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Intervention to Slow Progression of Peripheral Arterial Disease

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INTERVENTION TO SLOW PROGRESSION OF
PERIPHERAL ARTERIAL DISEASE

DISSERTATION

Presented in Partial Fulfillment of the Requirements for the Degree Doctor of Philosophy
in the Graduate School of the Ohio State University

By

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* * * * *

The Ohio State University

2003

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ABSTRACT

Lower extremity peripheral arterial disease (PAD), which results from peripheral atherosclerosis, affects up to 10 million people in the United States alone. This number is expected to increase in proportion to the increase in number of elderly in the population. Claudication, defined as a walking-induced pain in one or both legs relieved by rest, is the primary symptom of lower extremity PAD, and causes significant disability in many patients. As the disease progresses, functional capacity is lost as claudication is induced with even minimal activity, and can progress to rest pain and gangrene. The three main treatment options for PAD are lifestyle management, medical therapy, and surgical intervention. Lifestyle management has been found to be highly effective; specifically, exercise adoption and smoking cessation have become the cornerstones of managing claudication pain. Vascular nurses play a critical role in the collaborative care of PAD patients by offering counseling to change unhealthy behaviors, yet patients experience problems in actually overcoming sedentary lifestyle and nicotine addiction remains. Because the utility of exercise adoption and smoking cessation in treating claudication has been well documented, the purpose of the current study was to identify factors that promote the adoption and maintenance of exercise and smoking cessation behaviors with PAD patients. Therefore, a pretest-posttest control group design with a 12-week exercise

and smoking cessation intervention was implemented, with outcome measures assessed at baseline, 3 and 6 months post enrollment.

The foundational model used for developing this intervention study was the Transtheoretical Model of Behavior Change (TTM). The core constructs from the TTM that were measured were stages of change, decisional balance, and self-efficacy. While the TTM provided the structure for this intervention, principles of nicotine addiction and exercise determinants were used to develop personalized, stage-specific interventions. In addition, functional status, defined as pain free walking time (claudication pain time [CPT]) and maximal walking time (MWT) in minutes and seconds, was measured.

Data was available for analysis with 30 participants, 14 in the intervention group, and 16 in the usual care group. The intervention group did have significant increases ($p < .05$) from baseline in CPT at 3 and 6 months, and in MWT at 3-months only. There were no significant improvements in either functional status measure over time for the usual care group. There were no changes in exercise decisional balance scores over time for either group. Exercise self-efficacy did not change over time for the intervention group, but did significantly decrease ($p < .05$) at 6 months from baseline for the usual care group. In addition, there was a significant difference between groups ($p < .05$) for exercise stage of change at 3-months, but not at 6 months. There were no significant changes in either smoking decisional balance or smoking stage of change over time by group. As a result, all smokers data ($n = 15$) were collapsed and analyzed, with differences and trends discussed, and themes identified.

Results from this study support the premise that a nurse-managed, theory based exercise adoption intervention is effective in helping claudicants adopt a routine exercise program. In addition, when combined with a critical health event, a nurse-implemented, theory-based smoking cessation intervention may contribute to claudicants' successful smoking cessation.

As the incidence of PAD in the elderly population continues to increase, there will be a great demand for nurses to intervene to help claudicants make lifestyle changes that are known to be beneficial. Vascular nurses must lead the way in investigating the most effective means for counseling patients to begin regular exercise and quit smoking.

Dedicated to my husband

Rob Christman

who has tirelessly supported and encouraged me.

Thank you

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2. Christman, S.K., Ahijevych, K., & Buckworth, J. (2001). Exercise training and smoking cessation as the cornerstones of managing claudication. The Journal of Cardiovascular Nursing, 15(4). pp 64-77.
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CHAPTER 1

INTRODUCTION

Lower extremity peripheral arterial disease (PAD) is a result of peripheral atherosclerosis, usually in the aortic, iliac, femoral, or popliteal arteries. PAD affects approximately 8-10 million people in the United States alone, and this number is expected to increase in proportion to the increase in number of elderly in the population (Rockson and Cooke, 1998). Claudication, which is defined as walking-induced pain in one or both legs relieved by rest, is the primary symptom of lower extremity PAD (Fahey, 1999). Vascular nurses play a critical role in the collaborative care of PAD patients by offering lifestyle modification counseling, teaching patients about pertinent medications, and caring for patients after various invasive vascular procedures.

Peripheral arterial disease causes significant disability in many patients due to decreased functional capacity related to activity associated limb pain, also known as claudication. If untreated, PAD can progress to severe rest pain in the calf and feet, gangrene in the toes and feet, and finally amputation, which occurs in 3-8% of these patients every year (Hirsch, Treat-Jacobson, Lando, and Hatsukami, 1997). Risk factors for PAD include smoking, elevated blood lipids (cholesterol and triglycerides), hypertension, and diabetes (Hirsch, et al., 1997; Stewart, Hiatt, Regensteiner, and Hirsch,

2002). In addition, although sedentary lifestyle does not cause PAD, it can contribute to symptomatic progression of the disease from muscle deconditioning that may lead to a house-bound status (Stewart et al., 2002). Furthermore, there is a strong relationship between increasing mortality and decreasing systolic ankle pressures from peripheral atherosclerosis ($p < .0001$) (McKenna, Wolfson, and Kuller, 1991). The 5-year mortality rate of patients with intermittent claudication is two to three times that of the general population (Gajraj and Jamieson, 1994). This high mortality rate is generally a result of a myocardial infarction, and in fact the reported prevalence of coronary artery disease in patients with PAD has been reported as high as 92% (Gajraj and Jamieson, 1994).

While symptomatology, including claudication pain, is crucial in the diagnosis of lower extremity PAD, the ankle-to-arm ratio of systolic blood pressure (ankle-brachial index [ABI]), is also a critical indicator of lower extremity atherosclerosis. An ABI is readily obtainable with a standard blood-pressure cuff and a Doppler device (Stewart, 2002; Hiatt, 2001). This procedure involves having the patient lay supine, while an arm (brachial) systolic pressure is measured with the cuff and Doppler, followed by measurement of the ankle (dorsalis pedis and posterior tibial) pressures using the same equipment. In a normal healthy person with no PAD, the ankle pressure is equal to or slightly higher than the arm pressure due to the highly resistant vascular bed in the lower extremity (Fahey, 1999). Hence, when the arm pressure is divided into the ankle pressure, a ratio of 1.0 or greater is obtained. However, when PAD is present, the ankle pressure is less than the arm pressure, and the ratio is less than 1.0. In fact, the ABI is used as an index of the severity of peripheral arterial disease. Normal flow yields an ABI

of $>.95$, mildly abnormal shows an ABI of $.80-.95$, claudication will result from an ABI of $.40-.75$, and an ABI of $<.40$ results in resting pain, ischemia, and the risk of gangrene (Fahey, 1999). In addition to measuring ABI, the severity of claudication symptoms are also determined by having a patient walk on a treadmill. During a standardized walking test with a consistent speed and grade, claudication pain time (CPT) is recorded, which is the amount of time the patient can walk before they begin to have pain in the affected extremity. In addition, maximal walking time (MWT) is recorded, which is the maximal amount of time a claudicant can walk until maximal extremity pain forces them to stop.

There are several therapies available for treating claudication. These include lifestyle changes (e.g. smoking cessation and exercise training), medical management (e.g. lipid lowering medications, antiplatelets, and medications to enhance blood flow), and surgical management (e.g. peripheral angioplasty or bypass surgery) (Hirsch et al., 1997; Stewart et al., 2002). Medical and surgical management are generally reserved for patients with more severe claudication. In contrast, lifestyle changes have been found to be highly effective as a first-line treatment for claudication. Regular exercise training has been found to significantly increase time to initial CPT, and increase total MWT (Gardner and Poehlman, 1995). In addition, smoking cessation has been found to *prevent* progression of stable claudication symptoms to more severe ischemia requiring surgery or amputation (Fahey, 1999).

While exercise training and smoking cessation are two highly effective treatments for intermittent claudication, helping claudicants make these lifestyle changes can be very challenging for vascular nurses (Christman, Ahijevych, and Buckworth, 2001). As a

result, a research study was developed and implemented in order to determine the effectiveness of a nurse-managed, theory based exercise adoption and smoking cessation intervention with claudicants. Because we already knew that exercise training and smoking cessation were effective treatments for PAD, we were particularly interested in the factors that promote the *adoption* and *maintenance* of exercise and smoking cessation behaviors with PAD patients. This study was developed in collaboration with several vascular surgeons in the greater Columbus area, and subjects were referred and recruited from five different vascular surgery offices in the city.

A literature review about exercise training with PAD patients completed prior to the study revealed that the predictors of change in claudication pain distances during exercise were independently related to three exercise program components: 1) incorporating near maximal claudication pain end point (near maximum walk time) during the exercise training program, 2) at least 26 weeks of exercise, 3 times/week for at least 30 minutes/session, and 3) walking as the mode of exercise (Gardner and Poehlman, 1995). Furthermore, theory based smoking cessation interventions were found to be more effective than non-theory based interventions (Prochaska, DiClemente, Velicer, and Rossi, 1993). As a result, the three important exercise components were integrated into the program, and three theoretical models were used to develop the intervention: the Transtheoretical Model, the Model of Nicotine Addiction, and Exercise Determinants.

While the current study utilized a strong theoretical base to determine the effectiveness of a home based exercise adoption and smoking cessation program compared to usual care (control), there was a study conducted in 1997 by Patterson and

colleagues that was used to guide development of the current intervention. In 1997, a published study reported the differences between supervised and home based exercise for patients with intermittent claudication (Patterson, Pinto, Marcus, Colucci, Braun, and Roberts, 1997). The intervention for both groups included a 12-week class with a comprehensive curriculum covering such things as how to control hypertension, cholesterol, and diabetes, along with exercise training principles. Because PAD management includes more than just exercise and smoking cessation, it was determined that a similar class would be the basis for the current 12-week intervention class. The following chapters reveal that the nurses involved in the 1997 study were contacted and provided information about their program, which was used as a curricular guide for the current study. In the current study, the specific week-by-week curriculum for the intervention group class included the following: etiology of PAD, principles of exercise training, principles of smoking cessation, hypertension, coronary artery disease, healthy eating, cholesterol management, diabetes, foot care, stress management, current medications (what subjects were currently taking), and maintaining the change.

The following chapters are broken down according to the guidelines of the Ohio State University College of Nursing, which require three publishable papers be produced from doctoral research. Chapter two is an article that has already been published in the *Journal of Cardiovascular Nursing*, and addresses the problem of PAD, along with a detailed analysis of the important components of an exercise training and smoking cessation program specific to claudicants (Christman et al., 2001). Chapter three is a manuscript that will be submitted to the *Journal of Vascular Nursing*, and describes in

detail the theoretical base of the current study. Chapter four will be submitted to the Journal of Vascular Surgery, and reports the methods and results of the current study, along with a discussion of the results. Finally, chapter five provides a brief summary of the dissertation, along with recommendations for future research.

CHAPTER 2

EXERCISE TRAINING AND SMOKING CESSATION AS THE CORNERSTONES OF MANAGING CLAUDICATION

The chief complaint of those who suffer from lower extremity peripheral arterial disease (PAD) is intermittent claudication. Claudication, derived from the Latin infinitive “to limp” (claudicare), is defined as cramping muscle pain that occurs predictably each time a given distance is walked, and is relieved after a period of rest (Fahey, 1999). Claudication is a result of arterial occlusion (usually due to an atherosclerotic plaque) in the aortic, iliac, femoral, or popliteal arteries. Claudication pain is always experienced distal to the site of occlusion, and may be located in the gluteal muscle, hip, thigh, or calf (Fowkes, 1997).

PAD affects approximately 30% of older individuals in the general population (Gardner and Poehlman, 1995). With the estimated increase in the elderly population to 67 million by the year 2040, over one million elderly persons could develop symptomatic PAD every two years for the next 50 years (Rockson and Cooke, 1998). Based on research, the classic recommendation to prevent progression of lower extremity PAD given by clinicians is “start exercising and quit smoking” (Lindgarde, Jelnes, Bjorkman, et al., 1989). Unfortunately, a paramount problem for nurses is motivating targeted

individuals with PAD to begin and adhere to an exercise regimen, and/or quit smoking. While advances in the pharmacological management of PAD have been made recently, for many patients, it is minimally effective in reducing claudication pain (Hirsch, et al, 1997),. In contrast, exercise training alone has been found to increase time to the onset of claudication pain by 179% and the time to maximal claudication pain by 122% (Gardner and Poehlman, 1995).

Cigarette smoking has long been known to be a contributor to vascular disease, with PAD being no exception (Lindgarde et al., 1989). The 5-year mortality rate for persons with PAD who continue to smoke is approximately 40-50%, similar to rates observed with many common cancers (Hirsch et al., 1997). In addition to increasing mortality, cigarette smoking is linked to increases in morbidity from PAD, such as progression from asymptomatic PAD to stable claudication, conversion of stable claudication to rest pain, increasing failure rate of limb bypass grafts and limb angioplasty, and increasing amputation rate (Fahey, 1999).

In light of what is known about the benefits of regular exercise training and smoking cessation for patients with claudication, the purpose of this article is four-fold. First, the principles of exercise training in healthy adults, and in those who suffer from claudication will be discussed; second, the most current guideline for smoking cessation interventions will be presented. Third, the most recent literature related to PAD, exercise training, and smoking cessation will be reviewed; and fourth, a case study of a patient with PAD who attempted to begin a regular walking program and quit smoking will be

presented. It is our hope that this information will help health care professionals present current and accurate information to their patients who suffer from PAD, address the difficulties in lifestyle change, and intervene effectively.

2.1 PRINCIPLES OF EXERCISE TRAINING

Healthy Adults

The major objective in exercise training is to facilitate biologic adaptations that improve performance of specific tasks. Successful achievement of these adaptations requires adherence to carefully planned exercise programs, with attention focused on factors such as frequency of workouts per day or week, duration of exercise sessions, intensity, type (mode) of exercise, and rest intervals (ACSM, 2000). Although these factors vary depending on the performance goal, there are several basic principles of physiologic conditioning: 1) the overload principle, 2) the specificity principle, 3) the individual differences principles, and 4) the reversibility principle (ACSM, 2000).

The overload principle states that for a muscle or physiological system to improve its function, it must be worked at a load beyond which it is normally accustomed. This involves exercising at a frequency, intensity, and/or duration that is greater than normal in order to achieve a training effect. In addition, significant health-related benefits can be achieved by a given amount of overload, without necessarily improving cardiovascular fitness. This concept is reflected in the exercise recommendation from the Centers for Disease Control and Prevention and the American College of Sports Medicine to accumulate 30 minutes or more of moderate intensity exercise on most days of the week

(Pate, Pratt, Blair et al., 1995). This level of physical activity is considered minimal for health benefits, but not as effective for improving cardiorespiratory fitness as the more traditional exercise prescription (ACSM, 1990).

The specificity principle refers to the specific adaptations in the metabolic and physiologic systems that occur depending on the type of overload applied. For example, a strength training regimen produces strength adaptations in the specific muscles involved, while an aerobic or cardiovascular exercise program produces adaptations in aerobic metabolism and in the cardiorespiratory system. There is limited aerobic improvement derived from strength training, and vice versa (Hurley, Seals, Ehsani et al., 1984). Specificity is also demonstrated within anaerobic (e.g., strength training) and aerobic training. For example, swim training produces significant improvements in swimming endurance, but minimal improvements in running endurance (Magel, McArdle, Toner et al., 1975). In addition, overloading a specific muscle produces local changes that facilitate both oxygen transport and utilization (Green, Jones, Ball-Burnett, Farrance, and Ranney, 1995). These changes include an increase in the muscle oxidative potential, increased microcirculation, and increased cardiac output (ACSM, 2000; Green, et al., 1995).

The individual differences principle refers to the many individual variations that contribute to the training response. For example, the level of fitness at the beginning of an exercise program will influence potential changes in fitness at the end of the program, with greater relative changes possible for someone initially low in fitness. In addition, age, weight, history of past exercise, and comorbid illness, among many other things, will

influence an individual's response to any given type of exercise. It is best to remember that training benefits are optimized when programs are individualized to each participant, and their personal exercise capacities are taken into consideration (ACSM, 2000).

Finally, the reversibility principle states that detraining occurs rapidly when a person stops exercising. Significant reductions in both metabolic characteristics and exercise capacity can begin in only 1 or 2 weeks, and many of the training benefits are lost within several months (McArdle, Katch, and Katch, 1996). Ultimately, it is important to remember that even for highly trained athletes, the benefits derived from many years of regular exercise can be reversed in a very short period of time. Application of these four principles of exercise training will result in several physiological adaptations (see Table 1.1). Both the cardiovascular changes (e.g. increased stroke volume), and the local changes (e.g. increased capillary density and muscle oxidative capacity) work together to improve overall aerobic capacity and endurance. For example, over time, as stroke volume, cardiac output, and plasma volume increase, more oxygenated blood is available for the exercising muscle. As capillary density increases, the exercising muscle can receive more oxygenated blood. As oxidative capacity improves, the exercising muscle can take up and use more oxygen. Cumulatively, this change is represented by VO_{2max} , or maximum oxygen uptake. Maximum oxygen uptake refers to the maximum amount of oxygen that can be taken up and used by the muscles. In addition, not only is resting heart rate decreased, but heart rate is lower at any given work load (e.g., an untrained individual could have a heart rate of 150 beats/minute while running at 5 mph, but after training his or her heart rate might only be 130 beats/minute

running at the same speed). The combination of enhanced oxygen transport and utilization, and decreased heart rate from aerobic training results in greater endurance, better exercise tolerance, and less fatigue.

Finally, when discussing exercise training from the standpoint of encouraging others to begin a regular exercise program, determinants of exercise must be addressed. The term “exercise determinant” refers to factors that mediate or influence level of activity. These determinants can include characteristics of the person, of the environment, or of the physical activity (Buckworth, 2000). Some personal determinants that positively correlate with higher levels of physical activity are sex (men), age (younger), education (more), race (non-Hispanic whites), and job (white collar). Some modifiable determinants of exercise behavior include self-motivation, intention, self-schemata (see yourself as an exerciser), self-efficacy (confidence in the ability to engage in an activity), and enjoyment of exercise (Dishman and Buckworth, 1996). Environmental influences include social support (stronger for women), and objectively measured access to facilities (physically close to the exercise location) (Buckworth, 2000). Characteristics of exercise itself that are exercise determinants are intensity (better for lower intensities) and mode of exercise (Buckworth, 2000). Although a change in an exercise determinant (e.g. mode of exercise) does not guarantee a participant’s successful initiation and maintenance of exercise, it certainly enhances the probability of success. As a result, it is worthwhile for clinicians to assess their patients’ exercise determinants.

Patients with Claudication

The underlying pathophysiology of claudication involves tissue ischemia from decreased peripheral blood flow and oxygenation. Therefore, exercise testing is a commonly used means of quantifying the extent to which the patient with claudication is disabled by his/her disease. Because the pain of claudication is predictable and reproducible, a patient will be asked to walk on a treadmill at a standardized speed and grade (usually about 1.5 mph at a 10% grade). During the test, patients may be asked to indicate when claudication begins (claudication pain time), and exercise is stopped when disabling claudication occurs (maximal walking time). In addition, ankle pressures (measured over the dorsalis pedis or posterior tibial artery) are recorded before and after exercise. Normally, arterial flow increases in the extremity being exercised. However, in those with arterial occlusions, flow decreases distal to the stenosis, and pressures after exercise drop proportionally with the severity of the disease (Fahey, 1999). Because exercise training is known to increase claudication pain time and maximal walking time, one would assume that in some capacity, lower extremity blood flow is improved with exercise training, and by definition, peripheral pressures during and after exercise are improved. However, this is not the case as lower extremity blood flow has been found to either remain unchanged or minimally improve after routine exercise training (Patterson, et al., 1997; Tan, de Cossart, and Edwards, 2000).

The physiologic changes associated with exercise training in the PAD patient are the same as those seen in the healthy adult. However, it is important to remember that because of their symptom-limiting disability, the person with claudication may not be

able to begin exercise at the same intensity as that of the healthy adult, and therefore may see an attenuation of their physiological adaptations, particularly changes in heart rate, stroke volume, and cardiac output. However, even at lower intensity levels, PAD patients still experience improvements in claudication pain time and maximal walking without a correlating cardiopulmonary improvement (Ruell, Imperial, Bonar, Thursby, and Gass, 1984). This improvement seems to be a result of peripheral factors such as changes locally in oxidative capacity and oxygen utilization, increased capillary density, changes in hemoglobin oxygen affinity, normalization of plasma viscosity, and economization of walking (Ernst and Matrai, 1987).

Recently, twenty-three patients with claudication completed a 3-month unsupervised exercise program of walking 1 hour each day to the claudicating limit, 5 days per week (Tan et al., 2000). Pre and post exercise training, measures were taken during or after a standardized walking test to determine changes in maximal walking time, common femoral artery flow, oxygen uptake during exercise, plasma viscosity, total cholesterol with high-density lipoprotein (HDL) and low-density lipoprotein (LDL), triglycerides, exercise heart rate, and resting heart rate. Although maximal walking time significantly increased (82%), there were no significant changes in femoral artery blood flow, plasma viscosity, LDL, triglycerides, or resting heart rate. However, oxygen uptake and heart rate both significantly decreased during the standardized walking test, along with a significant drop in total cholesterol post training. The changes in exercise oxygen uptake and heart rate could have been an indication of improved physical fitness, or

possibly an economization of walking. In summary, the exact mechanism by which PAD patients improve their walking time by regular exercise training is not completely known.

The principles of exercise training are effectively the same for healthy adults and patients with claudication. First, the exercise must provide adequate overload to the affected muscles (intensity, frequency, and duration); the type of exercise must be specific to the type of improvement desired (walking exercise improves walking performance); the program of exercise must be individualized to account for personal preferences, degree of physical fitness, and extent of disability; and it must be maintained over a lifetime for the patient to see long term benefits. Finally, because of their symptom-limiting disability, patients with claudication usually will need to begin with up to 20 minutes of interval exercise (walk-rest-walk-rest) and work up to 30-45 minutes of continuous exercise. In addition, PAD patients may need to be assured that their claudication will not cause any physical damage despite the physical discomfort they feel.

2.2 PRINCIPLES OF SMOKING CESSATION

Tobacco use has been termed the agent most responsible for avoidable illness and death (Fiore, Bailey, Cohen et al., 2000). Tobacco use is the single most important cause of PAD (Ekers and Hirsch, 1999). In 1996, the US Department of Health and Human Services published a clinical practice guideline for developing smoking cessation programs based on a meta-analysis of all available tobacco related literature. This publication has been updated, and is entitled *Treating Tobacco Use and Dependence*

(Fiore et al., 2000). Since 1994, an additional 3000 articles related to tobacco dependence have been published, and the new guideline reflects the latest, effective clinical treatments for tobacco dependence.

More than one-third of current smokers report never having been asked about their smoking status or urged to quit (Thorndike, Rigotti, Stafford, and Singer, 1998). Thus, the first step in treating tobacco use and dependence is to identify tobacco users. Every patient should be screened for tobacco use, and this screening will result in four possible responses: 1) the patient uses tobacco and is now willing to make a quit attempt; 2) the patient uses tobacco but is not now willing to make a quit attempt; 3) the patient once used tobacco but has since quit; and 4) the patient never regularly used tobacco. The clinical practice guideline is organized to help clinicians develop simple, effective interventions for all patients (Fiore et al., 2000).

Healthy Adults

Smoking behavior is influenced by pharmacological, psychological, social, and environmental factors. The powerful pharmacological reinforcement associated with smoking (a combination of euphoria and sedation) leads to the strong psychological dependence reported by smokers (USDHHS, 1988; Shiffman, 1979). The subsequent alleviation of negative affective symptoms such as tension, anxiety, boredom, and irritability lead to a continuation of the smoking behavior (Shiffman, 1979). Therefore, assessment of the patient's willingness to quit is essential. For the patient willing to quit, the five major steps to intervention should be employed (see Table 1.2). Once the

assessment is completed, strong advice to quit tobacco use should be given. This should be clear, strong, and personalized, and might include a statement such as

“As your clinician, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. The clinic staff and I will help you” (Fiore et al., 2000, p 28).

The third step, which includes assessing a patient’s willingness to quit tobacco use will determine the type of intervention offered. Aiding the patient in quitting will at the very least include helping the patient with a quit plan, providing practical counseling, providing social support during treatment, helping the patient obtain social support after treatment, recommending the use of approved pharmacotherapy, and providing supplemental materials (See Table 1.3). Finally, scheduled follow-up should be conducted, either by telephone or in person. Contact should be made soon after the quit date, and the patient should be encouraged to continue with their plan.

Since the 1996 Guideline was published, extensive research has been conducted regarding the use of pharmacotherapies to aid in smoking cessation. Recommended pharmacotherapies help patients overcome their physical addiction, but do not alter the psychological, social, or environmental factors that influence smoking behavior. Therefore, these pharmacotherapies are intended as an adjunct to behavioral counseling and follow-up (Fiore et al., 2000). The current guideline recommends several pharmacotherapies as first-line medications, as they have been found to be safe and effective for tobacco dependence treatment, and have been approved by the US Food and Drug Administration for this use (see Table 1.4).

Bupropion, an oral neural reuptake inhibitor, has been found to double tobacco cessation rates compared to placebo (Fiore et al., 2000). Those taking Bupropion should be informed that the medication is begun prior to their quit date, and that they may lose their desire to smoke or spontaneously reduce the amount they smoke. In addition, if insomnia occurs, taking the evening dose a little earlier in the day may help. *Nicotine gum* has been found to improve long-term abstinence rates by approximately 30-80% as compared to placebo (Fiore et al., 2000). Patient education should include information about 1) chewing technique: chew slowly until minty taste emerges, then park the gum between the cheek and the gum; 2) absorption: avoid eating or drinking anything but water 15 minutes before and during chewing; and 3) scheduling: chew one piece every 1-2 hours. The *nicotine inhaler* can as much as double cessation rates compared to placebo (Fiore et al., 2000). Specific instructions to patients should include avoiding eating or drinking 15 minutes before inhalation to promote absorption; keeping the cartridge at temperatures above 40 degrees F to promote delivery of nicotine; and using the inhaler for up to 6 months with gradual reduction in frequency of use over the last 6-12 weeks of treatment. *Nicotine nasal spray* more than doubles long-term abstinence rates when compared to a placebo spray (Fiore et al., 2000). Patients should be instructed not to sniff, swallow, or inhale through the nose while administering doses as this increases irritating effects. Finally, the *nicotine patch* approximately doubles long-term abstinence rates over those produced by placebo interventions (Fiore et al., 2000). Instruct patients to apply the patch first thing in the morning, over a relatively hairless portion of the skin.

For patients who are unwilling to quit tobacco use, the motivation to quit should be promoted. In this case, the “5 R’s” are helpful to remember. First, the relevance of quitting should be discussed (e.g. health concerns). Next, the risks of smoking should be identified (e.g. progression of PAD). Third, the rewards of quitting should be stressed (e.g. improved health, feel better about yourself). Fourth, roadblocks to quitting should be identified (e.g. fear of failure or lack of support). And finally, repetition by the clinician is key—the motivational intervention should be repeated every time an unmotivated client is seen (Fiore et al., 2000).

For the patient who has recently quit, the clinician should focus on preventing relapse. This intervention focuses on the benefits derived from cessation, any success that patient has had in quitting, and discussion of the problems encountered or anticipated threats to maintaining abstinence. Meanwhile, patients should be encouraged and congratulated to continue with their tobacco abstinence.

For those clinicians who have the opportunity to provide a more intensive intervention than that discussed above, it is important to note that there is a strong dose-response relationship between counseling intensity and cessation success (Fiore et al., 2000). For example, patients receiving 31 to 90 minutes of counseling are 3 times as likely to succeed in smoking cessation compared to the patient who receives no counseling. Even the person who receives 1 to 3 minutes of tobacco cessation counseling is 1.4 times more likely to quit as the person who does not receive counseling. There are several critical features of a more intensive intervention. First, multiple types of clinicians are effective and should be used. This could include health care providers from

different disciplines providing education at different times. Next, the number of sessions with each patient should equal 4 or greater, each session length should be 10 minutes or more, and total contact time should be longer than 30 minutes. Third, individual or group counseling may be used, and telephone counseling is also effective. Fourth, as with less intensive therapies, pharmacotherapy should be encouraged. Finally, counseling and behavioral therapies should include problem solving/skills training, and intra-treatment and extra-treatment social support.

Patients with Claudication

One important question regarding quitting smoking is whether patients with PAD should receive the same cessation interventions as other populations. Unfortunately, this question has not been clearly answered in the literature, but there does not seem to be any evidence to the contrary. One factor to consider is that most patients with claudication are 50 years or older, and therefore smoking cessation strategies aimed at older adults would be appropriate (Rockson and Cooke, 1998). Fortunately, smoking cessation treatments developed by the guideline outlined above have been found to be effective with older adults (Fiore et al., 2000).

Another consideration is the use of pharmacotherapies to aid in smoking cessation with PAD patients. The incidence of cardiovascular disease is significantly greater in the PAD population than the general adult population. Soon after the nicotine patch was released, the media reported a possible link between the use of this medication and cardiovascular risk. Since then, researchers studying this question have found no association between the nicotine patch and cardiovascular deaths (Fiore et al., 2000). As a

result, nicotine replacement can be safely recommended for use with PAD patients. However, many clinicians still hesitate to recommend nicotine replacement to patients with claudication because of the peripheral vasoconstrictive effects of nicotine. Although the side effects of nicotine replacement must be considered, the short-term effects of nicotine replacement versus the long-term effects of continued smoking should also be compared. If nicotine replacement is considered a risk, then non-nicotine pharmacotherapies (e.g. Bupropion) can be recommended.

2.3 REVIEW OF RECENT LITERATURE

Exercise Training and PAD

The original recommendation for using routine exercise to treat intermittent claudication came from Erb in 1898 (Tan et al., 2000). Since then, many controlled trials have studied the effects of exercise training in patients with PAD. As a result, several meta-analyses have been conducted, with agreement among researchers that the outcome of a regular exercise program is good and that the improvement in exercise time is generally greater than 100% (Gardner and Poehlman, 1995; Robeer, Brandsma, van den Heuvel, Smit, Oostendorp, and Wittens, 1998). Recently, a meta-analysis of 21 exercise related research studies identified very specifically the predictors of change in claudication pain distances after participating in a regular exercise program. The three exercise program components that were independently related to improvement in walking time were: 1) incorporating near maximal claudication pain end point (near maximum walk time) during the exercise training program, 2) at least 26 weeks of exercise, 3 times/week for at least 30 minutes/session, and 3) walking as the mode of exercise

(Gardner and Poehlman, 1995). Since the publication of these meta analyses, other experimental studies have been conducted to assess the beneficial effects of exercise training, and similar conclusions were drawn (Gibellini, Fanello, Bardile, Salerno, and Aloi, 2000).

One component of a regular exercise program that has been addressed is the value of supervision versus no supervision. In a randomly controlled trial comparing supervised and home-based exercise, both groups improved ($p < .001$) in claudication pain time and maximal walking time at the completion of the 12-week program and maintained the improvement at 6 months (Patterson et al., 1997). However, the supervised exercise group did have a significantly ($p < .004$) greater increase in their 6-month claudication pain time and maximal walking time than the home-based exercise group (Patterson et al., 1997). Others have seen similar benefits derived from supervised exercise (Gardner and Poehlman, 1995). Even so, it is important to remember that if patients with claudication adhere to a home-based exercise program, significant benefits can be derived (Patterson et al., 1997). Unfortunately, only about 50% of individuals who participate in limited-duration preventive or rehabilitative programs continue beyond the 6-month mark (Burke and Dunbar-Jacob, 1995). This could be a result of the exercise “determinants” that were previously discussed, such as social support, proximity to the exercise facility, and type of exercise. Adherence-enhancing interventions have been identified and include educational strategies that enable patients to implement and maintain the regimen, and behavioral strategies such as goal setting and contracting

(Burke and Dunbar-Jacob, 1995). While these strategies have been used successfully with healthy adult populations, no such strategies have been used explicitly with PAD patients (Calfas, Long, Sallis, Wooten, Pratt, and Patrick, 1996).

Researchers have shown that exercise training is effective in increasing claudication pain time and maximal walking time. However, what is not clear is the relationship between walking time and quality of life in patients with PAD (Tan et al., 2000). Several researchers have investigated the differences in quality of life between healthy adults and patients with claudication (Barletta, Perna, Sabba, Catalano, O'Boyle, and Brevetti, 1996; Khaira, Hanger, and Shearman, 1996; Bauman and Arthur, 1997). While two of the three reports indicated that quality of life is significantly affected by decreased functional capacity (Khaira et al., 1996; Bauman and Arthur, 1997), the third did not find a correlation between treadmill performance and social or emotional function, but did find a correlation (small, but significant) between treadmill performance and physical function (Barletta et al., 1996). In two other studies, quality of life was measured using the SF-36 (MOS) (Patterson et al., 1997) and the SF-20 (MOS) (Regensteiner, Steiner, and Hiatt, 1996) at three and six months after the initiation of an exercise program. For all exercise subjects, treadmill performance significantly improved, in addition to significant improvements in the Physical function subscale (Patterson et al., 1997; Regensteiner et al., 1996), Bodily pain subscale (Patterson et al., 1997), and the Physical composite score (Patterson et al., 1997). Degree of supervision did not seem to make a difference as some of the subjects were involved in home-based exercise (Patterson et al., 1997). While there is a paucity of literature on the relationship

between PAD and quality of life, there is evidence that at least the physical function component of “quality of life” seems to be improved with regular exercise training.

Smoking and PAD

Despite the fact that smoking has been identified as the most significant factor contributing to the onset and progression of PAD, most information on the effects of smoking cessation is from natural history studies of persons with intermittent claudication (Radack and Wyderski, 1990). Despite several methodological problems associated with the majority of the natural history studies in PAD, two common themes have been identified: 1) fewer than 50% of patients reported smoking cessation despite participation in a supervised smoking cessation program, and 2) discontinuation or reduction of cigarette smoking as reported by subjects with intermittent claudication was associated subsequently with a reduced frequency of peripheral vascular complications (Radack and Wyderski, 1990). In addition, smokers have been found to have more debilitating claudication symptoms compared to non smokers (Gardner, 1996). These symptoms may include lower resting ankle pressures and more severe claudication pain.

In one experimental study conducted with persons with PAD, a smoking cessation program was implemented during visits to a peripheral vascular clinic (Power, Brown, and Makin, 1992). A health promotion officer provided a one-time only smoking cessation counseling session for 30-45 minutes, yielding no significant differences between the control and experimental groups on smoking cessation rates at one and six months. These authors concluded that their lack of significant findings could have been a

result of their older population with high smoking rates. They recommended smoking cessation counseling that emphasizes personal benefits of quitting and employing multiple methods tailored to the individual.

Despite the paucity of literature on successful smoking cessation interventions with PAD patients, it is realistic to expect patients with claudication to stop smoking. For example, only 30-40% of individuals with stable claudication are current smokers, although most of these individuals smoked in their past (Hirsch et al., 1997). The higher rate of current smokers in vascular clinics reflects the effect of tobacco on the acceleration of thrombosis and atherosclerosis (Hirsch et al., 1997). These data provide clinicians with the impetus to develop effective and pertinent interventions for their patients who continue to smoke.

2.4 SUMMARY

Exercise training and smoking cessation are the cornerstone of claudication management. The critical components of any training program aimed at treating PAD must include: exercise of adequate duration (at least 26 weeks, 3 times/week, 30 minutes each session); proper exercise mode (walking); and appropriate exercise intensity (walking to near maximum pain before stopping to rest). In addition, determinants of exercise behavior must be assessed in order to promote long-term maintenance of the behavior. Before developing an exercise prescription for patients with claudication, it is important to determine the patient's attitude toward exercise, the attitude of their spouse or significant other toward exercise, the source of their motivation to exercise, and their belief in their ability to begin and adhere to an exercise program. Clinicians also must

discuss the symptom-limiting nature of PAD, and that interval training is the best way for patients with claudication to begin a regular walking program. Finally, although a supervised exercise program is an effective way to manage claudication, the resources and/or the time is not always available for such an undertaking. For those patients unable or unwilling to attend a supervised program, clinicians can discuss home-based exercise using adherence enhancing strategies such as goal setting and contracting.

Despite the fact that cigarette smoking is the most significant risk factor in developing PAD and its subsequent progression, almost half of patients with claudication who continue to smoke do not contribute their disease to smoking (Bloom, Stevick, and Lennon, 1990). In fact, most of these same smokers do not plan to stop smoking until serious health and disease problems are manifested (Bloom et al., 1990). Clinicians should not despair from this information as the majority of patients with claudication are former smokers. However, assessing the patient's smoking status and readiness to quit is essential with every PAD patient. Current smokers must receive a clear, strong message in favor of quitting from their clinician. If the patient is ready to quit, in addition to encouraging the use of pharmacotherapy, develop a written plan for quitting, along with providing and helping the patient to find social support, and providing clinician follow-up. For the patient who is unwilling to quit smoking, promote the motivation to quit--perhaps by providing accurate information regarding the relationship between smoking and PAD.

In an effort to apply the principles discussed in this paper, a case study describing the efforts of one patient with claudication to quit smoking and begin exercising is

presented. This individual attended a 12-week class presenting the benefits of smoking cessation and exercise adoption. In addition, information about other pertinent topics for PAD patients was presented, including foot care, hypertension, heart disease, and nutrition.

2.5 CASE STUDY

K.L. is a 62-year-old Caucasian male with a 10-year history of stable claudication and a 42-year one pack per day smoking history. He works at a desk most of the day, and at our initial visit he was not exercising at all, but wanted to begin a regular walking program. He also stated he wanted to quit smoking, but did not think he was quite ready to make that change. His wife is a smoker who has no intention of quitting, but would be interested in starting to exercise with K. L. Upon initial assessment, K. L. stated he could walk about one block on level ground before claudication in both calves would force him to stop. He had been taking Cilostazol (Pletal) for several months with minimal subjective improvement in his claudication pain distance. Additional assessment included questioning him about exercise self-efficacy (confidence in his ability to exercise), which was determined to be quite high. In addition, his level of nicotine addiction was addressed. His level of psychological addiction seemed to be greater than his level of physical addiction as evidenced by his statement that he could go all day without smoking, but once he got home and faced some personal stress, he would feel the need for a cigarette. Finally, his actual exercise performance was assessed. During a standardized treadmill walking test, K. L. experienced initial claudication at 2 minutes 46 seconds, and maximal walking time was measured at 8 minutes 13 seconds.

Once the initial assessment was complete, K. L. began to attend a 12-week, one hour/week, small group counseling session where principles of exercise adoption and smoking cessation were discussed. Principles of exercise training were presented (e.g. the need for overload to specific muscles), and an individualized exercise program was designed for him based on what he felt he could do. He decided to start out at 10 minutes/day, 7 days/week of interval training, walking exercise. K. L. also decided to buy a treadmill to help him adhere to his exercise program. In addition, his progress was discussed on a weekly basis in the small group. Over the 12 weeks of counseling, K. L. progressed to about 15 minutes/day of continuous exercise, but never was able to increase his daily exercise time to the recommended 30 minutes/day. He stated his primary barrier to increasing his exercise time was a busy schedule. Despite probing questions, we were never able to determine ways for him to find more time for exercise.

Because K. L. had stated he was not quite ready to quit smoking, we worked on promoting his motivation to quit. On a weekly basis, we focused on the benefits of quitting smoking, primarily by slowing the progression of his PAD. On several occasions, he stated he wanted to make the commitment to quit smoking, but by the end of the 12-week program, he hadn't yet been able to so. K. L. refused the use of pharmacotherapies to aid him in quitting. He stated his major barrier to quitting was stress at home. As a result, we talked extensively about alternative ways to handle stress.

At the conclusion of the 12-week class, K. L. in conjunction with the other class members and the nurse facilitator, developed a contract for continuing exercise. During a repeat of the standardized treadmill walking test, K. L. experienced initial claudication at

8 minutes 32 seconds, which was nearly a 5-minute improvement. His maximal walking time increased to 10 minutes 40 seconds, which was greater than a 2-minute improvement. In addition, he stated he stopped the exercise test primarily because of fatigue and shortness of breath rather than from claudication.

For three months after he completed the 12-week program, K. L. was called every two weeks to promote adherence to his exercise regimen. However, after only about 2 months, K. L. was diagnosed with carotid artery disease, and underwent a carotid endarterectomy. K. L. stated that he felt this diagnosis was serious enough to motivate him to quit smoking. From the time of his surgery, K. L. has not smoked (about 2 months), and within about a week postoperatively, K. L. resumed his exercise regimen of 15 minutes walking/day. In a telephone conversation, K. L. stated he has never felt better, and is confident in his ability to continue exercising and to abstain from smoking.

Two lessons learned from working with K. L. include: 1) the importance of partnering with patients to develop plans for exercise adoption and smoking cessation, and 2) many smokers do indeed wait until a "critical health event" has occurred before they are ready to quit smoking. As clinicians, our role involves working with patients to provide accurate information and resources to facilitate exercise adoption. In addition, even when a patient states he or she is not ready to quit smoking, we must continue to promote the motivation to quit, so that when they are finally ready, they will be empowered to make the change successfully.

Physiologic variable	Change after exercise training
Vo ₂ max, mL/kg/min	Increased
Cardiac output, L/min	Increased
Stroke volume, mL/beat	Increased
Heart rate, beats/min	Decreased
Plasma volume, L	Increased
Capillary density, cap/mm	Increased
Oxidative enzyme capacity	Increased

Source: McArdle, Katch, and Katch, 1996

Table 2.1: Physiologic Consequences of Exercise Training

Ask about Tobacco use

Advise to quit

Assess willingness to make a quit attempt

Assist in quit attempt

Arrange follow-up

Source: Fiore et al., 2000

Table 2.2: A guide to the brief intervention

Strategy	Specific steps
Help the patient develop a quit plan.	<p><i>Set a quit date</i>—within 2 weeks.</p> <p><i>Tell</i> others about quitting</p> <p><i>Anticipate</i> difficulties in planned quit attempt</p> <p><i>Remove</i> tobacco products from your environment</p>
Provide problem solving and behavioral training).	<p><i>Abstinence</i>—Total abstinence is the goal.</p> <p><i>Past quit experience</i>—Review past quit attempts –what helped? What did not help?</p> <p><i>Anticipate challenges in upcoming quit attempt</i>—Discuss techniques to overcome them.</p> <p><i>Alcohol</i>—consider limiting/abstaining from alcohol while quitting.</p> <p><i>Other smokers in the household</i>—encourage housemates to quit or not smoke in their presence.</p>
As a clinician, provide social support.	<p><i>Demonstrate</i> your support during this difficult change.</p>
Help patient identify support persons.	<p><i>Help</i> patient list persons (family, friends, co-workers) who can provide social support during the quit attempt.</p>
Recommend use of approved tobacco treatment pharmacotherapy, except in special circumstances.	<p><i>Explain</i> how these medications have improved smoking cessation success and reduced nicotine withdrawal symptoms.</p>
Provide additional print materials.	<p><i>Sources</i>—Federal and nonprofit agencies, local/state health departments, or commercial providers.</p> <p><i>Review</i> materials to meet your particular patients’ needs related to culture, educational level, and age appropriateness.</p> <p><i>Maintain</i> a supply of materials and resources at every clinician's workstation.</p>

Source: Fiore et al., 2000

Table 2.3: Assisting the patient to quit smoking

Drug name	Dosage	Availability	Cost/day
Bupropion	150 mg qAM for 3d; increase to 150 mg BID	Zyban— prescription only	\$3.33
Nicotine gum	2mg/piece for those smoking <25 cigarettes/day; otherwise use 4mg/piece; for up to 12 weeks, no more than 24 pieces/day	Nicorette, Nicorette Mint—over the counter only	\$6.25 for 10, 2mg pieces \$6.87 for 10, 4mg pieces
Nicotine inhaler	4mg of nicotine is delivered over 80 inhalations; recommended 6-16 cartridges/day, for up to 6 months.	Nicotrol inhaler— prescription only	\$10.94 for 10 cartridges
Nicotine nasal spray	1 dose = 0.5 mg delivery to each nostril; 1-2 doses/hour. Maximum of 40 doses/day (5 doses/hour). Each bottle contains about 100 doses	Nicotrol NS— prescription only	\$5.40 for 12 doses
Nicotine patch	Varies from 7mg – 21 mg/patch. Individualize treatment to patient. Typically, patients start at a 21 mg patch /day for 4 weeks, followed by 14 mg/day for 2 weeks, and ending with 7 mg/day for 2 weeks.	Nicoderm CQ, Nicotrol, generic—over the counter Nicotine patches (various doses)-- prescription	\$4 - \$4.50 (brand name)

Source: Fiore et al., 2000

Table 2.4: Information on first-line pharmacotherapies to aid in smoking cessation

CHAPTER 3

THE TRANSTHEORETICAL MODEL, THE MODEL OF NICOTINE ADDICTION, AND EXERCISE DETERMINANTS AS THE BASE FOR DEVELOPING AN EXERCISE ADOPTION AND SMOKING CESSATION INTERVENTION

Peripheral arterial disease (PAD) affects up to 20% of older adults in the general population (Fowkes, 1997; Stewart, et al., 2002). Lower extremity PAD is a manifestation of atherosclerotic plaque, resulting in claudication, which is defined as walking-induced pain in one or both legs relieved by rest (Fahey, 1999). The treatment of this condition focuses on decreasing the functional impairment caused by symptoms of claudication, and treating the underlying systemic atherosclerosis in patients with claudication (Stewart et al., 2002). Cigarette smoking and sedentary lifestyle are known risk factors for symptomatic PAD (Christman, et al, 2001). Based on research, exercise training and smoking cessation have become the cornerstones of managing claudication. As a result, vascular nurses have a unique role to play in helping patients who suffer from lower extremity PAD manage their symptoms through life-style changes.

Regular aerobic exercise has long been known as an effective therapy for decreasing the functional impairment caused by symptoms of claudication (Rockson and Cooke, 1998). Exercise training alone has been found to increase time to the onset of

claudication pain by 179% and the time to maximal claudication pain by 122% (Gardner and Poehlman, 1995). While the improvement in claudication symptoms after exercise training are not completely understood, there is some research to support specific physiological, metabolic, and mechanical alterations which include formation of collateral vessels and increased blood flow to the affected muscle, changes in microcirculation and endothelial function, changes in muscle metabolism and oxygen extraction, and improved walking economy (Stewart et al., 2002). For the claudicant, the overall improvement in functional capacity after smoking cessation is also documented and includes benefits such as increased exercise tolerance, maintaining or improving ankle pressures (versus a reduction in ankle pressures for those who continue to smoke), and decreased claudication symptoms (Quick and Cotton, 1982; Hirsch, et al, 1997; Gardner, 1996). In addition, there appears to be a progressive decline in free-living daily physical activity with greater levels of smoking exposure in PAD patients, primarily due to smoking-related impairments in ambulatory function and peripheral circulation (Gardner, Montgomery, Womack, and Killewich, 1999).

While the benefits of regular aerobic exercise and smoking cessation as a treatment for claudication have been widely reported, the reality of helping people change long-standing unhealthy behaviors is more complicated (Christman et al., 2001). Recently published articles have supported the argument that a supervised exercise program yields improvements in the pain free walking time of claudicants almost double that of home based exercise programs (Patterson et al., 1998; Degischer, Labs, Hochstrasser, Aschwanden, Tschoepl, and Jaeger, 2002). Unfortunately, mean dropout

rates from supervised exercise programs reported around the world has remained at roughly 50% over the past 20 years (Dishman and Buckworth, 1996). In addition, while natural history studies with PAD patients have shown the benefits of a "non smoking" state, intervention studies to help claudicants quit smoking have yielded non-significant findings (Power et al., 1992; Fowler et al., 2002).

There is a paucity of literature regarding specific interventions to help claudicants adopt regular aerobic exercise and quit smoking, and in fact, none of these interventions have an identified theoretical base. Oberst (1989) has stated that atheoretical interventions are little more than trial and error regarding what does and does not work. Comparatively, in studies where nurse researchers have used strong theoretical frameworks to guide program development, the results have substantially more impact on practice and subsequent research than is the case for atheoretical studies (Oberst, 1989). The purpose of this article then, is to describe the theoretical basis for a nurse-implemented exercise adoption and smoking cessation educational program for persons with lower extremity PAD. Details of the intervention protocol and outcomes are reported elsewhere (Chapter 4). In order to develop a comprehensive program, three theoretical models were identified and utilized to develop this program: 1) the Transtheoretical Model, 2) nicotine addiction, 3) exercise determinants. Each model will be reviewed, followed by a description of how the model was used to develop and implement the intervention.

3.1 THEORETICAL MODELS

Transtheoretical Model

The Transtheoretical Model of Behavior Change (TTM) was first proposed in 1977 by a practicing psychologist (Prochaska, 1977). He had become interested in behavior change from experiences counseling people trying to change addictive behaviors. Subsequently, he reviewed 18 different systems of psychotherapy and found similarities among them. As a result, he proposed the use of a *transtheoretical* model (TTM) versus one isolated model of psychotherapy. In addition, observations were made and interviews were conducted with people who had successfully changed an addictive behavior (smoking) on their own to try and determine how they achieved success. A pattern of change consistently followed by successful changer began to emerge, and this process was named the “stages of change” (Prochaska and DiClemente, 1984). The original model consisted of 4 stages: precontemplation, contemplation, action, and maintenance. By the late 1980's researchers had identified a 5th stage called preparation, which preceded the action stage (Prochaska, Redding and Evers, 1997). From the initial studies with smokers, the TTM has expanded in scope to include investigations with a broad range of behaviors including but not limited to eating disorders and obesity, AIDS prevention, sun exposure, and sedentary lifestyle (Prochaska, 1994).

The core constructs of the TTM are stages of change, processes of change, decisional balance, and self-efficacy (Prochaska and Velicer, 1997). As people change a behavior, the five stages of change through which they pass are precontemplation (no intention for change in the next 6 months), contemplation (intend to change in the next 6

months), preparation (intend to change in next 30 days), action (change has occurred in last 6 months), and maintenance (changed more than 6 months ago). Movement through these stages occurs in a cyclical manner and many individuals make several attempts at behavior change before reaching maintenance (Prochaska, et al., 1997).

The processes of change, which are the strategies used by people to move forward through the stages of change, have been refined from the original publication and involve 10 cognitive/experiential and behavioral processes (Prochaska and DiClemente, 1983; Prochaska et al., 1997) (see Table 3.1). Although there are no specific processes that are used to change different behaviors, there is a relationship between cognitive processes and the earlier stages of change, and behavioral processes and the later stages of change (Prochaska et al., 1997).

Decisional balance reflects an individual's relative weighing of the pros (benefits) and the cons (consequences) of behavior change (Prochaska et al., 1997). In the earlier stages of change the cons of changing outweigh the pros, thus decisional balance is low. However, as progression is made toward action, the pros of changing outweigh the cons and decisional balance becomes higher. In fact, the construct of decisional balance is thought by some to be critical in predicting the success or failure of behavior change. An increase in pros score by one standard deviation, and a decrease in cons score by 0.5 standard deviation has been identified by Prochaska as a prerequisite to moving into the action stage of change (Prochaska et al., 1997).

The construct of self-efficacy is the situation specific confidence to engage in a behavior with known outcomes (Bandura, 1991). Confidence is the primary construct

and is related to the situation specific belief people have that they can cope with high-risk situations, such as exercising during inclement weather, or not smoking after eating (Prochaska et al., 1997). Theoretically, as people pass from precontemplation to maintenance, self-efficacy increases linearly (Prochaska and DiClemente, 1984).

The TTM and Exercise Adoption. In the early 1990's, Marcus and others applied the TTM to exercise (Marcus, Selby, Niaura, and Rossi, 1992; Marcus and Simkin, 1994). Subsequent research has clarified that description of the stage and the definition of exercise has consequences for staging of behavior (Reed, Velicer, Prochaska, Rossi, and Marcus, 1997). Although no particular definition of exercise has been advocated, longer, more complete definitions of exercise produce larger numbers of people in the early stages (precontemplation and contemplation), as opposed to the short definitions, which showed a higher percentage in the late stages (preparation and action) (Reed et al., 1997). These researchers also used the TTM to develop a questionnaire to measure the processes of change associated with exercise behavior (Marcus, Rossi, Selby, Niaura, and Abrams, 1992).

The original ten processes of change are used during exercise adoption, the cognitive processes have been found to peak in the action stage, while behavioral processes have been reported to increase from preparation to action and then remain constant (Marcus, Pinto, Simkin, Audrain, and Taylor, 1994). In an extensive review of the literature, Buxton and colleagues (1996) found that researchers have consistently found decisional balance to significantly differ between subjects in the different stages of exercise behavior change. Generally, the reasons for not exercising tended to outweigh

the reasons for exercising for those in precontemplation and contemplation, while there was a balance of the pros and cons in preparation (Buxton, Wyse, and Mercer, 1996). For those in action and maintenance, the pros of exercising outweighed the perceived disadvantages of exercise (Buxton et al., 1996).

Exercise self-efficacy is a widely studied construct, and has shown a consistent relationship with exercise stage, in addition to being one of the strongest predictors of present and future exercise behavior (McCauley and Blissmer, 2000; Buxton et al., 1996). Recently, investigators have confirmed a difference between those in the action and maintenance stages of exercise behavior according to maximal aerobic capacity (greater in maintenance), volume of exercise per week and number of months consistently active (higher in maintenance), decisional balance scores (higher “pros” score in maintenance than action), and 4 processes of change were different between stages (1 cognitive and 3 behavioral) (Buckworth and Wallace, 2002).

The TTM has been applied to interventions with healthy adults at both the community level, and in primary care settings (Marcus, Banspach, Lefebvre, Rossi, Carlton, and Abrams, 1992; Calfas, et al., 1996). At the community level, the results of an exercise intervention utilizing pre-printed stage-specific materials revealed that 62% of the participants originally in contemplation became more active while 61% of the participants originally in preparation became more active (Marcus et al., 1992). In primary care settings, the TTM has been used successfully to encourage exercise adoption utilizing 3 to 5 minutes of stage-specific physical activity counseling by the primary health care provider (physician or nurse practitioner) and one follow-up phone

call (Calfas et al., 1996). At approximately 5 weeks post intervention, the subjects in the intervention group reported significantly ($p < .05$) more activity than those in the control group. Neither of these studies assessed decisional balance or self-efficacy.

The TTM and Smoking Cessation. The TTM was originally developed by studying current smokers and successful ex-smokers (Prochaska et al., 1997; DiClemente and Prochaska, 1982). As a result, the TTM is applicable to smoking cessation behaviors. While the stages of change have been revised since the original four stages, the five current stages of smoking behavior have been found to have construct validity with a high level of reliability and stability (Spencer, et al., 2002). In an extensive review of the literature, Spencer and colleagues identified criticism of the stages of change construction in that some say there are more than five stages of change. Two descriptive cross-sectional studies of precontemplating smokers found significant differences between what they called “immotives”, who are not planning to quit within five years, and precontemplators, who are planning to quit within five years (Spencer et al., 2002). Recently, Prochaska and colleagues have addressed this issue by producing preliminary work on “cluster subtypes” within stages based on perceptions of well being, situational temptation, and tobacco use. In addition to the stages of smoking behavior, there are 10 processes of change utilized during movement between stages, with the cognitive/experiential processes used more frequently during the early stages, and the behavioral processes used more frequently during the later stages (Prochaska and Velicer,

1997). Finally, smoking self-efficacy has been found to peak at 18 months after quitting, with the temptation component of self-efficacy for smoking leveling out at approximately 36 months after quitting (Prochaska and DiClemente, 1984).

The TTM has been used in several smoking cessation intervention studies. In one large scale intervention study, current smokers were divided into four groups; three groups with varying types of stage matched interventions, and one group with a standard program (Prochaska, et al., 1993). Those in the stage matched intervention groups had 18-25% cessation rates at the 18-month follow-up compared to a 10% cessation rate in the control group. In another study, a smoking cessation manual was developed and used in an intervention targeted toward smokers over 50 years of age (Morgan, Noll, Orleans, Rimer, Amfoh, and Bonney, 1996). The *Clear Horizons* smoking cessation manual was developed based on the TTM, and emerged after conducting focus groups with older adults, a national survey, and a pilot test (Rimer and Orleans, 1994). Using a sample of 659 smokers ages 50-74, a randomized controlled trial compared usual care (control group) with physician-delivered brief quit-smoking advice and counseling supplemented by the *Clear Horizons* manual (Morgan et al., 1996). At 6-month follow-up, the quit rates in the intervention group were twice that of the control group (15.4% versus 8.1%). This study provides evidence that even a one-time admonition to quit smoking is beneficial when combined with a theory-based stage-specific manual. Although there is a growing body of well designed studies demonstrating stage-matched interventions to be more effective than non-stage matched interventions, there are also eight non-stage

matched interventions that also show forward stage progression (Spencer, et al., 2002). However, in their review of the related literature, Spencer et al. stated that as a whole, the non-stage matched interventions were not well-designed (2002).

Although the TTM has been successful in helping to develop smoking cessation interventions, some researchers dispute its predictive ability. In 1999, Herzog and colleagues reported that with their sample of smokers, cross-sectional results replicated previous studies with virtually all the processes of change and the cons of smoking increasing in linear fashion from precontemplation to preparation, and the pros of smoking decreasing. However, the baseline processes of change and the pros and cons of smoking failed to predict progressive stage movements at either the 1 or the 2-year follow-ups (Herzog, Abrams, Emmons, Linnan, and Shadel, 1999). The ability of the TTM to predict movement toward successful change has been questioned by others. In 1996, Farkas et al. compared the nicotine addiction model to the TTM to predict smoking cessation, and found that when stage membership was combined with baseline measure of addiction including smoking behaviors and quitting history, the stage of change was not a significant predictor of future cessation. This finding is not particularly surprising, since the TTM is a comprehensive model, and involves more than just the stages of change.

Nicotine Addiction

Nicotine in tobacco smoke is rapidly absorbed in the large surface area of small airways and alveoli of the lung (Benowitz, Porchet, and Jacob, 1990). Nicotine has a relatively short half-life of about 2 hours before it is converted to its major metabolite,

cotinine, by way of the cytochrome P450 system (Benowitz, Kuyt, Jacob, Jones, & Osman, 1983). The claim that nicotine is an “addicting” substance has been questioned in the past, but is more widely accepted today. In 1993, Hughes compared symptoms of tobacco use to the American Psychiatric Association’s Diagnostic and Statistical Manual (DSM-III) criteria for drug dependence, and concluded that tobacco use met at least 5 out of 9 criteria including marked tolerance, characteristic withdrawal symptoms, and substance taken to relieve or avoid withdrawal symptoms. Later, the DSM-IV was published which included a diagnosis of tobacco dependence (American Psychiatric Association, 1994)

Nicotine has pharmacologic properties (Fisher, Haire-Joshu, Morgan, Rehberg, & Rost, 1990). Nicotine exerts its action on the cardiovascular, respiratory, skeletal motor, and gastrointestinal systems through stimulation of peripheral cholinergic neurons via afferent chemoreceptors and ganglia of the autonomic nervous system (USDHHS, 1988). Inasmuch as both sympathetic and parasympathetic ganglia are stimulated by the presence of nicotine, the end result depends on the summation of the effects of the autonomic nervous system (USDHHS, 1988). Generally, the resulting peripheral physiologic changes resemble sympathetic stimulation, but there are some effects of nicotine and smoking that lead to physiologic relaxation. Common changes include increased heart rate and blood pressure, cutaneous vasoconstriction of distal extremities, relaxation of skeletal muscles, and increased gastric secretions with a decrease in motility (USDHHS, 1988). In addition, several studies have reported that nicotine exposure can

lead to state-dependent learning effects—in other words, optimal cognitive/behavioral performance may come to depend upon the continued self-administration of tobacco (USDHHS, 1988).

Nicotine is a psychoactive drug, which means that it is mood altering (USDHHS, 1988). Smokers report that with the self-administration of nicotine they feel euphoric, or have pleasant feelings. Recent studies have shown a relationship between tobacco use and increasing levels of the neurotransmitter dopamine, and a decrease in monoamine oxidase B (MAO B), an enzyme involved in breaking down dopamine (Stephenson, 1996). The implication of this finding is that chronic inhibition of MAO-B works synergistically with the stimulation of dopamine by nicotine and adds to the pleasant moods and enhanced concentration abilities of those who smoke. In addition, this also may be a pharmacological/physiological basis for nicotine as a gateway drug for other addictive substances such as alcohol (Stephenson, 1996).

Tobacco use is influenced by the pharmacologic and psychologic factors associated with nicotine. However, there are also social and environmental factors that strongly influence smoking behavior and continued use (Wewers and Ahijevych, 1996). While social and environmental factors influence the smoking behaviors of all smokers, the various social and environmental influences are specific to each smoker. For example, persons with disproportionately higher rates of smoking include men (25.7%) versus women (21.5%); Native Americans and Alaska Natives (40.8%); those with a general education development diploma (44.4%) versus those with higher education (8.5%); and persons between the ages of 18-44 (27%) versus those over the age of 65

(10.6%) (CDC, 2001). Other social/environmental variables that augment nicotine addiction include having family and friends who smoke and availability of smoking areas (McIntyre-Kingsolver, Lichtenstein, & Mermelstein, 1983; Ockene, Benfari, Nuttall, Hurwitz, & Ockene, 1982). In addition, the desire to handle cigarettes may be an important reason for smoking. Such stereotypical behaviors are characteristic of other forms of drug addiction and other compulsive behaviors not involving psychoactive drug self-administration (USDHHS, 1988).

The controlled and compulsive use of nicotine is additional evidence of nicotine addiction. Generally, naïve smokers begin smoking relatively few cigarettes per day, thus ingesting smaller doses of nicotine (USDHHS, 1988). However, as dependence develops, the amount of nicotine increases and then plateaus resulting in years of stable nicotine use (USDHHS, 1988). Most smokers maintain a certain amount of nicotine in their bodies despite type or size of cigarette smoked. This is done by the smoker changing smoking topography, which is defined as the smokers puffing characteristics and the associated respiratory inhalation and exhalation movements (Ahijevych and Parsley, 1999). Researchers have found that if smokers are pretreated with nicotine (e.g. IV nicotine) they will decrease the amount of self-administered nicotine with subsequent cigarettes (USDHHS, 1988). Conversely, if smokers are treated with a nicotine antagonist (e.g. mecamylamine), they will increase the amount of nicotine ingested with subsequent cigarettes (USDHHS, 1988). Practically speaking, if a smoker begins to smoke “light” (low-dose nicotine) cigarettes after years of smoking regular brands, they may change smoking topography or block the filters on the cigarette to achieve a higher

level of nicotine ingestion. This is called controlled use of nicotine. Compulsive use of nicotine involves continuing to use the substance despite negative consequences. This is clearly demonstrated by smokers who continue to smoke after laryngeal cancer or heart attack. In fact, 50% of smokers resume smoking after a smoking related surgery (West and Evans, 1986).

Pharmacological, psychological, social, and environmental factors are all part of the nicotine addiction equation. However, if the goal is to help people quit smoking, two other principles of addiction must be taken into consideration: tolerance and withdrawal. Tolerance involves needing greater amounts of nicotine to achieve the same pharmacological/physiological response. Two proposed physiological reasons for tolerance are: increased metabolism over time, and a decrease or alteration in the number of nicotine receptors (USDHHS, 1988). In general, the pharmacological and psychoactive nature of nicotine is influenced by individual metabolism of the drug (Benowitz, et al., 1990). There are various reasons for inter and intra-individual variations in nicotine metabolism. For example, eating increases nicotine metabolism by 42%, which may contribute to the enjoyment of an “after dinner” cigarette. There is also a genetic component to nicotine metabolism including number and type of nicotine receptors and enzyme activity. In addition, Ahijevych, Gillespie, Demirci, and Jagadeesh (1996) found that cotinine values (the major metabolite of nicotine) were significantly higher in African American women than in Caucasian women despite fewer cigarettes

smoked by African American women, and no differences in smoking topography (except longer exhalation by the Caucasian women). These authors advocated the need for further research to investigate these differences.

For persons who are trying to quit smoking, symptoms of withdrawal often cause relapse. Withdrawal symptoms fall into three categories: autonomic (cardiovascular, respiratory, and gastrointestinal); somatomotor (reflexes, auditory/visual changes, nociception); and behavioral (irritability, restlessness, sleep/wake disorder, attention deficits, weight gain). The most common withdrawal symptoms associated with nicotine are autonomic and behavioral in nature (USDHHS, 1988). Many withdrawal symptoms will be relieved within three to five days, but often smokers suffer from one to two symptoms for a longer period of time, such as attention deficits and weight gain. In assessing the risk for withdrawal symptoms, the number of cigarettes smoked per day is not considered a good predictor of withdrawal symptomatology (USDHHS, 1988). Levels of serum nicotine, or cotinine, are considered to have the best correlation with severity of withdrawal (Pomerleau, Fertig, and Shanhan, 1983).

The addiction to, or dependence on, nicotine is a factor that must be dealt with if nurses are to effectively help claudicants quit smoking (Fagerstrom, Heatherton, and Kozlowski, 1990). The Fagerstrom Test for Nicotine Dependence (FTND) was designed to indicate the strength of this dependence (Fagerstrom et al., 1990). The FTND has been found to have adequate test-retest reliability, internal consistency of cronbach's alpha = .64, and validity as evidenced by a significant correlation with cotinine (+.39) (Pomerleau, Carton, Lutzke, Flessland, and Pomerleau, 1994). Originally developed in

the late 1970's, the FTND has been refined and currently contains six categorical questions, yields a score between 0 and 10, and is used to measure degree of physical dependence and expected withdrawal symptoms (Heatherton, Kozlowski, Frecker, and Fagerstrom, 1991). Clinically, the FTND is used to determine the need for nicotine replacement therapy as an adjunct to a smoking cessation intervention.

Exercise Determinants

The US Public Health Service for the Year 2000 identified as a goal for the nation to understand the attitudes, environmental and social factors, and beliefs that are associated with exercise (Dishman and Sallis, 1994). Since then, extensive research has been conducted to identify determinants of exercise adoption and maintenance. However, these research studies have been conducted with pre- and quasi-experimental designs, and as a result, the term “determinant” refers to an association or prediction, NOT a cause and effect relationship (Dishman and Buckworth, 1996).

Exercise determinants do not represent a theoretical model, but rather factors that are associated with level of physical activity or exercise behavior. In several articles, exercise determinants have been classified according to characteristics of the person, characteristics of the environments, and aspects of the exercise itself (Buckworth, 2000; Dishman and Buckworth, 1996; Dishman and Sallis, 1994). Many characteristics of the person, environment, and exercise have been studied to determine a correlation with exercise behavior. Some of these characteristics have a documented lack of association,

or a weak or mixed association with exercise (Dishman and Buckworth, 1996). Some of the characteristics that have consistently lacked an association include: knowledge of health and exercise, activity during childhood/youth, school sports, and cost.

However, many characteristics have a consistent positive or negative association with exercise behavior. Personal attributes that correlate with exercise behavior include demographic variables, psychological traits, and cognitive variables such as attitudes and beliefs (Dishman and Buckworth, 1996). Specifically, characteristics that negatively correlate with exercise behavior include female gender (only at vigorous levels of activity), blue-collar occupation, lower income, and unmarried status (Buckworth, 2000). In addition, smoking has been found to negatively correlate with adherence to structured exercise programs (Franklin, 1988). A trait measure of self-motivation, which seems to reflect effective goal setting, self-monitoring of progress, and self-reinforcement, has been found to consistently correlate positively with exercise (Knapp, 1988). Finally, self-efficacy (the belief in one's ability to perform the activity), self-schemata (seeing oneself as an exerciser), and intention are also strongly correlated with exercise behavior.

Environmental factors that contribute to higher levels of physical activity include easily accessible facilities that are absent of real barriers to the exercise routine (Dishman and Buckworth, 1996). Specifically, perceived accessibility to facilities has not been found to be a predictor of exercise behavior, but real accessibility (actual distance) seems to be related to both the adoption and maintenance of exercise behavior (Buckworth, 2000). In addition, social support from family and friends, particularly for women, appears to be a strong correlate of exercise behavior.

Physical activity characteristics that may influence exercise behavior include exercise mode (e.g. cycling versus running), intensity (e.g. low versus high), duration (e.g. ten minutes versus 60 minutes), and frequency (e.g. every day versus once a week) (Buckworth, 2000). Frequency and duration of exercise have not been found to correlate specifically with exercise behavior (Dishman and Buckworth, 1996). For example, people who are given an exercise prescription to exercise ten minutes, one day a week, are not any more likely to exercise than a person given an exercise prescription for 30 minutes, five days a week. However, mode of exercise does become a determinant when active leisure is compared to exercise programs of greater intensity (Dishman and Buckworth, 1996). The implication here is that people may find it easier to adhere to a low intensity walking program than a high intensity dance aerobics program. Interestingly, although more intense forms of exercise decline with age, moderate intensity activities, such as walking, have been found to increase with age (Buckworth, 2000).

Although intervention studies are not conducted based on principles of “exercise determinants” alone, these factors must be taken into consideration when exercise adoption interventions are planned. First, the clinician must consider the non-modifiable characteristics that may influence exercise behavior, such as gender, level of education, occupation, and age. Second, modifiable characteristics should be assessed to identify what determinants may be able to be changed in the participant’s favor, such as self-efficacy, social support, or self-schemata. Finally, specific factors and their level of

influence will change as participants progress toward exercise adoption and maintenance, and clinicians must be willing to frequently reassess and modify the intervention (Buckworth, 2000).

3.2 DEVELOPING A THEORY BASED INTERVENTION

Based on research, exercise training and smoking cessation are two of the most effective therapies for treating claudication (Christman et al., 2001). Unfortunately, a paramount problem for clinicians is motivating targeted individuals with PAD to begin and adhere to an exercise regimen and/or quit smoking. While supervised exercise yields significant improvements in pain free walking time, the prescriptions of these programs is limited by the number of medical centers offering them (Patterson et al., 1998; Degischer et al., 2002). Home based exercise has been found to be a valid alternative to supervised exercise, providing a cost-effective intervention while still yielding significant improvements in pain free and maximal walking times (Patterson et al., 1998).

Experts estimate that half the occurrences of PAD in the community might be attributable to smoking, and 90% of PAD patients in the hospital have a history of current or recent smoking (Fowkes, 1997). The 5-year mortality rate for persons with PAD who continue to smoke is approximately 40-50%, similar to rates observed with many common cancers (Hirsch et al., 1997). Nurse managed, home-based smoking cessation programs have been found to be highly cost-effective when cost and years of life saved were examined in patients with vascular disease (West, 1997). While the typical smoking cessation rates among healthy adults offered group counseling is only 15%,

theory-based smoking cessation interventions can yield quit rates as high as 61% at 12 months (Fiore, Bailey, Cohen, et al., 1996; Taylor, Houston-Miller, Killen, and DeBusk, 1990).

In light of the known benefits of exercise training and smoking cessation for treating intermittent claudication, and taking into consideration the practical limitations of supervised exercise programs along with the low smoking cessation rates associated with many smoking cessation interventions, an exercise adoption and smoking cessation intervention was developed for patients with PAD. Specifically, we implemented a theory-based, nurse-implemented 12-week patient education program which was compared to the usual care provided of a one-time admonition to start exercising and quit smoking given by the vascular surgeon in the office. The following will provide a detailed description of the intervention, how the TTM was used as a foundation for the intervention, and how the models of nicotine addiction and exercise determinants were used to promote behavior change. In addition, some descriptive data will be presented which was collected during face to face or telephone contact with study participants, and recorded by the nurse implementing the program.

The Transtheoretical Model of behavior change was used as the foundation for the intervention, with a 12-week educational intervention, and data collection points at baseline, 3-months, and 6-months post-enrollment. Subjects were randomly assigned to either the intervention group, or the usual care control group in order to determine the effectiveness of the intervention. In order to utilize the model to the fullest advantage, all of the core constructs were utilized. At each data collection point, subjects were

classified into a stage of change for both exercise and smoking behaviors. Valid classification of stage of change was enhanced by using a detailed and rather limited definition of exercise, and a specific definition of smoking cessation. In addition, decisional balance for smoking cessation and exercise adoption, and exercise self-efficacy were measured. Finally, for those who smoked, expired carbon monoxide and saliva cotinine were measured in order to validate smoking status, and to help determine physical addiction to nicotine.

The exercise prescription was individualized for each subject in the intervention group, and all exercise activity occurred during the participant's own time. A description of the important components of an exercise prescription to improve functional capacity in patients with lower extremity PAD can be found elsewhere (Christman et al., 2001; Chapter 2). The educational intervention consisted of a weekly meeting for 12 weeks, and the content of the course was dictated by the theories from the TTM, nicotine addiction, and principles from the exercise determinant literature. During the 12-weeks, the pros of behavior change were stressed, while the cons were discussed and misconceptions addressed. For example, some people stated that it was hard to find an exercise activity they enjoy that was not affected by bad weather. This problem was discussed in class, and each participant was able to state where and how they could exercise even if the weather was inclement. For smokers, many believed that they were more relaxed and therefore more pleasant when smoking. This problem was addressed by discussing principles of nicotine addiction. First, the duration of nicotine withdrawal was identified (primarily 3-5 days), and the acknowledgement that one or two withdrawal

symptoms may last longer. Second, strategies for dealing with these symptoms were identified, for example nicotine replacement or relaxation techniques. In addition, the *Clear Horizons* smoking cessation manual was distributed. The *Clear Horizons* manual is modeled after the format of the magazine Modern Maturity, is written at an 8th grade reading level, and introduces stage-specific quit-smoking strategies using examples of smokers in their 50's, 60's, and 70's (Morgan et al., 1996). Non-smoking subjects also received a *Clear Horizons* manual, and were encouraged to be a part of the discussions and offer support and encouragement to their smoking counterparts, as positive peer support has been identified as a predictor of successful change.

For each subject, stage of change for smoking cessation and exercise adoption was identified. For those who participated in the intervention, specific strategies for helping them move to the next stage were utilized (Marcus, et al., 1992; Prochaska and Velicer, 1997). For those in the earlier stages, cognitive and experiential processes of change were used, such as self-reevaluation and self-liberation. For most smokers, they were already aware of the harmful effects of their behavior on themselves and others, so they were encouraged to think of themselves as “non-smokers” and as their thinking began to change, an actual commitment to change the behavior was scheduled (quit date). For those beginning an exercise program, consciousness-raising was the first step by helping them understand the relationship between PAD and sedentary lifestyle, followed by self-reevaluation and self-liberation. These processes clearly coincide with the exercise determinants that are known to correlate with exercise adoption such as self-schemata. In addition, because social support is a strong predictor of successful change,

subjects were encouraged to tell their friends and family about the change, and elicit their support. Finally, reinforcing the belief that subjects had the ability to successfully change was stressed, particularly regarding exercise behavior, in order to reinforce and improve their self-efficacy.

As subjects moved into the action stage of stage, the processes used became more behavioral, and again utilized principles from the theory of nicotine addiction and from the exercise determinant literature (Fiore et al., 2000; Buckworth, 2000). For smokers, counterconditioning and stimulus control became the most frequently used processes. For several smokers, a physical addiction to nicotine was identified, and they were encouraged to utilize nicotine replacement, and strategies to avoid high-risk situations were identified. For example, one smoker with a Fagerstrom questionnaire score of seven (out of a high of 10) utilized nicotine replacement via the patch continuously, and added gum for breakthrough cravings (Fiore et al., 2000). In addition, specific social and environmental factors contributing to nicotine addiction included such things as always smoking during bowling league, smoking only after work, smoking when at home because of stress from spouse's illness, and many subjects acknowledged enjoyment of the "hand-oral" manipulation. Again, counterconditioning strategies such as chewing gum, or playing with a rubber band or pencil were discussed. Smokers also identified helping relationships, either in the form of a significant other, or in one case, divine help through prayer, as being very beneficial for them. For those adopting exercise, counterconditioning, contingency management and helping relationships were most often used as behavioral processes. One subject bought a treadmill, three joined senior health

clubs, and one person enrolled in the citywide activity challenge being promoted at the time. In addition, others in the group and the facilitator of the class provided positive reinforcement for new behaviors, and many subjects stated that significant others in their lives were encouraging and positive about the change.

Finally, at the end of the 12-week intervention, subjects were asked to sign a contract for maintaining the behavior change for a two-week period. Contracting has the benefit of allowing the participant to develop a plan, provides a written statement of expectation, creates a form of public commitment, and provides a reward for goal attainment (Wewers, Ahijevych, and Sarna, 1998). The contract included a clear description of the desired behavior, reinforcements of the behavior (or absence of the behavior), and criterion for time or frequency limitations (Martin and Dubbert, 1984). Subjects in the intervention group were contacted by telephone every two weeks for three months post-intervention for encouragement, to discuss the contract, and to discuss plans to continue or update the contract (Fiore et al., 1996; Lombard, Lombard, and Winett, 1995). Although these strategies are not a specific part of the theoretical model, they are consistent with principles of the TTM, and were used to promote maintenance of the behavior change.

3.3 CONCLUSION

The transtheoretical model of behavior change, the theory of nicotine addiction, and principles from the exercise determinant literature were successfully integrated to develop a nurse-managed 12-week exercise adoption and smoking cessation intervention for patients with intermittent claudication. The components from the TTM utilized to

form the foundation of the intervention included stages of change, processes of change, decisional balance, and self-efficacy (Prochaska et al., 1997). The components from the theory of nicotine addiction that were integrated into the intervention included principles of physical, psychological, social, and environmental addiction, along with principles of withdrawal and the Fagerstrom Test for Nicotine Dependence (FTND) (USDHHS, 1988; Heatherton et al., 1991). Factors from the exercise determinant literature that were discussed with intervention participants included exercise intensity, self-efficacy, social support, and actual distance from the exercise location (Buckworth, 2000).

Exercise training is one of the most effective therapies for treating intermittent claudication, even when compared to pharmacological or surgical treatment (Stewart et al., 2002). This theory-based intervention to promote adoption and maintenance of exercise behavior with claudicants utilized principles from the TTM which overlapped with one of the most widely studied exercise determinants, self-efficacy (McAuley and Blissmer, 2000). For the intervention group, exercise self-efficacy was stressed during each class for the entire 12 weeks. At the end of the program, baseline self-efficacy and three and six month exercise stage of change were correlated. For all subjects (not separated by group), baseline self-efficacy correlated with 3-month exercise stage of change with a Kendall's tau-b coefficient of .357 ($p < .05$), but not with 6-month exercise stage of change ($p = .173$). When divided by group, this correlation was not significant for the intervention group at 3- or 6-months, but actually became stronger for the usual care group at 3-months only (correlation coefficient .625, $p < .01$), while the 6-month correlation was not significant. The implication from these results seems to be that for

those who begin with a high degree of confidence in their ability to begin and maintain an exercise routine, they will do so whether there is a formal intervention or not. In contrast, even for patients who do not have confidence in their ability to begin and maintain an exercise regimen, this lack of confidence can be overcome with a structured, individualized intervention.

Vascular clinicians have hypothesized that “the discomfort of claudication and/or the fear of amputation might serve as motivators for effective tobacco cessation interventions in the PAD population if the link between smoking and this severe limb disease were reinforced by intensive counseling interventions” (Hirsch et al., 1997). Using the TTM this link was made during the 12-week intervention, and using the theory of nicotine addiction, strategies for change were identified and implemented. Consciousness raising, one of the earliest cognitive processes of change, was used during the second weekly class. An entire class time was committed to understanding the risks of smoking, and the relationship between smoking and PAD. In addition, during this same class time, smokers in the class completed the FTND, and the concepts of nicotine addiction in all forms (physical, psychological etc) were discussed, along with symptoms of withdrawal and nicotine replacement (Fisher et al., 1990; Fiore et al., 2000). Finally, both the TTM and the theory of nicotine addiction identify social support (or helping relationships) as being integral in successfully quitting smoking (USDHHS, 1988; Prochaska and Velicer, 1997). Importance of social support was evidenced in this study when of the six smokers who failed to quit smoking, two had significant others who smoked, and three had a majority of friends who smoked. In addition, this principle was

significant irrespective of group. One of the usual care group members entered the study in the smoking stage of contemplation, but quickly jumped into preparation and then action when they started to date a non-smoker.

In summary, the TTM, the theory of nicotine addiction, and exercise determinants were effective in developing a nurse-implemented exercise adoption and smoking cessation intervention for patients with PAD. While study participants were not formally asked what they found helpful or not helpful about the program, at the end of the 6-month program, almost all intervention participants stated that they found the intervention to be generally helpful, and 85% of the intervention members (n=12) had moved into the action stage of exercise adoption. While few smokers (n = 2) had moved into the action stage of smoking cessation at the end of the 6-month study (neither of them intervention group members), during subsequent telephone follow-up, six additional smokers stated that they had quit smoking, five of whom had been involved in the 12-week class.

Vascular nurses play an integral role in helping claudicants begin an exercise program and quit smoking. Developing theory-based interventions may help claudicants be more successful in adopting and maintaining these healthy behaviors. The transtheoretical model of behavior change, the theory of nicotine addiction, and exercise determinants should be considered when developing these interventions, as they are practical, and can be integrated to develop wholistic interventions that can be individualized to each patient and their situation. In addition, the model of nicotine addiction and principles from the exercise determinant literature can be used to identify individual needs of participants within each stage of change.

Cognitive/Experiential Processes

Consciousness Raising: becoming aware of the dangers/effects of the behavior

Dramatic Relief: feeling the emotional response associated with engaging in the behavior
(e.g. fear of lung cancer)

Self Reevaluation: starting to view oneself as not engaging in the unhealthy behavior (e.g.
view oneself as someone who exercises)

Environmental Reevaluation: becoming aware of the harmful effects the behavior has on
others or the environment

Self Liberation: committing to change the behavior

Behavioral Processes

Social Liberation: society's actions to promote the behavior change (e.g. no smoking
zones, local activity challenges)

Counterconditioning: taking action to replace harmful behavior with positive (e.g.
nicotine replacement, joining a gym)

Stimulus Control: avoiding high risk situations or developing coping strategies for high
risk situations

Contingency Management: positive reinforcement of the new behavior

Helping Relationships: others who offer positive reinforcement of the new behavior

Source: Prochaska et al., 1997

Table 3.1 Processes of Behavior Change

CHAPTER 4

THE EFFECT OF A NURSE IMPLEMENTED, THEORY-BASED EXERCISE ADOPTION AND SMOKING CESSATION PROGRAM ON FUNCTIONAL STATUS, STAGE OF CHANGE, DECISIONAL BALANCE, AND SELF EFFICACY WITH CLAUDICANTS

Lower extremity arterial occlusive disease represents a major cause of morbidity in the elderly, with a prevalence of up to 20% in those over the age of 70 years (Criqui, 2001). Up to 40% of patients with peripheral arterial disease (PAD) suffer from intermittent claudication, and the overall number is expected to increase by approximately 1 million every 2 years for the next 50 years (Kannel and McGee, 1985). Treatment options for claudication include lifestyle changes, drug therapy, vascular surgery, or any combination of the three (Golledge, Ferguson, Ellis, et al., 1999; Degischer, et al. 2002; Regensteiner et al., 2002).

Lifestyle modifications for the treatment of claudication pain primarily include exercise training and smoking cessation (Christman, et al., 2001). Exercise training alone has been found to increase time to onset of claudication pain by 179% and maximal walking time by 122% (Gardner and Poehlman, 1995). Cigarette smoking is known to be a major contributor to PAD, including the progression of PAD from asymptomatic to

intermittent claudication, conversion of stable claudication to rest pain, increasing failure rate of limb bypass grafts and limb angioplasty, and increasing amputation rate (Fahey, 1999). Recent advances in drug therapy have been found to be effective in treating claudication. Cilostazol (Pletal), an oral type III phosphodiesterase inhibitor has been found to increase pain-free walking distance by 59% and maximal walking distance by 51% (Beebe et al., 1999). In addition, the combination of a supervised walking program and Clopidogrel (Plavix), an oral antiplatelet, was found to improve claudication pain time (CPT) by 200.6%, and maximal walking time (MWT) by 131.4% (Degischer et al., 2002). Finally, for most patients who choose to undergo angioplasty or surgical revascularization to correct the arterial occlusion, post-operative technical success is obtained. Improvement in MWT following angioplasty is equivalent to that found from exercise, and there can be a 75-100% improvement in MWT following surgical revascularization (Stewart, et al., 2002). However, successful symptomatic outcomes are not always achieved, as evidenced by one report documenting symptomatic improvement one year post operatively in only 51% of those undergoing femoropopliteal angioplasty (Golledge, et al., 1999).

Based on research, it is clear that exercise training and smoking cessation are two of the most effective therapies for treating claudication. Unfortunately, a paramount problem for clinicians is motivating targeted individuals with PAD to begin and adhere to an exercise regimen and/or quit smoking. Vascular nurses have a role in the collaborative care of claudicants, and should investigate ways to enhance exercise adoption and smoking cessation strategies. While supervised exercise has been found to

be consistently more effective than home based exercise, the prescription of supervised exercise is still limited by the number of centers offering such programs (Patterson et al., 1997; Degischer et al., 2002). In addition, while natural history studies with PAD patients have shown the benefits of a "non smoking" state, intervention studies to help claudicants quit smoking have yielded non-significant findings (Power et al., 1992; Fowler, Jamrozik, Norman, Allen, and Wilkinson, 2002).

Since there is significant published research that supports the benefits of exercise training and smoking cessation for the treatment of intermittent claudication, we focused primarily on identifying factors that would *promote adoption* and *maintenance* of these behaviors with PAD patients. Oberst (1989) has stated that atheoretical interventions are little more than trial and error regarding what does and does not work. Comparatively, in studies where researchers have used strong theoretical frameworks to guide program development, the results have substantially more impact on practice and subsequent research than is the case for atheoretical studies. As a result, three theoretical models were used to develop this nurse-implemented exercise adoption and smoking cessation program for persons with PAD. These three models were: 1) the Transtheoretical Model of Behavior Change; 2) Nicotine Addiction; 3) Exercise Determinants.

4.1 THEORETICAL BASE

The foundational model used for developing this intervention was the Transtheoretical Model of Behavior Change (TTM) (Chapter 3). The core constructs of the TTM are stages of change, processes of change, decisional balance, and self-efficacy (Prochaska and Velicer, 1997). As people change a behavior, the five stages of change

through which they pass are precontemplation (no intention for change in the next 6 months), contemplation (intend to change in the next 6 months), preparation (intend to change in next 30 days), action (change has occurred in last 6 months), and maintenance (changed more than 6 months ago). Movement through these stages occurs in a cyclical manner and many individuals make several attempts at behavior change before reaching maintenance (Prochaska, et al, 1997). The processes of change, which are the strategies used by people to move forward through the stages of change, involve 10 cognitive/experiential and behavioral processes (Prochaska and DiClemente, 1983; Prochaska et al., 1997).

Decisional balance reflects an individual's relative weighing of the pros (benefits) and cons (consequences) of behavior change. The construct of decisional balance has been reported to be critical in predicting the success of smoking cessation efforts (Prochaska et al., 1997). The construct of self-efficacy is described as an individual's beliefs regarding perceived capabilities in a particular domain. Exercise self-efficacy is a widely studied construct, and has shown a consistent relationship with exercise stage, in addition to being one of the strongest predictors of present and future exercise behavior (McCauley and Blissmer, 2000; Buxton et al., 1996).

While the TTM provided the structure for this intervention, principles of nicotine addiction and exercise determinants were used to develop personalized stage-specific interventions (Chapter 3). Nicotine is the major addictive agent in tobacco, and provides euphoriant and sedating effects which serve as reinforcements for maintaining smoking behavior (USDHHS, 1988). The four primary components of the nicotine addiction

model include pharmacological, psychological, social, and environmental factors (Fisher, et al., 1990). However, when helping people quit smoking, the principles of nicotine tolerance and withdrawal must also be taken into consideration. The Fagerstrom Test for Nicotine Dependence (FTND) was designed to indicate the strength of nicotine addiction, or nicotine dependence (Fagerstrom et al., 1990). Originally developed in the late 1970's, the FTND has been refined and currently contains six categorical questions, yields a score between 0 and 10, and is used to measure degree of physical dependence and expected withdrawal symptoms (Heatherton, et al., 1991). Clinically, the FTND is used to determine the need for nicotine replacement therapy as an adjunct to a smoking cessation intervention.

Exercise determinants are factors that are known to associate with or predict exercise behavior (Dishman and Buckworth, 1996). These determinants can include characteristics of the person, the environment, or the physical activity (Buckworth, 2000). Some modifiable determinants of exercise behavior include self-motivation, intention, self-schemata (see yourself as an exerciser), and self-efficacy (confidence in the ability to engage in an activity). Environmental influences include social support (stronger for women), and objectively measured access to facilities (physically close to the exercise location) (Buckworth, 2000).

As a result, we designed a study to evaluate the effect of a theory-based, nurse-implemented 12-week patient education program compared to the usual care provided of a one-time admonition to start exercising and quit smoking given by the vascular surgeon in the office. The primary endpoints in persons with PAD were functional status, based

on treadmill walking time, smoking cessation rate, decisional balance scores for both exercise and smoking, exercise self-efficacy scores, and stage of change. Three hypotheses were identified:

H₁ Intervention participants will have a greater increase in functional status, decisional balance for exercise adoption, and exercise self-efficacy compared to the usual care group from baseline to 3 and 6-months post enrollment.

H₂ Intervention participants will have a greater increase in decisional balance for smoking compared to the usual care group from baseline to 3 and 6 months post enrollment.

H₃ A greater percentage of intervention participants will progress forward through stages of change for exercise adoption and smoking cessation as compared to usual care group from baseline to 3 and 6 months post enrollment.

4.2 METHODS

Sample Selection and Recruitment

Smoking and non-smoking men and women between the ages of 40 and 75 with arterial claudication symptoms, who did not exercise were recruited for the study. A convenience sample was drawn from several large vascular surgery offices in a midwestern metropolitan area. These patients were either deemed ineligible for surgery and referred for potential recruitment, or had already had surgery and were still claudicating. Once a referral was made, the patient was either approached personally or sent a letter describing the study, with a phone call following the initial contact. If interest in participation was expressed, patients were screened using a 5-item stages of

change questionnaire for exercise adoption and a 3-question algorithm for smoking cessation. Once potential subjects were determined to be in the precontemplation, contemplation, or preparation stage for exercise and smoking (for those who smoked), additional health history questions were asked to determine the patient's ability to participate in the program. In addition, for patients with a known history of coronary artery disease, their cardiologist was contacted to obtain clearance for the patient to participate in the program. One hundred and eight patients were referred by name to the study. During the screening phone call, 57 people were excluded for lack of interest or because of inability to walk on a treadmill, 1 person was excluded because their cardiologist did not want them participating in an unsupervised exercise program, and 8 people were excluded because they were already in the action or maintenance stages of exercise.

Procedure

Once patients were deemed potentially eligible via phone, they were scheduled for a screening visit, which was conducted either at a participating community hospital's cardiovascular laboratory, or in an exercise laboratory located in the College of Nursing on the campus of the Ohio State University. As a result, this study was approved by both the Mt. Carmel Health System's Institutional Review Board, and the Ohio State University's Institutional Review Board, and two informed consents were signed by each subject. After signing informed consent, each patient underwent hemodynamic eligibility screening. Intermittent claudication from arterial insufficiency was established by resting ankle-brachial index (ABI) of less than 0.9 and/or a decrease in ankle pressure of 15

mmHg or more after a standard exercise protocol (10 degree incline, 1.5 mph, 10 minutes of exercise). Patients who did not meet these hemodynamic criteria or had ischemic rest pain or tissue loss were excluded. Additional exclusion criteria included an inability to tolerate exercise as a result of comorbid illness such as arthritis or chronic obstructive pulmonary disease.

Because a significant number of claudicants have associated coronary artery disease, all patients underwent additional cardiac screening before final enrollment in the program (Gajraj and Jamieson, 1994). First, a 12-lead EKG was recorded at rest in the supine position, and another 12-lead EKG was recorded during the standard exercise protocol, which were read by a cardiologist. EKG changes including ST segment depression, elevation, or dysrhythmia during rest or exercise excluded patients from participating in the study.

Forty-two people were personally screened, and four were deemed ineligible. One person failed cardiac screening and subsequently enrolled in a supervised cardiac rehabilitation program, one person had non arterial disease, one person did not claudicate during the 10 minute standardized test, and one person had no audible doppler signals in the affected extremity and was referred back to the vascular surgeon. Thirty-eight people were successfully screened and were randomly assigned to either the 12-week education intervention, or the usual care group. One person was unable to be contacted after the initial screening visit, and seven others were lost before the second data collection point for various reasons (Table 4.1 and Table 4.2). There were thirty participants available for at least one follow-up data collection point, 16 in the usual care group, and 14 in the

intervention group, with an overall study demographic of 21 men and 9 women, and 17% African American (Table 4.3). For these thirty participants, there were no differences between groups in the demographic or medical history characteristics at baseline, but there *was* a significant difference in their treadmill walking times at baseline, with the usual care group being able to walk significantly farther than the intervention group.

Study Design

Patients with arterial claudication were randomly assigned to either a 12-week education program consisting of a 1-hour class per week and a personalized home based exercise prescription, or to the usual care group, which consisted of an admonition by their vascular physician to begin exercising and quit smoking with no additional follow-up. The curricular content of the educational component and the study design were based on a 1997 study by Patterson and colleagues, where a supervised exercise program and a home based exercise program were compared, and an educational component provided for both groups (Patterson, et al., 1997). The vascular nurses from the Division of Vascular Surgery at the Miriam Hospital in Providence, Rhode Island were contacted and a curricular outline was obtained. The TTM, the model of nicotine addiction, and principles from the exercise determinant literature were used to modify the curriculum, which led to increased smoking cessation content, and an entire class time dedicated to strategies for maintaining behavior change. Additional theory-based strategies were also used during the program to aid with behavior adoption and maintenance. Outcome measures were assessed at baseline, 3-months and again at 6-months post-enrollment if the participant was available for follow-up.

Intervention

The experimental condition consisted of a 12-week, one-hour per week group education session. The average class size was four people, but one class had only two participants. The rationale for having a class with so few participants was the desire to start the intervention as close to the time of enrollment as possible without a long wait for any one subject. Participants received a folder of material developed by the nurse investigator teaching the course, and contained information related to weekly course content. Each week, principles of exercise and smoking cessation were reviewed in addition to scheduled, weekly topics including (but not limited to): the natural history of claudication, controlling cholesterol, understanding nutrition labels, foot care for PAD patients, understanding and controlling hypertension, and understanding and controlling diabetes.

An individualized exercise prescription was given to every intervention group member with initial frequency and duration based on physical ability, exercise history, and access to an exercise location. However, each prescription was based on three primary components which included: 1) walking as the mode of exercise, 2) the goal of working toward an exercise frequency and duration of three times/week for at least 30 minutes/session, and 3) incorporating near maximal claudication pain end point (near maximum walk time) during the exercise training program (Gardner and Poehlman, 1995). This prescription was based on a meta-analysis of 21 related research studies

which revealed that the predictors of change in claudication pain distances during exercise were independently related to these three exercise program components (Gardner and Poehlman, 1995).

In addition, the *Clear Horizons* smoking cessation manual was distributed to all participants. The *Clear Horizons* manual is modeled after the format of the magazine *Modern Maturity*, is written at an 8th grade reading level, and introduces stage-specific quit-smoking strategies based on the TTM using examples of smokers in their 50's, 60's, and 70's (Morgan et al., 1996). Non-smoking subjects also received a *Clear Horizons* manual, and were encouraged to be a part of the discussions and offer support and encouragement to their smoking counterparts. Positive peer support has been identified as a predictor of successful change (Heaney and Israel, 1996). No stage-specific literature was available for exercise promotion.

Stage Specific Intervention. Participants were identified by stage of change according to exercise and smoking behavior. For those in the precontemplation and contemplation stages of change, cognitive/experiential processes of changes were primarily used. Once a participant reached the preparation and action stages of change, behavioral processes were used more frequently (Chapter 3).

Once a participant began to exercise, they were asked to keep an exercise diary that was reviewed each week with the nurse investigator. Participants were identified as being in the action stage for exercise when they had begun to walk three or more times a week, for a total of at least 20 minutes per session, not including necessary rest times. They were encouraged to take rest breaks when they reached near maximal claudication

pain, and to resume exercise when the pain subsided. In addition, we originally planned to confirm self-reported exercise using a pedometer provided to each participant. The pedometer is a small device that is clipped to a belt or waistband, and calculates number of steps taken, miles walked, and calories burned, and has been found to be valid with the PAD population (Sieminski, Cowell, Montgomery, Pillai, and Gardner, 1997).

Unfortunately, so many of the participants lost, sat on, or somehow lost track of their pedometers, that these data were very incomplete, and were not used.

Participants were identified as being in the action stage of smoking cessation when they began to abstain from cigarettes. The use of a self-selected nicotine replacement therapy, such as transdermal nicotine or nicotine inhaler, was encouraged as an adjunct to behavioral counseling (Fiore, et al., 2000). Smoking status was confirmed using expired carbon monoxide levels, and saliva cotinine.

Follow-up. In order to promote maintenance of behavior change, at the end of the 12-week class, participants were asked to sign a contract for maintaining the behavior change for a two-week period (Wewers, et al., 1998). In addition, participants were contacted by telephone every two weeks post-intervention for encouragement and to discuss the contract and plans to continue or update the plan (Lombard, et al., 1995). Thus, each participant received a total of six follow-up phone calls.

Usual Care

This group received what is considered usual care. Usual care consists of being told by the physician in the office that they should start exercising and quit smoking, but in this practice setting there was no additional follow-up. These subjects were contacted

and seen by the coordinating nurse investigator for data collection on the outcome measures at baseline, three, and six months post-enrollment. In addition, at the end of six months they were offered the opportunity to participate in the 12-week education intervention, but no additional quantitative data was collected during this time. Six of sixteen usual care subjects decided to participate in the 12-week class after their 6-month wait time.

Measures

Exercise Measures. A graded, progressive treadmill exercise test initiated at 1 mph with a grade of 5%, increasing in speed and grade at 5-minute intervals through four stages to 2.5 mph at 10% grade was used to determine CPT and MWT in minutes and seconds. Each of the four stages has a predetermined metabolic equivalent unit (MET) level, with the final stage equivalent to 6.4 METS. The progressive treadmill test was repeated at 3-months (program completion) and 6-months.

Constructs from the TTM. Stage of Change for exercise and smoking cessation was determined by responses on the established respective questionnaires. The exercise stage of change instrument has a Kappa index reliability over 2 weeks of .78, and concurrent validity was demonstrated by its significant association with the Seven Day Recall Physical Activity Questionnaire (Marcus, et al., 1992; Marcus and Simkin, 1994). The stage of change questionnaire for smoking cessation is a standard 3-item algorithm (Prochaska and Goldstein, 1991).

Decisional balance was measured by subtracting the “cons” score from the “pros” score on a questionnaire specific to exercise and smoking. For the 20-item smoking

questionnaire, principal components analysis had yielded two orthogonal components labeled positive beliefs (pros) and negative beliefs (cons) about smoking with 10 items for each component and internal consistency of .87 and .90, respectively (Velicer, DiClemente, Prochaska, and Brandenburg, 1985). A balance score resulting in a more negative number indicates an individual having greater reasons to continue smoking, and as the score becomes positive, the cons of smoking outweigh the pros. The 16-item exercise decisional balance questionnaire has an alpha coefficient for the 6-item cons subscale of .79, and for the 10-item pros subscale of .95 (Marcus, Rokowski, and Rossi, 1992). The higher the balance score, the greater the individual's reasons for beginning or adhering to an exercise program. For both exercise and smoking, decisional balance was measured on a Likert scale from zero to five for each item. Decisional balance for exercise was measured for all subjects at each time point, and decisional balance for smoking was measured at each time point for smokers only.

Exercise self-efficacy was measured using a 13-item questionnaire specific for exercise, with responses on each item ranging from zero to 100, with an internal consistency of .88 which correlated significantly with exercise behavior ($r = .52, p < .05$) (McAuley, 1992). This questionnaire was designed to assess subjects' perceived confidence in their ability to exercise three times per week in the face of barriers to participation (McAuley, 1992). The highest score possible on this questionnaire is 1300, with the high score indicating complete confidence. Smoking cessation self-efficacy was

not measured because overall self-efficacy for smoking cessation peaks at 18 months, with the temptation component of self-efficacy for smoking leveling out at approximately 36 months after quitting (Prochaska and DiClemente, 1984).

Smoking cessation rate. The number of participants who smoke was biochemically confirmed at baseline, and for those who smoked at 3 and 6-months. A non-smoking status was defined as a salivary cotinine level <14ng/ml (Jarvis, Tunstall-Pedoe, Feyerabend, Vesey, and Saloojee, 1987). Cotinine, the primary metabolite of nicotine, is considered the most valid marker of tobacco smoke exposure, and detects light and intermittent smoking (Benowitz, 1983). Since cotinine levels are not appropriate for those on nicotine replacement therapy, expiratory carbon monoxide (CO) levels also were measured at baseline, 3 and 6 months. CO in expired air <8 parts per million is identified as nonsmoking status (Jarvis, et al., 1987). The sensitivity and specificity of CO for confirming smoking status has been reported at 95.8% and 100% respectively (Stokey, Katz, Olson, Drook, and Cohen, 1987).

Statistical Methods

Hypothesis one involved comparing the change over time in functional status (CPT and MWT), decisional balance for exercise adoption, and exercise self-efficacy by group from baseline to six months. The change over time in CPT, MWT, exercise decisional balance, and exercise self-efficacy was determined using slope analysis (Suter, Wilson, and Naqvi, 1991). This strategy involves regressing each participant's dependent variable (CPT and MWT) on time (baseline, 3-months, and 6 months). Once the slope was computed, a number was generated as the slope value (beta) for each subject. An

independent samples t-test was then used to determine differences between experimental and control groups based on the slope of each outcome variable. To determine within group differences, a one-group t-test was used, by comparing the beta value of the intervention group to a zero value to determine change from baseline to 6 months. Finally, post hoc analyses were conducted using t-tests to determine differences in each variable at each time point between groups, and paired t-tests to determine differences between two time points within group.

Hypothesis two involved assessing the change in smoking decisional balance over time by group from baseline to six months. The change over time in smoking decisional balance by group was initially assessed using slope analysis as stated above. In addition, post hoc t-tests and paired t-tests were used to determine if there were differences at individual time points both between and within groups, respectively. Significance was set at $p < .05$.

Hypothesis three involved comparing the number of smokers who quit smoking over time by group, and comparing the number of participants who progressed forward through the stages of change for exercise adoption by group from baseline to three and six months post treatment. The movement across stages by group was assessed using a chi-square for two independent samples. This test was used to examine between group differences at baseline, 3 and 6 months. In addition, at each of these three data points a Wilcoxon Signed Ranks test was used to examine within group differences related to movement between stages. These nonparametric statistics were appropriate because stage of change is ordinal level data involving counts or number of people per cell (Pett,

1997). In addition, in order to identify factors that related to adoption and maintenance of successful behavior change (stage of change), non-parametric correlations were conducted using the Kendall's tau b as the correlation coefficient. For these correlations, a one-tailed test was selected because the relationship between variables had been previously determined by the theoretical base of the study. All statistical analyses were conducted with the aid of SPSS for Windows 9.0.

During the 12-week intervention, during data collection appointments, and during follow-up telephone conversations notes were taken on comments made by participants. These statements were reviewed, and when similar comments were made by several participants, these were taken note of, and are reported here. In addition, for intervention and usual care participants who had to withdraw from the study early, follow-up phone calls were made, and self-reported exercise routines and smoking cessation rates are also reported here.

Based on previous research, the change in functional status was expected to yield a large effect size (Patterson et al., 1997). Thus, a power analysis for a repeated measures design using a large effect size, an alpha of .05, and a power of .80 was conducted, and determined the need for a sample size of 28, with 14 in each group (Stevens, 1996). To account for attrition, thirty-eight subjects were recruited, and the final sample yielded 14 in the intervention group and 14 in the usual care group available for analysis.

4.3 RESULTS

Thirty of the initial 38 participants were available for follow-up data collection. The baseline demographic characteristics of these 30 participants are found in Table 4.3.

There were no differences between groups except in walking times, with the usual care group being able to walk pain free almost two minutes longer than the intervention group, and maximally walk about four minutes longer than the intervention group. About 70% of both groups were men, almost half were current smokers, the vast majority had hypertension, and close to half had some form of diabetes. Many had never exercised before, very few had undergone a vascular surgery despite ankle brachial indices that would indicate rather severe claudication, and close to half were taking Cilostazol (Pletal) to help manage their disease.

Of the 38 subjects initially screened and enrolled in the study, 21 were originally assigned to the intervention group, with 14 participants completing the 12-week program and available for 3-month follow-up (Table 4.2). After enrollment, it was determined that one intervention group participant was not able to fully comprehend the abstract nature of the decisional balance and self-efficacy questionnaires, and they were not completed by this participant. There was additional attrition after the 3-month time point (Table 4.1), and at six months there were 10 intervention subjects available for follow-up (Table 4.2). The 6-month discrepancy between the treadmill walking time number ($n = 9$) and the questionnaire number ($n = 10$) was a result of one intervention subject having such high blood pressure at the 6-month appointment that they were sent to the emergency room and did not complete the treadmill test. In contrast, seventeen participants were originally assigned to the usual care group, with fourteen available for 3-month follow-up, and twelve available at 6-month follow-up (Table 4.1). Two of the usual care participants were unable to come for 3-month data collection, but were

available at 6-months. Reasons for attrition included medical problems (4); cardiac disorders (3) although no cardiac problems were reported during exercise, but rather found during routine cardiology appointments; surgery (3) with two usual care group members requiring peripheral revascularization, and one intervention group member needing a carotid endarterectomy; and inability to contact or refusal to further participate (7) (Table 1). It may be notable that most of those lost to follow-up were intervention group members. Perhaps the commitment was more than they had anticipated, or perhaps their health was a bit more unstable, with a loss of 6 intervention group members to health problems, versus 4 for the usual care group.

Exercise variables

A significant between group difference was found for exercise stage of change over time (Table 4.4). There were no differences between groups at baseline, with 50% of each group in preparation, about 20% of each group in contemplation, and about 30% of each group in precontemplation. However, at the 3-month time point, 85.7% of the intervention group (n = 12) had moved into action, with only 21.4% of the usual care group (n = 3) having moved into action. At the 6-month time point, there was no significant difference between the groups, but it is notable that 40% of the intervention group (n = 4) had progressed into the maintenance stage of exercise, while only 17% of the usual care group (n = 2) had done the same.

The functional status measures (CPT, MWT), along with exercise decisional balance and self-efficacy were assessed for between group differences according to change over time with slope analysis (Table 4.5). There were no significant between

group differences on any of these measures. While there was a greater change in walking time for the intervention group versus the control group (e.g. slope of 186.5 intervention versus 70 usual care), because of the wide variability in scores for both groups (as evidenced by standard deviations greater than 200), this difference was not significant. While a positive slope value indicates an increased score over time, conversely a negative slope value indicates that the scores decreased over time. For both the intervention and usual groups, exercise decisional balance scores decreased slightly. As expected, exercise self-efficacy scores increased for the intervention group as evidenced by a positive slope value (94), but actually decreased for the usual care group (-105) (Table 4.5).

Table 4.6 illustrates significant within group differences for exercise variables. The intervention group did have significant increases from baseline ($p < .05$) in CPT and MWT (Figures 4.1 & 4.2; Table 4.6). These differences were found at 3-months and 6-months with CPT (70% and 90% respectively), and only at 3-months for MWT (35%), even though there was a 30% increase ($p = .07$) from baseline to 6-months in MWT for the intervention group. There were no within group changes for exercise decisional balance or self-efficacy for the intervention group. In comparison, there were no within group differences in the usual care group for CPT, MWT, or exercise decisional balance, except for a significant drop ($p < .05$) in self-efficacy scores (Table 4.6). While there was an increase in CPT and MWT for the usual care group as a result of two control group

participants who began to exercise routinely, most of the control group participants maintained stable walking times or even decreased walking times in some cases, and therefore the overall change was not significant.

Based on the theoretical models used to develop this intervention, several variables were assessed for correlation with exercise stage of change at different time points. The only measure that significantly correlated with exercise stage of change was the baseline self-efficacy score. In fact, for all subjects (not separated by group), baseline self-efficacy correlated with 3-month exercise stage of change with a Kendall's tau-b coefficient of .357 ($p < .05$), but not with 6-month exercise stage of change ($p = .173$). When divided by group, this correlation was not significant for the intervention group at 3- or 6-months, but actually became stronger for the usual care group at 3-months only (correlation coefficient .625, $p < .01$), while the 6-month correlation was not significant.

Smoking variables

There were 15 self-reported smokers who enrolled in the study and were available for at least one follow-up visit. Initially, only 13 participants (43%) self-reported smoking. However, following high baseline CO levels, two additional participants admitted to smoking. Biochemical confirmation of salivary cotinine levels, which detect smoking history up to seven days, took longer to analyze. Based on cotinine analysis, there were 15 smokers, five in the intervention group, and 10 in the usual care group. One self-reported smoker had a zero level of salivary cotinine, (but an elevated CO), one self-reported smoker had a zero level of salivary cotinine (and a low CO) but stated she did not inhale when she smoked, and two self-reported non-smokers had elevated

cotinine concentrations (but low CO levels). Cotinine is widely accepted as the most valid marker of tobacco smoke exposure (Benowitz, 1983), and has a sensitivity and specificity of 99% and 91.5% respectively (Murray, Connett, Lauger, and Voelker, 1993). It is unclear why two usual care group members stated they were non smokers when biochemical analysis revealed otherwise. Both stated they had quit smoking more than 10 years previously, both had CO levels < 8ppm, and neither expressed any concern about collection of a saliva sample. Perhaps they were consuming smokeless or pipe tobacco and did not consider this cigarette smoking, or were using a form of nicotine replacement therapy. The reason one self-reported smoker had a zero level of cotinine but a high CO level is unclear. Because of the delay in receiving cotinine assay results from the laboratory, follow-up smoking data beyond baseline were not obtained from the two usual care “smokers” who self-identified as former smokers. In order to report conservative smoking cessation rates, these two usual care members were classified as smokers according to stage of change, but are not included in other smoking analysis. The two self-reported smokers whose cotinine values were low, are considered smokers and are included in all smoking data analysis. Therefore, smoking data for the two self-reported smokers who were biochemically identified as smokers is included only on Table 4.8 where they are classified as smokers in the earlier stages of change at all time points. In addition, unless specified otherwise, the text will refer only to the smoking data for the 15 self-reported smokers in the study, since additional smoking data was not collected for the two additional usual care group tobacco users.

Six smokers were randomly assigned to the intervention group, and nine smokers were assigned to the usual care group. There were no differences between groups on any of the pertinent smoking demographic variables including age, number of years smoked, and age of smoking initiation (Table 4.7). In addition, variables that tend to identify level of nicotine addiction such as time to first cigarette of the day, finding it difficult not to smoke in forbidden places, smoking more frequently in the morning than later in the day, smoking when so ill as to stay in bed, and mean Fagerstrom questionnaire score were not different between groups (Table 4.7).

Smoking variables that were measured at baseline, 3 and 6-months were decisional balance and smoking stage of change. There were no significant changes in either of these variables when comparing groups. Table 4.5 shows the lack of between group differences on smoking decisional balance score as evidenced by similar slope values indicating that both groups experienced increases in overall scores. Table 4.8 shows the distribution of participants according to smoking stage of change at every time point by group. Table 4.8 also indicates overall smoking rate, as the action stage is defined as complete smoking cessation, with one participant in each group having reached the action stage at 3-months, and one participant in the usual care group reaching action at 6-months. The usual care member who was in action at 6-months was not the same usual care member who was in action at 3-months, as the latter had dropped out of the program due to lack of time. In addition, when groups were compared individually, there were no within-group differences on any of the smoking variables.

As a result of the lack of significant findings by group, all the smokers were collapsed into one group, and analyzed for overall smoking trends and correlations. Table 4.9 shows mean decisional balance scores for all smokers which did not change over time. However, when stage of change data was analyzed for significant differences by time point, there was a significant change at 3-months ($p < .05$), with two participants overall moving into action, compared to baseline, but this significant change was not maintained at 6-months. This move into the action stage of smoking cessation is reflected in the significant change in CO values from 23 ppm at baseline, to 16 ppm at 3-months, and remaining lower at 16 ppm at 6-months (Table 4.9). This change is not reflected in the cotinine analysis because at 3-months four people were using nicotine replacement, and at 6-months, one person was on nicotine replacement.

Because there was no evidence that the intervention resulted in significant smoking cessation rates, other factors were analyzed for predictors of smoking stage of change movement. Two variables were found to significantly correlate with 3-month stage of change for the group of all smokers (Table 4.10). The first variable, baseline smoking decisional balance, confirms the premise of the TTM that the cons of smoking must outweigh the pros in order for successful change to occur. The positive correlation indicates that higher baseline decisional balance scores (greater cons of smoking) correlated with the higher smoking stages of change (preparation and action). The second variable, difficulty not smoking in forbidden places, reflects the effect of nicotine addiction. The question was asked so that a “yes” answer was coded “1”, and a “no” answer was coded “2”, thus at baseline, smokers who found it more difficult to refrain

from smoking in forbidden places were more likely to still be in the early (precontemplation and contemplation) stages of change at 3-months. Neither of these correlations were significant at 6-months.

In summary, two smokers out of 17 (12%) completely quit smoking during their time in the study, both of them in the usual care group. The one intervention group member who quit smoking at 3-months was still smoking two cigarettes a day at 6-months per self-report. However, almost all smokers reported smoking fewer cigarettes a day by the end of their study time, which is supported by the significant decrease in CO levels. Additional qualitative analysis was conducted based on personal interview and telephone follow-up with many smokers. Four usual care members who smoked chose to participate in the 12-week educational course after their 6-month wait time was completed. Three out of these four quit smoking during the 12-week class, and remained quit at the time of the final telephone follow-up. However, their data is not included in the statistical analysis because this study did not have a cross-over design. The three subjects who dropped out to have vascular surgery (2 usual care and 1 intervention) had also quit smoking after surgery per self-report. Finally, one intervention subject who cut back on number of cigarettes smoked/day during the program, reported during a telephone follow-up a complete cessation of smoking after a cardiac procedure, and reported maintenance of cessation at a 1-month follow-up phone call.

Including the two usual care subjects who quit smoking during their time in the study, and the seven who quit smoking after they were out of the study, a total of nine smokers (53%) had quit smoking as of the last telephone contact. In addition, those who

were still smoking reported a decrease in the number of cigarettes smoked per day from baseline (m = 15) to the final follow-up phone call (m = 9). From statements made by smokers during one on one conversation, three themes were identified as motivators for quitting smoking (Table 4.11). The first theme, time to prepare, was identified after 3 usual care group smokers quit smoking during the 12-week class they had waited to take. All three of these smokers had stated during their 6-month wait time that they were “waiting for the class”, and they “were planning to quit”. One of these smokers started to smoke again after the need arose to care for ailing parents, but then quit again about a month later. The second theme, significant life event, was identified when 4 smokers quit smoking after a major invasive procedure (3 vascular and 1 cardiac), and 1 smoker quit after a sister was diagnosed with cancer. These major life events seemed to give these smokers the motivation to quit smoking after years of trying to do so. The last theme, effect of significant other, was identified exclusively for one smoker, but seemed to play a part in the quit attempts of others. One usual care smoker quit smoking when they started dating a non smoker. Up until that point, this person was in the contemplation stage of change, but jumped into action for the sake of this new relationship. In this case, the effect of a significant other had a positive effect, but this theme was echoed with other smokers, particularly those who struggled to quit. Out of the remaining 6 subjects who failed to quit smoking, 2 had significant others who smoked, and 3 had a majority of friends who smoked.

4.4 DISCUSSION

Home-based walking programs have been found to be effective for improving claudication pain time and maximal walking time for patients with lower extremity PAD (Patterson et al., 1997; Degischer et al., 2002; Binnie, Perkins, and Hands, 1999). In the current study, intervention group participants had a significant improvement in CPT similar to other home-based programs (Patterson et al., 1998; Degischer et al., 2002). In addition, while the overall improvement in MWT for the intervention group was less than some researchers have reported (35% versus 70%) (Patterson et al., 1998), this improvement was better than others have reported (35% versus 5.4%) (Degischer et al., 2002).

It was hypothesized that there would be a significantly greater increase in CPT and MWT for the intervention group than the usual care group, and the lack of significant between group difference was unexpected. Knowing that exercise self-efficacy is a strong predictor of current and future exercise behavior (Dishman and Buckworth 1996), the plan was to work with the intervention group to improve confidence in their ability to exercise, hence increasing self-efficacy and increasing their chance of successfully adopting a routine exercise program. However, for all study participants, regardless of group, baseline self-efficacy was found to significantly correlate with exercise stage of change. In fact, this correlation was even stronger for usual care group members, but was not significant for intervention group members. As a result, individual baseline self-efficacy scores for usual care members were reviewed. Out of the four usual care members with the highest baseline self-efficacy scores ($n = 1100$), at 3-months three

were in the action stage of change for exercise and one was in the preparation stage. At 6-months two had moved on to the maintenance stage of change, one had regressed back to preparation, and one had moved into action. In contrast, almost all intervention group members moved into the action stage at 3-months despite baseline exercise self-efficacy scores. In fact, at 3-months the two intervention members with the lowest baseline self-efficacy scores ($n = 390$) both moved into the action stage of change, while at 6-months one moved on to maintenance. The implication from these results is that those who initially have a high degree of confidence in their ability to begin and maintain an exercise routine, will do so whether there is a formal intervention or not. In contrast, even for patients who do not have confidence in their ability to begin and maintain an exercise regimen, this lack of confidence can be overcome with a structured, individualized intervention.

At the beginning of the study, it was hypothesized that there would be a significant increase in the pros of exercise and a significant decrease in the cons of exercise, resulting in a change in exercise decisional balance score for the intervention group, but not the usual care group. This difference was not realized, probably because both groups started out with a basic belief in the pros of exercise, resulting in high baseline decisional balance scores that were maintained over time. The possible range of decisional balance scores has a low of -20 up to a high of 44, and for both groups the average baseline score was in the low 20's. This may have been a result of the recommendation to begin exercising given by a vascular physician to all study participants at the beginning of the program.

At the 3-month data collection point, 86% of the intervention group had progressed to the action stage of exercise adoption compared to 21% of the usual care group. At 6-months, 40% of the intervention group (n = 4) had progressed on to the maintenance stage. Many intervention subjects started to exercise upon enrollment. Random assignment to group occurred at the end of the screening visit, and subjects knew at that time if they would be part of the class immediately, or be asked to wait 6-months. Several intervention participants asked what type of exercise they should begin, and began to exercise at that time point, before the class actually started. This allowed four intervention group members to reach maintenance by the 6-month data point. In fact, the number of participants in the intervention group who progressed on to maintenance may have been greater than four. Two intervention group members who dropped out of the program for cardiac and surgical reasons reported that they were still exercising regularly despite having to take some time off for medical treatments, however this is not reflected in Table 4.4. None of the usual care subjects who had to drop out of the program were exercising per follow-up phone call.

While 70% of the intervention group reached action or maintenance for exercise adoption by the 6-month data point, 58% of the usual care group also reached action or maintenance by the same time point, which resulted in a lack of significant difference between the groups at 6-months (Table 4.4). This may have been a result of the usual care group participants being told that at the end of the 6-month usual care period, they would have the option of taking the same class offered to intervention participants. Six usual care subjects chose to participate in the class, one of whom was in the maintenance

stage of exercise adoption, three were in the action stage, one was in preparation, and one was in the precontemplation stage of exercise adoption, but stated they wanted to take the class to quit smoking (which they did).

The smoking cessation rates for the current study were a dismal 0% for the intervention group and 18% for the usual care group. It is not surprising that other intervention studies aimed at smoking cessation with PAD patients have found similar non-significant results (Fowler, Jamrozik, Norman, Allen, and Wilkinson, 2002; Power et al., 1992). In 1997, Hirsch and colleagues from the Vascular Medicine Program in Minneapolis, MN hypothesized that “the discomfort of claudication and/or the fear of amputation might serve as motivators for effective tobacco cessation interventions in the PAD population if the link between smoking and this severe limb disease were reinforced by intensive counseling interventions” (Hirsch et al., 1997). While the current study does not give statistically significant evidence to support this hypothesis, the anecdotal evidence does suggest support. Five out of the nine people who self-reported quitting smoking completed the 12-week intervention program. Two of the five did not quit until a month after the end of the intervention when they underwent a significant life event, and the other three participated in the 12-week intervention after completing the 6-months control group period. However, with all five, the link between smoking and their disease had been made, and strategies for successfully quitting were provided. The implication of these results is that it may be a more cost-effective use of resources to combine smoking cessation interventions with major health related events. This could be

done by offering individualized smoking cessation counseling to all claudicants undergoing vascular procedures, with initial counseling beginning in the hospital and follow-up continuing after discharge.

Smoking decisional balance scores did not change significantly over time by group, or for the entire sample of smokers. There is however strong support in the literature for a relationship between smoking decisional balance and stage of change (Prochaska et al., 1997), which was identified in the current study. In addition, many factors contribute to nicotine addiction including physical, emotional, social, and environmental factors (Fisher et al., 1990). All but one smoker in the intervention group was encouraged to use nicotine replacement as an adjunct to the smoking cessation counseling received in class, but only three intervention group smokers chose to use nicotine replacement. Of those three, one was in the action stage of smoking cessation at 3-months, but was back to smoking about two cigarettes a day at 6-months. The other two smokers had cut back in number of cigarettes used per day, but had not quit smoking at 3 or 6 months. In addition, one of the usual care members who quit smoking used transdermal nicotine replacement to aid in smoking cessation.

The other variable that correlated with smoking stage of change was the smoker's ability to refrain from smoking in places where it is forbidden, such as airplanes and movie theatres. This question is significant in that it reflects degree of addiction, but does not specify type of addiction. Smokers who find it difficult to refrain from smoking in places where it is forbidden may have a physical need to smoke, or perhaps a social need to smoke, as there is evidence that hand-oral manipulation contributes to degree of

addiction (USDHHS, 1988). In addition, the question of smoking in forbidden places is just one of the six questions on the Fagerstrom Test of Nicotine Dependence (FTND). While the total FTND score did not correlate with smoking stage of change at three or six months, this single question did. The reason for the lack of correlation between the FTND score and smoking stage of change is not clear. However, researchers have found that the question of smoking in forbidden places can differentiate between groups according to CO level (Heatherton et al., 1991). Upon further investigation of this group of smokers, there was a significant correlation between those who found it difficult to not smoke in places where it is forbidden and 3-month CO level (Kendall's tau b coefficient = $-.541$, $p < .05$), but not at six months (Kendall's tau b coefficient = $-.519$, $p = .122$). The negative correlation indicates a relationship between those who find it difficult to refrain from smoking in forbidden places (yes = 1 and no = 2), and a higher CO level. The implication of this finding may be that for this group, this single question captured the degree of nicotine addiction better than the total FTND score.

The positive correlations between decisional balance and smoking stage of change, and between smoking in places where it is forbidden and smoking stage of change emphasize the importance of assessing a smoker's view of the cons versus pros of smoking, and their level of addiction before beginning a smoking cessation intervention. This allows the clinician to address the unique needs of the smoker before an individualized intervention is begun. In addition, because of the influence that significant others seemed to have on successful behavior change, it may be prudent, if possible, to have significant others take part in smoking cessation interventions.

There are several limitations of this study. First, the sample size was adequate to detect the large improvements in functional status and the movement through the exercise stage of change, yet attrition resulted in a small sample size at 6-months. Although these results support the hypothesis that a theory-based intervention is beneficial for helping people adopt exercise behavior, the total attrition of 17 subjects over the course of 6-months limits the conclusions about this intervention significantly influencing maintenance of exercise behavior. Second, there was considerable variability within the groups. This is evidenced in Table 4.5 by the large standard deviations of the slopes for CPT, MWT, and exercise self-efficacy. The implication of this is that wide variability in the outcome measures may have resulted in lack of or decreased statistical significance that could have been accounted for by a larger sample size. Third, although the only baseline characteristics that were significantly different between groups were CPT and MWT, this may have been a reflection of an overall difference in physical health. Even though there were not significant differences in health history between groups, there were more intervention subjects with hypertension and diabetes, and fewer taking Pletal. Other researchers have matched groups at baseline according to MWT and CPT (Patterson et al., 1997), which may be a consideration in the future. Finally, there may have been limitations of the TTM that were not fully taken into consideration. Stage-matched interventions generally are developed based on homogeneity of subjects within each stage. In addition to the development of a high intensity intervention, an effort was made to overcome this problem by utilizing principles of nicotine addiction and exercise determinants to administer individualized exercise prescriptions and smoking cessation

counseling. However, particularly for smokers, those in precontemplation and contemplation may not have been challenged enough to set a quit date, and take action during the course of the intervention (Spencer et al., 2002)

Despite the limitations, the results of this study are significant. These results support the premise that a nurse-managed, theory-based exercise adoption intervention is effective in helping claudicants adopt a routine exercise program. In addition, when combined with a critical life event, a nurse-implemented, theory-based smoking cessation intervention may contribute to claudicants' successful smoking cessation. Considerations for future research should include implementing such a program with a larger group of PAD patients, and combining the smoking cessation portion of the program with hospital-based vascular procedures. There is evidence from the literature that smoking cessation rates can be increased greatly with just such a structure. When a nurse-managed smoking cessation intervention incorporating principles of social learning theory with addiction models for nicotine was implemented in the hospital with patients post myocardial infarction, and was followed-up with telephone calls, the smoking cessation rate of the intervention group was 61% versus 32% in the usual care group at 12 months (Taylor et al., 1990). These results were confirmed biochemically. Even brief smoking cessation interventions, when combined with a teachable moment such as a dentist office visit, has been found to significantly increase smokeless tobacco cessation rates (18.4% vs. 12.5%) (Stevens, Severson, Lichtenstein, Little, and Leben, 1995).

In clinical settings, assessing a patient's exercise self-efficacy is relatively simple, and should be considered as part of the initial clinical assessment of all claudicants. For

claudicants with low self-efficacy, an exercise adoption intervention would be effective in increasing their self-efficacy, thus increasing their chance of successfully adopting a routine exercise regimen. However, for claudicants with a high exercise self-efficacy during the baseline assessment, they may only need a one-time admonishment to begin walking, with reinforcement at subsequent visits.

<u>Reason</u>	<u>Time of Dropout</u>			
	<u>Program onset</u>	<u>During program</u>	<u>3-months</u>	<u>6-months</u>
General		Intervention: 1 Control: 1		Intervention: 2
Medical				
Cardiac		Intervention: 1		Intervention: 1 Control: 1
Vascular surgery				Intervention: 1 Control: 2
Couldn't contact	Intervention: 1	Intervention: 1	Intervention: 2	Intervention: 1
Refused		Intervention: 1		Control: 1

Table 4.1. Patient attrition during course of study and reason for loss from study

	Intervention group		Usual Care group	
	Exercise variables	Smoking variables	Exercise variables	Smoking variables
3 months	14 (CPT,MWT,SOC) 13 (DB) 12 (SE)	6	14	8
6 months	9 (CPT,MWT) 10 (DB,SOC,SE)	3	12	6

CPT, claudication pain time; MWT, maximal walking time; DB, decisional balance; SOC, stage of change; SE, self-efficacy

Table 4.2: Summary of the number of subjects available for follow-up data collection by group by time.

	Intervention group (n = 14)	Usual care group (n = 16)
Average age	66.14 ± 4.91	67.69 ± 2.94
% Male	71.4	68.8
% African American	28.6	6.3
% Less than HS education	35.7	13.3
% 4 year college education or more	21.4	20.0
% Current smoker	42.9	50.0
% Never exercised before	50.0	31.3
% With a partner who exercises	14.3	13.3
% Hypertension	84.6	66.7
% Previous MI	15.4	12.5
% History CHF	7.7	6.3
% Diabetic	57.1	31.3
% History of Stroke	14.3	18.8
% History of Vascular Surgery	21.4	6.3
% Taking Pletal	35.7	50.0
Baseline ABI	.58 ± .14	.64 ± .11
Baseline claudication pain time (minutes)	2.65 ± 2.04**	5.21 ± 3.52
Baseline maximal walking time (minutes)	6.62 ± 3.74**	10.68 ± 5.04

HS, High School; MI, Myocardial Infarction; CHF, congestive heart failure; ABI, ankle brachial index; ** significantly different from the usual care group.

Table 4.3: Baseline characteristics of the study sample by group.

Time	Stage	Intervention	Usual Care
Baseline	Precontemplation/Contemplation/Preparation	100%	100%
	Action	0%	0%
	Maintenance	0%	0%
3-months	Precontemplation/Contemplation/Preparation	14.3%**	78.6%
	Action	85.7%**	21.4%
	Maintenance	0%	0%
6-months	Precontemplation/Contemplation/Preparation	30%	41.6%
	Action	30%	41.7%
	Maintenance	40%	16.7%

**p < .01 significantly different from the usual care group at 3-months

Table 4.4: Percentage of subjects in each stage of exercise adoption at each time point by group.

Variable	Intervention group	Usual care group	p value
Claudication pain time	186.5 ± 202 (n = 14)	70 ± 209 (n = 14)	.132
Maximal walking time	159 ± 170 (n = 14)	64 ± 191 (n = 14)	.176
Smoking decisional balance	4.4 ± 6.4 (n = 5)	8.33 ± 20.5 (n = 9)	.688
Exercise decisional balance	-5.5 ± 12 (n = 12)	-2.4 ± 12 (n = 16)	.502
Exercise self-efficacy	94 ± 447 (n = 13)	-105 ± 459 (n = 16)	.250

Note: a “negative” slope indicates that the overall score decreased over time, while a “positive” slope indicates the overall score increased over time; the larger the slope, the greater the change over time.

Table 4.5: Between group differences: Comparison of change over time as indicated by the slope value

Outcome measure	Intervention			Usual Care		
	Baseline	3-months	6-months	Baseline	3-months	6-months
CPT (minutes)	2.7 ± 2.0 (n = 14)	4.5 ± 2.9* (n = 14)	5.0 ± 3.6 * (n = 9)	5.3 ± 3.7 (n = 14)	6.3 ± 4.5 (n = 14)	7.0 ± 5.1 (n = 12)
MWT (minutes)	6.6 ± 3.7 (n = 14)	8.9 ± 5.2** (n = 14)	8.2 ± 5.5 (n = 9)	10.8 ± 5.2 (n = 14)	11.2 ± 4.7 (n = 14)	12.1 ± 6.2 (n = 12)
Decisional Balance (mean)	23.6 ± 9.7 (n = 13)	24.3 ± 11.0 (n = 13)	21.5 ± 10.0 (n = 10)	23.5 ± 13.4 (n = 14)	24.4 ± 10.0 (n = 14)	20.2 ± 9.2 (n = 12)
Self-efficacy (mean)	831 ± 302 (n = 12)	923 ± 307 (n = 12)	782 ± 371 (n = 10)	819 ± 294 (n = 14)	762 ± 329 (n = 14)	684 ± 364* (n = 12)

*p < .05 significantly different from baseline

CPT, claudication pain time; MWT, maximal walking time

Table 4.6. Within group differences on the exercise measures for the intervention and usual care groups

Variable	Intervention (n = 6)	Usual Care (n = 9)
Age years	66	60
Carbon monoxide (ppm)	19.5 ± 11	24 ± 13
Cotinine ng/ml	146 ± 149	389 ± 458
	(n = 6)	(n = 8)
% with a partner who smoke	33%	22%
	(n = 2)	(n = 2)
Mean number of years smoked regularly	48 ± 7	36 ± 15
Mean age of smoking initiation	18 ± 6	22 ± 5
Mean number of cigarettes/day	13 ± 6	16 ± 8
Mean number of times tried to quit smoking	6 ± 5	7 ± 8
Mean time to first cigarette of the day in minutes	58 ± 92	21 ± 19
	(range 1-240)	(range 1-60)
% who find it difficult not to smoke in forbidden places	17%	25%
	(n = 1)	(n = 2)
% who smoke more frequently when they first get up versus the rest of the day	67%	63%
	(n = 4)	(n = 5)
% who smoke when ill enough to stay in bed	33%	38%
	(n = 2)	(n = 3)
Mean Fagerstrom score (range 0-10)	6 ± 1	6 ± 1

Table 4.7: Baseline demographics and smoking history of all self-reported smokers in the intervention and control groups.

Time	Stage	Intervention	Usual Care
Baseline	Precontemplation/Contemplation/Preparation	6	11
	Action	0	0
	Maintenance	0	0
3-months	Precontemplation/Contemplation/Preparation	5	10
	Action	1	1
	Maintenance	0	0
6-months	Precontemplation/Contemplation/Preparation	6	10
	Action	0	1
	Maintenance	0	0

Note: usual care numbers include the two subjects who said they didn't smoke but were smokers according to cotinine levels. There were no significant differences between groups at any time point. Those lost to follow-up was classified as a smoker

Table 4.8: Number of all smokers in each stage of smoking cessation at each time point by group.

	Baseline	3-months	6-months
Mean Decisional	11 ± 11	13 ± 14	10 ± 12
Balance Score	(n = 14)	(n = 13)	(n = 8)
Carbon monoxide in	23 ± 12	16 ± 11**	16 ± 14**
parts per million	(n = 15)	(n = 13)	(n = 9)
Cotinine	285 ± 371	328 ± 298	449 ± 445
	(n = 14)	(n = 13)	(n = 5)

Note: data from the 2 subjects who stated they were non-smokers but had elevated cotinine levels are not on this table.

**p < .05 significantly different from baseline

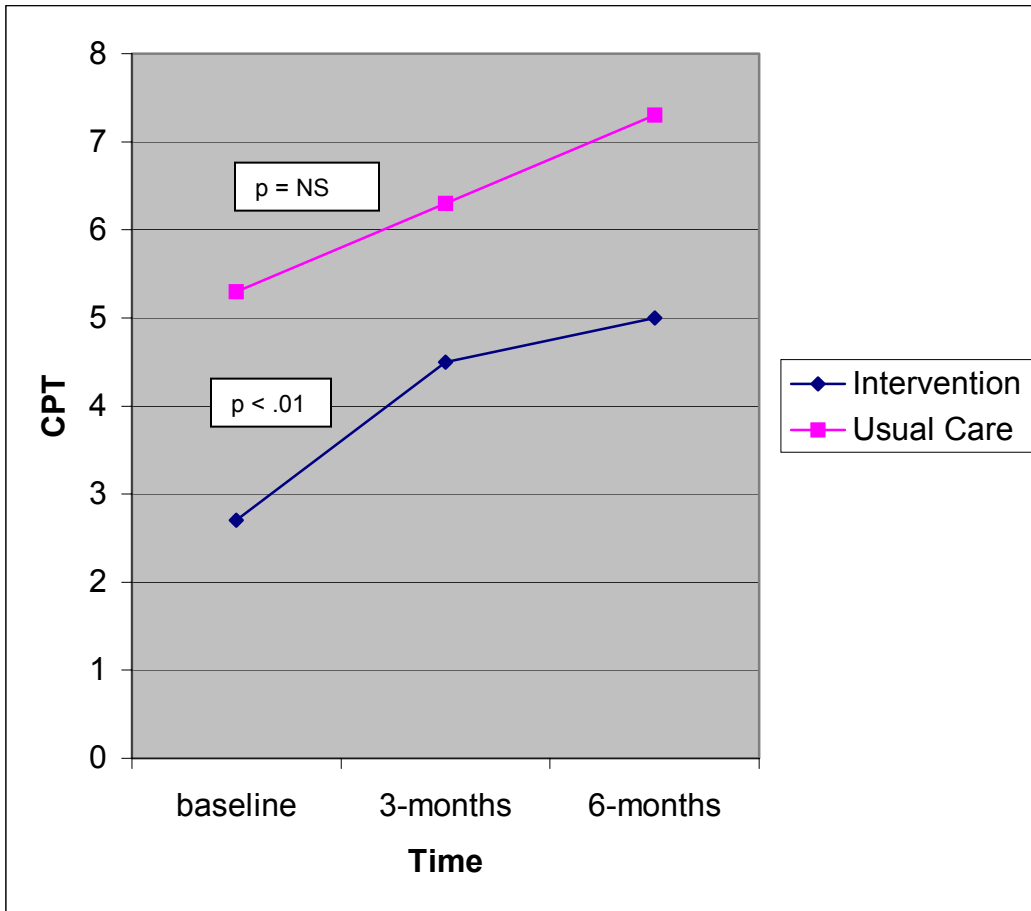
Table 4.9: Mean Smoking Decisional Balance Scores, Expired Carbon Monoxide and Cotinine values for all self-reported smokers at each time point

Variable	Kendall's tau b correlation coefficient	p value
Baseline smoking decisional balance	.523	.025
Difficult not to smoke in forbidden places	.451	.048

Table 4.10: Smoking variables that significantly correlated with 3-month smoking stage of change for all self-reported smokers.

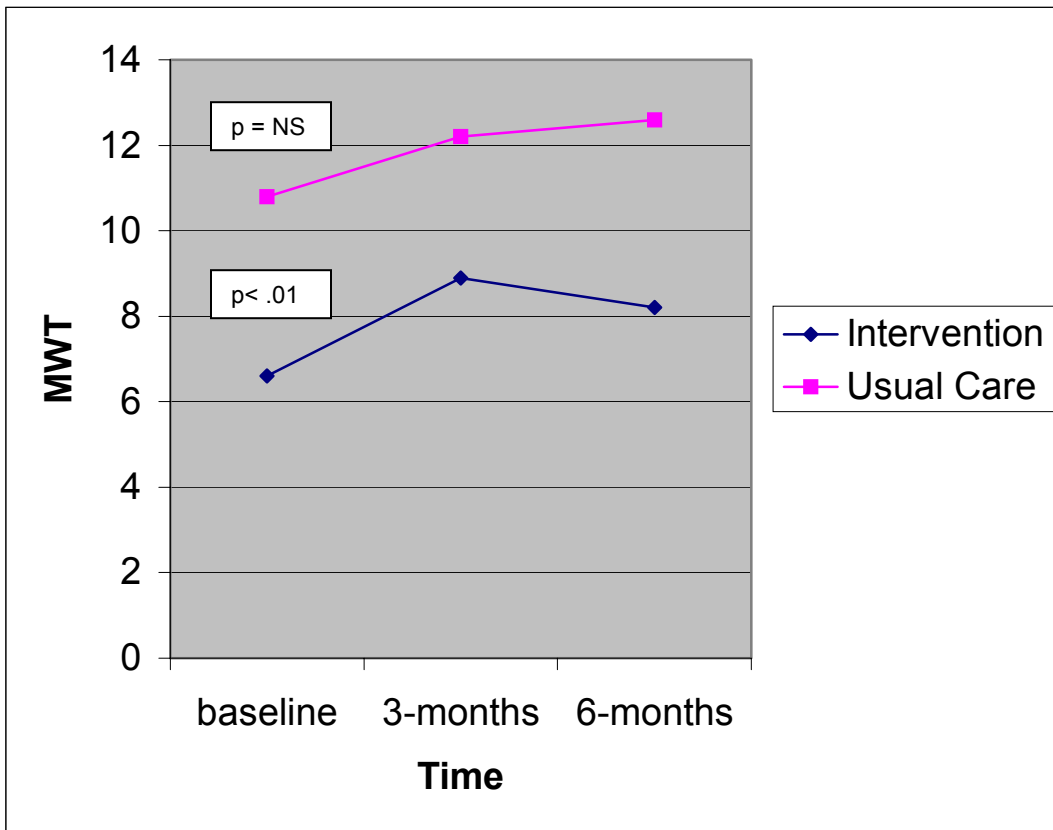
Identified theme	Number of smokers in this category
Time to prepare	3
Significant life event	5
Effect of significant other	1

Table 4.11: Themes influencing smoking cessation identified for those who quit smoking



note: p values indicate whether the slope is significantly different from 0 over time.
CPT, claudication pain time in minutes

Figure 4.1: Change in CPT in minutes over time by group



note: p values indicate whether the slope is significantly different from 0 over time
MWT, maximal walking time in minutes

Figure 4.2: Change in MWT in minutes over time by group

CHAPTER 5

SUMMARY

Subject recruitment and data collection for the current study began in September 1999 and was completed in February 2003. From September 1997 until the present time, relevant literature related to management of PAD, the transtheoretical model, and principles of nicotine addiction and exercise determinants were reviewed. While there have been no new recommendations in the past five years regarding exercise training for claudicants, there was a new medication marketed by Otsuka America Pharmaceutical, Inc, called Cilostazol (Pletal) which began to be widely prescribed by the vascular surgeons in Columbus in 1999-2000. This medication was found to significantly improve CPT and MWT in claudicants, and was incorporated into the current study (Regensteiner et al., 2002). After talking with the collaborating vascular surgeons, it was decided that two months would be enough time for the medication to take effect, and therefore, for patients who were prescribed Pletal, and wished to be enrolled in the program they were required to wait two months before screening and enrollment. This was done to prevent false improvements in walking time being attributed to exercise training.

A second update during the past five years came with the publication of a new *Clinical Practice Guideline for Treating Tobacco Use and Dependence* (Fiore et al., 2000). The guideline was reviewed for changes relevant to the current study, and of particular note was the lack of evidence for increased cardiovascular risk with nicotine replacement therapies (NRT). One collaborating vascular surgeon specifically said he did not want his patients to use nicotine replacement, and as an advocate for the patient, this information was shared with the surgeon, and in one case, the surgeon allowed the patient to use NRT.

While there have been no new recommendations in the past five years regarding exercise training for claudicants, it is important to note that the three critical components of an exercise program laid out by Gardner and Poehlman in 1995 were effective in this home-based exercise program. In fact, the definition of “regular exercise” for this study was slightly less intense than that of Gardner, with a definition of three times per week for 20 minutes per day versus 30 minutes per day. Even so, the concept of a walking intensity of near maximal claudication pain before resting, along with a frequency of three times/week for 20 minutes/day, and a duration of 26 weeks (6-months) was easily understood by this cohort of PAD patients, and was implemented to some degree by almost all intervention group members.

Exercise self-efficacy has consistently been found to be a strong predictor of exercise behavior, the current study being no exception (McAuley and Blissmer, 2000). However, it was of interest that low baseline exercise self-efficacy scores could be overcome by an intensive nurse-managed exercise adoption intervention. A

recommendation for future research includes an assessment of high intensity versus low-intensity nursing interventions to overcome low baseline self-efficacy in order to facilitate exercise adoption with PAD patients.

While researchers have supported the value of combining smoking cessation interventions with hospital admissions (Taylor et al., 1990), others have suggested that smokers with chronic health conditions were more ready to quit smoking than the general population of smokers, with illness being the primary motivation for wanting to quit smoking (Spencer et al., 2002). The current study revealed that at the time of the intervention, not all PAD patients were willing to quit smoking despite their chronic condition. However, when a critical health event occurred, they were able to use the information obtained during the intervention to quit smoking according to self-report. A recommendation for future research involves evaluating the effectiveness of a hospital-based nurse managed intensive smoking cessation intervention with PAD patients admitted for a vascular procedure.

Additional recommendations for future research include recruiting a larger sample size to account for variability and determine between group differences, taking baseline walking times into consideration when assigning patients to group, and following up with PAD patients for longer than six months. This research is the first of its kind to evaluate the effectiveness of a nurse-managed, theory-based exercise adoption and smoking cessation intervention with PAD patients. As the incidence of PAD in the elderly population continues to increase, there will be a greater demand for nurses to intervene to

help claudicants make lifestyle changes that are known to be beneficial. Vascular nurses must lead the way in investigating the most effective means for counseling patients to begin regular exercise and quit smoking.

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