Exercise Effects on Obesity

Obesity increases the risk for and mortality from CAD. Obesity is defined as a body mass index grater than 30. Obesity is becoming more prevalent among American women. In 2001, thirty percent of white American women, twenty three percent of Hispanic American women (forty percent among Mexican American women) and fifty percent of African American women were obese (AHA, 2005). Women tend to gain weight with advancing age thereby increasing their risk of CAD (Sternfeld et al., 2004). Abdominal and visceral fat are correlated with insulin resistance and dyslipidemia (Rendell, Hulthen, Tornquist, Groop, & Mattiasson, 2001; Ross, Freeman, & Janssen, 2000; A. Ryan, 2001) and abdominal fat is predictive of insulin resistance and triglyceride levels (Rendell et al., 2001). Obese women have a significantly increased

relative risk of death from heart disease compared to non-obese women (Hu et al., 2004). Exercise reduces obesity, which in turn impacts insulin resistance and dyslipidemia.

Obesity is lessened by endurance exercise. Endurance exercise alone without dietary changes can result in weight loss and specifically a reduction in abdominal fat (A. L. Dunn et al., 1997; Ross et al., 2000; Shepard & Balady, 1999; Sternfeld et al., 2004; Stewart et al., 2005). Endurance exercise spares lean body mass and increases resting metabolic rate, which enhances caloric expenditure (Brooks et al., 2000). Thus, exercise can reduce weight and the impact of obesity on CAD risk.

Endurance Exercise Effects on Insulin Resistance

Diabetes is a significant risk factor for CAD with 2/3 of diabetics dying from cardiovascular disease (AHA, 2005). Women with type 2 diabetes have a higher rate of mortality from CAD than men (Mosca et al., 1997). From 1994 to 2002 the prevalence of diabetes in the US increased by 54% (AHA, 2005). And, from 2000 to 2001 the prevalence rose by 8.2% (AHA, 2005). Insulin resistance typically progresses to diabetes in the absence of an intervention. Endurance exercise has been shown to be an effective intervention that improves insulin sensitivity in both diabetic and non-diabetic women.

The exercise-induced improvement in insulin sensitivity in non-diabetic women can delay or prevent the onset of diabetes (Brooks et al., 2000; A. Ryan, 2001; Shepard & Balady, 1999; Thompson et al., 2003). The intensity of exercise needed to achieve this effect is controversial. In two randomized control trials, moderate intensity endurance exercise performed for 30-60 minutes 3-5 days a week improved insulin sensitivity in non-diabetic women (Mensink, Feskens, Saris, Bruin, & Blaak, 2003; Tonnino, 1989). However, another randomized trial found that only individuals who performed vigorous

intensity exercise for 20 minutes 5 days a week along with making dietary changes showed significant improvement in insulin sensitivity (K. McAuley et al., 2002). Two cross sectional studies found a significant positive association between vigorous exercise performed 5 days per week and improved insulin sensitivity whereas individuals who performed moderate intensity exercise for 30 minutes 5 days a week followed the same trend but this trend did not reach statistical significance (Brown et al., 2000; Mayer-Davis et al., 1998). The Diabetes Prevention Program randomly assigned 3,234 participants with impaired glucose metabolism or insulin resistance to a control group or one of two interventions, a medication or behavioral modification. One intervention group received metformin (an oral medication for the treatment of type 2 diabetes) and the other intervention group followed a low-calorie and low-fat diet and a moderate intensity exercise program for 150 minutes a week. The trial was stopped early because of the significant differences between the treatment groups and the control group. After 2.8 years the incidence of the onset of diabetes was reduced by 58% in the diet and exercise group compared to the control group, providing compelling evidence for the role of exercise in improving insulin sensitivity and glucose metabolism (Diabetes Prevention Research Group, 2002). Moreover, exercise has been found to exert an independent effect on improving insulin sensitivity regardless of weight loss or dietary changes (Harding, Williams, Hennings, Mitchell, & Wareham, 2001; Kriska et al., 2001). Based on these studies, with the greatest credence given to the Diabetes Prevention Trial because of the large sample size, it can be concluded that moderate-intensity exercise performed 5 days a week can improve insulin sensitivity and that vigorous exercise or the addition to

exercise of a low-fat, low-calorie diet provides even greater improvements in insulin sensitivity.

Several mechanisms may contribute to the ability of exercise to improve insulin sensitivity. One mechanism is that endurance exercise increases GLUT-4 levels in muscles, the protein responsible for transporting glucose across muscle cell membranes, increasing transport of glucose into muscle cells (Brooks et al., 2000; A. Ryan, 2001). It has been determined that even a single bout of exercise promotes an increase in glucose movement into cells through insulin independent transporters, such as GLUT-4 (Brown et al., 2000). Exercise improves cellular level metabolism and oxidation, which leads to improved insulin sensitivity (Menshikova et al., 2004) Finally, exercise increases the enzymes that stimulate glucose metabolism and it suppresses hepatic glucose production (Brooks et al., 2000; A. Ryan, 2001) Thus, these mechanisms provide an explanation as to how exercise improves insulin sensitivity.

Endurance Exercise Effects on Dyslipidemia

Dyslipidemia is a risk factor for CAD. It is estimated that a 10% reduction in total cholesterol may reduce the incidence of CAD by 30% (AHA, 2005). Women over age 50 have a higher incidence of elevated total cholesterol than men (AHA, 2005). Endurance exercise improves lipid profiles.

Many trials have examined the frequency and intensity of exercise on lipid profiles. The evidence from these trials, although mixed, indicates that moderate intensity exercise, such as walking, performed at least 3 days a week for at least 30 minutes can reduce triglycerides, HDL cholesterol, and increase HDL cholesterol in women (Gill, Herd, Vora, & Hardman, 2003; Keller & Trevino, 2000; King, Haskell, Yound, Oka, &

Stefanick, 1995; Kraus et al., 2002; Park, Park, Kwon, Yoon, & Kim, 2003). Two studies found that moderate-intensity exercise improved lipid levels (Keller & Trevino, 2000; King et al., 1995). Furthermore, these studies found that moderate-intensity exercise performed with greater frequency may provide a greater improvement on lipid levels than moderate intensity exercise performed less often. However, in these studies many women did not adhere to an exercise program that prescribed exercise 5 times per week and therefore did not achieve maximum improvement in lipid profiles (Keller & Trevino, 2000; King et al., 1995). One study found that vigorous exercise performed 3 times a week showed greater improvements in lipids than the moderate intensity exercise (Kraus et al., 2002). The Stanford Five City Project, a large community-wide health promotion campaign, found that increases in moderate intensity activity during a five-year study period in post menopausal women increased HDL levels (D. Young, Haskell, Jatulis, & Fortmann, 1993). Two recent systematic reviews examining the effects of exercise on lipids concluded that moderate exercise can increase HDL cholesterol and decrease LDL cholesterol and triglycerides. However, both these reviews concluded there is not sufficient evidence to indicate that endurance exercise affects total cholesterol levels (Durstine et al., 2001; Leon & Sanchez, 2001). The evidence from these studies and reviews indicates that moderate intensity exercise performed at least 3 times a week can improve lipid profiles. Vigorous intensity exercise if performed 3 times a week provides additional improvements in lipid profiles.

The mechanism for exercise-induced changes in lipids is not well understood; it is hypothesized that exercise affects the enzymes involved in lipid metabolism. Improved lipid profiles may be due to an exercise-induced increase in lipoprotein lipase activity in

adipose tissue (Gill et al., 2003; Park et al., 2003; Tall, 2002). Lipoprotein lipase lowers VLDL and triglyceride levels (Brooks et al., 2000; Tall, 2002). A decrease of hepatic lipase activity due to exercise may play a role in increasing HDL levels and decreasing triglyceride levels (Tall, 2002) because hepatic lipase breaks down HDL lipids and triglycerides (Brooks et al., 2000; Tall, 2002). Although evidence indicates endurance exercise impacts lipids, further investigation to explain the exact mechanism is needed. *Endurance Exercise Effects on Hypertension* 

One in five Americans has hypertension and women after age 55 have a higher incidence of hypertension than men (AHA, 2005). Hypertension is a risk factor for CAD. Endurance exercise reduces diastolic and systolic blood pressure and this reduction is greater in individuals with hypertension (Fagard, 2001; Hagberg, Park, & Brown, 2000; Pescatello & Kulikowich, 2001; Seamus, Chin, Xin, & He, 2002).

At least four quantitative reviews have examined the long-term effect of regular endurance exercise on blood pressure reduction. Endurance exercise lowered blood pressure, on average 3-4 mmHg systolic and 2-3 mmHg diastolic for normotensive individuals (Fagard, 2001) and 7-10 mmHg systolic and 6-8 mmHg diastolic for individuals with hypertension (Fagard, 2001; Hagberg et al., 2000). Women with hypertension had a greater reduction in systolic and diastolic blood pressure compared to men with hypertension (Hagberg et al., 2000). Another review corroborated the findings that those with higher initial blood pressure, particularly in those with hypertension, had a greater reduction in blood pressure than those with a lower initial blood pressure. (Pescatello & Kulikowich, 2001). One review article discussed the concern that many studies were underpowered and the underpowered studies resulted in minimizing the

effects of exercise on blood pressure in the individual studies (Pescatello & Kulikowich, 2001). Evidence presented in another review indicated that endurance exercise reduces blood pressure with an overall pooled net reduction of 3.84 to 4.39 in systolic pressure and 2.58 to 3.05 in diastolic pressure. This reduction diminished in studies with longer follow-up after the exercise intervention ended, which the authors attributed to a lack of adherence to the exercise program once the intervention ended (Seamus et al., 2002). Thus, long-term and regular endurance exercise reduces blood pressure and these reductions were greater in those individuals with a higher initial blood pressure.

Several mechanisms contribute to the exercise-induced reduction in blood pressure. A central mechanism is the lessening of sympathetic nervous system activity, which decreases resting heart rate and dampens the heart rate response during endurance exercise in endurance trained individuals (Lesniak & Dubbert, 2001). Endurance exercise increases the vascularization to skeletal muscles and this results in decreased peripheral resistance and decreased afterload (Brooks et al., 2000; Lesniak & Dubbert, 2001). Exercise induced increased shear stress appears to decrease peripheral vascular resistance and improve arterial compliance (Lesniak & Dubbert, 2001). The exercise-induced increased shear stress also reduces free radicals and increases anti-oxidants thereby, increasing nitric oxide production, which in turn results in vasodilation and reduced arterial pressure (Lesniak & Dubbert, 2001). Thus, endurance exercise reduces blood pressure by several mechanisms.

The Dose-Response Relationship of Cardiorespiratory Fitness and Reduction in CAD Mortality and CAD Risk Factors in Women

Evidence from prospective, cohort studies supports a curvilinear relationship between cardiorespiratory fitness, physical activity levels and mortality from CAD. A

prospective study examined the relationship between levels of physical fitness and CAD mortality (Blair et al., 1989). Women who were more fit had a reduced incidence of CAD mortality compared to those who were the least fit. In addition, higher levels of fitness were associated with only small additional reduction in CAD mortality beyond those with moderately high levels of fitness. An observational cohort study of 7,080 women found that low cardiorespiratory fitness was a predictor of CAD mortality in women (Blair et al., 1996). The relative risk of CAD mortality from low cardiorespiratory fitness was 2.79, which was higher than that for cigarette smoking with a relative risk of 1.73, or elevated cholesterol with a relative risk of 0.99. Another prospective cohort study with 41, 836 women determined the relationship between CAD mortality and physical activity was graded (Kushi et al., 1997). No physical activity performed was the reference and moderate level activity that was performed greater than 4 times per week resulted in a relative risk of .53 and vigorous activity that was performed more greater than 4 times a week resulted in a relative risk .20. Thus, based on prospective data, increasing levels of cardiorespiratory fitness are associated with progressive reductions in the risk of CAD mortality with the highest levels of cardiorespiratory fitness adding only small additional reductions in the risk of CAD mortality, generating a curvilinear relationship.

A cross sectional examination of data within the Aerobics Center Longitudinal Study was undertaken to determine the physical activity patterns associated with cardiorespiratory fitness and risk of CAD mortality (Stofan, DiPietro, Davis, Kohl, & Blair, 1998). Participants reported physical activity levels on a self-report questionnaire and underwent treadmill exercise testing. The lowest fit based on exercise testing had the highest level of CAD mortality compared to those with moderate or high levels of fitness

based on exercise testing. Moderate levels of physical activity such as a brisk walk for 30 minutes performed on 5 days per week resulted in a level of cardiorespiratory fitness that has been associated with reduction in CAD mortality (Stofan et al., 1998). The estimated amount of exercise needed to achieve a reduction in CAD risk factors and mortality was 1.5 to 3 hours of moderate intensity exercise per week (Stofan et al., 1998). Therefore, a woman does not to be highly fit to achieve health benefits from exercise such as a reduction in CAD.

Increased physical activity or increased cardiorespiratory fitness has been found to improve CAD risk factors. A cross sectional study that included 1128 women found that cardiorespiratory fitness was inversely related to CAD risk factors (LaMonte et al., 2000). A randomized controlled trial of 119 women found that women who participated in moderate intensity exercise for 30 minutes most days of the week increased their cardiorespiratory fitness and improved their CAD risk factor profiles (A. L. Dunn et al., 1997). Thus, increased cardiorespiratory fitness, gained by performing moderate intensity exercise for 30 minutes on most days of the week, can improve CAD risk factor profiles in women.

## The Effects of Walking on CAD in Women

Because of the curvilinear dose-response relationship between physical activity and the health benefit of a reduction in CAD mortality, several prospective cohort studies have examined the effect of walking at various intensities, durations, and frequencies on the reduction of risk for CAD in women (Lee, Rexrode, Cook, Manson, & Buring, 2001; Manson et al., 2002; Manson et al., 1999; Sesso, Paffenbarger, HA, & Lee, 1999). A prospective cohort study of female alumni from the University of Pennsylvania found a

33% reduction in CAD for women who walk 6 miles per week (Sesso et al., 1999). The Women's Health Initiative Observational Study, that has enrolled 73,743 women, determined that walking could reduce the risk of CAD (Manson et al., 2002). Women who walked at a increasing pace and therefore increasing energy expenditure had graded reduction in relative risk of CAD mortality from a relative risk of .73 to .40, with walking at moderate intensity having the greatest reduction in relative risk (Manson et al., 2002). Data from the women's health study revealed that women who walked at least one hour per week at 3 mph had a 50% reduced risk of CAD than women who did not walk. Vigorous intensity exercise was associated with additional risk reduction beyond moderate intensity exercise (Lee et al., 2001). Based on self-report data from the Nurse's Health Study, a prospective cohort study, women who walked 1 to 2.9 hours per week at a brisk pace had a 30%-40% reduction in the risk of CAD. Women who walked at a faster pace and for more hours had an even greater reduction (Manson et al., 1999). Thus, these prospective studies indicate that walking at moderate intensity for approximately 2.5 hours per week is associated with a reduction in the risk of CAD with walking at vigorous intensity associated with an even greater reduction in the risk of CAD.

#### Exercise Recommendations

The exercise recommendations from the American College of Sport Medicine (ACSM) (Pollock et al., 1998), the American Heart Association (Pollock et al., 2000; Thompson et al., 2003) and the US Surgeon General (USDHHS, 1996) aimed at improving cardiorespiratory fitness and reducing morbidity and mortality, are based on the curvilinear dose-response relationship between exercise and health benefits, such as

the reduction of CAD mortality. Endurance exercise conducted from at least 55% to no more than 90% of maximum heart rate for a continuous or intermittent 30–60 minutes per day on three to five days a week is recommended. Bouts of at least ten minutes at the same intensity can be accumulated throughout a day to achieve 30 minutes in a day and has been shown to be equally as effective as one continuous bout of 30 minutes of exercise (USDHHS, 1996). Resistance and flexibility training have been included in exercise recommendations since 1990 but are not described here because this research project focuses on endurance exercise, which is the most widely studied exercise mode.

The Healthy People 2010 physical activity goals reflect the aforementioned recommendations. One goal is to increase from 15% to 30% the number of adults who engage regularly, preferably daily, in moderate physical activity for at least 30 minutes per day (USDHHS, 2000). Another goal is to reduce the proportion of adults who do not engage in leisure-time physical activity from 40% to 20% (USDHHS, 2000). Both of these goals would result in a greater percentage of the population performing the level of exercise that has been associated with a reduction in risk factors for and mortality from CAD.

Physical activity is one of the ten leading health indicators and one of the twenty-two focus areas in Healthy People 2010 (USDHHS, 2000). The attention of physical activity in Healthy People 2010 reflects the convincing evidence that physical activity reduces all cause mortality, specifically mortality from CAD, as well as providing other health benefits. However, 85% of adults do not participate in moderate intensity exercise for 30 minutes on most days of the week. Thus, the challenge remains as to how to

increase participation in physical activity to meet the recommended level and the Healthy 2010 goals.

#### Deconditioning

The gains in cardiorespiratory fitness from exercise are rapidly lost. Exercising less than two days a week or less than 55% maximum heart rate provides no improvement in fitness or health benefits (Pollock et al., 1998). There is a marked decline in fitness after two weeks without exercise, returning to previous fitness levels within two and a half to eight months. Four to twelve weeks without exercise can result in the loss of 50% of the training gain in cardorespiratory fitness (Pollock et al., 1998). Missing occasional days, or sessions, of exercise or decreasing the frequency or duration of exercise over no more than a 15 week period as long as intensity is maintained does not affect cardiorespiratory fitness and therefore risk reduction benefits (Pollock et al., 1998). Therefore, the development of exercise programs that promote regular exercise and prevent sustained lapses in participation are critical to reducing the incidence of risk factors for CAD in women.

### **Exercise Prescription**

An exercise prescription that will result in cardiovascular benefits must be based on the principles of exercise training. Key principles include overload, specificity, and progression. The principle of overload states that in order for an organ or tissue to benefit from exercise it must be exposed to a load that is greater than the habitual load it receives (Franklin, Whaley, & Howley, 2000). For example, if a woman takes care of her grandchildren and this involves some activity, her exercise program will need to add to her current amount of exercise. The specificity states that the effects from exercise are

specific to the type of exercise performed (Franklin et al., 2000). For example, a walking program has been found to improve fitness to a level that reduces the risk of CAD; however, walking will not increase upper body strength. The progression states that in order to receive continual benefits and improvements in fitness an individual must continually increase her level of exercise over a given period. For example, a woman may start exercising at 40% of her age predicted maximum heart rate for 10 minutes a day and gradual increase to 85% of her age predicted heart rate for 45 minutes a day. HTH will utilize these principles of an exercise prescription in order to develop individual exercise program and goals for each woman.

The stages of a lifetime exercise program include: initial, improvement, and maintenance (Franklin et al., 2000). ACSM recommends that the initial phase of a program will begin to slowly build the duration of exercise and typically lasts 4 weeks (Franklin et al., 2000). The goal at this stage is for the individual to habituate to an exercise program. In the improvement phase the intensity, frequency and duration will increase gradually, although a little more rapidly than the initial phase, until reaching the predetermined fitness or health goal (Franklin et al., 2000). The goal of the improvement stage is to provide a gradual increase in exercise volume to allow for an overload, which results in an improvement in cardiorespiratory fitness. In the maintenance phase, the exercise remains at the same intensity, duration and frequency or slightly decreased as achieved in the improvement phase with the goal of maintaining the benefits achieved from the exercise without burnout or injury (Franklin et al., 2000). HTH will follow the ACSM guidelines in order to enhance adherence to the adoption, defined as the initial 6

months, of an exercise program by developing a program that is safe, effective, and engaging.

## Physical Activity in Women

Knowledge regarding the health benefits of exercise is not a significant motivator to change exercise behavior in women. A survey of American adults conducted one year after the Surgeon General's report Physical Activity and Health indicated that women had a greater understanding of the health benefits of exercise than men, yet women reported less physical activity than men (Morrow, Jackson, Bazzarre, Milne, & Blair, 1999). Prominent determinants of exercise in women are self-efficacy (Eyler et al., 2002; JF Sallis et al., 1992), stage of change (Sherwood & Jeffery, 2000), social support (Eyler et al., 2002; Neis et al., 1998; JF Sallis et al., 1992), time (Neis et al., 1998), social interaction during (Sherwood & Jeffery, 2000) and enjoyment (Neis et al., 1998) of exercise. Key determinants in Latinas are selfefficacy (Duffy, Rossow, & Hernandez, 1996; Hovell et al., 1991; Laffrey, 2000), stage of change (Laffrey, 2000), social support (Evenson et al., 2002; Eyler et al., 2002; Hovell et al., 1991), time (Evenson et al., 2002; Eyler et al., 2002), lack of role models (Evenson et al., 2002), and family responsibilities (Evenson et al., 2002; Eyler et al., 2002). In contrast, convenience of exercise facilities or exercise equipment in the home are determinants of exercise in men (JF Sallis et al., 1992). Women have less leisure time to devote to exercise than men because of multiple roles and commitments to work, family, and community activities (Henderson, Shaw, Bialeschki, & Freysinger, 1995). Therefore, an intervention that specifically addresses the needs of women is needed.

# Physical Activity in Rural Women

Exercise determinants for rural women are similar to those for urban women (Wilcox et al., 2000), yet rural women have among the lowest level of physical activity (USDHHS, 1996). Rural women face more barriers to exercise than urban women, including caregiving responsibilities, lack of energy, lack of role models, and less social support for exercise (Wilcox et al., 2000). Rural white women reported that social support was critical to increasing exercise participation (Eyler & Vest, 2002). *Exercise Intervention Research* 

There have been at least seven systematic reviews examining exercise intervention research (Banks-Wallace & Conn, 2002; Baranowski, Anderson, & Carmack, 1998; Dishman & Buckworth, 1996; A. Dunn, Andersen, & Jakicic, 1998; Kahn et al., 2002; Krummel et al., 2001; L. Robbins et al., 2001). The interventions examined in these reviews had mixed results. The studies examined used a multiplicity of research designs, theories, mediating variables, measurement approaches, types and intensity of exercise, and targeted populations, complicating analysis across studies. Five of the seven reviews are qualitative, descriptive reviews of exercise interventions with differing foci. In one review, conducted by the Task Force on Community Preventive Services, effect sizes were calculated to determine effectiveness and to develop recommendations; however, the effect sizes are not reported in the review article (Kahn et al., 2002). The Task Force concluded that there was strong evidence to recommend social support interventions in community settings and individually adapted health behavior change programs, community-wide campaigns, and enhancing access to places for physical activity. There was one meta-analysis conducted in 1996 on 127

exercise intervention studies that found that interventions that focused on behavior modification, emphasized low to moderate intensity exercise and were administered in groups had larger effect sizes (Dishman & Buckworth, 1996). These seven reviews arrive at similar conclusions regarding the direction for future research. The overall identified gaps and recommendations from these reviews include: interventions need to be tailored to specific populations and settings, studies need to clearly delineate relationships between mediating and moderating variables derived from theoretical frameworks that act on behavior change, and the importance of using similar definitions and measures of physical activity and cardiorespiratory fitness across studies. The two reviews only looked at interventions that included women (Banks-Wallace & Conn, 2002; Krummel et al., 2001) and concluded that there is a need for additional research to understand the intervention strategies that are the most effective for, and preferred by, specific populations of women and that interventions need to be tailored to meet the specific populations of women.

There is a paucity of exercise interventions that are specifically tailored to meet the needs of women and even more scarce are interventions tailored to rural women. Three interventions that were specifically tailored to women had mixed results at the follow-up measurement point, which varied from 3-13 months. One study showed a significant change in exercise (Segar, Jayaratne, Hanlon, & Richardson, 2002), one measured exercise by stage of change and 41% were in a more active stage (Cody & Lee, 2000), and one found no significant change in exercise in both the control and intervention group (Y. D. Miller, Trost, & Brown, 2002). Integrating several behavior change theories in the development of interventions has been advocated as a way to

improve the effectiveness of exercise interventions (Baranowski et al., 1998). The study that showed the most effectiveness integrated four theories of behavior (Segar et al., 2002) whereas, in the least effective study no theoretical underpinnings were explicated (Y. D. Miller et al., 2002). These three studies suggest that a gender-tailored approach in and of itself may not be sufficient to produce an increase in exercise participation or adherence. The theoretical approach from which the gender-tailored intervention is developed appears to play a critical role. These findings suggest that interventions, which are grounded in theory, preferably an integration of theories, and tailored to women's needs has the most promising potential to increase exercise in women.

In addition to employing intervention strategies grounded in a theoretical framework and tailored to a specific population, it is recommended that intervention strategies be linked to mediating variables. The lack of a clear explication of the effect of intervention strategies on mediating variables or the effect of the mediators on the change in exercise participation can make it difficult to determine the strategies or mediating variables that brought about a change in exercise behavior (Baranowski et al., 1998; Lewis, Marcus, Pate, & Dunn, 2002). Baranowski et al. (1998) argue that because interventions change behavior by influencing mediating variables, researchers need to explicate the relationship between the outcome and mediating variables and the effect of the intervention strategies on the mediating variables in order to develop a greater understanding of what specific strategies can increase exercise. Therefore, in a well-designed study a theoretical framework forms the basis for developing intervention strategies that are designed to influence specific variables and a conceptual model delineates the relationship between the variables. This allows

the hypothesized relationships to be tested to determine what variables or strategies are most effective in increasing exercise participation in a specific population of women.

#### Theoretical Framework

Social Cognitive Theory

Social cognitive theory (SCT) defines a reciprocal relationship between the factors of behavior: personal, which includes cognitive, affective, and biological aspects; environmental; and behavioral (Bandura, 1997). According to the SCT, a change in one area impacts the other areas causing a dynamic interaction effect. SCT postulates that individuals proactively make choices regarding their actions and take control over themselves and their environment based on these interacting components of behavior. Furthermore, individuals can think abstractly and create symbols, which results in the ability to self-reflect, self-regulate, learn vicariously and think about the future (Bandura, 1997). These cognitive processes help to shape behavior.

Self-efficacy is a critical component of the cognitive factors that influence behavior. Self-efficacy is an individual's perceived capabilities of a specific behavior. People's self-efficacy affects their performance and hence their outcomes. Self-efficacy cognitions are situation specific rather than a global assessment of capability (Bandura, 1997). Self-efficacy regulates and is a predictor of the occurrence, the level of effort applied towards, and the persistence of a behavior (Bandura, 1997). Self-efficacy will influence the amount of time an individual will devote to changing a behavior, such as increasing exercise. Mastery and vicarious experiences, physiological, affective, and cognitive states, and social persuasion can generate self-efficacy (Bandura, 1997).

Because mastery experiences involve the person performing a task, this is the most powerful in changing self-efficacy beliefs.

Other important concepts of social cognitive theory define ways people think about and control their behavior, emotions and thoughts. Outcome expectations are the anticipated response to a behavior while outcome expectancies are the values placed on an outcome (Bandura, 1997). A woman may know that if she exercises she will lose weight (outcome expectation) and this will increase her physical attractiveness which she views as important (outcome expectancy). Environmental stimuli, which influence behavior, can be managed by altering the way one perceives the stimuli (Baranowski, Perry, Parcel, 1997). A woman may be afraid to walk alone for exercise and this emotional arousal may keep her from exercising. However, she may solve the problem and reduce the emotional stimulus by walking with a friend. She is cognitively coping with emotional triggered situations. Setting goals, self-reinforcement, and behavioral capacity, defined as knowledge and skill to perform a behavior, also effect behavior change (Baranowski, et al., 1997).

### Transtheoretical Model

According to the transtheoretical model (TTM) individuals progress through five discrete stages of change in order to internalize and integrate a new behavior (J.O. Prochaska & Marcus, 1994; J.O. Prochaska, Redding, & Evers, 1997; J.O. Prochaska & Velicer, 1997). In the precontemplation stage an individual is not interested in changing exercise behavior. In the contemplation stage an individual is beginning to consider the benefits of instigating a change in exercise behavior and is seeking out information. In the preparation stage an individual has decided that a change in exercise behavior will be

beneficial and is beginning to take steps to make a change. In the action stage an individual acknowledges the benefit of changing exercise behavior and is actively exercising. After six months of regularly exercising an individual moves into the maintenance stage and continues making an effort to exercise regularly. TTM describes the cognitive and behavioral processes an individual employs to move through the stages of change. Individuals who commit to a behavior change when they are not in the action stage will not adhere to the change since they have not gone through the necessary preparatory steps (Samuelson, 1998). An individual may develop a sense of shame after an unsuccessful attempt at increasing exercise resulting in more resistance to change in the future (J.O. Prochaska et al., 1997; J.O. Prochaska & Velicer, 1997).

There are ten processes of change that people use as they progress through the stages. These processes of change are conceptually the same as strategies. The first five cognitive, or experiental processes are relied on most heavily in the earlier stages. These processes are consciousness raising, dramatic relief, self-reevaluation, environmental reevaluation, and self-liberation. The behavioral processes, which are used more in the later stages, include social liberation, helping relationship (social support), counterconditiong, contingency management and stimulus control (Prochaska, Marcus, 1994, Prochaska, et al., 1997, Prochaska, Velicer, 1997). The processes of change will be employed as strategies to increase exercise participation in HTH.

The last two principal constructs to TTM are derived from different behavior theories. Decisional balance involves weighing the pros and cons of a behavior. As one moves into the action stage the pros of a behavior out weigh the cons and hence, propels the change in behavior. Self-efficacy is from Bandura's social cognitive theory. Self-

efficacy is necessary for an individual to move into a more active stage of change (J.O. Prochaska & Marcus, 1994).

Integration of Social Cognitive Theory and Transtheoretical Model

The constructs in SCT and TTM alone do not fully explain the complexity of behavior change. However, these theories when integrated provide a conceptually comprehensive explanation of behavior change. TTM places an individual along a continuum of change and explicates the processes an individual employs in order to move toward increasing exercise participation (J.O. Prochaska & Marcus, 1994; J.O. Prochaska & Velicer, 1997). This description of the process of behavior change is missing in the SCT. The SCT provides a dynamic context in which the stages and processes of change in the TTM occur. The dynamic interaction of intrapersonal, behavioral, and environmental aspects of behavior change described in SCT (Bandura, 1997) explains the complexities of behavior change and the intricacies of individual responses to change at each stage. The integration of these two theories can guide the development of a multi-pronged approach to increase exercise in women. Tailoring the activities in an intervention to match the stage and corresponding processes of change while acknowledging the influence of interacting intrapersonal, environmental and behavioral factors on change may encourage the adoption and maintenance of the desired behavior, increased adherence to an exercise program.

Concepts in the two theories are conceptually similar. Self-efficacy is a prominent component in SCT and TTM and a strong mediator of behavior change (Bandura, 1997; J.O. Prochaska & Marcus, 1994; J.O. Prochaska et al., 1997). SCT and TTM emphasize the importance of social support. TTM and SCT describe

intrinsic motivation and autonomy as essential for persistence of behavior change (Bandura, 1997; J.O. Prochaska & Velicer, 1997). The processes of change delineated in the TTM are strategies that can be employed to influence the factors of behavior as described in SCT.

## Conceptual Model

Social Cognitive Theory and the Transtheoretical Model form the basis of the investigator-developed model. It posits that intrapersonal and environmental factors influence behavior. HTH will impact a woman's behavior, exercise participation as measured by the outcome variables of exercise adherence, cardiorespiratory fitness, and physical activity through the hypothesized mediating variables of self-efficacy within the intrapersonal realm, and social support within the environmental realm. Figure 1 depicts the conceptual model for HTH. HTH was designed to influence the intapersonal factor of self-efficacy and the environmental factor of social support through a combination of individual oriented and group based strategies. Table 1 outlines the strategies, underlying theoretical concepts and empirical rationale for the HTH intervention.

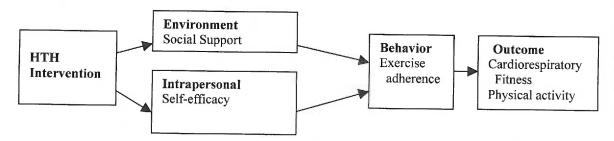


Figure 1: Proposed model of the interaction of intrapersonal, environmental, behavioral, and outcome variables in the HTH study.

Table 1: Intervention components, underlying theoretical concepts, and rationale

COMPONENT Strategies	UNDERLYING THEORECTICAL CONCEPTS	EMPIRICAL RATIONAL AND IMPACT ON STUDY OUTCOMES
GROUP BASED		
Motivational Interviewing process in group	Increase motivation to change	Increases: stage of change, self-efficacy(Foote et al., 1999; W. Miller &
activities	Support self-efficacy Enhance intrinsic motivation	Rollnick, 2002)
Check-in each week on progress	Supportive relationships	Increases: group cohesion, self-efficacy, stage of change, social support,
	Social interaction	exercise adherence(Bandura, 1997; Baranowski, Perry, & Parcel, 1997;
	Commitment & accountability	Carron & Hausenblas, 1998; Carron, Hausenblas, & Estabrooks, 1999; J.O. Prochaska & Marcus, 1994)
Discuss feelings regarding exercise experiences	Commitment	Increases: group cohesion, social support, exercise adherence (Bandura,
	Supportive relationships	1997; Carron et al., 1999; Carron, Hausenblas, & Mack, 1996;
	Emotional Camon matronal support	Rudolph, & Lox, 1994; J.O. Prochaska & Marcus, 1994; R. M. Ryan & Deci. 2000)
Group name & T-shirt	Distinctiveness	Increases: group cohesion(Carron et al., 1999; Carron & Spink, 1993;
		Spink & Carron, 1993)
Positive feedback from group leader	Professional helping relationship Positive reinforcement	Increases: social support, self-efficacy, stage of change, group cohesion, exercise adherence(Bandura, 1997; Carron et al., 1996; Deci & Ryan,
		1985; J.O. Prochaska & Marcus, 1994; R. M. Ryan & Deci, 2000)
Exercise buddies	Supportive relationships	Increases: social support, stage of change, group cohesion, self-efficacy, exercise adherence(Bandura, 1997; Carron & Hausenblas, 1998; Carron
		et al., 1999; Carron et al., 1996; J.O. Prochaska & Marcus, 1994)
Positive feedback from group members	Social persuasion	Increases: self-efficacy, stage of change, group cohesion, exercise
	Emotional & intotinational support	aurice inceptation at 1997; Carron & Itanscriptos, 1976; Carron et al., 1999; Carron et al., 1996; Krummel et al., 2001; J.O. Prochaska &
:	;	Marcus, 1994)
Walking & stretching together as group	Modeling experiences	Increases: self-efficacy, exercise adherence(Bandura, 1997; E. McAuley
Discuss substituting walking for sedentary	Functional & informational support	Concesses: stage of change self-efficacy social support exercise
behavior, reminders, strategies to overcome	Counterconditioning	adherence(Bandura, 1997; Baranowski et al., 1997; J.O. Prochaska &
barriers.		Marcus, 1994)
Establish group norms	Distinctiveness	Increases: group cohesion(Carron & Hausenblas, 1998; Carron et al., 1999; Carron & Spink, 1993; Spink & Carron, 1993)

INDIVIDUAL ORIENTED		
Individual counseling using motivational interviewing	Stage-matched counseling Support self-efficacy Enhance intrinsic motivation	Increases: stage of change, self-efficacy, exercise adherence(Burke, Arkowitz, & Menchola, 2003; C. Dunn, Deroo, & Rivra, 2001; Harland et al., 1999; W. Miller & Rollnick, 2002; Rollnick & Miller, 1995)
Establish Goals	Self-control Self-liheration	Increases: self-efficacy, stage of change, exercise adherence(Bandura, 1997: Baranauchi et al. 1997: T.O. Baranauchi et al. 1997: T.
Use heart rate monitor	Self monitoring Self-reinforcement	Increases: Self-efficacy, stage of change, exercise adherence(Bandura, 1997; Baranowski et al., 1997; J.O. Prochaska & Marcus, 1994)
Keep exercise log	Stimulus control Self-monitoring Self-reinforcement	Increases: Self-efficacy, stage of change, exercise adherence(Bandura, 1997; Baranowski et al., 1997; J.O. Prochaska & Marcus, 1994)
Check-in each week on progress	Stimulus control Self-monitoring	Increases: Self-efficient state of chance evening otherwood Description
Emphasize positive benefits	Commitment Physiologic responses	1997; Baranowski et al., 1997; J.O. Prochaska & Marcus, 1994) Increases: Self-efficacy exercise adherence (Bandura, 1997; Poei &
	Consciousness raising Intrinsic motivation	Ryan, 1985; E. McAuley, Blissmer, Katula, & Duncan, 2000; E. McAuley. Talbot. & Martinez. 1999: I.O. Prochaska & Marcus. 1994).
Substitute walking for sedentary behavior, reminders	Counterconditioning	Increases: Stage of change, self-efficacy, exercise adherence(Bandura, 1997: Baranowski et al., 1997: 10. Prochaska & Marcus, 1994)
Participatory	Autonomy	Increases: Stage of change, self-efficacy, exercise adherence(Bandura, 1997; Baranowski et al., 1997; Deci & Ryan, 1985; Krummel et al., 2001; J.O. Prochaska & Marcus, 1994)

# Variables and Strategies in the Heart-to-Heart Intervention Self-efficacy

Increasing self-efficacy is a prominent component of HTH because self-efficacy is a determinant and predictor of exercise participation in diverse groups of women, including Latinas (Calfas, Sallis, Oldenburg, & Ffrench, 1997; Dallow & Anderson, 2003; Laffrey, 2000; Marcus, Selby, Niaura, & Rossi, 1992; E. McAuley, 1992; E. McAuley, Jerome, Steriani, Marquez, & Ramsey, 2003; Neis et al., 1998; Petosa, Suminski, & Hortz, 2003; Resnick & Nigg, 2003; Rhodes, Martin, & Taunton, 2001; JF Sallis et al., 1992; Sherwood & Jeffery, 2000; JE Wilbur, Miller, Chandler, & McDevitt, 2003; Wilcox et al., 2000). Self-efficacy plays an important role in exercise participation. Self-efficacy explained between 8% and 24% of the variance in exercise participation in studies designed to increase self-efficacy and exercise participation in diverse groups of women (Calfas et al., 1997; E. McAuley et al., 1994; E. McAuley & Jacobson, 1995; Rhodes et al., 2001; JE Wilbur et al., 2003). Self-efficacy has been a significant and important predictor of exercise behavior both directly and indirectly in several models described by a path analysis with beta values ranging from 0.27 to 0.50 for direct paths (Litt, Kleppinger, & Judge, 2002; E. McAuley et al., 2003; Resnick & Nigg, 2003). Selfefficacy has been found to play more of a role in exercise adoption (initial six months) than maintenance (beyond the initial 6 months) (E. McAuley, 1992; Oman & King, 1998). HTH is aimed at promoting the adoption of exercise and thus, increasing selfefficacy is a crucial component of HTH.

Adoption of a new behavior requires the development of self-efficacy because if a woman perceives herself as efficacious in a behavior she is more likely to perform the

behavior (Bandura, 1997). Once a woman begins to develop self-efficacy, she will seek out mastery experiences that will further boost her self-efficacy and increase adherence to the new exercise program (Bandura, 1997; Deci & Ryan, 1985; J.O. Prochaska & Velicer, 1997; R. M. Ryan & Deci, 2000). For example, if a woman is able to successfully exercise for 3 days in one week, she is more likely to believe that she will be able to exercise 3 days the next week. In addition self-efficacy increases in response to interventions aimed at increasing self-efficacy in women (Cody & Lee, 2000; Dallow & Anderson, 2003; E. McAuley et al., 1994)

Self-efficacy influences affective responses to exercise. According to the social cognitive theory positive feelings towards exercise lead to an increase in self-efficacy for exercise and participation in exercise (Bandura, 1997). Women with higher self-efficacy have been found to have more positive feelings about exercising, such as a sense of more energy (Jerome et al., 2002; E. McAuley et al., 2000; E. McAuley et al., 1999).

Self-efficacy is a significant predictor of intrinsic motivation in exercise (E. McAuley, Wratih, & Duncan, 1991) and intrinsic motivation enhances persistence of a behavior (Deci & Ryan, 1985; R. M. Ryan & Deci, 2000). Intrinsic motivation is driven by an internal sense of pleasure in an activity and extrinsic motivation is derived from external sources, such as money. Self-determination, the perception of free choice, and self-efficacy are essential components of intrinsic motivation (Deci & Ryan, 1985). Self-determination in exercise is a predictor of exercise adherence (JE Wilbur et al., 2003). Intrinsic motivation is necessary for adherence to an exercise program (Deci & Ryan, 1985; R. M. Ryan & Deci, 2000).

## Increasing self-efficacy in HTH

Several strategies will be used in HTH to increase self-efficacy. HTH will provide opportunities for mastery and modeling experiences, the two most powerful sources of self-efficacy (Bandura, 1997). Opportunities for positive reinforcement will be included in HTH. Positive reinforcement by the self and others also enhances self-efficacy by highlighting improvement and providing encouragement. Positive and informational reinforcement will be given during HTH because they enhance self-efficacy and intrinsic motivation. Only reinforcement that is information is perceived as providing useful information about behavior. Reinforcement that is perceived as controlling undermines intrinsic motivation because it does not promote self-determination (Deci & Ryan, 1985, 1999; R. M. Ryan & Deci, 2000).

Women in HTH will monitor their progress because monitoring progress points out improvement and increases self-efficacy. Women will keep an exercise log and use a heart rate monitor to monitor their progress and to provide self-reinforcement. Setting goals can assist in developing self-direction and monitoring progress thereby enhancing self-efficacy; therefore, the women will develop attainable goals.

Rewards that are tied to positive reinforcement and individually determined goals can encourage the participation in a new or difficult activity (Bandura, 1997; Deci & Ryan, 1985). Rewards can contribute to the development of self-efficacy and thus intrinsic motivation (Bandura, 1997; Deci & Ryan, 1985; R. M. Ryan & Deci, 2000). Courneya et al. (1997) found that providing one month free membership at a fitness center as reinforcement for reaching the investigator developed goal of attending 12 sessions in one month increased attendance at the fitness center for one month. However,

another study found that reinforcing consistent attendance at in exercise class with lotteries did not increase exercise participation compared to a control group at 9 weeks of an 18-week intervention and at 2 months after the intervention (Marcus & Stanton, 1993). In both these studies the reinforcement was not tied to an individually developed goal or to positive informational feedback. Reinforcement alone may provide an initial boost to exercise participation but the boost is not sustained over time. The rewards that are tied to a goal and informative messages can then be phased out as indicators of intrinsic motivation are expressed, such as increased energy or improved mood with exercise. Incentives or rewards given at the end of the intervention undermine intrinsic motivation and decrease the likelihood of the newly adopted physical activity program enduring (Deci & Ryan, 1999).

Women will be informed of the normal physiological responses to beginning an exercise program, such as the potential for muscle soreness. This information may reduce frustration and drop out. Positive physiologic benefits of exercise, such as improved sleep and mood, will be emphasized because positive physiologic and affective responses to exercise increase self-efficacy for exercise (Bandura, 1997).

# Stage of Change

Stage of change is a determinant of exercise in women, including Latinas (Laffrey, 2000; Sherwood & Jeffery, 2000). Women of diverse backgrounds move to a more active stage of change (Cody & Lee, 2000; Dallow & Anderson, 2003; Marcus, Banspach et al., 1992; Marcus et al., 1998; Woods, Mutrie, & Scott, 2002), increase their level of physical activity (Calfas et al., 1997; Dallow & Anderson, 2003; A. L. Dunn et al., 1997; Koffman et al., 2001) and cardiorespiratory fitness

(Dallow & Anderson, 2003) in response to interventions that used stage matched strategies. More active stages of change are associated with greater levels of physical activity (Dallow & Anderson, 2003; A. L. Dunn et al., 1997; Fahrenwald & Walker, 2003; Laffrey, 2000; Sarkin, Johnson, Prochaska, & Prochaska, 2001; Schumann et al., 2002), increased cardiorespiratory fitness (Cardinal, 1997; D. R. Young, King, Sheelan, & Stefanick, 2002) and a reduction in CAD risk factors (A. L. Dunn et al., 1997) in diverse groups of women. In addition a more active stage of change is associated with higher self-efficacy for exercise (Cardinal, 1997; Fahrenwald & Walker, 2003; Herrick, Stone, & Mettler, 1997; Laffrey, 2000; Marcus, Banspach et al., 1992; Marcus, Selby et al., 1992; Rodgers, Courneya, & Bayduza, 2001; Sarkin et al., 2001) in diverse groups of women.

The majority of women, including Latinas, are in the contemplation, preparation, and action stages of change with percentages ranging from 51%-90% (Dallow & Anderson, 2003; Herrick et al., 1997; Laffrey, 2000; Marcus, Selby et al., 1992; Rodgers et al., 2001). Since the level of physical activity is associated with the stage of change, these reported percentages of women in contemplation, preparation, and action stages are consistent with the low levels of regular physical activity in U.S. women (USDHHS, 1996; USDHHS, 2000). It is anticipated that women agreeing to participate in HTH will be in the contemplation, preparation or action stages of change. By definition those in the maintenance stage of change are exercising regularly at least 3 days a week for over 6 months and therefore do not meet study criteria. Women in precontemplation by definition are unlikely to express interest in

participating in HTH because they are not considering an increase in their level of physical activity.

The transtheoretical model posits that individuals will predominantly use the 5 cognitive processes of change in the less active stages of change and the behavioral processes of change in the more active stages of change (J.O. Prochaska & Marcus, 1994; J.O. Prochaska et al., 1997; J.O. Prochaska & Velicer, 1997). However, in exercise behavior all the processes are used at all stages with those in more active stages of change employing more of the processes of change in their effort to increase exercise (Calfas et al., 1997; Dallow & Anderson, 2003; A. L. Dunn et al., 1997; Fahrenwald & Walker, 2003; Koffman et al., 2001; Marcus, Rossi, Selby, Niaura, & Abrams, 1992; Rodgers et al., 2001). Women, with diverse backgrounds, increased their use of the processes of change in response to interventions aimed at encouraging use of these strategies to assist in increasing physical activity levels (Dallow & Anderson, 2003; Koffman et al., 2001; Woods et al., 2002). In HTH all of the processes of change will be employed as strategies to promote increased exercise participation.

# Moving to a more active stage of change in HTH

HTH will employ processes of change as strategies to assist in moving women to a more active stage of change in the group exercise sessions. Each week the group exercise leader, who is the investigator, will provide information about the importance of exercise to health to the group (consciousness raising). Women will be encouraged to discuss the value of exercise, the impact of being physical active or inactive among the participants (self-re-evaluation, environmental re-evaluation) and individual goals and

strategies employed to increase exercise (self-liberation). Women will be encouraged to keep exercise logs, use heart rate monitors, and use visible prompts as reminders of exercise, which are forms of stimulus control. Women will be encouraged to discuss their progress with each other. Monitoring progress increases self-efficacy and self-determination. The group discussion will also increase social support and group cohesion, the process of helping relationships.

Understanding what stage an individual is in will guide the content of information needed to increase exercise that provides encouragement rather than discouragement (J.O. Prochaska & Marcus, 1994; J.O. Prochaska et al., 1997; J.O. Prochaska & Velicer, 1997; Rollnick & Miller, 1995; Samuelson, 1998). The exercise leader will discuss ways to substitute walking for sedentary activities, the impact of exercise on one's health and daily life, injury prevention, how to incorporate walking into daily life in the weekly group walking sessions. These topics include the processes of reinforcement management, self-liberation, counterconditioning, social liberation, environmental reevaluation, self-reevaluation and consciousness raising.

# Motivational Interviewing

Individual counseling sessions using the philosophy of motivational interviewing to provide the appropriate information, guidance and support to women participating in HTH will emphasize the processes of change associated with the women's stage of change. Motivational interviewing (MI) is a client centered and directed approach to changing behavior (Rollnick & Miller, 1995). MI tailors counseling strategies to the stage of behavior change. Counselors express empathy, support self-efficacy, and foster intrinsic motivation for change (Rollnick & Miller, 1995). MI has been used successfully

with African Americans to modify diet (Resnicow et al., 2001); however, use of MI with Latinas has not been described in a published report. MI is beginning to be employed in an effort to increase exercise participation. A recent study examining effects of differing intensities of MI on physical activity levels found that at 12 weeks the intervention groups increased physical activity by 38% (Harland et al., 1999). There was no significant difference between the groups that received one 40-minute MI session and the groups that received six 40-minute sessions. The findings from this study suggest that a brief intervention appears to be as effective as a more intense intervention in increasing exercise (Harland et al., 1999). In HTH women will receive an initial 30-40 minute counseling session using MI and then booster sessions of approximately 10 minutes each week by phone.

## Social Support

Social support and social interaction are important components in the environmental realm of behavior. Social support is a determinant of exercise in diverse groups of women including Latinas (Duffy et al., 1996; Eyler et al., 2002; Hovell et al., 1991; Laffrey, 2000; Nies & Kershaw, 2002; JF Sallis et al., 1992; Wilcox et al., 2000). Social support predicts exercise adherence in women (Litt et al., 2002; E. McAuley et al., 2003; Resnick & Nigg, 2003; Rhodes et al., 2001). Social support explains 12% of the variance in exercise adherence (Rhodes et al., 2001). Social support has been found to indirectly influence exercise behavior through its effect on self-efficacy (E. McAuley et al., 2003; Resnick & Nigg, 2003). Social support increases in response to exercise interventions targeted at improving social support (Cody & Lee, 2000; Rhodes et al.,

2001). Thus, increasing social support is a key component of HTH and HTH will employ several strategies to increase social support.

Social interaction and support from individuals who are not family members increase exercise adherence. A meta-analysis of the impact of social influences on exercise adherence found that support from important others had more impact than family members on exercise adherence (Carron et al., 1996). The authors of the meta-analysis proposed that the encouragement and reinforcement from friends or important others may have a stronger influence because these individuals are less well known and therefore, their support is more meaningful than a family member because it is unexpected and infrequent. Also, support from individuals other than family members may contain more informational messages (Carron et al., 1996), enhancing its potency by increasing selfefficacy and intrinsic motivation. A study looking at the relationship between social support received from an exercise group and exercise adherence found that provisions of reassurance of worth and guidance were factors that differentiated women who adhered to the exercise program from those who did not adhere (T. E. Duncan, Duncan, & McAuley, 1993). This finding supports the argument put forth by Carron et al. (1996) that support from friends or co-exercisers contains more informational messages or guidance and this enhances the strength of the support and ultimately adherence. Informational messages increase self-efficacy and intrinsic motivation, which enhance adherence.

Group-based interventions have been found to have a high overall effect size on average of 0.75 (Dishman & Buckworth, 1996). In a group members are united in a common goal, experience mutual benefit, and identify with the group. In addition a group

contains a social structure defined by group norms and processes including communication and interaction (Carron & Hausenblas, 1998; Toropainen & Rinne, 1998). Groups can provide a place for emotional expression and support and the processing of problems (Horne, 1999). Carron, Brawley and Widmeyer (1998) define cohesion as "a dynamic process that is reflected in the tendency for the group to stick together and remain united in the pursuit of its instrumental objectives and/or for the satisfaction of member affective needs" (p. 213). Group cohesion includes individual attractions to a group and integration with the group in terms of the goals of the group and the social interactions within the group (Carron et al., 1998; Carron & Hausenblas, 1998; Widmeyer, Brawley, & Carron, 2002).

Social interaction is an important determinant of exercise (Cox, Burke, Gorley, Beilin, & Puddey, 2002; Gillett, 1988; Sherwood & Jeffery, 2000). An intervention designed to increase cohesion within a women's exercise class found that social integration and perceptions of the social attractiveness of the group were the most prominent dimensions of cohesion (Spink & Carron, 1994). In addition individuals participating in exercise groups that are more cohesive have more positive affective states (Courneya, 1995). It is possible that the increased exercise adherence found with more cohesive women's exercise groups (Spink & Carron, 1992, 1994) is partly related to the social interaction manifested as informational support and reassurance given by the exercise group members.. Cohesive groups synergistically strengthen the group effect and exercise adherence by enhancing social support, enjoyment, reinforcement, self-efficacy and commitment (Carron et al., 1999).

In addition, developing a cohesive exercise group can create an environment for women to develop connections in concert with the caring ethic of women's development that enhance adherence to an exercise program (Gilligan, 1982; Surrey, 1991). Cohesive women's groups enhance the development of greater intimacy, security and more self disclosure than do men's groups (Horne, 1999). Schiller (1997) examined the stages of development in a woman's group and found that women's groups tend to establish a relational base from which women form connections. In addition, women's groups develop a sense of safety and develop mutuality and interpersonal empathy that fosters trust and disclosure early in the formation of a group. This relational base and mutuality can be a powerful source for learning and for beginning to develop an identity as an exerciser without the constraints of gender role expectations (Belenky, Clinchy, Goldberger, & Tarule, 1986; Henderson et al., 1995; Surrey, 1991). This new identify formation is important to the maintenance of the newly adopted exercise behavior (J.O. Prochaska & Velicer, 1997; R. M. Ryan & Deci, 2000; Surrey, 1991). In addition connectedness can enhance the internalization of new behavior and this internalization is necessary for intrinsic motivation to be realized (R. M. Ryan & Deci, 2000). Social relationships can foster adherence by providing informational and emotional support during the challenging phase of adopting and integrating a new behavior into the self and into daily life (Bandura, 1997; Carron et al., 1996; Deci & Ryan, 1985; Henderson et al., 1995; Markland, 1999; E. McAuley et al., 1994; J.O. Prochaska & Marcus, 1994; R. M. Ryan & Deci, 2000). If a woman believes that others are genuinely interested in her, she is more likely to develop a connection and make a commitment to change (Henderson et al., 1995) and thereby increase her exercise participation. Thus, the development of group

connections can increase a woman's self-efficacy, motivation, and commitment to change thereby, increasing adherence. Therefore, increasing social support among the exercise group members and creating a cohesive group are important components of HTH.

# Increasing Social Support in HTH

HTH will employ several strategies to increase social support and enhance group cohesion. Women will walk in a group once a week. This group-based walk will allow opportunities to develop relationships with other women beginning to adopt an exercise program. The women will meet for one hour once a week to walk around a track together and will be encouraged to walk with a woman at a similar walking pace. This will provide opportunities for the development of support thereby increasing self-efficacy (Bandura, 1997; Baranowski et al., 1997) and adherence (Carron et al., 1999; Krummel et al., 2001). The women will be encouraged to share their experiences with exercising in the past week and progress toward reaching their goals. This sharing of experiences may reinforce a woman's commitment to change, enhance support amongst the group (Carron et al., 1999), establish trust and accountability (Hoffman & Jones, 2002); thereby, increasing adherence to the program.

Women will be encouraged to form a cohesive group and to bond with each other to enhance adherence to the exercise program (Carron et al., 1999). The women will decide on a group name and T-shirt design in order to foster group distinctiveness and tighten group bonds (Carron et al., 1999). Women will be asked to assist each other, provide guidance to each other, and give informative feedback, all of which increase connectedness and group cohesion.

Adopting exercise is challenging because of the barriers to incorporating exercise into daily life. The components of behavior change dynamically interact with each other as a woman embarks on a program to increase exercise. Self-efficacy is a key component in the adoption of exercise. Self-efficacy and social support are predictors of exercise and they dynamically interact with each other to increase exercise participation. Social interaction can enhance enjoyment and increased enjoyment enhances intrinsic motivation and adherence (Markland, 1999). Social relationships can assist in developing ways of coping with transitions and challenges in life including fitting exercise into their daily lives. Clear, positive and informational reinforcement enhances self-efficacy and self-determination especially if friends, co-exercisers, or the group leader gives the feedback (Bandura, 1997; Carron et al., 1996). An increase in self-efficacy is necessary to move into more active stages of change (J.O. Prochaska & Marcus, 1994; J.O. Prochaska & Velicer, 1997), develop self-determination (Bandura, 1997; Deci & Ryan, 1985; Markland, 1999; J.O. Prochaska & Marcus, 1994; J.O. Prochaska & Velicer, 1997; R. M. Ryan & Deci, 2000) and ultimately to enhance exercise adherence and reduce CAD risk factors.

# Significance of the Proposed Study

One in two women will die of heart disease in the U.S (AHA, 2005). Rural women, including Latinas, are at increased risk for CAD because of lower SES, and diminished individual and community resources. Rural women, including Latinas, have higher incidence of risk factors for and worse outcomes from heart disease compared to their urban counterparts (AHA, 2005; National Center for Health Statistics, 2001). Physical inactivity is a significant risk factor for women (AHA, 2005).

Endurance exercise reduces the risk of CAD through inhibiting atherosclerosis and by reducing obesity and blood pressure, and improving lipid profiles and insulin sensitivity. Walking 30 minutes 3 to 5 days a week at a moderate intensity level is associated with a reduced risk of CAD in women. Women need to maintain this level of participation in exercise in order to continue to experience a reduction in risk. Women can increase their exercise through a well-designed, progressive exercise-training program that promotes adherence. However, adopting and maintaining an exercise program is a challenge for rural women. Interventions grounded in a theoretical framework and aimed at affecting the key determinants or exercise for rural women, including Latinas can increase exercise participation by increasing adherence to an exercise program.

HTH, grounded in an integration of the social cognitive theory and the transtheoretical model and aimed at key determinants of exercise for rural women, is designed to increase exercise participation and therefore targets one of the significant risk factors for heart disease in rural women and Latinas. Women have different determinants for exercise than men (JF Sallis et al., 1992) and respond differently to interventions designed to increase exercise (The Writing Group for the Activity Counseling Trial Research Group, 2001). Thus, interventions designed specifically for women are needed. Intervention studies aimed specifically for rural women, including Latinas, are extremely rare. HTH begins to fill this gap by targeting both white and Latina rural women and focusing on the known determinants of exercise for rural women. This pilot study will help to define the modifications to HTH that are needed for optimal outcomes in rural women, including Latinas.

# CHAPTER THREE RESEARCH DESIGN AND METHODS

## Design

This pilot study used a randomized two-group, pretest, posttest design to test the feasibility of implementing HTH in a rural area with both white and Latina rural women. Participants were randomly assigned to either the HTH group or the control group. Study variables were measured in both the HTH and control groups at the beginning and end of the study.

## Sample and Setting

#### Setting

Polk county has a total population of 62,380 with 92% white, 0.7 % African American, 3.1% American Indian/Alaskan Native and 8.8 % Hispanic (U.S. Census Bureau, 2002). The main industries in the county providing employment include education, health and social services (23.9%), manufacturing (12%), public administration (10.4%), and retail trade (10 %). Agriculture, forestry, fishing, hunting and mining constitute only 5.4% of employment in the county. The per capita income in 2000 was \$19, 282 (U.S. Census Bureau, 2002). The county has a total land area of 741 square miles, resulting in a population density of 8 people per square mile (U.S. Census Bureau, 2002).

Recruitment occurred in two private family practice offices and two public health clinics within the county. The practices or clinics were each in a different town within the county. The two public health clinics tended to serve a more diverse population and were included to heighten Latina recruitment. The health care providers and staff at each location were oriented to the study and expressed enthusiasm about the study.

## Sample

Women met the following study criteria for entry into the study. Inclusion criteria included: 1) ability to speak and read English, 2) age 21-65, 3) physically inactive, as defined by not meeting the US Surgeon General's recommended level of physical activity of 30 minutes on most days of the week (USDHHS, 1996) and assessed by asking how many days they exercised at moderate intensity in the last month, 4) interested in increasing the amount of exercise, and 5) approval by the primary care provider to safely engage in exercise. Exclusion criteria included: 1) history of heart disease based on self-report, 2) a physical condition that precluded exercise, e.g., musculoskeletal or neurological disorder, or 3) pregnancy.

The sample size was determined with a power analysis using data measuring cardiorespiratory fitness both pre and post intervention from a walking intervention for urban women (Shin, 1999). The data from that study revealed an effect size of 0.46 for a between group difference on the interaction of time and group. To achieve this effect size at a 0.05 significance level (power of 0.80) in this study required a minimum of 20 women per group. Attrition rates of women in exercise intervention studies range from 6% to 22% (Castro, Sallis, Hickman, Lee, & Chen, 1999; Cody & Lee, 2000; Cress et al., 1991; Gillett, White, & Caserta, 1996; A. M. Miller, Stewart, & Brown, 2002; Shin, 1999; Warren et al., 1993). The goal was to enroll 48 women to allow for a 20% attrition rate.

<u>Age</u>

The broad age range (21-65) enhanced inclusiveness. In addition, a meta analysis of exercise intervention studies determined that exercise interventions that used a broad age range had higher effect sizes (Dishman & Buckworth, 1996). Although women of different ages will have different life experiences, the exercise determinants that are targeted in this intervention have been reported across the age spectrum (E. McAuley, 1992; Neis et al., 1998; Wilcox et al., 2000).

# Gender Inclusion

This study focused on rural women. Women experience a significant health disparity in heart disease. Societal mores, gender roles, working conditions, multiple conflicting roles and responsibilities, less access to health resources, lower educational attainment and socioeconomic status adversely influence a women's risk of and outcome from (CAD) (Casper et al., 2000; Douglas, 2002). Women have significantly higher rates of, morbidity and mortality from, and at or beyond age 65 incidence of CAD than men (AHA, 2005; Douglas, 2002). Women are not evaluated and treated as aggressively as men and women's symptoms frequently are unrecognized or minimized by health care providers (Canto et al., 2002; Douglas, 2002; Schoenberg, Peters, & Drew, 2003). Women also have a higher incidence of risk factors for CAD than men (American Heart Association, 2005; Douglas, 2002). Latinas have a higher incidence of risk factors for and a higher prevalence of CAD than white women (American Heart Association, 2005) and, because of their ethnicity, receive less evaluation and treatment for heart disease than white women (Winkleby et al., 1998).

Rural women, in particular, are at increased risk for heart disease. Rural areas are more likely to be economically underdeveloped, have a lower level of resources, and lower per capita government expenditures on economic, social, and health services than urban areas (Casper et al., 2000). Rural areas have inadequate medical resources (Eberhardt, Ingram, Makuc, & et al., 2001). Rural women are likely to have lower levels of education and earnings, experience higher rates of poverty, have higher rates and increased severity of chronic illness, and a higher incidence of risk factors for and morbidity and mortality from CAD than urban women (Casper et al., 2000; Eberhardt et al., 2001).

Furthermore, there is a dearth of research examining exercise interventions tailored to women and specifically, rural women. In addition, men and women have been found to respond differently to exercise interventions (The Writing Group for the Activity Counseling Trial Research Group, 2001), demonstrating the need to develop gender-tailored exercise interventions. Thus, this study is aimed at rural women and testing an exercise intervention tailored to them.

## Minority Inclusion

The investigator established a goal of Latinas comprising 30% of participants. Several strategies and outreach activities were undertaken to enhance Latinas recruitment. A recognized limitation to recruiting rural Latinas was the inclusion criterion of English speaking. Many Latinas living in rural Oregon are not bilingual, thus the criterion of English speaking narrowed the pool of Latinas who could potentially participate. This criterion was made because the investigator, who

conducted all aspects of the study, only speaks English. It was not financially feasible to hire and train a bilingual research assistant for this pilot study.

Outreach activities began early in the study timeline. In July 2003 the investigator met with a bilingual staff person who worked at a community health clinic that serves Latinos in a rural community. She stated that most Latinas in the area are not bilingual and this would be a significant barrier. In addition, she recommend that the women who enrolled in the study be paid approximately \$100 to participate because it was her belief that Latinas would not enroll in an exercise study if they were not compensated. Since providing monetary compensation for participation contradicted the underlying theoretical framework of the HTH program, which emphasizes building self-efficacy and intrinsic motivation, this avenue to enhance Latina recruitment was not pursued further.

In August 2003 the investigator established a relationship with a community liaison within the Latina community. She is a registered nurse who works for a local hospital as nurse outreach worker for Washington County. She and the investigator discussed several outreach activities to enhance recruitment that could be implemented once IRB approval was obtained. Therefore, the decision was made to add Washington County as a recruitment area with the goal of enrolling 16 women, predominately Latinas, and conducting one session in Washington County. The investigator maintained communication with the Latina liasion throughout the recruitment phase of the study

In January and February 2004 the investigator attended a local hospital

Hispanic Education Task Force annual meeting and a Hispanic Community Analysis

meeting. At these meetings the investigator established a contact with the manager at a community health clinic that serves Latinos in the area. She expressed excitement and interest in the clinic participating as a recruitment site for the study. However, once IRB approval was obtained, the investigator made multiple attempts to contact her by email in order to begin recruitment and received no return response. Therefore, this lead was not pursued further.

In April 2004 the investigator met with the Latina liasion and another Latina outreach worker at to outline a strategic plan for Latina recruitment. In this meeting the Latina outreach worker agreed to hand out study fliers to friends, family, and acquaintances, who are bilingual Latinas in a rural town within Washington County. In addition, the Latina liasion sent fliers to the plant manager of a manufacturing plant, with whom she had a longstanding working relationship. She placed fliers at an annual women's tea sponsored by a local hospital and traditionally attended by many Latinas. She sent fliers to the managers, with whom she had a working relationship, of wineries in Washington County. In her work with both the manufacturing plant and the wineries she had determined that a large percentage of the Latina workers were bilingual and therefore, the decision was made to focus on these employment places. Therefore, these locations were attractive because of the potential to recruit bilingual rural Latinas. The investigator spoke with the manager of the manufacturing plant to inquire if the investigator could come to the plant and give a presentation regarding the study. The manager stated he had given a flier to every woman in the plant. He did not give his permission for a presentation to be given at the plant. These leads and activities did not produce any response.

Since the investigator had not received any phone inquiries in response to fliers placed at any of the locations in Washington County by June 2004, the investigator began to pursue other strategies. At that time the investigator met with a faculty consultant and planned further outreach activities to enhance Latina recruitment in Washington County. The faculty consultant distributed fliers to all the staff at a local community clinic that serves Latinos. The investigator spoke over the phone with a contact at the clinic who stated that she had spoken with the bilingual staff and none, including herself, were interested in participating. At this point the decision was made not to pursue further recruitment activities in Washington County.

Recruitment strategies to enhance Latina recruitment were pursued in Polk

County beginning in June 2004. The investigator established contact with the staff at a

small community health clinic in the area because a large percentage of the clinic patients

are Latina. The investigator provided a lunch and gave a presentation of the study to the

staff and providers at the clinic. Fliers were placed in several locations in the waiting

room and at the front desk. In addition, colorful posters, made using the fliers, were

displayed in each of the exam rooms. The investigator brought incentives for the staff

every two weeks, such as fruit and baked goods, in order to maintain excitement in the

study with the staff. The major barrier to recruitment from this site was that most of the

patients were not bilingual. A few women enrolled in the study in response to the fliers,
including one Latina.

The investigator also established and built a relationship with the manager the local health department clinic because this clinic has a significant percentage of Latina patients. The investigator gave a presentation to the staff about the study during a

monthly staff meeting. Fliers were placed in several locations in the waiting room and at the front desk. In addition, colorful posters, made using the fliers, were displayed in each of the exam rooms. The investigator brought incentives for the staff every two weeks, such as baked goods, in order to maintain excitement in the study with the staff. A few women enrolled in the study in response to theses fliers; however, none was Latina.

In addition, the investigator informed the Latina liaison that the decision had been made not to continue recruitment efforts in Washington County. The investigator inquired if she had any contacts in Polk County. She had worked with a few wineries in Polk County and she sent the study fliers to the managers of those wineries. No response was received from the fliers placed at these wineries.

By August of 204 only two Latina women had enrolled in the study; therefore, the investigator met with another faculty consultant to discuss additional strategies. The faculty consultant made contact with a colleague whose research involves demographics of the Latina community in Polk County. This contact stated that the Latina community in Oregon is relatively new and isolated making it a difficult to reach the community. He referred me to a church in the area that conducts a mass in Spanish. The investigator met with the church secretary. She was very enthusiastic about the study and stated the parish was interested in promoting exercise. She offered to put a flier in the mailbox of all the members of the Women's Guild. In addition, she offered to display the fliers after the mass for interested women to pick up. No responses were received from this community contact. By the end of September the recruitment goal of 48 women had been met and so recruitment was closed and further outreach activities were not pursued. A total of two Latinas were recruited and enrolled in the study.

The inclusion criterion of the ability to speak English was a significant barrier in recruiting rural Latina women. Since the investigator is not bilingual, it was difficult to establish and build a relationship within the Latina community in either Washington or Polk Counties. In addition, the investigator does not live or work in these areas and therefore, did not have established relationships prior to embarking on the study within the two areas. Having a bilingual research assistant, preferably from the area with established connections in the Latina community would enhance the capability to outreach to rural Latinas. Additional monetary and personnel resources to assist in the time intensive stage of recruitment would also increase the capability to reach out to rural Latina women, especially since the community is isolated.

#### **Procedures**

### Recruitment

A several step recruitment process was utilized. Since the HTH program involved group-based activities, it was necessary to have 16 women recruited before a session began. In this way there would be 8 women in the HTH group and 8 women in the control group. In addition, Jones et al. (2002) demonstrated that a multiple step recruitment process extending over 6 weeks enhanced retention in a 3-month exercise intervention because the recruitment process necessitated persistence from the participants. Those who dropped out in the recruitment phase would most likely have dropped out in the intervention phase. Therefore, the multi-step process reduced attrition in the intervention phase. Table 2 delineates the recruitment steps.

The investigator initially established contact with a private practice in the summer of 2003. She met with the medical director to discuss the study and the

### Table 2:Recruitment Steps

## Recruitment Steps

- 1. Place fliers in family medical clinics. Staff directed women to fliers
- 2. Interested women contact investigator by phone
- 3. Phone conversation describing study, women determines if meet inclusion/exclusion criteria, using screening form
- 4. Face-to-face meeting to describe study, risks/benefits, participation, obtain informed consent, give projected start date based on number women recruited at time completes consent
- 5. Call each week to update on recruitment status
- 6. 1-2 weeks before start date complete pre-test measures
- 7. Randomization

director enthusiastically agreed for the practice to be a recruitment site. In March of 2004 the investigator provided a lunch and gave a presentation of the study to the staff and providers at the practice. Fliers were placed in several locations in the waiting room and at the front desk. In addition, colorful posters, made using the fliers, were displayed in each of the exam rooms. The investigator brought incentives for the staff every two weeks, such as fruit and baked goods, in order to maintain excitement in the study with the staff. In June 2003 a second private practice was added to enhance recruitment. The investigator met with the clinician to discuss the study and she agreed to participate as a recruitment site. Next, the investigator held a luncheon meeting for the office staff. Fliers were placed in a few locations in the waiting room and in each exam room. The investigator brought incentives for the staff every two weeks, such as fresh picked fruit in order to maintain excitement in the study with the staff. Staff at both locations were involved in pointing out the posters, directing women to the fliers, and answering basic questions the women may have had concerning the study.

#### Randomization

After 16 women were recruited then appointments to conduct the pre-test measures were scheduled and occurred at a private location in or near the woman's home. The test of caridiorespiratory fitness was conducted at a local track. Once 16 women completed the pre-intervention measures, they were matched on ethnicity and cardiorespiratory fitness (meters walked in 12 minutes) and then randomized to either the HTH or the control group. Since the investigator collected the data and conducted the intervention, a researcher besides the investigator conducted the randomization to dispel any concern regarding the potential for bias.

#### Interventionist

The investigator, an advanced practice nurse, conducted the intervention. She received training over a 6-month period in motivational interviewing (MI) by a certified MI trainer on faculty at OHSU School of Nursing. Prior to the start of the intervention a motivational interviewing session was recorded and coded by trained coders. The coding determined that she had reached proficiency in motivational interviewing. She successfully passed a certification examination as a health and fitness instructor from the ACSM. Thus, she had the skills necessary to conduct the intervention.

# Intervention-HTH Group

First, women met individually with the investigator for 60 minutes. This meeting occurred at a private location in or near a woman's home. This initial session was scheduled after randomization. In this initial meeting the investigator provided individually tailored, stage-matched counseling, using MI, to enhance the adoption of an exercise program. The average length of the counseling session was 30 minutes (Appendix A). The remainder of the initial meeting consisted of reviewing an individualized and progressive exercise prescription based on the ACSM's principles of training (Franklin et al., 2000). The Karvonen method, also known as the heart rate reserve method, was used to determine the target heart ranges in the prescription. The women learned how to use the Polar® heart rate monitor (HRM), selected because of its accuracy (Bassett, 2000). They also learned how to fill out an exercise log. Using a heart rate monitor and an exercise log fostered the development of self-monitoring, stimulus control, self-reinforcement, motivation and independence. These factors

strengthen self-efficacy (Bandura, 1997), increase women's exercise adherence (Baranowski et al., 1997; Krummel et al., 2001) and are processes of change (J.O. Prochaska & Marcus, 1994). Also, women were given standard educational material on exercise because this is the current standard of care in the community. Since this material was given to the control group, giving it to the intervention group controlled for any effect of the educational material on exercise behavior.

Eight women met as a group for one hour once a week for 12 weeks. scheduled at a mutually agreed upon and convenient time, to walk around a centrally located track together. They were encouraged to walk with a woman of a similar walking pace during the group walk. The investigator moved back and forth across the track to provide encouragement and positive reinforcement to each woman during the walk. Women discussed and shared their experiences with each other regarding exercising in the past week and progress toward reaching their goals. Prior to the beginning of each weekly walk, women participated in a 10-minute group discussion. Using the principles of MI the investigator directed the weekly discussions that centered on topics germane to the women. Team building strategies were implemented to encourage the formation of a cohesive group and enhance the connections among the women. These included the development of a group name, a group T-shirt and, the sharing of experiences, and establishment of acceptance and support between women as a group norm. Group cohesions can enhance adherence to an exercise program (Carron et al., 1999).

The investigator attempted to contact the participants by phone weekly, outside of meeting time, to discuss progress, provide individually tailored and stage-matched

counseling using MI, and to remind them of the group walk. The phone contact lasted on average approximately 5-10 minutes. The phone contact was planned to decrease to every other week in the third month in order to foster independence and autonomy. The women put together a phone contact list and were encouraged to phone each other to discuss progress, provide support and reinforcement, and remind each other of the group walk. Women were encouraged to continue the weekly walks as the intervention came to an end. This fostering of independence encouraged persistence with exercise (Bandura, 1997; Deci & Ryan, 1985; Krummel et al., 2001; J.O. Prochaska & Marcus, 1994; R. M. Ryan & Deci, 2000).

Incentives or rewards given at the end of the intervention can undermine intrinsic motivation and decrease the likelihood of the newly adopted physical activity program enduring (Deci & Ryan, 1999). Therefore, no financial incentive was given for completing the study.

### Control Group

Women met individually with the investigator for approximately 20 minutes at the beginning of the 12-week study period. Women received a 5-10 minute individual counseling session focusing on the health benefits of exercise, goal setting, and overcoming barriers to regular exercise. In addition, the investigator reviewed standard educational material on exercise. Women were instructed in how to fill out the exercise log.

The women received limited contact monthly from the investigator. The investigator mailed a new exercise logbook to each woman and provided a stamped and addressed envelope to return the previous month's log. The investigator

attempted to call each woman once a month to provide 5 minutes of reinforcement. These activities kept women actively involved in the project and connected with the investigator and enhancing retention.

#### Data Collection

The investigator recorded weekly data from the heart rate monitors and entered field notes at the end of each group-walking meeting in a password-protected file in a laptop computer. Exercise logbooks were collected monthly at the group walk for women in the HTH group and by mail for women in the control group. Women in the intervention group were asked to participate in a focus group at the end of the intervention. This was conducted at a local coffee shop. The investigator did not have access to a private office or meeting room in the area. The focus groups were audiotape recorded. The investigator transcribed the recordings for analysis. The investigator was able to reach most of the women who dropped out of the study to inquire about reasons for dropping out. Data collection forms and questionnaires were number coded. No names were attached to data on the forms or in the computer. All data has been kept confidential and is stored in a locked file cabinet at OHSU School of Nursing.

#### Measures

Physiologic markers or risk factors of heart disease were not expected to change during this 12-week walking program; therefore, physiologic markers were not measured in this study. However, height and weight were measured and BMI was calculated for descriptive purposes. Also for descriptive purposes, resting heart rate and blood pressure were measured.

The data were collected at the beginning and end of the 12-week period except the demographic data, which was only be collected at the beginning and the group cohesion questionnaire that was completed by only the women in the HTH group at the end of the 12-week intervention. The data were completed through an interview process in a private location chosen by each woman. Focus group data was collected at the end of the 12-week intervention.

Demographic Data

Demographic data included marital status, history of risk factors for heart disease- tobacco use, hypertension, diabetes, hyperlipidemia- employment status, age, educational level, time as a rural dweller, hormone uses, and ethnicity and race (Appendix B).

Physiologic Data

Height, weight, resting heart rate and blood pressure were collected pre and post.

The BMI was calculated from the height and weight using the following formula: BMI=

[weight in pounds/ (height in inches)<sup>2</sup>] X 703.

Primary Outcome Measures

#### Exercise Adherence

Data from the exercise logs (JE Wilbur, Chandler, & Miller, 2001) were used to measure the 3 dimensions of exercise adherence; frequency, duration and intensity of exercise. Wilbur et al. (2001) found a correlation of 0.962 between number of walks recorded in an exercise log and on a heart rate monitor, thus the logs are considered a reliable measure of the 3 dimensions of adherence. Women were instructed to record the number, intensity, and duration of each exercise session

performed. The recordings in the logbooks were used to determine the number, duration, and intensity of sessions each week. Frequency was measured by the total number of exercise sessions a woman recorded in the logbooks during the study period. The average number of minutes in the exercise sessions was calculated to arrive at a duration measure. Intensity was measured based on the self-reported level of intensity recorded in the logbook. The intensity level (moderate, hard, very hard) was then converted to a number that was used for analysis. Since there were significant correlations between the 3 dimensions of adherence and between the frequency dimension of adherence and VO<sub>2</sub>max scores (JE Wilbur et al., 2001; JE Wilbur et al., 2003), Wilbur et al. (2003) used the frequency dimension as the measure of adherence in their data analysis of a walking program with women. Therefore, in this study, the frequency dimension was used as the outcome variable of exercise adherence entered for the statistical analysis.

In addition, women in the HTH group were instructed to wear a HRM each time they exercised and during the group walks. They were instructed to record each session in the HRM memory. The HRM saved only one exercise session in the memory. This recorded session was downloaded into a Polar program in the investigator's laptop computer at each group-walking meeting attended by the women. The data downloaded into the laptop was used as an additional source to determine the number, duration and intensity of exercise sessions performed by women in the HTH group. The HRM recorded one exercise session per week; therefore, the last recorded session was downloaded. This was done prior to the start

of the group walk. Attendance in the weekly group walk was taken and provided another data source regarding walking sessions performed.

# Cardiorespiratory Fitness

Cardiorespiratory fitness was measured using a 12-minute walk test (12 MWT) (K. H. Cooper, 1968). This test is more feasible than a graded exercise test because of the limited healthcare resources in the rural county in which the study was conducted. The 12-MWT is highly correlated with VO<sub>2</sub>max, r= .90 (K. H. Cooper, 1968). Test-retest reliability was r= .98 for patients with chronic obstructive pulmonary disease (Larson et al., 1996). The change in distance walked in 12 minutes is physiologically expected to change with regular, moderate intensity exercise in 3 months. (Brooks et al., 2000) The 12 MWT detected a difference in distance walked with a magnitude (effect size, d) of 0.85 in a walking program in women with breast cancer (Mock et al., 1997). In HTH a difference in the magnitude, measured by effect size, of 0.3-0.4 is expected.

The 12 MWT was used instead of the 6 MWT. Both the 12MWT and the 6 MWT have been widely used in the elderly and patients with chronic illness. A recent qualitative review found that both the 6MWT and the 12MWT produced consistent and dependable results in varied populations. In a supervised treadmill or cycle ergometer test the resistance and speed can be manipulated to achieve a submaximal or maximal test; however, this is not possible in a field test. It is speculated that women walking for the longer duration of 12 minutes are possibly more likely to reach a higher intensity, particularly in women not habituated to the walk test.

The 12 MWT was administered to each woman individually on a local school track that was most convenient to each woman. Women were instructed to walk at a slow pace for 5 minutes to warm up. Next, each woman was instructed to walk briskly for 12 minutes and to cover as much distance as possible without reaching exhaustion on a standard oval race track. Then, each woman was instructed to walk at a slow pace for 5 minutes to cool down. The distance markers already imprinted on the track were measured by the investigator and used to measure distance walked around the track. The distance covered was measured in meters and recorded on a data collection form.

## Physical Activity

The 7-day physical activity recall (PAR) (Blair et al., 1985; JF Sallis, 1997; JF Sallis et al., 1985) was used to measure physical activity in the last 7 days (Appendix B) and was administered by an interview. The revised version and protocol were used (JF Sallis, 1997). The total amount of energy expenditure per week was calculated from the amount and level of activity recorded on the PAR. The PAR measures activity beyond planned exercise sessions, such as yard work or household chores. Respondents were asked to estimate the number of hours spent during each day in sleep, moderate, hard, and very hard activities because these activities compared to light activities are more likely to be recalled by the respondent. It is assumed the rest of the day is spent in light activities that may not be easily recalled. The PAR has been sensitive to changes in activity level in response to exercise interventions aimed at increasing physical activity (Blair et al., 1985; Dallow & Anderson, 2003; A. L. Dunn et al., 1997; Rejeski et al., 2003; The Writing Group for the Activity

Counseling Trial Research Group, 2001). Significant correlations between the PAR and V0<sub>2</sub>max support concurrent validity (Blair et al., 1985). The PAR is widely used and has been used with Latinas (Blair et al., 1985; Dallow & Anderson, 2003; A. L. Dunn et al., 1997; Rejeski et al., 2003; JF Sallis et al., 1985; The Writing Group for the Activity Counseling Trial Research Group, 2001). The PAR was intended to provide additional information beyond the exercise logbooks and heart rate monitors by capturing women's overall physical activity level as well as the planned exercise sessions. The number of minutes spent in sleep, light, moderate, hard and very hard activities are totaled for the week. Then the number of minutes at each level of intensity is multiplied by the respective MET value. This provides the number of kilocalories per kilogram for each intensity level. Then, these results are added together to derive the total weekly energy expenditure in kilocalories per kilogram.

Secondary Outcomes

# Exercise self-efficacy

The Self-efficacy for Exercise Habits Survey (JF Sallis, Pinski, Grossman, Patterson, & Nader, 1988), used widely with adults, including Latinas (Castro et al., 1999; Glasgow, Strycker, Toobert, & Eakin, 2000), was used (Appendix B). The concept of self-efficacy has been found to be relevant and meaningful to Latinas (Laffrey, 2000). There are 12 statements regarding exercise behaviors that pertain to 2 factors, resisting relapse and making time for exercise. Respondents rated their confidence at being able to do the behaviors on a 5-point Likert scale with 1 indicating low self-efficacy and 5 indicating high self-efficacy (JF Sallis et al., 1988). The broad representation of situations that challenge an individual's motivation to

exercise and that are likely to be encountered support content validity. Sallis et al (1988) hypothesized that the test-retest reliability of 0.68 may reflect improvement in self-efficacy. Cronbach's alpha was 0.85 for resisting relapse and 0.83 for making time. Significant correlations between level of self-efficacy and self-reported amount of exercise supported concurrent validity (JF Sallis et al., 1988). Construct validity was supported by significant correlations between self-efficacy and locus of control for health behaviors (JF Sallis et al., 1988).

This measure has predicted exercise adherence at 3 months in an exercise program (Rhodes et al., 2001). Two interventions (Castro et al., 1999; JE Wilbur et al., 2003) found a decline in self-efficacy at post intervention; however, these were individually based interventions. Two studies found a slight increase in self-efficacy after an intervention (A. M. Miller et al., 2002; Rhodes et al., 2001) and the intervention with the most group interaction (Rhodes et al., 2001) had a larger magnitude increase in self-efficacy. Since HTH was aimed at developing a cohesive group and emphasizing social interaction, it was expected to have a larger increase in self-efficacy than the aforementioned interventions because the dose of the social interaction in HTH was larger. Thus, it was theorized that the intervention would result in a small to moderate increase in self-efficacy.

# Exercise stage of change

The Exercise Stage of Change Short Form (Marcus, Rossi et al., 1992), widely used with adults including Latinas (Laffrey, 2000; Marcus, Banspach et al., 1992), was used to determine the stage of change (Appendix B). The concept of stage of change has been found to be relevant to Latinas (Laffrey, 2000). It contains 5

statements that relate to an individual's readiness to exercise and respondents answered yes or no to each statement. The respondent is then staged based on the pattern of the response to the statements. The kappa index of reliability over a two week period was 0.78 (Marcus, Rossi et al., 1992). Higher VO<sub>2</sub>max was associated with later stages of change, supporting concurrent validity (Cardinal, 1997).

The measure detected changes in stage of change in response to a similar 10-week exercise intervention with women. Sixty-nine percent of women had progressed to a more active stage of change at the end of the intervention (Cody & Lee, 2000). By combining MI and a group-based exercise intervention it was theorized that HTH program will result in a larger percentage of women in the intervention group moving to a more active stage of change than reported in these studies.

# Social support

The Social Support for Exercise Survey (JF Sallis, Grossman, Pinski, Patterson, & Nader, 1987), widely used with adults, including Latinas (Blair et al., 1998; Glasgow et al., 2000), measures emotional, appraisal, instrumental and informational support, which are important in exercise (Appendix B). The scale consists of 13 statements regarding behaviors people may do in response to the respondent's exercise behavior. Respondents rated the frequency of the behavior on a 5-point Likert scale, for both family and friends. A 1 indicates a low level of support and a 5 indicates a high level of support. This scale was found to correlate better with exercise behavior than a general social support measure (JF Sallis et al., 1987). Test-retest reliabilities ranged from 0.55 to 0.79, and Cronbach's alpha ranged from 0.61 to 0.84 for the 3 factors revealed from a factor analysis (JF Sallis et al., 1987).

Significant correlations between self-report exercise level and social support level supported concurrent validity (JF Sallis et al., 1987).

Since, HTH was aimed at increasing social support from friends, it was expected that HTH would affect only social support from friends. However, the social support from family was entered into the analysis in order to determine if HTH had an affect on social support from the family. The measure has demonstrated sensitivity to change in response to a similar, 10-week exercise intervention with women targeting social support with an effect size (d) of 1.5 (Cody & Lee, 2000).

Process Variable

## Group Cohesion

The Physical Activity Group Environment Questionnaire (PAGEQ) (Carron, Widmeyer, & Brawley, 1985; Estabrooks & Carron, 2000) was used to measure group cohesion (Appendix B). The PAGEQ is modified from the GEQ, developed for sport teams, to measure group cohesion in exercise classes. There are 21 items that measure 4 factors of group cohesion. Respondents rated their level of agreement with the statements on a 9- point Likert scale. A score of 1 indicates low cohesion and a 9 indicates high cohesion. A factor analysis confirmed the same 4-factor structure as the GEQ and the correlation between the PAGEQ and the GEQ was 0.81(Estabrooks & Carron, 2000). The four factors are group integration, task and social, and individual attractions to the group, task and social. Internal consistency for the 4 factors ranged from 0.72 to 0.91. Association with class attendance and self-efficacy supported predictive validity. Group cohesion is a process variable and will be measured using

the PAGEQ to determine if the desired dose of the intervention was achieved. Only women in HTH group completed the PAGEQ at the end of the 12-week period.

Qualitative Data

Focus group guide

The investigator, using an investigator-developed-guide (Appendix B), led 3 focus groups of 45-60 minutes. Focus groups consisted of the women in the intervention group. Each focus group was held one week after the end of the 12-week intervention. Data collection can be enriched by the group interaction and dynamics. Data may emerge that may not in an individual interview. Focus groups are considered particularly suited for intervention refinement (Morgan, 1998) and group interaction is a familiar way to gain knowledge for Latinas (Madriz, 2000).

### Data Analysis Plan

# Preliminary analysis

Data were entered into SPSS version 11.5 and it was used for all the quantitative analysis. The distribution for all variables was examined for normality. To determine if randomization achieved balanced groups, baseline data was compared between the HTH and the control groups and between the 3 walking sessions using t-tests or analysis of variance (ANOVA) for parametric data or Chi-square for nonparametric data. In addition, to determine if the three exercise sessions were similar, an ANOVA was conducted on the group cohesion variable collected at the end of the 12 weeks. The data from the logs and the scores on the PAGEQ were examined to summarize the magnitude of the dose of the group-based aspects of the intervention and to look for any differences in the three sessions. The number of

counseling phone calls using MI that were received was calculated to determine the dose of the individual-based aspect of the intervention. The number of calls was compared between the three sessions. A p of .05 was set a priori for all the analyses.

#### Aim 1

Determine the magnitude of change in exercise adherence, cardiorespiratory fitness, and physical activity for rural women in HTH and rural women in the control group and whether this magnitude differs for rural women in HTH and rural women in the control group.

Hypothesis: Women in HTH will have a greater magnitude of change in exercise frequency, cardiorespiratory fitness, and physical activity than women in the control group.

Three 2 X 2 ANOVAs were conducted with group and time as the independent variables and exercise frequency as the dependent variable in the first ANOVA, cardiorespiratory fitness in the second ANOVA, and physical activity in the third ANOVA. A significant group by time interaction would demonstrate support for the hypothesis. In the case of a significant interaction effect, the magnitude of the difference in change over time between the HTH and the control group was summarized using effect sizes calculated from the means and the pooled standard deviation.

#### Aim 2

Examine the magnitude of change in self-efficacy and social support for rural women in HTH and rural women in the control group and whether the magnitude of change differs for rural women in HTH and rural women in the control group.

*Hypothesis*: Rural women in HTH will have a greater magnitude of change in self-efficacy and social support then women in the control.

Four 2X2 ANOVAs were conducted with group and time as the independent variables and the factors for self-efficacy and for social support as the dependent variables. A significant group by time interaction would demonstrate support for the hypothesis. In the case of a significant interaction effect, then the magnitude of the difference in change over time between the HTH and control group was summarized using effect sizes calculated from the means and the pooled standard deviation.

#### Aim 3

Examine whether self-efficacy and social support are mediators between HTH and the outcome variables of exercise adherence, cardiorespiratory fitness, and physical activity.

Hypothesis: Self-efficacy and social support mediate the relationship between HTH and the outcome of exercise adherence, cardiorespiratory fitness, and physical activity.

Barron and Kenny's (1986) model (Figure 2) was used to test mediation with change in self-efficacy and social support as the hypothesized mediators. Group assignment (intervention) was the independent variable. Change in cardiorespiratory fitness was the dependent variable. For each hypothesized mediator, a series of regressions was planned. First a regression with a mediator as the dependent variable and HTH as the independent variable would be tested (path a, figure 2). If this relationship would be significant, then a second regression with the outcome variable as the dependent variable and HTH intervention as the independent variable would

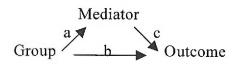


Figure 2: Mediator Model

be tested (path b, figure 2). If this relationship would be significant, then a third regression with the mediator and the HTH intervention (treatment group) as the independent variables and the outcome variable as the dependent variable would be tested. A variable would be established as a mediator and support the hypothesized mediating relationship between the intervention and outcome if in the first regression path a would be significant, in the second regression path b would be significant and in the third regression path c would be significant and path b would be less significant than in the second regression. An alpha of .05 was planned for each regression

#### Aim 4

Describe HTH participants' experiences with the intervention to aid in refinement of HTH.

Methodological triangulation can ensure a more complete understanding of a research problem (Morse, 1991). Qualitative data from the focus groups and the investigator's weekly field notes aided in understanding the women's experiences with adopting and maintaining exercise and with the HTH program. In particular, this analysis is intended to increase the understanding of the complexities that influenced the rural women's adoption and maintenance of exercise. Qualitative analysis is expected to assist in refining HTH based on the women's experiences.

Qualitative data were analyzed using qualitative content analysis (Sandelowski, 2000). The goal of qualitative content analysis is to provide clear, informative description (Sandelowski, 2000). Qualitative content analysis allows for unanticipated responses and a more expansive description of the participants' experiences than

quantitative content analysis (Sandelowski, 2000). The codes emerge from the data rather than being established a priori. Data were coded based on the emerging concepts and themes that reflect the experience of the exercise program in the participants' daily lives. These themes were used to provide in depth description and to add completeness to the quantitative findings. The researchers in the qualitative seminar, including faculty with expertise in qualitative analysis, reviewed the coding to ensure it was grounded in the data and the summary analysis to ensure it was an accurate portrayal of the participants' experiences.

# **Study Limitations**

Because this was a pilot study testing the feasibility and utility of HTH and the dose of the intervention, some limitations are acknowledged and deemed acceptable. Having the investigator conduct the intervention and collect the measures introduces the potential for bias; however, this potential was accepted because hiring an interventionist for the dissertation was not feasible. Since the study occurred within a small community there was the potential for contamination of the control group. The proposed measures have limited data documenting their sensitivity to change; therefore, this pilot study tested the sensitivity of the measures to detect change for rural white women and Latinas before considering their use in a larger trial. Having separate groups for the white women and the Latinas was considered because groups of dissimilar ethnicities may influence attendance. However, an earlier focus group conducted as part of a multiphase study by the investigator showed that women of different ethnicities can develop strong bonds in a short time despite their differences (Perry & Rosenfeld, 2005). Table 2 outlines the dissertation study timeline.

Table 2: Study timeline

IRB 11/03-2/04	Start-up Activities 1/04 – 2/04	Recruitment 3/04 - 9/04	Intervention 6/04 –12/04	Data Analysis 1/05 - 2/05	Dissertation Preparation & Defense	Manuscript Preparation 4/05 - 6/05
					2/05 - 4/05	

# Protection of Human Subjects

# Risks to the Subjects

# Human Subjects Involvement and Characteristics

Involvement

At baseline participants completed four questionnaires, Exercise Stage of Change, Self-efficacy for Exercise Habits Survey, Social Support for Exercise Survey, Seven-day Physical Activity Recall, and demographic data. This was expected to take approximately 30 minutes. Then, they completed a 12-minute walk test, which including the warm up and cool down, took approximately 20 minutes. Control group: Women in the control group had an individual counseling session regarding physical activity at the beginning of the study period and this was expected to take approximately 10 minutes. The women were asked to fill out an exercise log and mail it in monthly in a provided stamped envelope. The women were called monthly for reinforcement and this was expected to take approximately 5 minutes. They were asked to perform moderate intensity exercise for thirty minutes most days of the week. At the end of the 12 weeks the women completed 4 questionnaires and the 12minute walk test. The total time was expected to take approximately 40 minutes. Intervention Group: Women in the intervention group received an initial individual counseling session with the investigator and learned how to use the heart rate monitor and keep an exercise log. This took approximately 45minutes. They were asked to keep exercise logs and to record data in the heart rate monitor memory. They were invited to participate in weekly group walks on a local track. This meeting included stretching exercises before and after, walking 30 minutes and discussing their

progress with others and took approximately 60 minutes. They were asked to perform moderate intensity exercise for thirty minutes most days of the week. Initially the investigator planned to call the participants once a week to discuss progress, provide individual counseling and to remind them of group walks. Each phone call was expected to last between take 5-15 minutes. In the third month the phone calls were planned to decrease to every other week. Women were encouraged to phone each other to discuss progress, provide support, reinforcement and remind each other of the group walk. The investigator organized the weekly group walks. The study period was 12 weeks. The women were asked to provide feedback regarding their experiences adopting and maintaining an exercise program during the group walking sessions. At the end of the 12 weeks the women completed the 4 questionnaires plus an additional questionnaire, the Physical Activity Group Environment Questionnaire, and 12-minute walk test. This took approximately 45-60 minutes. They were invited to participate in a focus group to discuss their experiences with the intervention and about the factors that influenced exercise adherence. The focus group lasted approximately 45-60 minutes.

#### Characteristics

The target sample was rural dwelling adult women who were between 21 and 65, and were physically inactive. Inclusion criteria included: 1) English speaking, 2) age 21-65, 3) physically inactive, assessed by asking how many days they exercised in the last month, 4) interested in increasing amount of exercise, 5) approval by her primary care provider to engage in moderate intensity exercise. Exclusion criteria included: 1)

documented history of CAD, 2) presence of musculoskeletal or neurological conditions that preclude regular exercise, and 3) pregnancy.

Rural women are considered particularly vulnerable based on their gender, socioeconomic status, and location; therefore, only rural women were included in the study.

### Sources of Materials

The sources of data were self-report measures of 1) Exercise Stage of Change, 2) Self-efficacy for Exercise Habits Survey, 3) Social Support for Exercise Survey 4) Seven-day Physical Activity Recall 5) Physical Activity Group Environment Questionnaire. Demographic data including: age, martial status, ethnicity, race, employment status, educational level, history of risk factors for heart disease, current or past tobacco use, and length of time as a rural dweller was asked. Individuals were asked to self identify, from a list of the categories as described by the US federal government, first their ethnicity and then their race as 2 separate questions per the NIH recommendation. Respondents had the option to select one or more racial designations. Also, data were collected from heart rate monitors and exercise logs from the women in the intervention group. Data were collected through focus groups with the women in the intervention group at the end of the study period. The focus groups was audiotaperecorded and transcribed. Data were collected from informal discussions with the women during the intervention and was recorded by the investigator in a field notebook. These data were collected specifically for research purposes.

#### Potential Risks

There were three potential risks for the participants. 1) Women could have experienced psychological discomfort related to disclosure during informal discussions and focus groups. 2) Women could have experienced musculoskeletal injury and muscle soreness. 3) Women could have experienced cardiovascular symptoms such as chest discomfort, lightheadedness, fatigue, and shortness of breath while exercising.

# Adequacy of Protection Against Risks

# Recruitment and Informed Consent

Recruitment strategies and informed consent procedures were approved by IRB at OHSU. Women were recruited from two private practices and two community health clinics in Polk County. The investigator does not practice at either of the clinics. Recruitment began in March 2004 and continued through September 2004. The recruitment strategies included posting fliers at each of the primary care clinics informing them of the study and providing contact information. Women who were interested in the study contacted the investigator by phone. Only the investigator answered the phone line provided on recruitment materials and the voicemail with it. Initially the investigator described the study's purpose, participation, risks and benefits using a phone script. A phone screening form was read that listed of the screening criteria of English speaking, age, and physical inactivity (doesn't meet the recommendations for physical activity), no history of heart disease, and not pregnant. If the women qualified based on the screening form and was still interested in participating then the investigator met with the women in the community at a private location determined by the participant. In this meeting the investigator explained the study in detail and obtain written informed consent

if the women was still interested in participating. The investigator obtained written informed consent in accordance with the guidelines of the OHSU IRB. The woman were given a projected date for the start of the intervention. The investigator called the women weekly to update on the status of recruitment. One to two weeks before the start-date another meeting was arranged for the women to complete the baseline measures. The initial counseling session was held one to two weeks before the first group meeting. The day and time of the group walking meeting was arranged to accommodate the women's schedules and preferences. Participation in the study was voluntary and women could drop out or withdraw at any time. Specific outreach activities to encourage recruitment and enrollment of minorities are discussed in the subsection, inclusion of minorities.

Retention of participants in the intervention group was achieved by maintaining weekly contact with participants in the intervention group and monthly contact with participants in the control group. Women in both groups received an individualized exercise prescription based on the guidelines of the American College of Sports Medicine. All participants were asked to keep an exercise log. In addition, the participants in the intervention group received 12 weeks of individual exercise training and behavioral counseling from an American College of Sports Medicine certified health and fitness instructor with an estimated value of \$120.

### Protection Against Risk

Obtaining approval from the primary care provider minimized the risks.

The probability of these risks was low and the severity was considered low because women gradually built up to moderate intensity exercise, performed

stretching exercises and were supervised through phone contact. Additionally women in the intervention group had weekly in-person supervision. 1) Risk of psychological discomfort: The investigator reminded participants each week that data were being collected and that the participant could chose not to answer any questions or provide any data and that they could withdraw or drop out from the study at any time without repercussions. The self-report questionnaires were completed in a private location. 2) Risk of musculoskeletal injury and muscle soreness: The investigator discussed the importance of stretching before and after exercise and of building up gradually to increasing amounts of exercise. The investigator provided information on injury prevention. Women were asked to have clearance from their primary care provider before resuming exercise if any significant injury had been sustained. Women were asked about injuries each week at the beginning of the group walk. The principal investigator, who is a family nurse practitioner and certified as a health and fitness instructor by the American College of Sports Medicine, served as a fitness instructor, coach, and provided role modeling. 3) Cardiovascular symptoms: To reduce the potential risk of cardiovascular symptoms from exercise the women were required to obtain clearance from their primary care provider to participate in moderate intensity exercise. They were instructed to stop exercising if they felt chest discomfort, fatigue, lightheadedness, or shortness of breath with exercise and to contact their primary care provider to be evaluated. They were instructed that if they experienced these symptoms and the symptoms do not resolve within 5 minutes after stopping exercise they should call 911 for immediate evaluation. The women

were instructed not to resume any exercise until after they had been evaluated by their primary care provider. The primary care provider was to determine whether the participant could continue in the study. The investigator asked the participants about these symptoms weekly to determine if any of the participants had experienced these symptoms in the past week. If a participant had reported experiencing any of these symptoms the investigator would have asked the participant to stop participation and contact the primary care provider to be evaluated. The primary care provider was to determine if the participant could continue in the study. The investigator carried a cell phone during the group walks. If a woman had experienced cardiovascular symptoms, while participating in the group walk, she would have been asked to stop walking If the symptoms did not resolve in 5 minutes after stopping then the investigator would have used the cell phone to call 911. If the symptoms had resolved within 5 minutes after stopping then the woman would have been instructed not to resume any exercise until she had been evaluated by her primary care provider.

Risks to confidentiality: All data collected from this study is being kept confidential. No names have been attached to the questionnaires, exercise logs, heart rate monitor data, field notes or the audiotapes and transcripts from the focus groups. All data were numbered coded. The number coding document, all data, and signed consent forms are being kept in different locked file cabinets in an office at Oregon Health & Science University School of Nursing. It was kept in a locked box during transport from the data collection site to the School of Nursing.

Potential Benefits of the Proposed Research to the Subjects and Others

Potential benefits of participation included adopting and maintaining a regular exercise program, improving cardiovascular fitness, deriving other potential physical and mental benefits from exercise, building social support for exercise with other women in the group, developing new friendships, and improving self-efficacy towards exercise. The participants provided information that may help to refine an intervention that can be implemented on a wider scale resulting in the potential benefit for other women rural dwellers. The direct potential benefits to the participants and the potential benefits to other women rural dwellers outweigh the potential risks addressed above.

# Importance of the Knowledge to be Gained

Physical inactivity is a significant risk factor for heart disease, which is the number one cause of death and disability in women. Although there are countless interventions that have been tested to increase the level of exercise, few have been directed toward women and even fewer toward rural women. Adopting and maintaining regular exercise reduces the risk of heart disease. The knowledge gained from the study will increase understanding regarding the factors that contribute to adopting and maintaining an exercise program for rural women in Oregon. The results will provide information on the feasibility of a group-based walking program in a rural area.

Women and Minority Inclusion in Clinical Research

# Inclusion of Women

Women are less physically active than men and as women age they become even less active (AHA, 2005; USDHHS, 1996). In addition, women have higher morbidity and mortality from and a higher incidence of risk factors for heart disease than men (AHA,

2005). Women are not evaluated and treated as aggressively as men (Chandra et al., 1998; Devon & Zerwic, 2002; Schulman et al., 1999) resulting in worse outcomes after an MI. Women have different determinants for exercise than men (JF Sallis et al., 1992) and women and men respond differently to exercise interventions (The Writing Group for the Activity Counseling Trial Research Group, 2001). Therefore, interventions that aim to increase exercise must have different strategies for each gender to address the different determinants of exercise for men and women. There are very few studies that are specifically designed for women (Krummel et al., 2001; LB Robbins et al., 2001).

Because of these considerations only women were included in this study.

Only rural women were included in the study because rural women have the highest incidence of obesity (R. Cooper et al., 2000; Lantz et al., 1998) and are the least physically active (USDHHS, 1996). Rural areas are more likely to be economically underdeveloped, have a lower level of resources and lower per capita government expenditures on economic, social and health services than urban or suburban areas. Rural women earn less than urban women and rural men (Rogers, 1997; US Department of Agriculture, 2001b). Socioeconomic status is inversely associated with mortality form heart disease and this association is stronger for women (R. Cooper et al., 2000; Lantz et al., 1998). Thus, rural women experience a greater health disparity than rural men. Inclusion of Minorities

All English-speaking minorities were recruited and included in the study. It is acknowledged that the criterion of English speaking was a limitation in the recruitment of minorities.

Recruitment in these communities was likely to under represent minorities and therefore the following outreach activities were conducted to encourage minority enrollment. The investigator worked with an identified community liaison within the Latina community. Recruitment strategies included 1) putting fliers several work sites that the community liaison worked with 2) having fliers available at several community health education events 3) networking with colleagues of the Latina community liaison. Additional strategies included recruiting from community health clinics with significant Latina patients and recruiting from a local church that had a significant Latina parish. The goal of achieving 30% Latinas in the study sample was not achieved by these outreach strategies.

# Data and Safety Monitoring Plan

## Study Performance Review Process

The investigator produced administrative reports on a monthly basis that described study progress including: accrual, demographics, study subject status, outstanding study forms, error rate pertaining to adherence the inclusion/exclusion criteria and the study protocol. These reports were reviewed internally by the investigator and the dissertation committee chair. Reports were submitted to the IRB as required.

# Safety Reports

The investigator would have produced safety reports that list adverse events, serious adverse events and deaths after each event, however, none of these occurred during the course of the study. Any reports would have been submitted to the OHSU IRB as required.

### Interim Data Review

The Principal investigator had regular contact with the participants and asked each woman if she had experienced any symptoms or injuries. If a woman had reported any symptoms or concerns, she would have been asked to stop participation and would have been referred to her primary care provider for evaluation and clearance before the women could have resumed participation in the study. If any unusual or concerning heart rate data had been noted from the heart rate monitors, the woman would have been referred to her primary care provider for evaluation and clearance before she could have resumed participation.

# CHAPTER FOUR

# **RESULTS**

### Sample

Sixty-seven women contacted the investigator in response to fliers placed at two community health clinics and two private offices in the county (figure 3). Forty- six women were enrolled in the study that was conducted in three sessions during 2004. One session ran from June through August, one ran September through November, and one ran October through December. After the 12 week program began, three women dropped out because of time limitations and one was withdrawn because of a flare up of chronic hip pain, not related to HTH. A woman was considered withdrawn if she needed to stop participation for a medical reason and a drop out if she chose to stop participation for any other reason (Appendix A). The reported results are based on the forty-two women who completed the 12-week program and the baseline and post program measures.

There was an overall attrition rate of 12% and a retention rate of 88%. In the intervention group there was an attrition rate of 8% and a retention rate of 92%. This is compared to a retention rate of 91% in a study using a similar multi-step recruitment process for a group-based exercise intervention with women with fibromylagia (Jones et al., 2002). Retention rates in similar group-based exercise programs for women include 79% (A. M. Miller et al., 2002), and 88% (Cody & Lee, 2000) and in home-based walking programs for women include 88% (J. Wilbur, Vassalo, Chandler, McDevitt, & Miller, 2005) and, 84% (Castro et al., 1999).

Tables 4 summarize the socio-demographic characteristics, risk factors, anthropomorphic measures, social-cognitive characteristics, and physical activity and

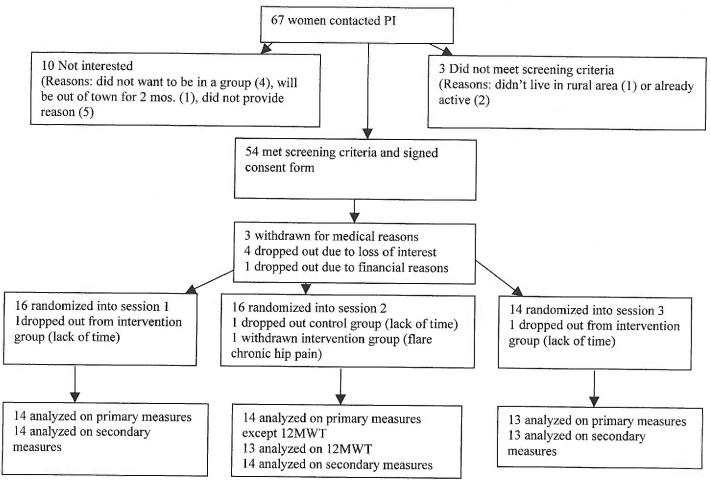


Figure 3: Participant recruitment and progress through the study period

Table 4: Baseline Characteristics by Group, N=42

	Intervention, N=20	Control, IN=22	
Socio-Demographic			
Ethnicity No. (%)			
Hispanic	1(5)	1 (4.5)	
Non-Hispanic	(56) 61	21 (95.5)	
Racial Background No. (%)			
White	19 (9.5)	21 (95.5)	
African American	0 (0)	1 (4.5)	
Native American/Alaskan Native	1 (9.5)	0(0)	
Martial Status No. (%)			
Married	16 (80.0)	17 (77.3)	
Steady Partner	1 (5.0)	1 (4.5)	
Single	2 (10.0)	1 (4.5)	
Divorced	1 (5.0)	2 (9.1)	
Separated	(0) 0	1 (4.5)	
Work Outside the home No. (%)			
Yes	15 (75)	16 (72.7)	
No	5 (25)	6 (27.3)	
Age M (SD)	46 (10.92)	44 (11.20)	
Years of education M (SD)	15 (3.60)	15 (2.34)	
Years lived in current location M (SD)	16.4 (11.01)	12 (11.17)	
Years lived in rural area M (SD)	29 (16.91)	25.24 (16.96)	
Hours per week worked outside home M (SD)	37.04 (18.2)	36.13 (10.39)	
Risk Factors			
Hypertension No. (%)			
Yes	4 (20)	3 (13.6)	
No	16 (80)	19 (86.4)	
Diabetes No. (%)			
Yes	5 (25)	1 (4.5)	

Hyperlipidemia No. (%)	15 (75)	21 (95.5)
Yes	4 (20)	6 (27.3)
No Currently Smokes Cigarettes No (%)	16 (80)	16 (72.7)
Yes	2 (90)	1 (4.5)
No Formerly Smoked Cigarettes No. (%)	18 (10)	21 (95.5)
Yes	6 (33.3)	6 (27.3)
	12 (66.7)	16 (72.7)
Hormone Status Menstrual Cycle No. (%) Yes	12 (60)	13 (59.1)
No Paking Hormones No. (%)	8 (40)	9 (40.9)
OCPs	0 (0)	3 (13.6)
Depoprovera HDT	0 (0)	2 (9.1)
	3 (15)	2 (9.5)
Anthropomorphic BMI M (SD)	32 37 (7 ())	20.45 (5.51)
Resting Heart Rate M (SD)	78 (12)	79 (9.7)
Blood Pressure-diastolic M (SD)	118 (10.9)	
Blood Pressure-systolic - M (SD)-	78 (7.2)	81 (7.5)
Socio-cognitive Initial Stage of Change No. (%)		
Contemplation	17 (85)	13 (59.1)
Preparation Action	3 (15)	9 (40.9)

Self-Efficacy-Sticking to it M (SD)	3.99 (.563)	4.01 (.655)
Self-Efficacy-Making time M (SD)	4.13 (.565)	4.08 (.755)
Social Support-family participation M (SD)	25.55 (6.19)	21.86 (5.12)
Social Support friends participation M (SD) Score range: 10-50	15.90 (5.64)	17.09 (6.29)
Physical Activity & Fitness 7-day physical activity recall (Leal/Leylay) - M (SD)	242.0 (15.78)	249.05 (30.74)
(meters) M (SD)	1206.68 (165.35)	1214.18 (179.76)

Table 5: Baseline Characteristics by Session, N=42

	AT 1			1	1	· -
	Number (%)	M(SD)	Nimber (0/)	A CODY	SESSION 5, IN-15	71
Socio-Demographic	(a/) racrimet	(UC)IVI	Number (%)	M (SD)	Number (%)	M (SD)
Ethnicity						
Hispanic	0 (0)		2 (143)		(6) (6)	
Non-Hispanic	15 (100)		2 (17.3) 12 (85.7)		0(0)	
Racial Background			(1.60).1)		(1001)	
White	15 (100)		14 (100)		11 (8/16)	
African American	000		(0) (0)		1 (04.0)	
Native American/Alaskan Native	(0) 0		000		1 (7.7)	
Martial Status					(/-/)	
Married	12 (80)		12 (85.7)		0 (60 2)	
Steady Partner	0(0)		(0.0)		2 (15.4)	
Single	1 (6.7)		(0) 0		2 (15.4)	
Divorced	2 (13.3)		1 (7.1)		(13.4)	
Separated	0 (0)		1 (7.1)		09	
Work Status			(1)		(0)	
Work outside the home	13 (86.7)		7 (50)		11 (816)	
Does not work outside the home	2(13.3)		7 (50)		7 (15.4)	
Age		46 (8.66)*	(2.2)	45 (12 38*)	(1.0.1)	12 (10 41) *
Years of education*		17 (3.47)		15 (7 41)		45 (12.41) " 14 (2.10)
Years lived in current location		14.3 (8.90)		14.2 (12.07)		13.8 (13.2)
Years lived in rural area**		21.46 (11.36)		37.6 (17.7)		22 (16.75)
		*		*		**
Hours per week worked outside home		40.23 (14.46)		37.86 (9.06)		30.85 (16.38)
Risk Factors						
Currently Smokes Cigarettes						
Yes	1 (6.7)		2 (14.3)		0.00	

No	14 (93.3)		12 (85.7)		13 (100)	
Formerly Smoked Cigarettes Yes No	2 (14.3) 12 (85.7)		5 (38.5) 8 (61.5)		5 (38.5) 8 (61.5)	
Hormonal Status Menstrual Cycle Yes No	8 (53.3) 7 (46.7)		9 (64.3) 5 (35.7)		8 (61.5) 5 (38.5)	
Laking Hormones OCPs Depoprovera HRT	1 (6.7) 0 (0) 3 (20)		1 (7.1) 0 (0) 2 (14.3)		1 (7.7) 2 (15.4) 0 (0)	
Anthropomorphic BMI Resting heart Rate Blood Pressure-diastolic Blood Pressure-systolic		29.21 (5.75) 77 (12.4) 118 (13.5) 79 (8.38)		31.74 (5.71) 77 (8.4) 120 (12.0) 79 (8.94)		31.68 (6.36) 81 (11.3) 125 (9.78) 81 (7.46)
Socio-cognitive Initial Stage of Change Contemplation Preparation Action	10 (66.7) 5 (33.3) 0 (0)		9 (64.3) 5 (35.7) 0 (0)		11 (84.6) 2 (15.4) 0 (0)	
Self-Efficacy-sticking to it Score range: 1.0 to 5.0 Self-Efficacy-making time Score range: 1.0 to 5.0	3.84 (.696)		4.12 (.554) 4.11 (.539)		4.07 (.547)	

		STATE OF THE PERSON NAMED IN COLUMN TWO IS NOT THE OWNER.	
Social Support-family participation Score range: 10.0-50.0	24.60 (6.42)	24.71 (5.30)	21.31 (5.68)
Social Support friends participation Score range: 10.0-50.0	15.20 (4.33)	17.50 (5.81)	17.00 (7.67)
Physical Activity & Fitness Level 7-day physical activity recall	240.33 (12.48)	244.08	253.77
(kcal/kg/day)		(18.74)	(37.77)
12 minute walk test	1293.93	1153.93	1149.23
(meters)	(182.96)	(41.43)	(151.19)
*Moon difference hoterson seesing 1 8. 7 : "	0.00		

\*Mean difference between session 1 & 3 is significant, p=.030 \*\*Mean difference between session 1 & 2 is significant, p=.020 and between 2 &3, p=.031

fitness level of the participants at baseline in the HTH and control groups. The women were matched on the baseline measure of fitness, the 12-minute-walk test (12 MWT), and ethnicity then randomized into the intervention or control group. There were no significant differences between the intervention and control group on the baseline characteristics. The comparisons of the group means were determined using T-test for independent samples for parametric data and Chi Square for nonparametric data. Table 5 summarizes the baseline data for each of the three sessions. There were statistically significant differences between the three sessions on two of the baseline sociodemographic characteristics. The mean differences between sessions were determined using ANOVA for parametric data and Chi Square for nonparametric data. First, there was a difference on the number of years of education F(2,40) = 4.346, p = .020, post hoc Bonferroni revealed mean difference between session 1 and 3 of 2.78 years, p=.034. Second, there was a difference on the years lived in a rural area F(2,40) = 5.010, p=.012; and post hoc Bonferroni revealed a mean difference between sessions 1 and 2 of 16.20 years, p=.022 and a mean difference between sessions 2 and 3 of 15.66 years, p=.036. When examining the original 46 who entered the study these results persist.

#### Reliabilities

Cronbach's alpha was calculated to determine the internal consistency of each scale. Scales with acceptable internal consistency (Cronbach's alpha) were entered into subsequent analysis. An acceptable Cronbach's alpha for established scales is considered to be .8 or greater. Since this was a pilot study with a relatively small sample size reliabilities of .6 or greater were deemed acceptable. Table 6 lists the scales by factor,.

Table 6: Internal Consistency of Scales (N=42)

Scale	Cronbach's	Number
	Alpha	of Items
Self-efficacy		
Exercise self efficacy: sticking to it, pretest	.7377	8
Exercise self efficacy: sticking to it, posttest	.8613	8
Exercise self efficacy: making time for exercise, pretest	.6310	4
Exercise self efficacy: making time for exercise, posttest	.5089	4
Social Support		
Social support: family participation, pretest	.7052	10
Social support: family participation, posttest	.8820	10
Social support: family rewards & punishments, pretest		3
Social support: family rewards & punishments, posttest	.4815	3
Social support: friends participation pretest	.8375	10
Social support: friends participation posttest	.8724	10
Group Cohesion		
Individual attractions to the group-task	.7432	6
Individual attractions to the group-social	.9052	6
Group integration-task (without item 16)	.7571	5
Group integration-social	.6348	4

Cronbach's alpha, and the number of items for each scale. The social support from family, rewards and punishments factor did not have acceptable internal consistency. There were three questions in this factor. In the pretest measure, there was no variance in the individual scores on two of the three questions. Thus, the Cronbach's alpha was not calculated because it is not applicable for only item. In the posttest measure, one question had no variance; therefore, the remaining two questions were used to calculate the Cronbach's alpha, which was .4815. This level of internal consistency was below the level deemed acceptable for this study. Additionally, this scale did not appear to have much relevance to the women in this study because almost all the women reported that family members did not perform the actions described in these three items. Despite these concerns, it was entered into analysis in aim 2 for exploratory purposes. Thus, all the scales were entered into the study aim analyses.

### Dose of the Intervention

Women's attendance at the group walks and the level of group cohesion determined the dose of the teambuilding and group formation aspects of the intervention. The number of phone calls using MI that each woman received determined the dose of the individual promotion aspect of the intervention. Table 7 lists the means for attendance at group walks, scores on the group cohesion scales, and the number of phone calls received by session. The means of these variables were compared to determine any differences between the sessions using ANOVA. There was no significant difference between sessions except on one of the dimensions of group cohesion. This finding is discussed under the group cohesion section.

Table 7: Dose of Intervention, N=42

Variable	Session 1,	Session 2.	Session 3.
	N=15	N=14	N=13
	M (SD)	M (SD)	M (SD)
Exercise Group Environment Questionnaire	6.6 (1.10)	6.88 (1,00)	677 (1 02)
Individual attractions to the group-task		(2212) 2212	(70:1)
Possible range 1-9 (higher score = greater			
cohesion)			
Exercise Group Environment Questionnaire	6.81 (1.15)	7.14 (.97)	6 94 (1 11)
Individual attractions to the group- social			(1111)
Possible range 1-9 (higher score $=$ greater			
cohesion)			
Exercise Group Environment Questionnaire	6.46 (1.20)	6.11 (1.33)	5.70 (.77)
Group integration-task			
Possible range 1-9 (higher score = greater			
cohesion)			
Exercise Group Environment Questionnaire	6.54 (.74)*	6.86(.71)* **	4.83 (1.6)**
Group integration-social			
Possible range 1-9 (higher score = greater			
cohesion)			
Number of MI phone calls	4.3 (1.7)	5.6 (1.7)	4.9 (1.6)
Total possible $=10$	,		
Attendance at group walks	9.0 (3.16)	7.7 (2.29)	8.83 (2.14)
Total possible $=12$			
*Conificant different Later 1	100		

\*Significant difference between session 1 & 3, p= .031

\*\*Significant difference between session 2 & 3, p= .010

### Group-Based Aspects of HTH

#### Attendance

One measure of the dose of the group-based aspects of the intervention was attendance at the group walks. The mean number of the 12 potential group walks attended by the women in all three sessions was 8.50 with a range from 4-12. Moreover, 65% of the women attended at least 60% (8) of the group walks and 80% attended at least 50% (6) of the group walks. There was no significant difference in attendance between the three sessions. In each session, the majority of women received a solid dose of the group-based aspects of HTH based on attendance.

In comparison, in a group-based exercise intervention for women lasting 18 weeks and meeting three times a week only 28% of women attended 66% of the classes (Marcus & Stanton, 1993). The attendance rate in the HTH intervention was considerably higher with 65% of women attending 60% of the group walks. In a group-based exercise intervention that met weekly for 10 weeks, 78% of the women attended 50% of the classes (Cody & Lee, 2000). The attendance rate in the HTH interventions was similar, 80% attended 50% of the group walks.

The difference in the attendance rates between the three times a week and the one time a week group meeting affirms an underlying premise of the HTH program. This premise is that conducting group-based activities once a week is more feasible than three times a week for women to fit into their complicated and busy lives. Therefore, it is critical to develop an intervention, such as HTH that considers women's time constraints and complex schedules by condensing the beneficial aspects of a group into a limited time frame.

### **Group Cohesion**

Group cohesion scores also determined the dose of group-based aspects, particularly the team building and group formation strategies of the intervention. The overall mean scores on the 4 group cohesion dimensions were 6.97 for individual attractions to the group-task, 6.77 for individual attractions to the group-social, 6.11 for group integration task, and 6.14 for group integration-social. The possible range in scores was 1-9, with a higher number indicating greater cohesion.

Team building activities increase group cohesion with women (Spink & Carron, 1993) and therefore, were an integral part of the intervention. The team building activities incorporated in the group walks emphasized the social dimensions of group cohesion. These activities included encouraging women to walk in pairs during the group walk, encouraging women to contact each other outside of the weekly-group-walks, providing informational and emotional support within the group, establishing a group norm of acceptance, establishing a group name, and receiving group T-shirts. The team-building activities focused on enhancing social dimensions of cohesion because the social dimensions are the most influential in increasing exercise adherence in women (Spink & Carron, 1993). It is postulated that the team-building activities influenced the relatively high level of group cohesion the women reported on the social dimensions.

Although the task dimensions of group cohesion were not emphasized, the mean score on the individual attractions to the group-task was the highest of the group cohesion dimensions. It is possible the group discussion, using motivational interviewing, enhanced this task dimension of group cohesion since the group discussions centered on the task of trying to fit walking into daily life.

There was a significant difference between the sessions on group integrationsocial dimension of group cohesion, F(2,20) = 6.642, p = .007. Post hoc Bonferronni test revealed a mean difference between sessions 1 and 3 of 1.70, p = .031 and between session 2 and 3 of 2.02, p = .010. There are several possible explanations related to the development of connectedness within each session for the lower level of social integration reported in the third session. In the first and second sessions some of the women in each session knew each other prior to their participation in the HTH program either from work, community, or child-related activities. None of the women in the third session knew each other prior to the start of the program. Since some of the women in the first and second sessions had already established connections they were able to build upon them to develop a cohesive group. Women in the third session did not have this advantage. Indoor facilities were not available in the area; therefore the group walks were conducted on an outdoor-track. After the return to standard time at the end of October, the group walks were conducted in the dark because they were held in the evening to accommodate women who worked during the day. Thus, the group walks in the third session were almost exclusively carried out in the dark and cold. The investigator observed that in response to the cold and darkness, women in the third session were spending little time in the group discussion. In order to facilitate social interaction and support, the group discussion was moved from before to after the group-walk when women were warm from walking. In addition, the investigator brought hot chocolate and tea for the women to drink while engaging in the group discussion. Although, these modifications increased the time women spent in the group discussions, it was still less than in the other sessions. Also, the women in the third session had a tendency to walk by

themselves around the track; whereas, in the first and second sessions the women had a tendency to walk in pairs. This tendency to walk alone in part may have been related to the darkness, to differences in fitness levels, or the initial the lack of familiarity with each other. Thus, unlike the first and second sessions there was limited social interaction while walking around the track. These differences may explain the observed phenomenon that women in the third session developed a connectedness only after the seventh week, whereas in the first and second sessions women developed a connectedness within the first two weeks.

In addition, there were three women in the third session who stated that they did not want to be part of a group. This opinion may have affected their level of interaction with the other women. In the second session there was one woman who didn't want to be part of a group and she was initially was reserved in the group discussions. Since there were three out of the six women in the third group, who did not want to be part of a group, compared to only one such woman in the second session, their more individually oriented preference may have had a greater impact on the group discussions.

Interestingly, three of these four women stated that they would not have adhered to the walking program if they had not been part of the group and by the end of the 12-weeks expressed gratitude that they had been randomized to the HTH group. These differences in the experiences with the group interaction in the third session also may have contributed to the lower degree of the social integration dimension of group cohesion.

#### Individual Oriented Aspects of HTH

### Phone Calls

The dose of the intervention that the women received for the individual oriented aspects of the intervention was low. Overall the mean number of phone calls women received in the intervention was 4.85, with a range of 4 to 6, much less than the planned number of 10 calls. There was no significant difference in the number of phone calls received between the three sessions. Although, the investigator attempted to call each woman each week, she was not successful in reaching each woman each week. The most common reason for not reaching women was that they were not at home at the time of the call. To increase the chance of reaching each woman at home, the investigator scheduled a window of time in which to call each week. Despite this strategy, the number of calls in which MI occurred remained low. When the investigator reached an answering machine she left a message that included a reminder of the next group walk. Although the women received a reminder of the group walk each week, they received less than half the number of planned MI phone calls. Thus, the women experienced a low dose of this aspect of the intervention. In future studies, a planned schedule of phone calls every other week for a 12-week intervention or every month for a 24- week or longer intervention would be more feasible. The investigator could stagger the calls over a 2 or 4-week time frame, allowing more time and opportunities to reach women by phone within a given week.

# Study Aims Analysis

Next, the analyses of the three aims of the study were conducted. The analysis of each aim is discussed under separate sections. Table 8 lists the baseline and posttest means and standard deviations by group for the outcome measures and hypothesized

Table 8: Outcome measures pre and post, N=42

Measure	Interver	Intervention, N=20	Control. N=22	N=22
	Pre M (SD)	Post M (SD)	Pre M (SD)	Post M (SD)
7-day physical activity recall (kcal/kg/day)	242.0 (15.78)	243.32 (19.04)	249.05 (30.74)	241.59 (16.93)
12 minute walk test (meters)*	1206.68 *(165.35)	1301.05 (228.71)*	1214.18 (179.76)*	1208.85 (196.02)*
Self-Efficacy-Sticking to it Score range: 1.0 to 5.0	3.99 (.563)	4.0 (.711)	4.01 (.655)	3.95 (.619)
Self-Efficacy-Making time Score range: 1.0 to 5.0	4.13 (.565)	4.35 (.535)	4.08 (.755)	4.13 (.690)
Social Support-family participation Score range: 10-50 **	25.55 (6.19)**	28.30 (8.95)**	21.86 (5.12)**	25.68 (8.62)**
Social Support friends participation Score range: 10-50***	15.90 (5.64)***	24.85 (8.34)***	17.09 (6.29)***	25.68 (8.62)***

\*= significant interaction effect, P= .057
\*\*= significant main effect, p=.004
\*\*\*= significant interaction effect, p=.004

mediators. Exercise frequency was the dimension of exercise adherence used for exercise adherence for analysis. It was obtained by summing the entries recorded in the logbooks throughout the 12 weeks. Thus, there is only one value for exercise frequency for each participant. The skewness of the distribution for each measure was determined using the formula: skew statistic/standard error for skew. If the skewness value was between –1.96 to 1.96 then the variable was considered normally distributed. The scores on the outcome variables and the hypothesized mediators were normally distributed except exercise adherence, PAR pretest, PAR posttest, social support from friends' participation pretest, and self-efficacy making time for exercise pretest. Because the skewness values for these variables were relatively close to the range the original values were used for analysis rather than performing a transformation, such as a log transformation, in an attempt to normalize the distribution.

#### Aim 1

Aim 1: Determine the magnitude of change in exercise adherence, cardiorespiratory fitness, and physical activity for rural women engaged in HTH and rural women in the control group and whether this magnitude differs significantly for rural women in HTH and rural women in the control group.

Hypothesis: Rural women in HTH will have a greater magnitude of change in exercise adherence, cardiorespiratory fitness, and physical activity than rural women in the control group.

#### Exercise Adherence

Exercise adherence was determined from the frequency dimension of exercise adherence. The total number of entries that women recorded in the logbooks was 37 for

women in the HTH group and 40 for women in the control group. The range was from 5-67 for women in the HTH group and from 0 to 115 for women in the control group. If women had followed the exercise prescription then the total possible number of entries would be between 50 and 54. However, several women walked more than once a day and walked 30 minutes or greater each time and therefore, had multiple entries per day.

Figures 4 and 5 are bar graphs that illustrate the total exercise frequency for women in the HTH group and in the control group. Thus, women in the control group recorded slightly more entries than women in the HTH group during the 12-week study period.

A T-test for independent samples was conducted to determine if there was a statistically significant difference in exercise frequency between the women in the HTH group and women in the control group. The assumptions of interval level data and random assignment of the T-test were met and the assumption of normal distribution was not met for the exercise adherence variable. The skewness value was 8.95, indicating considerable skewness to the data. However, the T-test was still conducted. The difference between the groups was not significant, t = -.447, p = .658 (table 9).

There are several possible reasons to explain these unexpected results that did not support the hypothesis. These reasons are related to the reliance on self-report. Two women in the control group did not hand in any logbooks. Three women in the control group did not hand in the third logbook. Four women in the HTH group only handed in the first logbook. One woman in the HTH group just recorded an estimated number of times walked in a week rather than recording separate entries in the logbook. Several women in the HTH group verbally reported the number of times they walked in a week, either at the group walk or during a phone call, and did not record these as entries into the

logbooks. Since this information was reported informally, the investigator did not enter them into the logbook records. Five women in the HTH group handed in their third logbook at the last group-walk and did not record any sessions for the 12<sup>th</sup> week of the program. In these five cases mean substitution was used to determine an entry for the 12th week and entered into the logbooks by the investigator. The HRM that women in the HTH group used stored one exercise time a week in its memory. These data were downloaded each week. In some cases the data downloaded from the HRM were not recorded as entries in the logbooks. These were added as entries in the logbooks by the investigator. In addition, attendance records were matched with the recorded entries in the logbooks. In some cases women attended a group walk and did not record it in the logbook. These were added as entries into the logbooks by the investigator. Finally, two women, one in the control group and one in the HTH group, chose to accumulate 30 minutes of walking during a day in either 2 15-minute walks or 3 10-minute walks. In these cases, the 2 or 3 entries were combined into 1 entry because entering either 2 or 3 would have falsely inflated the number of times the women walked during the 12-week period. However, if any women walked more than once a day and each time she walked for 30 minutes or longer than each time was entered as a separate entry. Thus, one can conclude that the entries recorded in the logbooks did not accurately reflect the actual number of times walked during the twelve-week program. Although the logbook is a valuable tool for self-monitoring, which is one of the processes of change and which increases self-efficacy, it is not an accurate tool to measure exercise adherence. In future studies it is recommended that logbooks be incorporated into an intervention for the purpose of self-monitoring rather than for data collection.

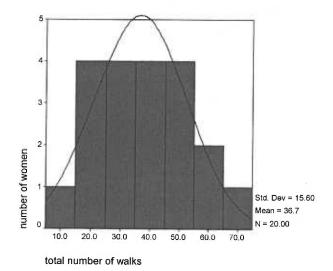


Figure 4: Exercise Frequency in HTH group, N=20

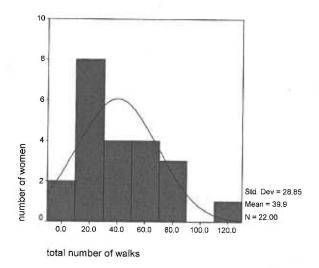


Figure 5: Exercise Frequency in Control Group, N=22

Table 9: T-Test: Exercise Frequency, N=42

	t	df	Sig. (2- tailed)	Mean Difference	Std. Error Difference		of the
Equal variances assumed	436	40	.665	-3.16	7.263	Lower -17.842	Upper 11.525
Equal variances not assumed	447	32.923	.658	-3.16	7.071	-17.551	11.224

Another explanation for the unexpected results is related to three women in the control group receiving part of the group-based components of HTH. One woman, who was disappointed that she was not randomized to the HTH group, joined a group-based walking program through an athletic shop in Salem. She was an outlier in the control group with a total of 115 separate exercise entries. Additionally, two women who were friends both wanted to participate in the HTH group. When they were randomized into the control group they decided to form a walking group so that they could reap the benefits from being part of a group. The total number of walks for these women was 85 and 72. These three women in the control group sought out and most likely obtained some of the beneficial features of the team building and group formation aspects of the HTH program. These three women "dropped-in," that is they received some dose of the treatment (Friedman, Furberg, & DeMets, 1998). Hence, based on the hypothesis of aim one, these women would be expected to have a greater level of exercise adherence as measured by exercise frequency because they in essence received part of the HTH intervention.

Based on the intention-to-treat principle all women who completed the study were included in the analysis. However, a subsequent analysis was conducted without the three women in the control group who "dropped-in" to the team building and group formation aspects of the HTH program. The subsequent analysis provided an examination of the study aims by comparing women in the control group who received no benefits from participating in a group with women in the HTH group. All women in the HTH group were retained in all the analyses regardless of the dose of the intervention they received. This was done to measure the effectiveness rather than the efficacy of the HTH program

in a rural setting (Shadish, Cook, & Campbell, 2001). Thus, each study aim was analyzed with the intent-to-treat analysis and with a subsequent analysis that excluded the three drop-ins from the control group.

The subsequent analysis for exercise adherence did not reveal a statistically significant difference between women in HTH group and the control group. The mean number of entries in the logbooks in the intervention group was 37 and in the control group was 32. An independent T-test was conducted to determine if there was a statistically significant difference. There was not a significant difference, t=.836, p=.408 (table 10).

# 12 Minute-Walk-Test

The 12 MWT was used to measure cardiorespiratory fitness. A repeated-measures analysis of variance (ANOVA) was conducted to determine if women in the HTH group compared to women in the control group had a greater magnitude of change in cardiorespiratory fitness. The assumptions for ANOVA of random assignment, mutually exclusive groups, interval level data, and normal distribution were met. The test of sphericity was significant and therefore, the correction with the Greenhouse-Geisseer is reported. This is the most common correction calculated by SPSS and therefore, it is reported. However, the F-value and p-level were the same for the corrected and uncorrected test result, F(1,39) 3.852, p= .057 with an observed power of .106 (table 11). Since the level of significance was very close to the a priori established value of .05 it can be concluded that there was a strong trend towards an interaction effect between group assignment (the intervention) and time. Figure 6 illustrates the interaction effect between group and time. Although this result does not support the hypothesis, it does illustrate a

Table 10: T-Test: Exercise Frequency, N=39

	t	df	Sig. (2-	Mean Difference	Std. Error Difference	95% cor Interval	
			tailed)			differen	
Equal variances assumed	.836	37	.408	4.86	5.809	Lower -6.912	Upper 16.628
Equal variances not assumed	.830	33.650	.412	4.86	5.850	-7.034	16.750

trend toward a larger magnitude of change in cardiorespiratory fitness between women in the HTH group and in the control group. It is possible that a statistical difference was not found because of the low observed power. Sometimes in pilot studies a more liberal alpha of .10 is used. If an alpha of .10 was used in the analysis then the observed power would increase to .612 and the p-value would be considered significant and therefore, support the hypothesis. It is postulated that with a larger sample size, and therefore more power, a statistically significant greater magnitude of change in cardiorespiratory fitness is probable for women in the HTH group compared to women in the control group.

Since the magnitude of the difference between the two groups reached statistical significance, with an alpha of .10, an effect size was calculated from the means and pooled standard deviations. The following formula was used:

(E<sub>post</sub>- E<sub>pre</sub>)- (C<sub>post</sub>-C<sub>pre</sub>)/ $\sqrt{[(\sigma_1^2 + \sigma_2^2)/2]}$ , where E= the means of the HTH group, C= the means in the control group, and  $\sigma_1$ ,  $\sigma_2$  = the pretest standard deviation of the HTH and Control groups. The resulting effect size, d, was .58. According to Cohen's criteria this demonstrates a moderate effect. Thus, the HTH intervention improved cardiorespiratory fitness in rural women. Therefore, the HTH intervention warrants further testing with a larger sample of rural women.

A subsequent analysis without the three women in the control group who dropped-in was conducted. A repeated- measures ANOVA was conducted to determine if women in the HTH group compared to women in the control group had a greater magnitude of change in cardiorespiratory fitness. This analysis revealed a statistically difference between women in the HTH group and women in the control group. The interaction effect of group and time was significant, F(1,36) = 4.531, p = .040, with an

Table 11: ANOVA: 12 Minute Walk Test, N=42

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	40423.379	1	40423.379	3.074	.087	.073
Time *	50656.598	1	50656.598	3.852	.057	.090
Group						
Error (Time)	512909.597	39	13151.528			

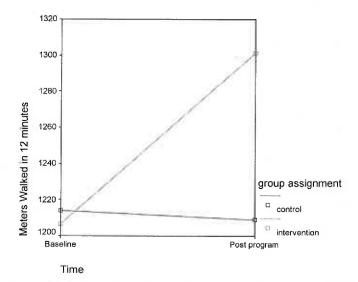


Figure 6: Interaction effect of group assignment and change in cardiorespiratory fitness over time

observed power of .545 (table 12). The significant interaction effect is depicted in figure 6. Using an alpha of .10 the observed power was .671. Since there was a significantly greater increase in cardiorespiratory fitness in the women in the HTH group, an effect size was calculated using the formula he following formula was used:  $(E_{post}$ -  $E_{pre})$ -  $(C_{post}$ -  $C_{pre})$ /  $\sqrt{[(\sigma_1^2 + \sigma_2^2)/2]}$ , where E= the means of the HTH group, C= the means in the control group, and  $\sigma_1$  and  $\sigma_2$ the pretest standard deviation of the HTH and Control groups. The resulting effect size, d, was .648. According to Cohen's criteria this demonstrates a moderate effect. This significant difference between groups supports the hypothesis that women in the HTH group compared to women in the control group would have a greater magnitude of change in cardiorespiratory fitness. In this subsequent analysis, there was an even greater magnitude of difference in cardiorespiratory fitness between the two groups. This confirms the effectiveness of the HTH program with a population of rural women.

The length of time between the end of the 12-week program and the performance of the 12 MWT may explain why the hypothesis was not supported in the intent-to-treat analysis. There is a marked decline in cardiorespiratory fitness after two weeks without exercise, returning to previous fitness levels within two and a half to eight months. Four to twelve weeks without exercise can result in the loss of 50% of the training gain in cardorespiratory fitness (Pollock et al., 1998). There were varying lengths of time between when a woman completed participation in the 12-week program and the posttest 12 MWT was conducted (table 13). Seven woman in the HTH group and 3 women in the control group completed the 12 MWT after 2 weeks when a marked decline in cardiorespiratory fitness occurs. And, 2 women in the HTH group and 1 woman in the

Table 12: ANOVA 12 Minute Walk Test, N=39

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	N - X
Time	2656.961	1	26568.961	1.952	.171	.051	*************
Time *	61674.013	1	61674.013	4.531	.040	.112	
Group							
Error (Time)	489966.562	36	13610.18				

Table 13: Length of time between end of program and posttest

Number of weeks after program completed 12 MWT	Number women in HTH group	Number women in the control group			
1	1	5			
2	11	13			
3	6	3			
4	1	0			
5	0	1			
6	1	0			

control group completed the 12 MWT after 4 weeks when they could have potentially lost 50% of the gain in cardiorespiratory fitness that they had achieved by participating in the program. More women in the HTH group than in the control group completed the 12 MWT after enough time had lapsed since the end of the program to negatively affect the gains in cardiorespiratory fitness achieved from the program. Two of the three women not included in the subsequent analysis completed their posttest 12 MWT within a week and the third woman completed it within two weeks. It is conceivable that if all the women had completed the 12 MWT within 2 weeks after the end of the 12-week program, there may have been a significantly greater improvement in cardiorespiratory fitness among women in the HTH group compared to women in the control group in the intent-to-treat analysis.

The challenge in finding time that each woman and the investigator could meet explains the length of time between the end of the 12-week program and the administration of the posttest. Appointments were scheduled around the women's work and other commitments and the investigator's other study (recruitment, conducting the intervention), teaching, and family commitments. This left limited time available in which to schedule appointments. In addition, the investigator was a 1 ½ to 2-hour drive away from the location where the testing occurred. The testing was conducted near the women's home. Furthermore, some women traveled out of town for extended periods of time right after completing participation in the 12-week program. Women traveled to fulfill work or family obligations. In subsequent studies, it is recommend that one investigator conduct the recruitment and administer the baseline and pottest measures and another investigator conduct the intervention. Additionally, training women who live in

the community to conduct the recruitment, the testing, and the intervention will reduce the travel time to a minimum and increase access to the community. This will allow for each investigator to focus on specific parts of the study and increase available time in which the investigator could schedule appointments.

# Physical Activity

The amount of physical activity performed in kcal/kg/day during the previous week was calculated from the 7-day physical activity recall (PAR). A repeated-measures ANOVA was conducted to determine if women in the HTH group compared to women in the control group had a greater magnitude of change in physical activity. The assumptions for ANOVA were met except the PAR pretest and posttest were not normally distributed. The skewness value was 7.83 for PAR pretest and 2.96 for PAR posttest. The test of sphericity was significant and therefore, the correction with the Greenhouse-Geisseer is reported. This is the most common correction calculated by SPSS and therefore, it is reported. However, the F-value and p-level of F(1,39) 1.01, p=.319were the same for the corrected and uncorrected test result (table 14). Thus, this indicates that there was not a significant interaction effect. It can be concluded that there was not a significant difference in the magnitude of change in physical activity between women in the HTH group and women in the control group. In addition, there was not a significant main effect, F(1,39). 499, p=.484 (table 14). Thus, there was no difference in physical activity over time for women within the HTH group and within the control group. Since there were no statistically significant differences, either between the groups or within the groups, an effect size was not calculated.

Table 14: ANOVA: Physical Activity Recall, N=42

Source	Type III Sum of	df	Mean	F	Sig.	Partial Eta
	Squares		Square		_	Squared
Time	192.098	1	192.098	.499	.484	.013
Time *	392.098	1	392.098	1.018	.319	.025
Group						
Error (Time)	15024.780	39	385.251			

In the subsequent analysis this lack of a significant difference persisted. There was not a significant interaction effect, F(1,36) = .480, p=.493 (table 15). There was not a significant main effect, F(1,36) = .157, p=.694 (table 15).

There are several possible reasons that statistically significant differences over time, either within the groups or between the groups, were not found. The questionnaire used to measure physical activity, (PAR), relies on self-report calling into question its accuracy in measuring physical activity.

The women may not have correctly recalled their physical activity over the last week. Typical household chores are not necessarily that memorable compared to a planned and structured bouts of exercise and therefore the frequency and duration of these activities may not be recalled accurately. Sallis and Saelens (2000) in a recent assessment of physical activity recall measures postulate that the low validity of recall questionnaires is related to the low salience of these unplanned and routine activities. Women may have over reported their amount of physical activity in order to provide the perceived socially desirable response of engaging in at least some moderate or greater intensity physical activity daily. Furthermore, several of the women commented that they did not want to appear as though they had done nothing during the week being recalled. This sentiment indicated that some women equated light or sedentary activities with doing nothing. This belief may also have lead to an over reporting of physical activity because they wanted to appear productive with their time. Thus, the PAR may not accurately portray the frequency and duration of physical activity.

In addition, the women may have reported either a higher or lower intensity level to the physical activities than was actually the case. Although, the investigator did try to

Table 15: ANOVA: Physical Activity Recall, N=39

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	59.066	1	59.066	.157	.694	.004
Time * Group	180.118	1	180.118	.480	.493	.013
Error (Time)	13513.36	36	375.370			

determine the actual activity, in some cases the women were vague and it was difficult to ascertain if the reported intensity level was an adequate reflection of the actual level. Recent studies examining the reliability and accuracy of the PAR found that women, particularly sedentary and obese women, over report the amount and intensity of their physical activity (Conway, Seale, Jacobs, Irwin, & Ainsworth, 2002; G. Duncan, Sydeman, Perri, Limacher, & Martin, 2001; Hayden-Wade, Coleman, Sallis, & Armstrong, 2003). In one study the correlation (Pearson product coefficients) between the 7-day PAR and a TriTrac accelerometer were .32 for moderate intensity activity but .74 for very hard intensity of activity (Hayden-Wade et al., 2003). Another study ascertained that the PAR overestimated energy expenditure by 30% compared to the doubly labeled water method, which is considered the gold standard (Conway et al., 2002). Additionally, women who are less fit compared to women who are more fit tend to report a higher intensity level for similar types of physical activity (G. Duncan et al., 2001). Based on these studies, it is postulated that the women in the current study most likely over rated the intensity of their physical activity.

Another possible explanation is the effect of history on the PAR. Women in the third session completed the PAR the week after the New Year's holiday; whereas, women in the other two sessions did not complete their PAR right after a holiday week. The women in the third session may have been less active during the week between the Christmas and New Year's holidays and this would have been reflected in the posttest PAR.

Of concern is that the intensity categories for the 7-day PAR have not been validated against objective measures of physical activity, such as a HRM or

accelerometer (Hayden-Wade et al., 2003). Recently as part of a larger study, the fixed MET values used to determine energy expenditure in the PAR were examined. These values over estimated the actual energy expenditure in middle-aged, sedentary adults (G. Duncan et al., 2001). Although the PAR is widely used, it does not accurately reflect the intensity of physical activity, particularly moderate intensity, and therefore energy expenditure of physical activity in adults. Since current exercise recommendations state that moderate intensity exercise is sufficient to achieve health benefits, it is important to reconsider the use of the PAR to determine energy expenditure.

Although the hypothesis of aim 1 was not supported in the intention-to treat analysis there were some promising findings pointing to the effectiveness of the HTH program to improve cardiorespiratory fitness and therefore reduce the incidence of heart disease in rural women. In future studies, using exercise logbooks for self-monitoring rather than data collection is recommended. Also, the use of the PAR as a data collection tool needs to be reexamined before use in future studies. The statistically significant results indicating a larger magnitude of change in cardiorespiratory fitness between women in the HTH group and in the control group combined with the effect size of .58 provides evidence that the HTH intervention warrants further testing. Furthermore, the subsequent analysis supported the hypothesis that women in the HTH group compared to women in the control group experienced a greater increase in their cardiorespiratory fitness. Since the subsequent analysis removed the impact of team building and group formation on the three women in the control group who participated in a group, it is considered a more accurate reflection of the effectiveness of the HTH intervention with rural women.

Aim 2: Examine the magnitude of the change in self-efficacy and social support for rural women in HTH and rural women in the control group and whether the magnitude of change differs significantly for rural women in HTH and rural women in the control group.

Hypothesis: Rural women in HTH will have a greater magnitude of change in self-efficacy and social support than rural women in the control group.

There were two factors for self-efficacy and three factors for social support that were analyzed. Four repeated measures ANOVAs and one independent T-test were conducted to examine this study aim. The independent variable was group assignment (the intervention) in each ANOVA. The dependent variable was selfefficacy sticking to it in the first ANOVA, self-efficacy making time for exercise in the second ANOVA, social support from family participation in the third ANOVA, and social support from friends participation in the last ANOVA. The assumptions for the ANOVA were met except the social support from friends participation was not normally distributed with a skewness value of 2.4, and self-efficacy making time for it posttest was not normally distributed with a skewness value of 2.2. However, in both cases the skewness value is close to that of 1.96 the upper limit of the skewness value for normal distribution. In addition, the test for sphericity is significant: therefore, the corrected test, Greenhouse-Geisser, is reported. It is reported because it is the most common correction calculated by SPSS. Therefore, the ANOVAs were still conducted. An independent T-test examined the difference in social support from

family, rewards and punishments. Only the posttest values were examined because the scale was not valid in the pretest.

## Self-efficacy

Self-efficacy was analyzed in the first two ANOVAs. The first ANOVA examined self-efficacy sticking to it. There was not a significant interaction effect, F (1,40)=.10, p=.754 (table 15). Thus, there was not a difference in the magnitude of change on self-efficacy sticking to it between women in the HTH and control groups. Additionally there was not a significant main effect, F(1,40)=.056, p=.814 (table 16). In the subsequent analysis there were not statistical differences either within groups or between groups (table 17). Therefore, there was not a difference in the magnitude of change on self-efficacy sticking to it over time for women within the HTH or control groups.

The second ANOVA examined self-efficacy making time for exercise. There was not a significant interaction effect, F (.421), p= .520 (table 18). Thus, there was not a difference in the magnitude of change on self-efficacy making time for exercise between the HTH and control groups. And, there was not a significant main effect, F (1,40)= 1.166, p= .287 (table 18). Thus, there was not a difference in the magnitude of change on self-efficacy making time for exercise over time for women within the HTH or control groups. In the subsequent analysis the lack of a significant interaction or main effect persisted (table 19).

The hypothesis that women in the HTH group would experience a greater magnitude of change in self-efficacy was not supported. In both scales the women's baseline level of self-efficacy was close to or greater than 4.0, indicating a high level of

Table 16 ANOVA: Self-efficacy sticking to it, N=42

Source	Type III Sum of	df	Mean	F	Sig.	Partial Eta
	Squares		Square			Squared
Time	.013	1	.013	.056	.814	.001
Time * Group	.024	1	.024	.100	.754	.002
Error (Time)	9.553	40	.239			

Table 17 ANOVA: Self-efficacy sticking to it, N=39

Source	Type III Sum of	df	Mean	F	Sig.	Partial Eta
	Squares		Square		_	Squared
Time	.141	1	.141	.613	.438	.016
Time * Group	.170	1	.170	.741	.395	.020
Error (Time)	8.491	37	.229			

Table 18 ANOVA: Self-efficacy making time for exercise, N=42

Source	Type III Sum	df	Mean	F	Sig.	Partial Eta
	of Squares		Square			Squared
Time	.369	1	.369	1.166	.287	.028
Time * Group	.133	1	.133	.421	.520	.010
Error (Time)	12.667	40	.317			

Table 19 ANOVA: Self-efficacy making time for exercise, N=39

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	.202	1	.202	.634	.431	.017
Time * Group	.239	1	.239	.747	.393	.020
Error (Time)	11.808	37	.319			

self-efficacy prior to starting the 12-week program. Women in both groups experienced a minimal increase in their level of self-efficacy; however, there was most likely a ceiling effect because the highest possible score was a 5.0. Thus, there was not much improvement that could be measured using these scales.

Additionally, the measurement of self-efficacy poses challenges and these challenges may have impacted the results in this study. Experience can impact the estimation of self-efficacy. Those who have not experienced particular barriers to exercise may over or under estimate their capability to surmount them (DuCharme & Brawley, 1995). The context and frequency in which a women may have encountered a barrier will impact encoding and retrieval of the experience and hence influence the perceived confidence in overcoming the barrier. This causes either over or under estimation (Menson & Yorkston, 2000). In studies measuring the change in self-efficacy in response to an intervention the initial over or under estimation can be problematic because a change in self-efficacy score from pre to post intervention may not be due to the intervention but rather individuals' adjusted appraisal of their capabilities in light of recent experience. It is possible that the women didn't have much experience with the barriers described in the self-efficacy questionnaire used in this study and hence initially overestimated their self-efficacy. The women may have had a greater improvement in their self-efficacy than was reflected in their change scores on the questionnaire over time because of an initially overestimation of their self-efficacy.

Emotional responses at the time of an event also impact the encoding and retrieval of the memory of that event (Kihlstrom, Eich, Sandbrand, & Tobias, 2000). Low levels and very high levels of emotional arousal are associated with poor encoding and therefore

limited ability to retrieve memories from these events (Kihlstrom et al., 2000). On the other hand moderate to high levels of emotional arousal are associated with higher levels of attention, improved encoding and improved retrieval of memory (Kihlstrom et al., 2000). The level of emotional arousal experienced with respect to beginning but not persisting in an exercise program in the past may impact self-report responses on an instrument to measure self-efficacy. Indeed, McAuley and colleagues (1990) found that some women reported experiencing intense emotion, such as shame, guilt or frustration, in response to dropping out of an exercise program. And, these women experienced similar intense emotions when recalling this past attempt at exercise even if a considerable time had passed. Thus, those with a moderately strong emotional response and therefore more easily retrieved memory may underestimate their capability to surmount barriers to exercise whereas those with less emotional arousal and less easily retrieved memory may overestimate their capability. In the current study the women reported relatively high levels of self-efficacy. Possibly the women overestimated their capability because past attempts at exercise did not cause strong negative emotions and hence were not well encoded or retrievable.

## Social Support

Social support was analyzed in the remaining two ANOVAs. The third ANOVA analyzed social support from family participation. There was not a significant interaction effect, F(1,40)=.246, p=.623 (table 20). Thus, there wasn't a difference in the magnitude of change on social support family participation between women in the HTH and control groups. There was a significant main effect, F(1,40)=9.304, p=.004 (table 20). These same results hold in the subsequent analysis;

Table 20 ANOVA: Social Support family participation, N=42

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	225.977	1	225.977	9.304	.004	.189
Time * Group	5.977	1	5.977	.246	.623	.006
Error (Time)	971.511	40	24.288			

Table 21 ANOVA: Social Support family participation, N=39

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Time	198.402	1	198.402	7.978	.008	.177
Time * Group	3.786	1	3.786	.152	.699	.004
Error (Time)	920.086	37	24.867			

there is not a significant interaction effect but there is a significant main effect (table 21). These findings indicate that there was difference in the magnitude of change of social support family participation over time for women within both the HTH and the intervention groups. Figure 7 depicts the change over time of social support from family participation within the HTH group and control group. Social support from family increased for women in both the HTH intervention group and control group. This was a surprising finding because most women, in both groups, reported that family responsibilities were a significant barrier to exercise. Furthermore a frequent topic in the weekly group discussions was frustrations with and strategies for balancing family responsibilities with exercise goals. A previous group-based intervention targeted at women with young children found an increase in social support from friends and partners but not other family members (Cody & Lee, 2000). The measure used in this current pilot study did not differentiate partner and other family members support. In a future study it may be instructive and aid in the development of strategies to promote exercise to differentiate the source of family support.

An independent T-test was conducted to determine if there was a difference in the posttest scores on family participation, rewards and punishments. There was not a statistically significant difference between women in the HTH group or the control group on social support from family, rewards and punishments in either the intention-to-treat analysis or the subsequent analysis (tables 22 and 23). This scale did not appear to pertain to this sample of women. Most did not experience any of the three situation described in the questions.

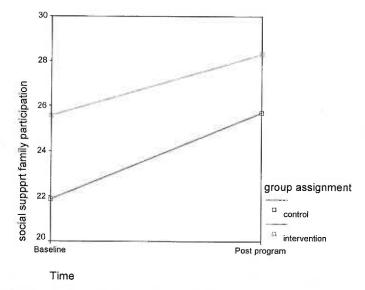


Figure 7: Main effect of change in social support family participation over time

Table 22: T-Test: social support family, rewards and punishments, N=42

	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% con Interval difference	of the
Equal variances assumed	-1.082	40	.286	46	.428	Lower -1.329	Upper .402
Equal variances not assumed	-1.067	38.876	.293	46	.434	-1.346	.418

Table 23: T-Test: social support family, rewards and punishments, N=39

	t	df	Sig. (2- tailed)	Mean Difference	Std. Error Difference	95% con Interval differen	of the
Equal variances assumed	-1.147	37	.259	52	.454	Lower -1.442	Upper .400
Equal variances not assumed	-1.155	35.461	.256	52	.451	-1.437	.395

The HTH intervention did not target increasing social support from families. A meta-analysis analyzing the impact of social influences on exercise adherence determined that social support from friends and important others had more impact than family members on exercise adherence (Carron et al., 1996). These researches proposed that the support from friends or important others may have a stronger influence because these individuals are less well known than family members and therefore, their support is more meaningful than a family member because it is less frequent and less expected. Therefore, the HTH emphasized social support from fellow group members and the investigator.

The final ANOVA analyzed social support from friends, participation. There was a significant interaction effect, F(1,40)=9.141, p=.004 (table 24). In the subsequent analysis there was a significant interaction effect as well, F(1,37)=8.349, p=.006 (table 25). Thus there is a significant difference in the magnitude of change of social support from friends, participation between women in the HTH and the control group. Figure 8 illustrates the interaction effect between the groups over time. This demonstrated significantly greater increase in social support from friends for women in the HTH group compared to women in the control group supports the hypothesis.

The HTH intervention was designed to increase social support from friends by creating a cohesive group, which provided social support, thereby increasing the level of social support from friends. At the end of the intervention women planned to continue the weekly group walks in part because of the support provided by the group. In the group discussion women reported feeling validated and supported by members in the

Table 24: ANOVA: Social support friends participation, N=42

Source	Type III Sum	df	Mean	F	Sig.	Partial Eta
	of Squares		Square			Squared
Time	572.013	1	572.013	17.985	.000	.310
Time * Group	290.727	1	290.727	9.141	.004	.186
Error (Time)	1272.225	40	31.806			

Table 24: ANOVA: Social support friends participation, N=39

Source	Type III Sum	df	Mean	F	Sig.	Partial Eta
	of Squares		Square			Squared
Time	524.004	1	524.004	15.843	.000	.300
Time * Group	276.158	1	276.158	8.349	.006	.184
Error (Time)	1223.791	37	33.075			

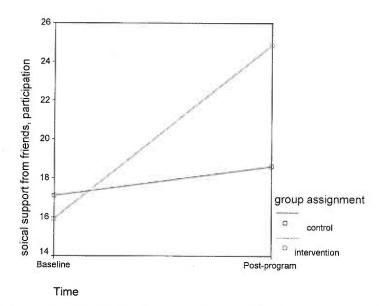


Figure 8: Interaction effect of group assignment and change over time in social support from friends.

group and enjoying the camaraderie of the group. However, a few women found a friend who was not part of the group to walk with outside of the weekly group walk. The social support measure did not distinguish support from friends who were group members and friends who were not group members. It is probable that the increase in social support came from both members of the group and friends outside the group. In future studies it may be informative to distinguish the source of the social support from either group members or friends outside the group.

Since there was a significantly greater increase in social support from friends, participation, the effect size was calculated from the means and pooled standard deviations. The following formula was used:  $(E_{post}$ - $E_{pre})$ -  $(C_{post}$ - $C_{pre})$ /  $\sqrt{[(\sigma_1^2 + \sigma_2^2)/2]}$ , where E= the means of the HTH group, C= the means in the control group, and  $\sigma_1$  and  $\sigma_2$ . = the pretest standard deviation of the HTH and Control groups. The effect size, d, was 1.3. Using this same formula with the means and pooled standard deviations in the subsequent analysis, the effect size, d, was 1.3. According to Cohen's criteria this is a large effect. It can be postulated that the source of the increase in social support was from the women in the exercise group. Thus, the HTH intervention had a powerful effect on increasing social support with rural women.

A recent study determined that social support from within an exercise group is of particular importance in influencing self-efficacy and ultimately exercise adherence in older women (Litt et al., 2002). A study looking at the relationship between social support received from an exercise group and exercise adherence found that provisions of reassurance of worth and guidance were factors that differentiated women who adhered to the exercise program from those who did not adhere (T. E. Duncan et al., 1993). This

strengthens the argument put forth by Carron et al. (1996) that social support from friends or co-exercisers contains more informational messages or guidance and this enhances the strength of the support and ultimately adherence. The findings from these studies support the emphasis in the HTH program on the source of the support coming from the connectedness and cohesiveness in the exercise group rather than from family members. It is probable that the teambuilding and group formation aspects of the HTH program were effective in increasing social support and it is recommended that these aspects of the HTH intervention be retained.

#### Aim 3

Aim 3: Examine whether self-efficacy and social support are mediators between HTH and the outcome variables of exercise adherence, cardiorespiratory fitness, and physical activity.

Hypothesis: Self-efficacy and social support mediate the relationship between HTH and the outcome variables exercise adherence, cardiorespiratory fitness, and physical activity.

Barron and Kenny's (1986) model was used to determine if self-efficacy and social support were mediators by conducting a series of regressions. Only the outcome variable of cardiorespiratory fitness was considered for this analysis because it was only outcome variable in which there was a statistically significant greater improvement in women in the HTH group compared to women in the control group. A change score was calculated for each of the following variables: the outcome of cardiorespiratory fitness and the secondary outcomes of self-efficacy sticking to it, self-efficacy making time for exercise, social support friends, and social support

family. The change score was obtained by subtracting the posttest value from the pretest value to arrive at the change from pretest to posttest. Bivariate correlations were determined between the pretest variables, posttest variables and the change variables. These are listed in tables 26, 27, and 28. Since the outcome variable of the change in cardiorespiratory fitness as measured by the change score on the 12 MWT did not significantly correlate with any of the secondary outcomes, the test for a mediator was not conducted. If there is not a linear relationship between the hypothesized mediator and the outcome of cardiorespiratory fitness then there cannot be a mediating relationship.

Social support and self-efficacy are interrelated. According to the social cognitive theory, social support strengthens self-efficacy (Bandura, 1997). Two recent studies examined the role of social support on physical activity with older adults. In both studies a path analysis determined that social support had an indirect relationship with physical activity level by influencing self-efficacy which in turn influenced physical activity (E. McAuley et al., 2003; Resnick & Nigg, 2003). It can be conjectured that this relationship may hold for adults at other ages. In that case, the high effect size of the HTH intervention on social support suggests that the HTH intervention may have increased self-efficacy in addition to social support. If women overestimated their level of self-efficacy at baseline then any increase in self-efficacy would not have been captured because of the falsely high levels at baseline. If the increase in social support had impacted the level of self-efficacy it would not have been detected. Therefore any influence from an increase in self-efficacy on cardiorespiratory fitness would not have

been discovered, potentially suppressing the ability to detect the indirect influence of social support on cardiorespiratory fitness.

Table 26: Bivariate correlations of study variables pretest, N=42

71011 .072	.041 .010 .430**	.316* .136	101 .229
.072			229
	120**		
	.430.	.025	.136
		251	.019
			.353*

<sup>\*</sup> significant at p=.05 level \*\* significant at p=.01 level

Table 27: Bivariate correlations of study variables posttest, N=42

Variables	1	2	3	4	5	6
1. Group assignment		.217	.041	.173	.151	.356*
2. 12 MWT			.032	.146	.317*	.165
3 Self-efficacy: sticking to it				.371*	.269	.243
4. Self-efficacy: making time					.103	.328*
5. Social support: family participation				5		.257
6. Social Support: friends participation						

<sup>\*</sup> significant at p=.05 level \*\* significant at p=.01 level

Table 28 Bivariate correlations of study change variables, N=42

Variables	1	2	3	4	5	6
1. Group assignment		.300	.006	.102	078	.431**
2. 12 MWT			005	024	122-	.152
3 Self-efficacy: sticking to it				.405**	074	.237
4. Self-efficacy: making time					057	.213
5. Social support: family						.157
participation						
6. Social Support: friends						
participation						

<sup>\*</sup> significant at p=.05 level \*\* significant at p=.01 level

Describe HTH participants' experiences with the intervention to aid in refinement of HTH.

This aim was analyzed using data from field notes of the weekly group walks and the individual phone calls as well as from the three focus groups. The focus group discussions were audio-tape-recorded and transcribed by the investigator. The data was analyzed using qualitative content analysis or descriptive analysis (Sandelowski, 2000). Data were coded based on emerging themes and concepts that reflected the women's experiences. Researchers in the qualitative seminar, including faculty with expertise in qualitative analysis, reviewed the coding to ensure it was grounded in the data and the summary analysis to ensure it was an accurate portrayal of the participants' experiences.

The major themes that emerged were categorized into barriers and motivators.

The barriers included family responsibilities, work responsibilities, travel, poor health, negative physiological responses to exercise, and the weather. Family responsibilities emerged as the predominant and most difficult barrier to overcome. The main motivators were social support, accountability and commitment to a walking partner and group members, positive physiological changes from exercise, increased confidence, role models, and self-monitoring. Many of the motivators described by the women coincided with specific components of the HTH intervention.

The following description of the women experiences with HTH is organized into their experiences with the group-based and individual-oriented aspects of HTH.

## **Group-Based Aspects**

Group Commitment

The commitment to the group walk helped many women begin to embark on regular exercise. Many women struggled with balancing family responsibilities and fitting in time to walk. They expressed the sentiment that if they went out and exercised that they were at some level abandoning the family during that time frame. Several women observed that being committed to a group that met regularly made it easier to justify to themselves and their family the time they spent at the group.

Because I think not so much for me but for them [family members] they knew, Monday night I did this and there was no question about it I couldn't cancel. I was devoted to a group. So being part of a group made a difference. It was a set thing, and a set time. And I could just say I have got a meeting. I have got my meeting that night. So it gave enough incentive for everybody to find their own hours other days of the week to do it on.

Several discussed the importance of the group meeting to getting out and walking: Below is an interchange that occurred in one of the focus groups that illustrates the importance of the group to getting out and exercising.

"You know if I have a meeting with someone, someone else then I don't feel guilty taking time out."

"Right it is a hard thing to do otherwise."

"Yeah."

"Yeah."

"It is hard to do and that way you know there are other people waiting."

"You fight with it if it is just me and I just have this."

"Having a set time is helpful too."

"No matter what is going on"

"For me once I tend to get home then it is hard for me to get motivated to leave again. And this is something that I could do."

Additionally, the women's accountability to the group propelled them through the tough days. For example, one woman who began to notice an improvement in fitness stated the

connection with the group kept her motivated to walk and therefore build on the early changes.

I noticed even like when the weather was real hot I still it's like if I had been on my own I would have said ah it's hot out I don't want to go out there. But you know I figured well they are going to be there and it is only for 45 minutes you know. So there is definitely that accountability and camaraderie and that had a big impact.

The support of the group assisted her in sticking with it despite experiencing barrier of extreme weather. The consistency of the group walk provided a foundation from which women could create a regular pattern of exercise that was accepted by family members and in concert with family needs.

Several stated that the accountability to the group provided motivation to walk on the other days of the week because they did not want to have to report to the group that they hadn't walked at all since the last group walk. One woman stated, "...if we didn't meet every week I am sure I would not have walked as much. Remember I wanted to be in the individual group [control group] and this really [was helpful]. And another, "the group meeting was more of an incentive to walk [than other aspects of the program]. And another, "I'd say don't miss those ones when you know you got to go for the group." Thus the commitment to the group got them started and the accountability to the group kept them coming and motivated.

## **Group Support**

Group members provided information and advice to each other. Women learned from each other. One woman felt frustrated that she was not losing weight. A group member suggested that she hang in there and she will notice a difference in how she feels from walking. She found that the next week she started to notice improvements. She then

shifted her focus from monitoring her weight to monitoring her fitness and positive physiological changes. She remarked that she felt improved mood, increased stamina, and by the end of the 12 weeks was able to jog up a hill that she had struggled to walk up at the beginning. This information and encouragement from a group member was influential in her continuing to walk until she began to notice positive physiological changes that motivated her to persist with a regular regime.

Women learned from each other's experiences. Initially, women thought that being flexible with their walking time in order to fit around family schedules, particularly children's schedules, was preferable. One woman described a strategy of carrying a change of clothes in her car so that she could respond to last minute changes and be ready to walk at any time. Unfortunately, she learned that frequently she ended up not finding time to walk. One woman described a day where she felt frustrated that the day had gone by and she had not had a chance to walk. She decided to go on her walk at 10pm; however, she felt energized after her walk and had difficulty going to sleep afterwards. Another woman discussed her frustration with family demands usurping her exercise time. She summed up her frustration:

I mean we talked on a Tuesday night, yep I am going to be there and then I would not make it on Wednesday because in that 24-hour period you know something change. And um so even though I would want to, it is just, it's so hard to make those commitments and not have other things become more important with the way that my family structures, is structured, and my work is structured. It just drives it all out of me. It plays such a huge, huge factor and um things change dramatically in even 24 hours, you know.

One woman found it difficult to walk after work because her son had sports events and husband did not want her to walk alone in dark for safety reasons. One woman succinctly stated, "too much flexibility makes it difficult." Another woman described the

dilemma that they each struggled with in trying to fit their exercise around the family demands:

Well and a lot of things too, most times we are very busy with family, children, obligations, and we don't focus so much on ourselves, for our own nutrition or walking or exercise because we have other family members that take precedence. I have that trouble putting, putting yourself up here and do something good for yourself.

As the women struggled to fit walking into the ever-changing family schedule, they realized that frequently they didn't find a time to walk. Thus, their interaction helped them to realize that the solution that appeared to be the most workable, being flexible, was not necessarily the optimal approach.

The women learned that having an established time set aside for walking made it easier to work around demands from the family and work. Those with school aged-children at home discovered that walking in the morning became the easiest solution. One woman found that going early in the morning was the only time that demands from family would not interfere with her chance to exercise. A few women walked in the early morning after driving their children to school and before work. Women who did not work and had very young children found that taking young children with them in the stroller while walking worked out well. Single woman who worked and had school-aged children had the most difficulty. These women felt uncomfortable walking in the morning and leaving young children asleep and alone in the home. Yet, the children were old enough that they could not just be put in the stroller and taken with them. By sharing their approaches to coordinating with family needs, the women benefited from each other's experiences.

One woman in the group described over the 12 weeks her struggles with fitting in exercise around her family. She discussed her frustration with the group and her realization that she needed to walk in the morning while family members still slept. She described the many positive changes that came about from exercising in the morning, such as increased energy, mental alertness and improved mood. Another woman inspired by her perseverance stated,

I have decided for me, and I have learned this from you and from your determination, that has been really encouraging for me, that all day long I put it off, put it off, and put it off... So I am gong to change my whole schedule and I decided today that and I think I have learned this about myself I have to do it in the morning...And I think that will revolutionize and just reorganize my whole day. So I am excited to force myself to try.

Thus, women learned from themselves and from each other as they tried different strategies to work around the barriers to exercising and toward achieving maximum benefit from the time they could devote to exercise. This interaction assisted them in defining the most advantageous time that they could devote to exercise.

Role Models

Some of the group members were role models for others in the group. During one of the focus groups two women discussed how the example of others encouraged them to work harder.

"I ended up liking the idea of walking with a group more than I thought I would. If I didn't [know] that was going on I think I would slough off on my own time."

"I was actually informed by how the pace of other people walked at. Because I'll lollygag if I can and like walking with K. or L. Yeah like I mean she has like flames flying after her. She would go around the track and I am like OK just two steps faster, two steps, come on, come on. And, you know, so it just, it just helped me, having, helped me pushed a little harder than my, than I am inclined to do."

"It pushed me more. I know I did a lot better when I was out walking with the group then I do when I walk on my own. Sometimes I'll tend to lollygag."

"And it was encouraging though, you know."

Women also observed the progress of each other. This modeling of success strengthened the resolve of those who had yet to develop a regular routine to persist in their efforts to achieve a regular routine. One woman remarked that she was impressed with the noticeable improvements of some in the group walk. And, these noticeable improvements provided encouragement to summon up the energy to continue to surmount the barriers to exercise.

All the women, with the exception of the two who did not engage in the program, reported experiencing support from participating in the group. They reported that the group provided encouragement, knowledge, and validation. Their commitment to the group motivated them to walk with the group and to walk other days of the week. They reported that participating in the group helped them to persist in pursuing a goal of regular exercise. The support women expressed experiencing appeared to be an important aspect in reinforcing their motivation to exercise. These findings suggest that the group-based activities of the HTH provided support for and motivation to exercise.

# Individual Oriented Aspects

Positive Physiological Changes

Five women experienced early positive and in some cases dramatic physiological changes. These early changes strengthened motivation to work through barriers to exercise. These changes prompted women to monitor their progress. Additionally, as their fitness improved their self-efficacy increased further cementing regular exercise into

their life. One woman described her improvement in fitness and self-efficacy and the influence on her exercise participation.

One of the things that, I mean there are several impacts that, that the program has had which I, I find pretty amazing just given, you know given that we have only done it for 12 weeks, um, I think, I definitely feel at a point now that I am consistent with exercise I have no doubt that I'll continue with that, which is a really, really nice feeling. Um, I am still amazed with the Portland to coast that I felt at a place that I could say yeah I'll do it, you know and I would not have been otherwise. Um, I, there is no way I would have felt, because I would have felt like I would not have been able to hold up my end of the deal you know I could have walked it but I would have been slower then I would have wanted but um, so that one was a real good fun one for me. I think the fact that you know that I really want to consistently jog now and that has really become a part of my, my exercise program has a big impact um, and through, through the consistency in exercising as well as I have been doing weight watchers for 8 weeks now I think and I have lost 18 pounds.

The majority of women experienced physiological changes; however, they did not experience them early in the course of the 12-week program. Although, they were walking more than they had prior to participating in the program, by the end of the 12 weeks they were still struggling with developing a regular routine. One woman missed most of the group walks due to work commitments. She experienced positive physiological changes. She realized that she could walk up a flight of stairs without getting short of breath. Because of this she felt confident in her ability to go hiking with friends. On the hike she noticed she was not out of breath. She realized that she might have made even greater strides if she had greater participation with the group; however, she felt she had received some support from the group and that this support made a difference.

Even as a person who did not fully take advantage of the whole deal, which [I didn't] during this 12 weeks actually because I have been part of the group I still have I mean I still have that same desire. I will still

go and you know exercise and when I don't have to drive to X every day I will start walking to work but I don't have that freedom and um every place I go I am in enough better shape where I could have been walking with people and not worried about [deep breathing] behind them and whatever so its, even though I haven't been doing it to the same level I have still made incredible improvements by just participating still and that support.

Thus, the combination of improved fitness and the group support, albeit limited, encouraged her to keep working toward a goal of regular fitness.

Another woman noticed physiological changes early in the program that were motivating. She noticed that she had more control over her body and felt stronger. She had begun to develop a regular schedule of walking and was excited about it. However, she moved out of the area half way though the program and was not able to attend the remainder of the group walks. She continued to receive the individual oriented aspects of the HTH. For example, she continued to keep a logbook, used the heart rate monitor, and received phone calls utilizing motivational interviewing. Once she moved, she reported that she found that she was having difficulty getting back into a regular routine and noted she was losing some of the physical benefit she had initially felt. She felt frustrated and realized that she needed support from the group or a buddy to help her get back to a routine. Thus, continued support from the group appears to be important in augmenting the motivating influence of positive physiological changes.

## Self-Monitoring

The heart rate monitors assisted many of the women in identifying their moderate level of exercise intensity and the corresponding level of exertion. Many stated that they did not know how hard they should walk or push themselves. They wanted to get the maximum benefit. The heart rate monitors allowed them to determine how hard they

needed to walk or jog to gain maximum benefit from their efforts. In addition, the heart rate monitors helped women track their progress. One woman stated, "I think it [the heart rate monitor] gave me a better sense of, where I should [be] of what I should feel like when I am working out." Another stated:

The other thing that I found helpful for me to document my own progress was I used, and not that I won't have a heart monitor now, but I documented my average heart rate and that helped me to see some progress. It also helped me to see that, that if I had been at that same average heart rate maybe I really need to push myself a little bit harder you know that I should be able to, to get a little bit more out of it, myself.

For some it increased the enjoyment of exercising. "It [the heart rate monitor] made it kind of fun I thought, to wear it I mean.... it was a positive feature." Some women liked monitoring their progress in the logbooks; however, most preferred the heart rate monitors. Thus, the heart rate monitors enhanced their awareness of and self-efficacy in performing at the intensity of exercise needed to achieve health benefits as well as increasing their enjoyment with exercising.

#### Chronic Illness

A few women who participated fairly regularly in the group became overwhelmed with their chronic illness. This minimized the motivating effect of positive changes they experienced. Chronic pain and frustration with chronic illness inhibited their ability to relish any positive changes. In these cases the women became overwhelmed with the barriers to exercise and mired with their chronic health problems.

I am kind of like you though sometimes family got in the way and then my health was getting in the way and so. I do enjoy the walking, you know. I, I feel better after I walk. A lot of things get in the way.

Another missed many of the group walks due to health problems and family responsibilities and therefore, didn't benefit as much as she wanted from the group interaction and support. She was still trying to fit in walking and expressed disappointment at missing so many of the group walks. And, she did recognize that she had learned from and was inspired by the group and felt better when walking.

Well if we keep trying though even though we don't do as much as the other girls because they were, didn't have a problem walking I think that in the long run we feel better. I always feel better. And I get time to think by myself when I go walk alone or with a group and um I enjoy it. But um, some of these girls were doing really good with it. I am really proud to see that, racing around the track.

By the end of the 12-week program they felt discouraged and were walking sporadically; yet still recognizing the beneficial effects of exercising. The group provided some support but not a sufficient amount to aid in prevailing over the detrimental effects of chronic illness and pain. Possibly more group interaction combined with attention to the chronic health issues would provide the needed support to achieve a regular routine in walking and improvement in health.

## **Summary**

There were four common response patterns to the HTH program. These consisted of those who established a regular exercise routine, those who were walking more than before yet still struggling to establish a regular walking routine, those who experienced exacerbations of chronic illness, and those who were still trying to make a change. For women in the first response pattern, early positive physiological changes in response to walking were critical to the development of a regular walking routine. Women who experienced early positive physiological changes were able to establish a regular routine by the end of the 12-week program. These women expressed an increase in self-efficacy

to perform exercise and a belief that exercise had become part of their life. Women in the second response pattern did not experience early positive physiological changes continued to struggle with overcoming barriers at the end of the 12-week program. Although they were walking more than they had before the start of the program, they had not yet established a regular exercise routine. These women took advantage of the group support and some of the individual aspects of the program. In the third response pattern women were overwhelmed by their chronic illness and this appeared to thwart their ability to overcome other barriers to exercise. Finally, in the last response pattern a couple of women did not become engaged in the program and appeared to make little change.

Social support from the group appeared to augment the motivating influence of positive physiological changes, particularly increased fitness and energy. The individual promotion aspects of the program, particularly self-monitoring, appeared to enhance intrinsic motivation. Self-monitoring provided an avenue to track improvement in fitness and other beneficial effects of walking; thereby, highlighting these positive changes. Ultimately, this increased awareness enhances motivation. It appears that there is a necessary threshold of consistent group interaction in order to continue to reap the benefits of the group-social support. In addition, chronic illnesses, specifically chronic pain, need to be effectively managed in order for women to direct their mind toward overcoming barriers and relishing the positive changes. The HTH program's effectiveness can be improved by drawing more attention to positive changes and working with women to exercise at the intensity that will induce these changes early on in the program.

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#### APPENDIX A

### Heart-to-Heart Program Protocol

- 1. Study Definitions
  - a. Drop-outs and Withdrawals
- 2. Recruitment
  - a. Recruitment Protocol
  - b. Study Flier
  - c. Initial Phone Contact Procedures
  - d. Phone script
  - e. Informed Consent Procedures
  - f. Consent and Authorization Form
  - g. Weekly Phone Calls
  - h. Baseline Data Collection Procedures
  - i. Randomization Procedures
- 3. HTH Program Protocol
  - a. Intervention Study Activities Timeline
  - b. HTH Program Protocol
  - c. Initial Counseling Session
  - d. Weekly Phone Calls
  - e. Group Session Procedures
  - f. Posttest Data Collection Procedures
  - g. Focus Group Procedures
- 4. Control Group Protocol
  - a. Control Group Study Activities Timeline
  - b. Control group Protocol
  - c. Initial Counseling Session
  - d. Monthly Mailings
  - e. Monthly Phone Calls
  - f. Posttest Data Collection Procedures
- 5. Exercise Prescription
- 6. Written Exercise Information
- 7. Data Management
  - a. Tracking Procedures
  - b. Data Storage

# STUDY DEFINITIONS

## **Study Definitions**

## Dropouts and Withdrawals

# Dropouts:

- 1. Participant can drop out at any time
- 2. Inquire about reason dropping out
- 3. Enter reason in accelerator notes section
- 4. Thank you letter mailed to participant

#### Withdrawals:

- 1. Participant will be withdrawn from the study if no longer meets study criteria
- 2. Participant will be withdrawn at request PCP
- 3. Enter reason of withdrawal in accelerator notes section

# RECRUITMENT

#### Recruitment Protocol

- 1. Place fliers in family medical clinics
- 2. Community contacts to hand out fliers to potential participants
- 3. Interested women contact investigator by phone
- 4. Phone conversation describing study, women determine if meet inclusion/exclusion criteria
- 5. Face-to-face meeting to describe study, risks/benefits, participation, obtain informed consent, give projected start date based on number women recruited at time completes consent
- 6. Call each week to update on recruitment status
- 7. 1-2 weeks before start date complete pre-test measures
- 8. Randomization

# Women: Interested in Walking for Exercise?

You are invited to take part in a study about exercise and women being conducted in your area



#### If you are:

- Between the ages of 21 and 65
- Interested in exercising more
- Live in a rural area
- Have no history of heart disease
- Currently not exercising regularly
- Currently not pregnant
- Speak English

We would like you to join us in our study. It will involve a 12-week walking program.

For information please contact: The principle investigator: Cindy Perry, FNP Oregon Health & Science University School of Nursing 503-494-3816

**OHSU** 

OHSU is an equal opportunity, affirmative action institution.

IRB # 8061

ID		

#### **Initial Phone Contact**

- Read description of study phone script
   Complete telephone screening form
   Obtain name and phone number

- 4. Set appointment date, time, and location
- 5. Enter in accelerator and excel tracking

#### Heart-to-Heart: An Exercise Intervention for Rural Women Description of Study Phone Script

#### Phone Script:

The purpose of this study is to learn about a new way to help women living in rural areas exercise regularly. There are 2 groups in the study: 1) a counseling group and 2) a counseling and exercise group. There will be 48 women participating in the study. I will meet with each woman at the beginning to discuss exercising and ways to try and fit in exercise. Women in the study will be advised to walk for exercise beginning at 15 minutes 3 times a week and working up to 30 minutes 5 days a week. Women in the counseling and exercise group will meet weekly to walk together around a track nearby. I will also call women during the 12 weeks to see how things are going and to provide guidance or support. The walking program will last for 12 weeks. You will be assigned to one of the groups by a computer so it is based on chance, you don't get to choose.

#### Informed Consent Procedures

- 1. Arrange to meet in a quiet and private place at the potential participants' choice
- 2. Read and review the informed consent with the potential participant
- 3. Participant and investigator to sign 2 copies of the consent form
- 4. Participant will keep one copy
- 5. Investigator will put one copy in a locked file cabinet, separate from data collection forms

Protocol Ap	proval	Date:
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# OREGON HEALTH & SCIENCE UNIVERSITY Research Consent and Authorization Form

TITLE: Heart-to-Heart: An Exercise Intervention for Rural Women

**PRINCIPAL INVESTIGATOR**: Cindy Perry, MSN, FNP (503) 494-3816

CO-INVESTIGATOR: Anne Rosenfeld, PhD, RN, CNS

Associate Professor (503) 494-0133

#### **PURPOSE**:

You have been invited to be in this research study because you are a woman interested in increasing your exercise. The purpose of this study is to learn about a new way to help women living in rural areas exercise regularly. You will be in this study for 15 weeks. There will be 48 women enrolled in the study. There will eight women in an exercise session. It can take up to 8 weeks from the time you sign the consent form until enough women volunteer before the exercise study begins. The investigator will call you each week until the study begins to let you know how many women have volunteered.

#### **PROCEDURES**:

This is a randomized study. Neither you nor the investigator can choose whether you will be in the Heart-to-Heart Group or the Control Group. You have a 1 out of 2 (50%) chance of being in the Heart-to-Heart Group or the Control Group. The investigator will ask you some questions to make sure that you qualify for the study. Also, you will be given a permission form to have your nurse practitioner or doctor sign and mail back to Cindy Perry. You will need your nurse practitioner or doctor's permission to participate in the study.

#### Heart-to-Heart Group:

#### Before the Exercise Program Starts

You will meet with the investigator who will ask you questions from five questionnaires. The questionnaires will ask about your confidence in your ability to exercise regularly, how often you exercise, types of physical activities you do, support you receive from family and friends to help you exercise, and some questions that describe you, such as your age. The investigator will also measure your weight, height, blood pressure and pulse. This will take about 45-60 minutes. You will walk around a track for 12 minutes.

A week later, you will meet with the investigator for 40-50 minutes to talk about your exercise goals and strategies to reach your goals. This meeting will be audio taped. The investigator will show you how to use a heart rate monitor and how to keep an exercise logbook. You will wear a heart rate monitor when you exercise and write in your logbook when you exercise. The investigator will record data from the heart rate monitor once a week. You will hand in your logbook each month and receive a new one. You will walk at least 3 times a week for exercise.

#### 12-week Exercise Program

You will meet once a week with seven women in the study for one hour. You will discuss your experiences with exercising during the past week. The investigator will take notes on how you are doing. You will stretch and walk around a track near to your home. The investigator will call you once a week to see how you are doing with exercising during the first 8 weeks. The investigator will call every other week for the next 4 weeks. Each phone call will take about 10 minutes and will be audio taped.

#### End of the 12-weeks

At the end of 12 weeks, you will answer questions that the investigator reads from five questionnaires. The questionnaires will ask about your confidence in your ability to exercise regularly, how often you exercise, types of physical activities you do, support you receive from family and friends to help you exercise, and about the group. The investigator will also measure your weight, height, blood pressure and pulse. This will take about 45-60 minutes. You will walk around a track for 12 minutes. You will be in a 60-90 minute focus group to talk about your experiences with the group and with exercising. The focus group meeting will be audio taped. Below is a table that shows what will happen each week of the study.

	Week														
Activity	1 2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Questionnaires	X														X
12-minute walk test	X												4		X
Initial counseling session		X													
Group walk			X	X	X	X	X	X	X	X	X	X	X	X	
Phone call			X	X	X	X	X	X	X		X		X		
Focus group															X

#### Control Group:

Before the Exercise Program Starts

You will meet with the investigator who will ask you questions from five questionnaires. The questionnaires will ask about your confidence in your ability to exercise regularly, types of physical activities you do, how often you exercise, support you receive from family and friends to help you exercise, and some questions that describe you, such as your age. The investigator will also measure your weight, height, blood pressure and pulse. This will take about 45-60 minutes. You will walk around a track for 12 minutes. A week later, you will meet with the investigator for 15 minutes to talk about your exercise goals and strategies to reach your goals. This meeting will be audio taped. The investigator will show you how to keep an exercise logbook. You will write in your logbook when you exercise. You will be asked to mail in your logbook each month in an envelope provided by the study. We will mail a new log book each month to you.

#### 12-week Exercise Program

You will be asked to walk at least 3 times a week for exercise. The investigator will call you once a month to see how you are doing with your exercise. This phone call will take about 5 minutes and will be audio taped.

#### End of the 12-weeks

At the end of 12 weeks you will be asked to answer questions that the investigator reads from four questionnaires. The questionnaires will ask about your confidence in your ability to exercise regularly, how often you exercise, types of physical activities you do, and support you receive from family and friends to help you exercise. The investigator will also measure your weight, height, blood pressure and pulse. This will take about 45-60 minutes. You will walk around a track for 12 minutes. Below is a table that shows what will happen each week or the study.

	Week														
Activity	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Questionnaires	X														X
12-minute walk test	X									1 _					X
Initial counseling session		X													
Phone call						X				X				X	

We will keep all information collected from you confidential. Only members of the research team listed on the front of this consent form will have access to the information collected. Information collected from you will be kept in a locked file cabinet or/and in a password protected computer file in a locked office at Oregon Health & Science University School of Nursing. Once audio tapes have been transcribed and the transcript compared with the tape, the tape will be destroyed.

#### **RISKS AND DISCOMFORTS:**

You may find it inconvenient to meet weekly with seven women from the study.

You may notice some muscle soreness from walking. The investigator will give you information on stretching and how to keep from having an injury. You may injure yourself while walking. For example, you may twist your ankle. If you are injured, you will be asked to see your nurse practitioner or doctor for an evaluation. You will need a note from your nurse practitioner or doctor stating that it is okay for you to continue in the study. If your nurse practitioner or doctor does not think it is good for you to continue in the study, then you will be withdrawn.

You may experience dizziness, shortness of breath, lightheadedness or chest discomfort or pain when exercising. These symptoms can be signs of problems with your heart. If you have any of these symptoms, you will be asked to see your nurse practitioner or doctor. You will need a note from the nurse practitioner or doctor stating that it is okay for you to continue in the study. If the doctor or nurse practitioner determines from their evaluation that it is not good for you to continue in the study then you will be withdrawn.

Some of these questions from the questionnaires or in the focus group may seem very personal or embarrassing. You may refuse to answer any of the questions that you do not wish to answer.

#### **BENEFITS**:

You may or may not benefit from being in the study. By serving as a subject, you will help us learn more about helping women to exercise regularly.

#### **ALTERNATIVES:**

You may choose not to be in this study. You may chose to exercise on your own with your nurse practitioner's or doctor's guidance.

#### <u>CONFIDENTIALITY AND PRIVACY OF YOUR PROTECTED HEALTH</u> INFORMATION:

If you sign this form, you are agreeing that OHSU may use and disclose protected health information collected and created in this research study. The specific health information and purpose of each use and disclosure are described in the table below:

	Information as applicable)	Purpose(s) (Enter corresponding letter(s) from Purpose Categories)
The fo	ollowing checked item(s) will be generated/collected duri	ng the course of this study:
⊠ Qı	uestionnaires	<u>a, c, f, i</u>
∑ 12	2 minute walk test	a, c, f, i
⊠ Не	eight and weight	a, c, f, i
	ood pressure and resting pulse	a, c, f, i
	itial meeting to discuss exercise goals	<u>a, c, f, i</u>
	none calls about exercise goals and progress	$\frac{\overline{a}, c, f, i}{a}$
	kercise logbooks	a, c, f, i
	ata from heart rate monitors	<u>a, c, f, i</u>
	ocus group discussion	a, c, f, i
a. b. c. d. e. f. g. h. i. j. k.	and the same of th	disease being studied being studied study regulations ent(s)
1.	To place in a repository or "bank" for future research p	ourposes.
m.		
****		

The persons who are authorized to use and disclose this information are: Cindy Perry, FNP, Dr. Anne Rosenfeld, Dr Kathleen Potempa, Dr. Jill Bennett, Dr. Nancy Perrin, Dr. Judy Kendall and the Oregon Health & Science University Institutional Review Board.

The persons who are authorized to receive this information are: federal or other governmental agencies responsible for research oversight.

We may continue to use and disclose protected health information that we collect from you until we have completed the study including the study analysis. Within the next five years it is possible that a secondary data analysis may be conducted.

While this study is still in progress, you may not be given access to medical information

about you that is related to the study. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study. If this study has not collected any medical information about you, you will be advised of that.

You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed on page one of the Consent and Authorization Form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date he/she receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OHSU.

The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law. However, federal or state law may restrict re-disclosure of HIV/AIDS information; mental health information; genetic information; and drug/alcohol diagnosis, treatment, or referral information. OHSU tries to protect against re-disclosure without your permission by being very careful in releasing your information. The ways in which we will limit the further release of your protected health information are: not releasing your information in a way that could identify you.

#### **COSTS**:

If you are in the Heart-to-Heart intervention group, you will need to pay for the gas you use in your car to get to the track where you will meet the women and Cindy Perry each week.

#### LIABILITY:

The Oregon Health & Science University is subject to the Oregon Tort Claims Act (ORS 30.260 through 30.300). If you suffer any injury and damage from this research project through the fault of the University, its officers or employees, you have the right to bring legal action against the University to recover the damage done to you subject to the limitations and conditions of the Oregon Tort Claims Act. You have not waived your legal rights by signing this form. For clarification on this subject, or if you have further questions, please call the OHSU Research Integrity Office at (503) 494-7887.

#### **PARTICIPATION:**

Cindy Perry, FNP, (503) 494-3816, has offered to answer any questions you may have about this study. If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study,

there will be no penalty or loss of any benefits to which you are otherwise entitled. If you decide to no longer participate in the study you will be asked to share with the investigator why you do not want to continue. You can refuse to share your reasons or to answer the investigator's questions.

Your consent to participate in this study and your authorization to let us use and disclose your protected health information are voluntary. You may refuse to sign this consent and authorization form. If you refuse to sign this consent and authorization form, your health care and relationship with OHSU will not be affected, however, you will not be able to enter this research study.

You will be asked not to participate in the study if it is learned that you do not meet the study qualifications. After you sign the consent for you will be asked some questions to determine if you can enroll. You will be asked not to participate in the study if your nurse practitioner or doctor thinks that you should not be in the study or continue to be in the study.

You will be given a copy of this consent and authorization from.

## **SIGNATURES**:

Your signature below indicates that you h be in this study.	ave read this enti	re form and that you	agree to
Printed Name of Subject			
a *			
Signature of Subject			Date
G. CI			D :
Signature of Investigator			Date

#### Weekly Phone Calls During Recruitment Phase

- 1. Call each enrolled participant weekly at predetermined time
- 2. Inform how many enrolled in study and projected time to start
- 3. Determine time for call the next week
- 4. Enter into phone call excel database and into accelerator
- 5. Once have 16 women
  - a. Arrange meeting for baseline measures
  - b. Obtain day & time preference for group meeting in case randomized to HTH

#### Baseline Data Collection Procedures HTH and Control Groups

#### Baseline Measures:

- 1. Administer Exercise Stage of Change
- 2. Administer 7-day PAR
- 3. Administer Exercise Confidence Survey
- 4. Administer Social Support and Exercise Survey
- 5. Administer Demographic Questionnaire
- 6. Administer 12-Minute Walk Test Protocol

#### Items Needed:

- 1. Pen
- 2. Stopwatch
- 3. Measures and protocols

#### Randomization Procedure

Once 16 women have enrolled then baseline measures will be completed. Women will be matched in pairs based on score on 12 MWT and ethnicity. A faculty member at OHSU School of Nursing will conduct randomization rather than the investigator.

#### HTH PROGRAM PROTOCOL

# Intervention Group Study Activities

	Week														
Activity	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Questionnaires	X														X
12-minute walk test	X					·									X
Initial counseling session		X													
Group walk			X	X	X	X	X	X	X	X	X	X	X	X	
Phone call			X	X	X	X	X	X	X		X		X		
Focus group															X

#### HTH Program Protocol

- 1. Follow recruitment protocol
- 2. Baseline measures
- 3. Randomization
- 4. Initial 45 minute MI counseling session
- 5. Weekly group walk session at nearby track- date & time determined by group
- 6. Weekly 10 minute MI counseling phone call
- 7. Week 4- give reward for reaching goal
- 8. Week 4, 8, & 12 collect logbooks and hand out new logbooks
- 9. Post test measures
- 10. Thank you letter for participation
- 11. Focus group
- 12. Thank you letter for focus group

#### Initial Counseling Session HTH Group: 45 minutes

D	ate	:		

#### Procedures:

- 1. MI counseling
- 2. Discussion Exercise Prescription
  - a. Give written exercise prescription
- 3. Review exercise Logbook
  - a. Give exercise logbook
- 4. Review Heart Rate Monitor
  - a. Set monitor for participant
- 5. Standard Exercise Information
- 6. Inform Day, Time, and Location of Group Session

#### Items Checklist:

- 1. HRM
- 2. Logbook
- 3. Standard Exercise Information
- 4. Written Exercise Prescription
- 5. Audiotape
- 6. Tape Recorder

#### Weekly Phone Calls HTH Group 10 minutes

- 1. Counsel using MI: 10 minutes
- 2. Determine time for call next week
- 3. Remind of group session
- 4. Enter into accelerator and excel phone call data base

#### HTH Group Session Procedures

- 1. Welcome as participants arrive
- 2. Download HRM data of those who arrive early
- 3. Lead group discussion using MI: 10 minutes
  - a. Potential topics
    - i. ways to substitute walking for sedentary activities
    - ii. the impact of exercise on one's health and daily life
    - iii. injury prevention
    - iv. how to incorporate walking into daily life,
    - v. the value of exercise
    - vi. the impact of being physical active or inactive
    - vii. individual goals and strategies employed to increase exercise
    - viii. relapse prevention
- 4. Warm up stretching exercises: 5-10 minutes
  - a. Quads, hamstring, hip adductors, gluteus, gastrocnemius, soleus, anterior tibialis, chest, obliques
- 5. Group Walk
  - a. Intensity
    - i. Weeks 1-4: 50% MHR
    - ii. Weeks 5-12: 55-65%MHR
  - b. Duration
    - i. Week 1: 15-20 minutes
    - ii. Weeks 2-3: 20-25 minutes
    - iii. Week 4: 25-30 minutes
    - iv. Weeks 5-12: 30 minutes
- 6. Cool down Stretching Exercises- 5-10 minutes
  - a. Quads, hamstring, hip adductors, gluteus, gastrocnemius, soleus, anterior tibialis, chest, obliques
- 7. Closing: 3-5 minutes
- 8. Download HRM data

#### **Equipment Checklist**

- 1. Fully charged laptop computer
- 2. Fully charged cell phone
- 3. First Aid kit
- 4. HTH HRM
- 5. Water
- 6. Group T-shirt
- 7. Sunscreen
- 8. Hat

#### Posttest Data Collection Procedures

#### Posttest Measures

#### HTH Group:

- 1. Administer 7-day PAR
- 2. Administer Exercise Confidence Survey
- 3. Administer Social Support and Exercise Survey
- 4. Administer Exercise Group Environment Questionnaire
- 5. Collect anthropomorphic measures
- 6. Administer 12-Minute Walk Test Protocol

#### Control Group:

- 1. Administer 7-day PAR
- 2. Administer Exercise Confidence Survey
- 3. Administer Social Support and Exercise Survey
- 4. Collect anthropomorphic measures
- 5. Administer 12-Minute Walk Test Protocol

#### Items Needed:

- 1. Pen
- 2. Stopwatch
- 3. Measures and protocols

#### Focus Group HTH

#### In Preparation:

- 1. Invite all in group to attend
- 2. Set date and time
- 3. Arrange location
- 4. Reminder calls day before focus group
- 5. Purchase refreshments

#### Day of Focus Group

- 1. Items to bring
  - a. Refreshments
  - b. Plates, cups, napkins, utensils
  - c. Tape recorder
  - d. Audio tape
  - e. Note pad and pen
  - f. Focus group guide (begin with warm up questions)

#### CONTROL GROUP PROTOCOL

# Control Group Study Activities

	Week														
Activity	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Questionnaires	X														X
12-minute walk test	X														X
Initial counseling session		X													
Phone call						X				X				X	

#### Control Group Protocol

- 1. Follow recruitment protocol
- 2. Baseline measures
- 3. Randomization
- 4. Initial 10 minute counseling session/advice
- 5. Monthly phone call- 5 minute reinforcement
- 6. Monthly mail out new log book, SASE, & incentive for continued participation
- 7. Post measures
- 8. Thank you letter for participation

#### Initial Counseling Session Control Group 10 minutes

Date:		
Date.		

#### Procedures:

- 1. Discussion Exercise Prescription
  - a. Give written exercise prescription
- 2. Review Exercise Logbook
  - a. Give exercise logbook
- 3. Standard Exercise Information
- 4. Arrange First Monthly Phone Call Date and Time

#### Items Checklist:

- 1. Logbook
- 2. Standard Exercise Information
- 3. Written Exercise Prescription
- 4. Audiotape
- 5. Tape Recorder

# Monthly Mailings Control Group

#### Items to Mail:

- 1. Letter
- New Logbook
   SASE to return logbook

# Monthly Phone Calls Control Group 5 minutes

- 1. Provide Reinforcement
- 2. Give advice
- 3. Remind to mail in logbook4. Arrange next call time and date

#### Posttest Data Collection Procedures

#### Posttest Measures

#### HTH Group:

- 1. Administer 7-day PAR
- 2. Administer Exercise Confidence Survey
- 3. Administer Social Support and Exercise Survey
- 4. Administer Exercise Group Environment Questionnaire
- 5. Collect anthropomorphic measures
- 6. Administer 12-Minute Walk Test Protocol

#### Control Group:

- 1. Administer 7-day PAR
- 2. Administer Exercise Confidence Survey
- 3. Administer Social Support and Exercise Survey
- 4. Collect anthropomorphic measures
- 5. Administer 12-Minute Walk Test Protocol

#### Items Needed:

- 1. Pen
- 2. Stopwatch
- 3. Measures and protocols

#### EXERCISE PRESCRIPTION

#### **Exercise Prescription**

#### Weeks 1 and 2

Heart rate: 45% HRR

Length of exercise session: 20 Number session per week: 3

#### Weeks 3 and 4

Heart rate: 50% HRR

Length of exercise session: 25 Number session per week: 4

#### Weeks 5 and 6

Heart rate: 55% HRR

Length of exercise session: 30 Number session per week: 4

#### Weeks 7 and 8

Heart rate: 60% HRR

Length of exercise session: 30 Number session per week: 4

#### Weeks 9 and 10

Heart rate: 65% HRR

Length of exercise session: 30 Number session per week: 5

#### Weeks 11and 12

Heart rate: 65% HRR

Length of exercise session: 30 Number session per week: 5-7

#### WRITTEN EXERCISE INFORMATION



# Why Should I Be Physically Active?

If your doctor has advised you to begin an activity program, you should follow that advice. People who don't get enough physical activity are much more likely to develop health problems.

Regular, moderate physical activity can lower your risk of...

- · Heart disease and heart attack
- High blood pressure
- High total cholesterol and low HDL (good) cholesterol.
- Overweight or obesity
- Diabetes
- Stroke



If you haven't been active and want to start exercising, first check with your doctor for a program that's right for you. Once you start, you'll find that exercise isn't just good for your health — it's also fun!

## What else can physical activity do for me?

Physical activity also offers these benefits:

- Strengthens your heart, lungs, bones and muscles.
- Gives you more energy and strength.
- Helps control your weight and blood pressure.

- Helps you handle stress.
- · Helps you sleep better.
- Helps you look good.
- · Helps you feel upbeat.

#### What kind of activities should I do?

You don't have to be an athlete to lower your risk of heart disease and stroke! If done on most or all days, you can benefit from moderate activities like these:

- Pleasure walking
- Gardening and yard work
- Moderate to heavy housework
- Pleasure dancing and home exercise

More vigorous exercise can help improve the fitness of your heart and lungs. Start slowly, and build up as your heart gets stronger. First, discuss exercise with your doctor or nurse. Then try one or more of these:

- Brisk walking, hiking or jogging
- Stair climbing
- Bicycling, swimming or rowing
- Aerobic dancing or cross-country skiing

#### How often should I exercise?

- Work up to 30 to 60 minutes of activity.
- Make sure it's regular most or all days of the week.

#### What else can I do?

Look for ways to add more activity to your daily routines. Making small changes in your lifestyle can make a big overall difference in your health. Here are some examples:

- Take a walk for 10 or 15 minutes during your lunch break.
- Take stairs instead of escalators and elevators.
- Park farther from the store and walk through the parking lot.

#### How can I learn more?

- Talk to your doctor, nurse or health care professional. Or call your American Heart Association at 1-800-242-8721, or the American Stroke Association at 1-888-478-7653.
- If you have heart disease or have had a stroke, members of your family also may be at higher risk. It's very important for them to make changes now to lower their risk.

## Do you have questions or comments for your doctor?

<ul> <li>Take a few minutes to write your own questions for the next time you see your doctor. For example</li> </ul>	
How much should I exercise?	

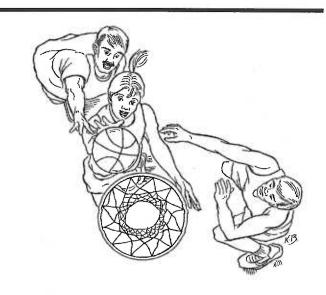




# How Can Physical Activity Become a Way of Life?

If you aren't in the habit of being physically active, you're probably being told you should start. That's because regular physical activity reduces your risk of heart disease and stroke. It also helps you reduce or control other risk factors — high blood pressure, high blood cholesterol, excess body weight and diabetes.

But the benefits don't stop there. You may look and feel better, become stronger and more flexible, have more energy, and reduce stress and tension. The time to start is now!



#### How do I start?

- Talk to your doctor about a physical activity plan that's right for you if...
  - you've been inactive a long time or have medical problems,
  - you're middle-aged or older, and
  - you're planning a relatively vigorous exercise program.
- Choose activities you enjoy. Pick a starting date that fits your schedule and gives you enough time to begin your program, like a Saturday.
- Wear comfortable clothes and shoes.
- Start slowly don't overdo it!
- Try to exercise at the same time so it becomes a regular part of your lifestyle.

For example, you might exercise every day (during your lunch hour) from 12:00 to 12:30.

- Drink lots of water before, during and after each exercise session.
- Ask a friend to start a program with you use the buddy system!
- Note the days you exercise and write down the distance or length of time of your workout and how you feel after each session.
- If you miss a day, plan a make-up day.
   Don't double your exercise time during your next session.

# What will keep me going?

- Get your family into physical activity!
   It's great to have a support system, and
   you'll be getting them into an important
   health habit.
- Join an exercise group, health club or YMCA.
- Choose an activity you like and make sure it's convenient for you. If you need good weather, have a back-up plan for bad days (e.g., when it rains, walk in the mall instead of the park).
- Learn a new sport you think you might enjoy, or take lessons to improve at one you know.

- Use variety to keep your interest up. Walk one day, take a swim the next time, then go for a bike ride on the weekend!
- Try renting a few exercise videotapes to find the one(s) you like best. Then you can buy one or more and have a good workout in the comfort of your own home!
- Make exercise a regular routine so it becomes a habit that you do automatically.
- If you stop for any length of time, don't lose hope! Just get started again — slowly — and work up to your old pace.

#### What else should I know?

- Try not to compare yourself with others.
   Your goal should be personal health and fitness.
- Think about whether you like to exercise alone or with other people, outside or inside, what time of day is best, and what kind of exercise you most enjoy doing.
- If you feel like quitting, remind yourself of all the reasons you started. Also think about how far you've come!
- Don't push yourself too hard. You should be able to talk during exercise. Also, if you don't feel recovered within 10 minutes of stopping exercise, you're working too hard.

#### How can I learn more?

- Talk to your doctor, nurse or health care professional. Or call your local American Heart Association at 1-800-242-8721, or the American Stroke Association at 1-888-478-7653.
- If you have heart disease or have had a stroke, members of your family also may be at higher risk. It's very important for them to make changes now to lower their risk.

# Do you have questions or comments for your doctor?

• Take a few minutes to write your own question:	s for the next time you see your doctor. For example:
Should I take my pulse?	
Can I exercise "too much?"	



Fighting Heart Disease and Stroke

National Center 7272 Greenville Avenue Dallas, Texas 75231-4596 americanheart.org

## DATA MANAGEMENT

#### **Tracking Procedures**

- 1. Enter appointments (visits & calls) into accelerator phone book calendar
- 2. Enter into notes in phone book on each phone call, appointment, group session
- 3. Enter by participant number into excel database data collection dates
- 4. Enter phone calls by participant number into phone call excel sheet
- 5. Enter attendance into attendance sheet in excel by group session
- 6. Print out report each week of number participants contacted, signed consents & enrolled, dropout, withdrawals

#### Data Storage

#### Paper Data:

- 1. Keep data collection forms in file folder by participant number in locked file drawer
- 2. Keep contact information in separate locked file
  - a. Connects participant name and participant number
- 3. Keep signed consents in separate locked file

#### Computer files:

- 1. Contact information, notes, and calendar keep in phone book data base
  - a. HTH phonebook
- 2. Data tracking sheets kept in excel files
  - a. Data collection
  - b. Phone call sheet
  - c. Attendance sheet
- 3. SPSS
  - a. Coded data entered into SPSS file

#### APPENDIX B

#### Measurement Tools

- 1. Sources of Data Collection
- 2. Data Collection Timeline
- 3. Psychometric Properties of Study Measures
- 4. Collection Exercise Adherence Data
- 5. Data Collection Instruments
  - a. Telephone Screening Form
  - b. Screening After Informed Consent
  - c. Contact Information Form
  - d. Primary Care Provider Permission Form
  - e. Seven-Day Physical Activity Recall
  - f. Self-efficacy for Exercise Habits Survey
  - g. Social Support for Exercise Survey
  - h. Exercise Stage of Change Short Form
  - i. Physical Activity Group Environment Questionnaire
  - j. Demographic Questionnaire
  - k. Scoring of the Measurements
  - 1. Anthropomorphic Data Collection Form
  - m. 12-minute Walk Test Protocol and Data Collection Form
  - n. Exercise Log
  - o. Focus Group Guide

# Sources of Data Collection

Variable	Measure	Data Collection Form	Collection Times
Physical activity	Seven-day Physical Activity Recall (PAR)	PAR protocol and worksheet	Baseline, post
Self-efficacy	Self-efficacy for Exercise Habits Survey	Exercise Confidence Survey	Baseline, post
Social Support	Social support for Exercise Survey	Social Support and Exercise Survey	Baseline, post
Exercise Stage of Change	Exercise Stage of Change Short Form	Exercise Stage of Change	Baseline, post
Group Cohesion	Physical Activity Group Environment Questionnaire	Exercise Group Environment Questionnaire	Post
Group Cohesion		Field notes	Weekly
Exercise Adherence		Exercise log books	Monthly
Exercise Adherence		Heart rate monitor data	Weekly
Exercise Adherence		Attendance at group sessions	Weekly
Cardiorespiratory	12-minute walk	12-minute walk test protocol	Baseline, post
Demographics		Demographic questionnaire	Baseline

# Study Activities Timeline

Activity	Baseline	1	2	3	4	5	6	7	8	9	10	11	12	post
Questionnaires and 12-minute walk test	•													•
Initial face-to-face counseling session HTH: Establish goals, learn to use heart rate monitor & keep exercise log using MI approach Control: Establish goals, learn to keep exercise log		•												
Group formation/team building Components listed in table 1 done weekly (group name week 4, group T-shirt, week 6).		•	•	9	9	9	•	9	•	•	•	•	3	
Phone call  HTH: individual exercise promotion components discussed using MI approach Control: reinforcement		•	•	•	•	•	•	•	•		•		●	
ocus group														

Key: • = HTH group, ₩ = control group

# Psychometric Properties of Study Data Collection Instruments

	Self-efficacy for Exercise Habits Survey	Exercise Stage of Change Short Form	Social Support for Exercise Survey	Physical Activity Group Environment Questionnaire	7-day Physical Activity Revall
Sample characteristics	40 subjects, 50% white, interviewed for 1 hour & responses used to construct the items.  Administered to 171 subjects, 154 were undergrad students, 17 university staff of a health promotion study 75% female, 90% white	1,172 employees of 2 worksites. 66% female, average age 37.2 years	171 psychology students and 17 research staff	118, 90% women average age 70.8	1,120 women and 1,006 men between ages 20-74
Number of items Number factors	12 2	5	13 3(1 for friends,	21 4	
Time to complete	5 minutes	3 minutes	2 for family) 5 minutes	5 minutes	
Reliability					
Internal consistency	0.85 resisting relapse		0.61-0.84	0.72-0.91	
consistency	0.83 making time				
Test-retest	0.68 sub-sample 52 students completed the survey 1-2 weeks later	0.78	0.55 to 0.79 sub-sample 52 students completed the survey 1-2 weeks later		64 repeated 2 weeks later 0.75 moderate, 0.83 vigorous
Validity				Statements reflect dimensions of group cohesion, experts established content validity	
Content (Face)	Broad realistic representation of situations that challenge an individual's motivation to exercise and are likely to be encountered support face validity	Clear statements that are congruent with the definition of each stage.			
Construct Convergent	Health locus of control scale, correlations with internal locus of control (p<.001) R=.29 resisting relapse R=.42 making time but also significant				

Construct Discriminant	correlations with powerful others and chance None reported				
Criterion	Correlation with	Significant	Correlation	Correlation	Correlation
Concurrent	self report exercise, r=0.32, p<.001, for resisting relapse and r=0.40 for making time, p<.001	correlation with self-report seven-day physical activity questionnaire developed by Marcus & Simkin. Higher VO <sub>2</sub> max associated with later stages of change.	with self-report exercise 0.23- 0.046, p<0.001	between the GEQ and the PAGEQ of 0.81, p<0.05	between PAR and VO2max
Criterion	Predictive of	onango.		Associated with	
Predictive	exercise adherence			class attendance and self-efficacy	
Sensitivity to	Has been found	Detected	Detected		
change	to increase in response to group exercise study.	changes in stage of change in a 10-week exercise program	change in a 10- week exercise intervention with women with an effect size of 1.5		
Comments	Can score subscales	Widely used. Used in Latinas			
	separately to determine which factor more problematic. Widely used. Used in Latinas				

#### Collection Exercise Adherence Data

#### **Exercise Logbooks**

- 1. <u>HTH Group</u>: Collected monthly at the group session. Will be reminded in weekly phone call to bring logbook to session. Will be given new logbook at exercise session.
- 2. <u>Control Group</u>: Investigator will mail out new logbook, letter, and SASE to participants monthly. Will be instructed to mail back previous month logbook.

#### **Heart Rate Monitor**

1. Data will be downloaded into laptop computer weekly at the group session.

#### Attendance

1. Investigator will take attendance each week at group session.

# DATA COLLECTION INSTRUMENTS

#### Heart-to-Heart: An Exercise Intervention for Rural Women

#### Telephone Screening Form

The investigator will read the list of study criteria given below and the potential participant will state whether she believes that she qualifies. If the potential participant believes that she qualifies than a visit will be scheduled

#### Script:

Investigator: I am going to read a list of criteria for the study. When I am done I will ask you to answer yes or no. Don't answer after each item. (Investigator reads lists)

Are all of these true for you:

- 1. Between the ages of 21 and 65
- 2. Exercise less than 3 days a week and less than 30 minutes a day when you exercise
- 3. Exercise at a slow pace when you exercise
- 4. Desire to increase the amount you exercise

Are all of these true for you? Yes or no

Investigator: Again I will read a list of criteria. When I am done I will ask you to answer yes or no. Don't answer after each item.

Are any of these true for you?

- 4. Have heart disease
- 5. Have a physical condition that limits you from exercising
- 6. Are pregnant

Investigator: Are any of these true for you? Yes or no

You do (do not) fit this study.

#### Heart-to-Heart: An Exercise Intervention for Rural Women

#### Screening Form After Informed Consent Obtained

Once a signed consent has been obtained the investigator will then read each question and obtain a yes or no answer to each question listed below to ascertain participant meets study criteria.

1. Are you between the ages of 21-65

Yes No

2. Did you exercise 3 or more days last week?

Yes No

3. When you exercise, do you exercise for 30 minutes?

Yes No

4. When you exercise do you exercise moderate, like a brisk walk?

Yes No

5. Did you exercise about the same amount in the past month?

Yes No

6. Have you been told by a medical provider that you have heart disease?

Yes No

7. Do you have a physical condition that limits how much exercise you can do in a day?

Yes No

8. Are you interested in exercising more than you do now?

Yes No

9. Are you pregnant?

Yes No

ID		Pre	Post
	Heart-to-Heart: An Exercise Intervention for Rural Women		

# Contact Information

Name			
Street			
Address			_
City	State	Zip	
Code			
Phone			
Second Phone			
Best time to call			

# Heart-to-Heart: An Exercise Intervention for Rural Women Primary Provider Permission Form

has volunteered to participate in a research study looking at how to increase exercise in rural women. The study is entitled Heart-to-Heart: An Exercise intervention for Rural Women. This study is being conducted by Cindy Perry, MSN, FNF under the auspices of Oregon Health & Science University for her dissertation research. Ms Perry is family nurse practitioner and a doctoral student at Oregon Health & Science University School of Nursing. Dr. Anne Rosenfeld, PhD, RN, CNS is the dissertation advisor and will be supervising the study.
There will be a control group and an intervention group in the study. Women in the control group will be advised to walk for exercise for 12-weeks. For women in the intervention group the investigator will develop a 12-week walking program. The American College of Sports Medicine Guidelines will be followed to develop each participant's exercise program. Women will be advised to begin at 45% of age-predicted maximum heart rate for 15 minutes 3 days a week. The women will gradually increase this level of exercise to 55% of age predicted maximum heart rate for 30 minutes 5 days a week by the end of the study. Women in the intervention group will meet face-to-face with Ms Perry and other participants for a group walking session weekly. Otherwise Ms Perry will not be present for all other walking and exercise sessions in which the women partake. Women who have heart disease or are pregnant are excluded from participating in this study.
If you have any questions or concerns regarding the study please contact Cindy Perry, MSN, FNP at office phone 503-494-3816 or email <a href="mailto:perryci@ohsu.edu">perryci@ohsu.edu</a>
Sincerely,
Cindy Perry, FNP
Your signature below indicates that there are no medical contraindications to participating in this amount of exercise and that does not have heart disease.
Primary Care Provider Name:Address:
Address:Office Phone:

Date

Signature of Primary Care Provider

7-Day	Phy	/sical	Activity	<b>Recal</b>
-------	-----	--------	----------	--------------

SSN

PAR#: 1	234567				<b></b>		<b></b>		
		Inter	rviewer		Today is				
<ol> <li>Were you employed in the last seven days?</li> </ol>					0.	No (Skip to	Q#4) 1.	Yes	
	many days of the					_ days			
3. How r	many total hours	did you work	in the last s	even days	? _	hours last	week		
4. What	two days do you	consider yo	ur weekend	days?	·	ark days belo		.:!-\	
WORKSH	IEET			1	DAYS	irk days belo	iw with a squ	iiggi <del>e</del> )	
	SLEEP	1	2	3	4	5	6	7	
M O	Moderate								
R N I	Hard								
N G	Very Hard								
A F T	Moderate								
E R N	Hard								
0 0 N	Very Hard								
E V	Moderate								
E N	Hard								
N G	Very Hard								
Total Min	Strength:								
Per Day	Flexibility:								
was last w	ared to your physic eek's physical acti	vity more, les	s, or about th	e same?	6. Do you think	0. N	0		
<ol> <li>More</li> <li>Were the</li> </ol>		Less with the PAR	3. About th interview?	ie same	7. Were there	any special c	, go to the bac ircumstances	concerning thi	s PAR ?
Were there any problems with the PAR interview?     No			O. No I. Injury all wee I. Injury part wee	ek 2. Illnes	s all week	hat were they?  3. Iliness part 6. Other:			
				I		2.,,09			

#### Heart-to-Heart: An Exercise Intervention for Rural Women Exercise Confidence Survey

Below is a list of things people might do while trying to increase or continue regular exercise. I am interested in exercise like, running, swimming, brisk walking, bicycle riding, or aerobics classes.

Whether you exercise or not, please rate how confident you are that you could really motivate yourself to do things like these consistently, *for at least six months*.

Please circle one number for each question.

How sure are you that you can do these things?

		I know I cannot		May can	be I	I know I can	Does not apply
1. Get up early, even on the weeke exercise.	nds, to	1	2	3	4	5	8
2. Stick to your exercise program a long, tiring day at work.	after a	1	2	3	4	5	8
3. Exercise even though you are for depressed.	eeling	1	2	3	4	5	8
4. Set aside time for a physical activities for at least 30 minutes, 3 week.	uous	1	2	3	4	5	8
5. Continue to exercise with others though they seem too fast or too sl you.		1	2	3	4	5	8
6. Stick to your exercise program undergoing a stressful life change divorce, death in the family, moving	(e.g.,	1	2	3	4	5	8
7. Attend a party only after exercis	sing.	1	2	3	4	5	8
8. Stick to your exercise program your family is demanding more tin you.		1	2	3	4	5	8
9. Stick to your exercise program vehave household chores to attend to	-	1	2	3	4	5	8

ID						Pre	Post	
10. Stick to your exercise program even when you have excessive demands at work.	1	2	3	4	5		8	
11. Stick to your exercise program when social obligations are very time consuming.	1	2	3	4	5		8	
12. Read or study less in order to exercise.	1	2	3	4	5		8	

in the state of the

*	-
Pre	Pos

#### Heart-to-Heart: An Exercise Intervention for Rural Women Social Support and Exercise Survey

Below is a list of things people might do or say to someone who is trying to exercise regularly. If you are not trying to exercise, then some of the questions may not apply to you, but please read and give an answer to every question.

Please read each question *twice*. Under *family*, rate how often anyone living in your household has said or done what is described during the last three months. Under *friends*, rate how often your friends, acquaintances, or coworkers have said or done what is described during the last three months.

Please write *one* number from the following rating scale in each space:

none	rarely	a few times	often	often	not apply
1	2	3	4	5	8
During the	e past three mor	nths, my family	(or members	of my househole	d) or friends:
				Fami	ly Friends
1. Exercis	sed with me.				
2. Offered	d to exercise w	ith me.			
	ne helpful remitonight?")	inders to exerci	ise ("Are you g	oing to	
4. Gave n program.	ne encouragem	ent to stick wit	h my exercise		
5. Change	ed their schedu	le so we could	exercise togeth	ner.	
6. Discus	sed exercise w	ith me.	-		
7. Compl	ained about the	e time I spend e	exercising.		
8. Criticia	zed me or made	e fun of me for	exercising.		

ID	Pre	Post
9. Gave me rewards for exercising (brought me something or gave me something I like).	 	
10. Planned for exercise on recreational outings.		
11. Helped plan activities around my exercise.		
12. Asked me for ideas on how <i>they</i> can get more exercise.		
13. Talked about how much they like to exercise.		

# Heart-to-Heart: An Exercise Intervention for Rural Women Exercise Stage of Change

Exercise includes activities such as brisk walking, jogging, swimming, aerobic dancing, biking, rowing, etc. Activities that are primarily sedentary, such as bowling, or playing golf with a cart would not be considered exercise. Regular exercise means a total of 30 minutes of exercise each day and done at least 5 days a week. For example, you could take a 30-minute walk or 3 10-minute walks each day

Circle yes or no after each of the statements below

I currently exercise	Yes	No
I intend to exercise in the next 6 months	Yes	No
I currently exercise regularly	Yes	No
I have exercised regularly for the past 6 months	Yes	No
I have exercised regularly in the past for a period of at least 3 months	Yes	No

# Heart-to-Heart: An Exercise Intervention for Rural Women Exercise Group Environment Questionnaire

Please write one number from the following rating scale in each space:

Strongly Disagree	Strongly Disagree	Disagree	Slightly Disagree	Neither Agree or Disagree	Slightly Agree	Agree	Strongly Agree	Very Strongly Agree	
1	2	3	4	5	6	7	8	9	
Statemen	t					R	Lating		
1. I like tl	he amount o	of exercise l	get in this	program.		15			
	xercise grou ity to impro t								
3. I am happy with the exercise intensity in this program.									
4. I like the program of exercise done in this group.									
5. I enjoy new exercises done in this exercise group									
6. This exercise group provides me with good opportunities to improve my personal fitness.									
7. This exercise group is an important social unit for me.									
8. I enjoy my social interactions within this exercise group.									
9. I like meeting the people who come to this exercise group.									
10. When this program ends, I will miss my contact with the other participants.									
11. In terms of the social experiences in my life, this exercise group is very important.									
12. The social interactions I have in this exercise group									

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are important to me.	
13. Our group is united in its beliefs about the benefits of the exercises offered in this program.	
14. Our group is in agreement about the program of exercise that should be offered.	
15. Members of our group are satisfied with the intensity of exercise in this program.	
16. Members of our group enjoy helping if work needs to be done to prepare for the exercise sessions.	
<ul><li>17. We encourage each other in order to get the most out of the program.</li><li>18. Members of our exercise group often socialize during exercise time.</li></ul>	
19. Members of our exercise group would likely spend time together after the program ends.	
20. Members of our group sometimes socialize together outside of exercise time.	
21. We spend time socializing with each other before	

Pre Post

a. Yes

# Heart-to-Heart: An Exercise Intervention for Rural Women Demographic Questionnaire

1.	What is your birth date?
2.	What is your ethnicity? (Circle one)
	a. Hispanic
	b. Not Hispanic
3.	What is your racial background? (Circle one)
	a. American Indian/Alaska Native
	b. Asian
	c. Native Hawaiian or Other Pacific Islander
	d. Black or African American
	e. White
4.	What is the highest grade level you completed in school?
5.	How long have you lived in this town?
6.	How long have you lived in a rural area?
7.	What is your marital status (circle one)
	a. Married
	b. Steady partner
	c. Single
	d. Divorced
	e. Separated
	f. Widow
8.	Do you work outside the home?

D_		
	b.	No
	c.	If yes, how many hours a week do you work outside the home?hours
9.	Have	you been told by a health care provider that you have any of these
	condit	ions? (Circle all that apply)
	a.	High blood pressure
	b.	Diabetes (high blood sugar)
	c.	High cholesterol
10.	. Do yo	u currently smoke cigarettes?
	a.	Yes
	b.	No
	c.	If yes, how many packs a day? and for how many years?
11.	. Did yo	ou used to smoke cigarettes?
	a.	Yes
	b.	No
	c.	If yes,
		i. How many packs a day?
		ii. For how many years?
		iii. What year did you quit?
12	. Do yo	u have menstrual cycle (monthly periods)? (Circle one)
	a.	Yes
	b.	No
	c.	If yes:
		i. How long does your period last? days

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ii. How often do you have a period Every days
13. Do you take birth control pills? (Circle one)
a. Yes
b. No
i. If yes, for how long?years months
14. Do you take depoprovera shots? (Circle one)
a. Yes
b. No
i. If yes, for how long?yearsmonths
15. Do you take hormone replacement therapy? (Circle one)
a. Yes
b. No
i. If yes,
1. For how long?years,months
2. Do you take estrogen (premarin)?

3. Do you take progesterone (provera)?

### **Scoring the Measurement Instruments**

#### Seven-day physical activity recall

The number of hours spent in sleep and different activity levels are obtained. Time spent in sleep (1MET), light (1.5 METs), moderate (4METs), hard (6 METs), and very hard (10METs) activities for the past 7 days are multiplied by their respective MET value and then summed. An estimate of total kilocalories of energy expenditure per day is calculated.

Rounding:

10 and 20 min are rounded to 15 min= .25 25 and 35 min. are rounded to 30 min= .50

40min and 45 min are rounded to 45 min. = .75 55 min and 65 min are rounded to 60 min= 1.0

Sleep: Hours x 1 MET= kcal/kg

Light: Hours x 1.5 METS= kcal/kg Moderate: Hours x 4 METS= kcal/kg

Hard: Hours x 6Mets=kcal/kg

Very Hard: Hours x 10 METS= kcal/kg

Weight in lbs  $\div 2.2$ = weight in kg.

Total weekly expenditure= sum total (kcal/kg/wk)

Total kcal per week =  $\frac{kcal}{kg}$  wk x weight in kg=  $\frac{kcal}{wk}$ 

Total daily expenditure=  $\frac{kcal}{kg}$  wk ÷ 7d/wk =  $\frac{kcal}{kg}$  d

Total kcal per week:  $\frac{kcal}{kg}dx$  weight in  $kg = \frac{kcal}{d}$ 

# Exercise Confidence Survey

Higher score indicates greater self-efficacy. Two Factors are scored separately. Code 8 and blanks as missing values.

Sticking to it: take the mean score of items 2, 3, 5, 6, 8-11

Making time for exercise: take the mean score of items 1, 4, 7, 12

ID\_\_\_\_

#### Social Support and Exercise Survey

Code 8 as a 1. Two factors 1) participation and 2) rewards and punishment are scored separately. Family and Friend are scored separately. Higher scores in participation scale indicates greater support and a lower score in rewards and punishment scale indicates greater support.

Family participation: take the sum of items 1-6 and 10-13

Family Rewards and Punishment: take the sum of items 7-9

Friend participation: take the sum of 1-6 and 10-13

Do not score the rewards and punishment scale for friend because it did not emerge in the factor analysis.

#### Exercise Group Environment Questionnaire

Four factors are each scored separately, attraction. A higher score indicates greater group cohesion.

Individual Attractions to the Group-Task: take the mean of items: 1, 2, 3, 4, 5, 6

Individual Attractions to the Group-Social: take the mean of items: 7, 8, 9, 10, 11, 12

Group Integration-Task: take the mean of items: 13, 14, 15, 16, 17

Group Integration-Social: take the mean of items: 18, 19, 20, 21

#### Exercise stage of Change

No=0, yes=1

Item 1 =exercise stage 1 (exstg1)

Item 2=exercise stage 2 (exstg2)

Item 3= exercise stage 3 (exstg3)

Item 4= exercise stage 4 (exstg4)

Item 5= exercise stage 5 (exstg5)

If exstg1=0 and exstg2=0 then precontemplation

If exstg1=0 and exstg2=1 then contemplation

If exstg1=1 and exstg3=0 then preparation

If exstg1=1, exstg3=1, and exstg4=0 then action

If exstg1=1, exstg3=1, and exstg4=1 then maintenance

Notes: for precontemplation and contemplation stages, subjects should respond to exstg3 and exstg4 with 0's to ensure consistency in responses

The algorithm places subjects into a particular stage at a certain point in time Therefore, in the preparation, action, and maintenance stages whether or not a subject intends to exercise in the next 6 months9exstg2) is inconsequential for that time point.. The intention to exercise in the next 6 months may be highly relevant for intervention planning.

## Data Collection Initial and Post Measures

Date	_
Circle One: Pretest	Posttest
Blood Pressure	:
Resting Pulse:	
Height:	
Weight:	

Investigator to Record:

#### The 12-minute walk test protocol

The 12-minute walk test will begin with a 1-2 minute warm-up period where the participant will walk on the track at a light pace, slower than their anticipated test pace. After the warm-up period, the speed of walking will be increased to a test pace that is self-selected by the participant. The participant will walk in lane 1 and begin at the mark on the track designated as the start point. The participant will be encouraged to select a speed that they feel is challenging, yet that can be maintained for 12 minutes (walking briskly in order to cover as much distance as possible without reaching exhaustion). Once the self-selected speed is achieved, the 12-minute test will start. During the test, the participant will have the ability to increase or decrease the speed of the walking pace depending on her perceived fatigue level. The participant will be able to see the timing of the test, so she can best estimate her ability to complete the test at a given pace and then adjust accordingly. The investigator will count the number of laps the participant walks. At the end of the 12-minutes, the investigator will call out stop, and note the point on the track where the participant is located. The investigator will instruct the participant to slow down to the warm-up pace. The investigator will then record the distance traveled. The participant will continue walking at this slower pace for a 3-5 minute cool-down. After the cool-down period, heart rate will be taken and if under 100 bpm the subject will stop. If the heart rate is over 100 bpm at the end of the first cool-down, this period will be extended another 3 minutes at a slower pace than the previous speed. Heart rate will be re-measured and if sufficiently low, the participant will stop. If heart rate continues to be high, the cool-down period will again be extended as previously described.

0				
Number of Laps:	X 400	meters		
Ending Point:	meters (based on imprinted distance marker from star			
marker on track)				
Total Meters:	meters			
Date	Pretest	Posttest (circle one)		

# DAILY EXERCISE LOG

Please complete after each exercise session. Use one line for each day. You can put more than one exercise session in a line. Use one sheet for each week.

100				
HOW FEELING AFTER EXERCISE				
HOW FEELING BEFORE EXERCISE				
MODERATE HARD VERY HARD (LIST ONE)				
TIME EXERCISING (IN MINUTES)				
TYPE OF ACTIVITY				
DATE			4.55	

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#### Focus Group Guide

- 1. How did HTH work out for you?
- 2. What did you like about HTH?
- 3. What did you dislike about HTH?
- 4. What motivated you to join the study?
- 5. What did you like/dislike about walking as a group?
- 6. What helped you continue to walk with the group and on the other days?
- 7. What was your experience with the heart rate monitor?
- 8. What was your experience with the exercise logs?
- 9. Do you think you will be able to continue the program?
- 10. What might make it easier/harder to continue?
- 11. What would you change in HTH?