2011

EFFECT OF THE STEPTM AND HOME-MONITORING TECHNOLOGY IN RURAL PRIMARY CARE ON BLOOD PRESSURE AND FITNESS IN METABOLIC SYNDROME

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EFFECT OF THE STEP^{TM} AND HOME-MONITORING TECHNOLOGY IN RURAL PRIMARY CARE ON BLOOD PRESSURE AND FITNESS IN METABOLIC SYNDROME

(Spine title: Effect of STEP^{TM} and home-monitoring on metabolic syndrome)

(Thesis Format)

by

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Graduate Program in Kinesiology

A thesis submitted in partial fulfillment
of the requirements for the degree of
Master of Science

The School of Graduate and Postdoctoral Studies
The University of Western Ontario
London, Ontario, Canada

THE UNIVERSITY OF WESTERN ONTARIO

SCHOOL OF GRADUATE AND POSTDOCTORAL STUDIES

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entitled:

Effect of the STEP Protocol and Home-Monitoring Technology in Rural Primary Care on Blood Pressure and Fitness in Metabolic Syndrome

is accepted in partial fulfilment of the requirements for the degree of Master of Science

Date_________________________

Chair of the Thesis Examination Board

Abstract

Adults with metabolic syndrome (MetS) are at a high risk for developing type II diabetes and cardiovascular disease. As well, rural populations have lower access to lifestyle modifications (recreational centres) to manage this condition. Adults with MetS were recruited from rural southwestern Ontario. At each visit, resting blood pressure (BP) was measured, a predictive fitness (VO_2max) test was offered and exercise was prescribed using the Step Test Exercise Prescription (STEP™). Home-monitoring technology included a Blackberry™, BP monitor and a pedometer. Clinical systolic BP (SBP) and diastolic BP (DBP) decreased from baseline to 3 months (V1) and continued to decrease into 6 months (V2). At-home SBP decreased at V1 and was maintained at V2. At-home DBP followed the same pattern as clinical. A lifestyle intervention in primary care using STEP with home-monitoring technology decreased BP and increased fitness and quality of life in adults from rural communities with MetS.

Keywords: metabolic syndrome, step test, blood pressure, exercise prescription, primary care, rural.

Acknowledgement

Firstly, I'd like to thank my supervisor, Dr. Robert Petrella, for his direction and support in the 2 years of my graduate work as well as for his countless edits and encouragement. I'd also like to thank Dr. Cheri McGowan from my supervisory committee for her continued advice throughout the writing process of my thesis despite a minor distance barrier. Thank you as well to Gateway Rural Health Research Institute for the use of their facilities for the ARTEMIS study and thank you to all the participants that made it to the facility, especially during the winter months.

I'd like to thank our lab staff who've come and gone in the past 2 years of my study, Kathy, Leanne, Nicole, Brittany, and Dennis, without your help this research would not have gone as smoothly. Fellow ARGC researchers, Noah and Joe, thank you for helping in Seaforth with our participant load. Thank you ARGC administrative assistant, Bonita for keeping me well organized for the past 2 years.

Special thanks to the study coordinator, Sheree Shapiro and fellow graduate student Melanie Stuckey, for their consistent and never failing support throughout my research, their encouragement and advice in many endeavours has made this whole process both an enjoyable and positive learning experience. I couldn't have asked for a better team.

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BP	Blood pressure
BMI	Body mass index
CVD	Cardiovascular disease
DBP	Diastolic blood pressure
HDL	High density lipoprotein
HR	Heart rate
MetS	Metabolic syndrome
QOL	Quality of life
RR	Relative risk
RHR	Resting heart rate
SBP	Systolic blood pressure
T2D	Type II diabetes
WC	Waist circumference

CHAPTER ONE

Literature Review

1.1 Introduction

Cardiovascular disease (CVD), such as myocardial infarction and stroke, is the leading cause of death in Canadian men and women (Statistics Canada, 2004). Prominent risk factors include, but are not limited to, increased blood pressure (BP), abdominal obesity, low fitness, low levels of high density lipoprotein cholesterol (HDL), and increased fasting plasma glucose (American College of Sports Medicine, 1990; Campbell et al., 2009; Canadian Diabetes Association, 2008; Pescatello & VanHeest, 2000).

When multiple CVD risk factors cluster together, they increase the risk of developing CVD greater than merely the sum of the risk factors (Aizawa et al., 2009). The common clustering of certain key risk factors has been identified and termed Metabolic Syndrome (MetS). More specifically, the National Institutes of Health Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (NCEP ATP III) defined MetS as a disorder where an individual has at least three of the following characteristics: waist circumference (WC) >102 cm for men and >88 cm for women; triglycerides $\geq$1.69 mmol/L; high density lipoprotein (HDL) <1.03 mmol/L in men and <1.29 mmol/L in women; fasting serum glucose $\geq$ 6.1 mmol/L; and a resting arterial BP $\geq$130/85 mmHg (National Institutes of Health, 2002). Individuals classified as having MetS are also at a much greater risk of Type II Diabetes Mellitus (T2D) (Alberti et al., 2009). According to the Canadian Diabetes Association (CDA), individuals with T2D are at a greater risk of developing CVD and up to 80% of T2D will experience a fatal heart attack or stroke (Canadian Diabetes Association, 2008).

The prevalence of MetS increases with age and therefore the aging population is of greatest risk in developing MetS (Ford, Giles, & Dietz, 2002; Galassi, Reynolds, & He, 2006). MetS is highly related to lifestyle choices made in the areas of exercise and nutrition (Virgin & Schmitke, 2003). Individuals with MetS tend to be on average, more overweight, less active and possess more risk factors for CVD than age matched controls.

This leads to these individuals having elevated resting BP (hypertension), low fitness and increased serum glucose and lipid levels, each of which can individually increase the risk of developing CVD (Virgin & Schmitke, 2003).

Centralized obesity (abdominal fat) contributes to the development of CVD (Bjorntorp, 1992) as well as metabolic diseases such as T2D (Pescatello & VanHeest, 2000). Increased abdominal fat, measured by WC, is a contributor to MetS. Obesity, as a result of an increased WC, has also become a major concern to the health care community due to the increasing cost of medical care for obesity related diseases and disabilities (Pescatello & VanHeest, 2000; Vega, 2001).

Hypertension is one of the most prevalent medical disorders and has been shown to lead to an increased incidence of CVD mortality. Hypertension is defined as ≥140 mmHg and ≥90 mmHg for systolic BP (SBP) and diastolic BP (DBP), respectively (Pescatello et al., 2004). According to the 2008 Canadian Hypertension Education Program (CHEP), hypertensive patients have an increased risk of developing T2D due to the frequent clustering of cardiometabolic risk factors, especially when associated with central obesity (Campbell et al., 2009).

1.2 Metabolic syndrome and cardiovascular disease

The identification that a clustering of risk factors including hypertension, low levels of HDL and increased fasting blood glucose may be an underlying factor for future CVD was a concept proposed by Reaven (1988). This clustering of risk factors, now formally referred to as MetS has had a variety of different classifications: the two most widely used guidelines being from the previously mentioned NCEP ATP III definition (National Institutes of Health, 2002) and the World Health Organization (WHO) definition (Alberti, Zimmet, & WHO Consultation, 1998). A third, less widely used definition comes from the International Diabetes Federation (IDF) (Alberti, Zimmet, & Shaw, 2006).

The WHO definition includes glucose intolerance or diabetes mellitus and/or insulin resistance together with two or more of the following: raised arterial pressure ≥160/90 mmHg, raised plasma triglycerides (≥1.7 mmol/L) and/or low HDL-cholesterol (<0.9 mmol/L in men; <1.0 mmol/L in women), central obesity (waist to hip ratio >0.90 men; >0.85 women) and/or BMI >30 kg/m^2, and microalbuminuria (urinary excretion rate ≥20 ug/min or albumin:creatinine ratio ≥20 mg/g). The ATP III definition was previously described.

Although these definitions allow for the early identification of at-risk individuals as a pre-emptive fight against future CVD, the underlying issue is that these definitions would not identify the same people as having MetS and in turn, not classify them as at risk for CVD. In 2006 a meta-analysis was completed that addressed the issue of the two separate and widely used guidelines. Galassi et al. (2006) found that the use of the two definitions for MetS left inconsistent results for the association between MetS and the risk of CVD. They identified 20 articles that met their eligibility criteria that included the use of WHO or ATP III definitions, an incidence or mortality of CVD, CHD, stroke, or all-cause mortality as an endpoint associated with MetS, and a prospective cohort study design. Follow-up of the studies ranged from 2.8 to 13.5 years. They found that overall, individuals defined as having MetS compared to those without MetS, had a relative risk (RR) of CVD of 1.61, meaning there is an increased risk of developing CVD with MetS (an RR <1 would indicate a reduced risk). When separating the studies into the WHO definition or the ATP III definition, individuals defined as having MetS by WHO criteria had a higher RR for CVD than with ATP III. This study also showed that MetS was associated with a higher incidence of coronary heart disease (RR 1.52) and stroke (RR 1.76) as well as an increased risk of mortality from all causes (RR 1.35) and CVD (RR 1.74) compared to no MetS. Galassi et al. attributed the higher RR of CVD with the WHO definition to the fact that the WHO requires the presence of insulin resistance while the ATP III was developed for clinical practice and therefore only requires fasting hyperglycemia. Individuals who are more insulin resistant are at greater risk for CVD (Galassi et al., 2006), therefore the WHO definition of MetS detects individuals who are at a greater risk than those detected by the ATP III definition. As well, the WHO has a higher threshold for BP than the ATP III, which may explain the greater RR associated with the WHO definition. This analysis was unable to conclude whether the WHO or

ATP III definition had better predictive values. It has been shown however, that the ATP III definition for abdominal obesity, which is lower than the circumference cut offs for WHO, identified diabetes more frequently during a 4-year follow-up on men aged 40-64 (Laaksonen et al., 2002).

The third definition, the IDF consensus worldwide definition of MetS, was released by the IDF in 2006 and is therefore the most recently released definition of MetS (Alberti et al., 2006). To be identified as having MetS according to the IDF definition, a person must have central obesity measured by WC. The IDF separates WC thresholds into ethnicities where the threshold for North Americans is the same as the ATP III and separate WC thresholds exist for European, Asian, and North American populations. Central and South America, Middle Eastern, Eastern Mediterranean and Africa do not have their own thresholds and are to use the corresponding data mentioned in the IDF publication. According to the definition, along with an increased WC, a person must also have (or treatment for) any two of the following: increased triglycerides (≥1.7 mmol/L), decreased HDL (<1.3 mmol/L in males, <1.29 mmol/L in females), increased BP (SBP ≥130 mmHg or DBP ≥85 mmHg), or increased fasting blood glucose (≥5.6 mmol/L) or previously diagnosed T2D. The IDF created these guidelines to address the need for a single, universally accepted definition that is simple to use in clinical practice.

1.3 Treating metabolic syndrome

In a proactive effort to reduce CVD-related mortality and concomitantly reduce health-care costs, primary prevention has become a key objective of health-related research. Primary prevention is highly focused on physical activity, weight management, nutrition guidance, and in some cases pharmacological control. With respect to physical activity as a primary tool for prevention, studies have shown that individuals who engage in physical activity for most days of the week at a moderate to somewhat strong intensity (60-85% maximal oxygen uptake [VO_2max]) tend to develop less risk factors for CVD.

Evidence supports an aggressive approach to treating the individual risk factors of MetS, which include hypertension, obesity and increased fasting blood glucose (Canadian

Diabetes Association, 2008). Lowering elevated BP reduces the risk of future CVD. Rosenzweig et al. (2008) recommends that the type and intensity of BP lowering therapy be chosen for optimal risk reduction, safety, and cost-effectiveness. Specifically, that BP be reduced to less than 140/90 mmHg in individuals without diabetes through the use of lifestyle modifications and moving to medication if previous modifications are not successful. Lifestyle management needs to be the first-line therapy for individuals with MetS or those who are at an increased risk for CVD. This includes applying a program of weight reduction/maintenance depending on the need, by combining physical activity, diet, and behaviour modification programs to decrease body weight/WC below the targets indicated for MetS classification (National Institutes of Health, 2002; Rosenzweig et al., 2008).

The ATP III (2002) stated the importance of treating individuals classified as having MetS with drastic lifestyle changes as a preventative measure against T2D (National Institutes of Health, 2002). The CDA guidelines also promote the identification of those with MetS and the treatment of the components of MetS as a means to significantly reduce the occurrence of cardiovascular morbidity and mortality. To address this, physical activity and increased cardiorespiratory fitness is recommended by the CDA to reduce T2D in both men and women (Canadian Diabetes Association, 2008).

1.3.1 Interventions in metabolic syndrome

The use of pharmacological control is necessary in some stages of MetS, such as in the case of uncontrolled hypertension. However a study by Knowler et al. (2002) showed that the use of the drug metformin (Glucophage) to control elevated fasting plasma glucose levels was not as effective in preventing diabetes as a lifestyle modification program that included increased physical activity and no pharmacological control. The lifestyle modification consisted of a 16-lesson curriculum covering diet, exercise, and behaviour modification to help participants achieve at least 150 minutes per week of moderate physical activity and a healthy low-calorie, low-fat diet. Therefore, to prevent T2D and future risk of CVD, lifestyle modification through increased physical activity, as well as diet, is recommended as primary prevention before the use of pharmaceuticals.

Leisure-time physical activity, classified in categories of low-, medium-, or high-intensity activities has been shown to predict the development of MetS in men aged 40-60 (Laaksonen et al., 2002). Using a sample of 612 men with no MetS at baseline, Laaksonen et al. (2002) found that men who participated in >3 hours of leisure time physical activity were half as likely to have MetS compared to sedentary men at a 4 year follow-up (using the WHO and ATP III definitions of MetS). Adoption of an active lifestyle (aerobic exercise, 3 days/week, 30-40 minutes) in older adults (55-75 years) has also been shown to reduce the development of risk factors associated with MetS (SBP, cholesterol, triglycerides, insulin and WC) compared to age and location matched controls (Petrella, Lattanzio, Demeray, Varallo, & Blore, 2005).

In addition, leisure-time physical activity has also been shown to decrease the incidence of T2D. In a study by Helmrich, Ragland, Leung, and Paffenbarger (1991) male alumni (*n* = 5,990) were followed between 1962-1976 in which a total of 202 men developed T2D. They found leisure-time physical activity to be inversely related to the development of T2D. In the individuals with the highest risk for T2D (high BMI, hypertension, family history of T2D), the protective effect of vigorous physical activity was strongest. Individuals with a BMI >26 kg/m^2, had a much lower chance of developing T2D when leisure-time physical activity averaged >2000 kcal/week, even those averaging 500-1999 kcal per week had a lower RR for developing T2D. The case is similar for a family history of hypertension, where those with a history were at a lower risk of developing hypertension if they averaged >500 kcal per week of leisure-time physical activity.

There have been several studies that have investigated lifestyle-based interventions in individuals with MetS. Katzmarzyk et al. (2003) identified participants from the HERITAGE Family study (Bouchard et al., 1995) (*n* = 621), as sedentary but otherwise healthy, to participate in a 20 week supervised aerobic training program. At baseline, 105 participants (16.9%) had MetS and of those, 32 participants (30.5%) were no longer classified as having MetS after the training (using the ATP III definition of MetS). Training consisted of three supervised sessions per week on a cycle ergometer with a gradual increase in duration and intensity of training. Participants were instructed not to change their health or lifestyle habits outside of the study. Most participants who were no longer classified as having MetS after the training experienced a lowering of triglycerides (43%), followed closely by a lowering of BP (38%) and decreased WC (28%); improved HDL (16%) and fasting plasma glucose (9%) were not as prominent (Katzmarzyk et al., 2003).

Carroll, Borkoles, and Polman (2007) used a non-dieting lifestyle intervention program to examine the short-term effects on fitness in premenopausal obese women with MetS (using the IDF definition of MetS). The intervention program consisted of structured, women only exercise classes in a community centre. Participants were also encouraged to accumulate a minimum of 4 hours of physical activity per week with at least two of those hours being participation in the structured exercise classes. Goal setting and problem solving for weight management were also employed. Thirty-one participants with MetS were randomized to receive either intervention or a waiting list control. Twenty individuals completed repeated baseline measures after the 3 month intervention period. The lifestyle group (n = 10) had a higher relative VO_2max compared to the control group at 3 months as well as lower DBP and less additional IDF metabolic components.

The use of dietary modification as well as regular exercise has shown various improvements in risk factors of MetS including decreased BP, WC, fasting glucose, total cholesterol and LDL cholesterol levels. Aizawa, Shoemaker, Overend, and Petrella (2009) used a Mediterranean-style diet as well as at-home exercise prescribed according to baseline fitness level and stage of change. They compared individuals with MetS to those without MetS with the same intervention (using ATP III definition of MetS). After 24 weeks they found both groups to experience a significant decrease in resting heart rate (RHR) and increased VO_2max. The 24 week BP decrease in those with MetS was -6.9±16.1 mmHg for SBP and -5.6±9.2 mmHg for DBP. Unfortunately, because of the implementation of a dietary as well as an exercise modification, a definite cause of the change could not be determined.

Carroll et al. (2007) also examined the effect of their non-dieting, exercise intervention on psychological well-being of the premenopausal obese women with MetS. They found that participants in the exercise intervention group experienced a 17.3% increase in general well-being score indicating an improvement in quality of life (QOL) despite the lack of change in body weight or composition. While physiological risk factors for CVDs are important to target in individuals with MetS, it has also been found that health related QOL is lowered in those with MetS (using the IDF definition of MetS) and therefore lifestyle interventions to improve risk factors in MetS should also positively effect QOL (Han et al., 2009; Ma, King, Wilson, Xiao, & Stafford, 2009).

QOL has been shown to improve with a lifestyle modification intervention in women with MetS from rural communities. Oh et al. (2010) randomly allocated 52 women with MetS (using the ATP III and WHO definitions) from rural communities into a 6 month therapeutic lifestyle program ($n = 31$) or a control group ($n = 21$). The therapeutic lifestyle program consisted of counselling, health education, exercise, and dieting. There was a significantly greater decrease in WC and body weight in the intervention group compared to the control. Using the Medical Outcomes Trust SF-36 (Ware & Sherbourne, 1992), Oh et al. observed significantly greater improvements in the intervention group in the areas of physical function, general health, vitality and mental health compared to the control group.

1.3.2 Exercise training to reduce risk factors associated with metabolic syndrome

Exercise training, as opposed to physical activity, has (also) been shown to improve risk factors for CVD including hypertension (Paffenbarger, Wing, Hyde, & Jung, 1983), development of diabetes (Canadian Diabetes Association, 2008), obesity (Pescatello & VanHeest, 2000) as well as physiological determinants of risk including arterial stiffness (Aizawa et al., 2009; Goldberg, Boaz, Matas, Goldberg, & Shargorodsky, 2009). For the purpose of the present study, exercise training will be defined as a subset of physical activity that is planned and supervised by a professional with the intention of increasing intensity, while physical activity is unsupervised exercise that results in energy expenditure including leisure-time, occupational, household or other activity (Caspersen, Powell & Christenson, 1985).

In terms of hypertension and training-induced reductions in risk, a study conducted by Paffenbarger, Wing, Hyde and Jung (1983), followed male university alumni for 6-10 years beginning 16-50 years after they graduated (n = 14,998). The investigators noted that although participation in varsity athletics, walking or light sports did not have an effect on the incidence of hypertension, a background presence of participation in vigorous sports did show a decreased incidence of hypertension among the male alumni (Paffenbarger et al., 1983). Other factors that increased the incidence of hypertension in the male alumni were weight gain since college ($\geq$11.5 kg), parental history of hypertension, overweight, as well as lack of participation in vigorous sports. Therefore, due to research similar to the study previously mentioned, physical fitness has been widely accepted as a preventative measure to mortality from CVDs and as such, guidelines have been created to quantify the minimum amount necessary to improve or maintain health.

The American College of Sports Medicine (ACSM) recommends at least 5 days per week of moderate intensity (40-60% of VO_2reserve) aerobic activities and at least 3 days per week of vigorous intensity ($\geq$60% VO_2reserve) aerobic exercise with 2-3 days a week of muscular strength and endurance and resistance exercise (American College of Sports Medicine, 1990; American College of Sports Medicine, Thompson, Gordon, & Pescatello, 2010). A combination of moderate and vigorous intensity exercise is ideal for improvements in health and fitness in most adults. When choosing the exercise modality to include in an exercise program the ACSM recommends taking consideration into the individual's goals, physical ability, health status and available equipment. The quantity of exercise is a function of frequency, intensity and duration of the exercise performed and reflects a dose-response relationship between the volume of exercise and the health and fitness benefits from it (American College of Sports Medicine, 1990; American College of Sports Medicine et al., 2010; Church, Earnest, Skinner, & Blair, 2007). Even small increases in the volume of exercise performed could improve health or fitness; with the greatest improvements seen in sedentary individuals. The duration component of exercise, can be performed in one session a day or accumulated throughout the day with multiple sessions of activity at a minimum of 10 minutes each (American College of

Sports Medicine et al., 2010). Overall, the exact composition of frequency, intensity, time, or type (FITT) of exercise will vary depending on an individual's abilities and goals including their health status and exercise tolerance.

With respect to resistance training, recommendations put forth by the ACSM suggest that individuals with hypertension perform resistance exercises only in conjunction with an aerobic/endurance exercise program (with the exception of circuit training) (American College of Sports Medicine, 1993). Referring to a resistance program for individuals with MetS, low levels of resistance training may improve metabolic risk factors, however data on high levels of resistance training are not yet conclusive (Strasser, Siebert, & Schobersberger, 2010). Goals for a resistance program should be to decrease the physiological stress of everyday activities on the individual and to manage, postpone and possibly prevent future diseases.

The ACSM recognizes individuals with MetS (as defined using the ATP III guidelines) as a clinical population and therefore has developed treatment recommendations in addition to the previously mentioned guidelines. Treatment guidelines for MetS focus on weight control, physical activity, and treatment of possible CVD risk factors that could include pharmacotherapy (American College of Sports Medicine et al., 2010; National Institutes of Health, 2002). With individuals who have MetS, ACSM recommends initial exercise training to be performed at a moderate intensity and increasing to vigorous training when appropriate for greater improvements in health and fitness. Because of the high chance of individuals with MetS being overweight or obese, ACSM also recommends gradually increasing exercise levels to reach the 60 minutes of aerobic exercise 5 days a week, specifically focusing on a minimum of 10 minutes sessions accumulated throughout the day.

In January 2011, the Canadian Society for Exercise Physiology (CSEP) announced the release of new Canadian Physical Activity Guidelines (Tremblay et al., 2011). They state that adults and older adults need at least 150 min per week of moderate- to vigorous-intensity physical activity. The greater the variety, intensity and duration of the exercise performed, the greater the health benefit. In agreement with the ACSM, CSEP recommends individuals who are physically inactive (sedentary) to perform amounts below the recommended levels. For these adults, health benefits will be seen with lower amounts and require the use of gradual increases in frequency, intensity, and duration to meet the recommended guidelines.

Low physical fitness in those with MetS is associated with greater CVD risk. For example, using a longitudinal study design, Katzmarzyk, Church, and Blair (2004) have shown that low cardiorespiratory fitness (measured as relative VO_2max) is an important risk factor for premature mortality in healthy men and men with MetS. The RR of mortality was the greatest in men with MetS who had the lowest level of fitness; the authors conclude that an increased cardiorespiratory fitness had a protective effect against mortality from CVD in healthy and MetS men. A prospective study of healthy men and women with an average follow up of 8 years showed that higher levels of physical fitness (measured by a timed treadmill test) could delay all-cause mortality primarily by a reduction in the rates of CVD and cancer (Blair et al., 1989); this effect was also noted in pre-hypertensive men (Kokkinos et al., 2009). It should be acknowledged however, that there may be differences in outcomes in studies addressing hypertension/pre-hypertension versus those where individuals have multiple risk factors of MetS and therefore extrapolation of the results should be applied to individuals who most resemble the population tested.

1.3.3 Mechanisms of exercise-based benefits in metabolic syndrome

The potential mechanisms responsible for decreases in BP with exercise include neurohumoral, vascular and structural adaptations. Decrease in total peripheral resistance appears to be the primary mechanism that reduces resting BP after exercise, specifically through changes in vessel diameter, where small changes in diameter can have a large impact on vascular resistance (Knowler et al., 2002; Pescatello et al., 2004). Training decreases sympathetic nerve activity (SNA) and therefore may prevent the vascular changes that are associated with increased BP or hypertension since an increase in SNA is a hallmark of hypertension (Abboud, 1982; Knowler et al., 2002; Pescatello et al., 2004). Additionally, exercise training changes the vascular responsiveness to norepinephrine and endothelin-1, both effective vasoconstrictors, as well as increases the production of nitric oxide which improves vasodilation in otherwise healthy adults (Pescatello et al., 2004).

1.4 Exercise prescription in primary care

Primary care physicians have the first line of contact with individuals who have MetS as they have not yet been diagnosed with T2D or CVD. Therefore primary care may be the optimal grounds for identifying and treating these individuals to avoid future CVD or T2D (Grandes et al., 2009; Kraushaar & Kraemer, 2009; Petrella & Lattanzio, 2002). Petrella and Wight (2000) randomly surveyed 362 Canadian general or family physicians from rural and urban populations and found that only 67.4% of physicians felt confident in their exercise prescriptions but 93.8% were interested in improving these skills. Petrella, Lattanzio, and Overend (2007) identified barriers that Canadian family physicians have found to be responsible for the decreased percent of exercise being prescribing at the primary care level. These barriers include, but are not limited to, a lack of skill in prescribing exercise and a lack of standard office testing equipment (Grandes et al., 2008; Petrella et al., 2007).

1.4.1 Step Test and Exercise Prescription

In 2000, the Step Test and Exercise Prescription (STEP^{TM}) tool was developed by Petrella and Wight (2000) to address the lack of primary care physicians who were counselling their patients about their exercise habits. It is an office-based instrument to be used at the primary care level to eliminate some of the barriers physicians face with exercise counselling. The STEP^{TM} consists of a stepping test to predict VO_2max and a prescription portion that includes determining the level of fitness and training heart rate (HR) of the patient (Petrella, Koval, Cunningham, & Paterson, 2001). Petrella and Wight compared two types of counselling in the primary care setting, one using the ACSM guidelines (American College of Sports Medicine, 1990) and another using counselling plus the STEP^{TM} administered by 293 of the surveyed physicians. While results showed a longer time to administer the STEP™ than ACSM counselling, there was also a significant improvement in physician confidence and knowledge using STEP™.

The STEP™ was validated in 2001 for the use in older adults to predict VO_2max (Petrella et al., 2001). The test-retest correlation coefficients for VO_2max (ml/kg/min) were 0.97 for men and 0.98 for women. There were no observed differences in predicted versus measured VO_2max and the test showed sensitivity to change in both groups. The STEP™, compared to regular counselling using ACSM guidelines, showed a greater increase in VO_2max as well as a decrease in SBP and BMI after 12 months of intervention in healthy older adults (*n* = 284, aged >65 years) (Petrella, Koval, Cunningham, & Paterson, 2003).

STEP™ has also been administered to individuals with MetS. In 2009, STEP™ was administered along with a dietary intervention to significantly reduce SBP, DBP, WC, fasting glucose levels, and improved carotid artery distensibility and beta stiffness index (Aizawa et al., 2009). Stuckey et al. (in press), as a pilot for the current study, used STEP™ in rural populations to increase daily physical activity and fitness and showed significant improvements in DBP and VO_2max. As well, psychological data with the STEP™ has shown an increase in exercise self-efficacy among elderly community dwelling adults (Petrella et al., 2003), there is no data yet on the effect of STEP™ on health related QOL.

1.4.2 Primary care and technology

To assist with at-home lifestyle changes, technology is becoming more popular in the management of diabetes and MetS. Changes in behaviour including increased physical activity, weight reduction and self-monitoring of blood glucose and BP are recommended and are thought to positively impact cardiovascular health (Logan et al., 2007; Ma et al., 2009).

A simple and inexpensive piece of technology validated for use in research and practice is the pedometer (Tudor-Locke, Williams, Reis, & Pluto 2002). Pedometers are used as an assessment tool for daily exercise levels as well as a motivational tool for physical activity behaviour where an index of required steps/day is used to guide the individual wearing the pedometer (Tudor-Locke & Bassett Jr., 2004). The use of pedometers is also supported by the ASCM to assess the quantity of exercise (American College of Sports Medicine et al., 2010).

Russell-Minda et al. (2009) looked at the effectiveness, feasibility and compliance of self-monitoring technology in individuals with type I or T2D. The review included self-monitoring of blood glucose, pedometers, and cell phone or wireless technologies. The self-monitoring of blood-glucose was shown to be effective in managing diabetes however, the results of the review indicate a need for further research in the area of technology on diabetes as well as other areas of health including CVD.

Some recent studies have shown that reminders sent to study participants using cell phone or text messaging (via cell phone) will help the patient to respond positively to the requested behaviour change (Faridi et al., 2008; McKay, King, Eakin, Seeley, & Glasgow, 2001). Recently, Park, Kim, and Kim (2009), looked at the effect of an 8 week intervention using short message service (SMS; text messages) through a cellular phone on BP, weight, and serum lipids in obese and hypertensive patients. The intervention group (n = 28) was required to record BP and weight weekly on an internet-based diary through either the internet or by cell phone. There was a significant decrease in both SBP and DBP in the intervention group and no change in the control group (n = 21). Body weight, WC and HDL cholesterol each improved in the intervention group with no change or worsening in the control group with no access to the internet-based diary. Throughout the study, the intervention group received SMS from the research team nurse regarding education on diet, exercise, medication adjustment and body weight levels.

1.5 Rationale for study

Exercise-intervention studies have shown that supervised and structured aerobic training has the ability to decrease the risk factors of T2D and CVD in individuals with and without MetS. However, to date they have not examined at-home aerobic exercise prescription in the primary care setting within rural communities. Since primary care physicians are the first to access individuals with MetS but are not regularly visited by individuals from rural populations, examining the effect of prescriptive exercise using the STEP™ in combination with remote technology may provide insight for additional means to manage T2D and CVD in rural areas. It is hypothesized that a 6 month intervention using exercise prescribed with the STEP™ protocol at the primary care level in combination with remote monitoring technology will decrease SBP and DBP as well as increase VO_2max and QOL in individuals with MetS from rural southwestern Ontario.

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CHAPTER TWO

Effect of the STEP Protocol and Home-Monitoring Technology in Rural Primary Care on Blood Pressure and Fitness in Metabolic Syndrome

2.1 Introduction

Cardiovascular diseases (CVDs), such as myocardial infarction and stroke, are the leading causes of death in Canadian men and women (Statistics Canada, 2004). When multiple CVD risk factors cluster together, an individual's risk of developing CVD is greater than merely the sum of the risk factors (Aizawa et al., 2009). The clustering of three out of five key risk factors has been identified and termed metabolic syndrome (MetS); specifically, high blood pressure (BP), low HDL, high fasting glucose, high triglycerides and high waist circumference (WC) (National Institutes of Health, 2002). Individuals diagnosed as having MetS are also at a greater risk for Type II Diabetes Mellitus (T2D) (Alberti et al., 2009). According to the Canadian Diabetes Association (CDA), individuals with T2D are at a greater risk of CVD, as up to 80% of individuals with T2D will experience a fatal heart attack or stroke (Canadian Diabetes Association, 2008).

Exercise training is a hallmark intervention to increase fitness and lower CVD risk in non-clinical and clinical populations, including those with MetS, T2D and CVD (American College of Sports Medicine, Thompson, Gordon, & Pescatello, 2010). Exercise training interventions are efficacious in decreasing the specific CVD risk factors in individuals with and without MetS (Aizawa, Shoemaker, Overend, & Petrella, 2009; Carroll, Borkoles, & Polman, 2007; Church, Earnest, Skinner, & Blair, 2007; Dunn et al., 1997; Katzmarzyk et al., 2003; Katzmarzyk, Church, & Blair, 2004; Oh et al., 2010). High BP is one of these specific CVD risk factors and is important to control in those with MetS because the clustering of risk factors within MetS contributes to the development and progression of hypertension (Cheung et al., 2008; Hagberg, Park, & Brown, 2000). As many individuals with MetS have not yet been diagnosed with T2D or CVD, primary care physicians are often the first line of contact to identify and treat these individuals in an effort to avoid future complications (Grandes et al., 2009; Kraushaar & Kraemer, 2009; Petrella & Lattanzio, 2002).

The Step Test and Exercise Prescription (STEP™) is a tool designed for use by physicians in the primary care setting as a means of testing fitness and providing exercise and nutritional counselling (Aizawa et al., 2009; Petrella, Koval, Cunningham, & Paterson, 2001). Exercise counselling has been shown to increase fitness (as assessed via maximal aerobic capacity; VO_2max) and decrease resting arterial blood pressure (BP; a prominent CVD risk factor) similarly to exercise training in a supervised environment (Dunn et al., 1997; Dunn et al., 1999). The use of STEP™, in combination with a dietary intervention, in primary care has been shown to increase fitness and decrease resting BP in individuals with MetS (Aizawa et al., 2009). However, the effect of the STEP™ on the quality of life (QOL) of individuals with MetS has yet to be considered.

The use of home-monitoring technology in primary care, such as cell-phones, internet and pedometers has shown encouraging results in the management of hypertension, diabetes, obesity, and physical inactivity by decreasing BP, fasting glucose levels and body weight (Logan et al., 2007; Ma, King, Wilson, Xiao, & Stafford, 2009; McKay, King, Eakin, Seeley, & Glasgow, 2001; Park, Kim, & Kim, 2009; Tudor-Locke, Williams, Reis, & Pluto, 2002). The combination of primary care and home-monitoring technology may be beneficial for the rural population as they tend to have less access to physicians compared to urban populations. However, combining technology with primary care interventions has not been investigated to date.

Therefore, the purpose of this study was to evaluate the effectiveness of a 6 month aerobic-based exercise intervention in primary care using STEP™ with home-monitoring technology to improve prominent CVD risk factors associated with MetS in adults from rural southwestern Ontario as a means to address the lack of physicians available in the area as well as the high occurrence of T2D. Primary outcomes of the study were SBP and DBP, both in the clinic and at-home. VO_2max and QOL were secondary outcomes while weight, BMI, WC, and RHR were tertiary outcomes. It was hypothesized that a 6 month intervention using the STEP™ protocol with remote home-monitoring technology will decrease systolic BP (SBP) and diastolic BP (DBP) as well as increase VO_2max and improve QOL in individuals with MetS.

2.2 Methods

Participants

Sixty one adults (18-70 years of age) from rural southwestern Ontario (Huron, Perth and Grey-Bruce counties) with MetS were recruited for this study using a variety of social marketing techniques including posters, newspaper and radio advertisements. Rural residency was confirmed by postal code and proximity to the clinic. Recruitment occurred from October 2009 to June 2010. MetS was defined as having at least two of the following risk factors: SBP ≥130 mmHg or DBP ≥85 mmHg; high density lipoprotein cholesterol (HDL) <1.29 mmol/L in women and <1.03 mmol/L in men; fasting serum glucose of ≥6.1 mmol/L; triglycerides ≥1.69 mmol/L; and WC ≥102 cm for men and ≥88 cm for women (National Institutes of Health, 2002). Interested participants were screened both on the phone and at the initial visit. Exclusion criteria for the study included: mean SBP ≥180 mmHg and/or DBP ≥110 mmHg, uncontrolled hypertension, type I diabetes, history of myocardial infarction, angioplasty, coronary artery bypass or cerebrovascular ischemia/stroke, unstable cardiac health, unstable pulmonary disease, use of medications known to affect heart rate, second or third degree heart block, history of alcoholism, drug abuse or other emotional, cognitive or psychiatric problems, a pacemaker, uncontrolled diabetes, orthopaedic problems that could impair ability to exercise, started, or changed dose of, a lipid lowering agent(s) within the previous 3 months and being currently enrolled in a clinical research trial.

Study Design

This study is part of the larger, ongoing, ARTEMIS (A multi-center, prospective, Randomized study To determine the effects of Exercise Managed Intervention Study) study looking at the effects of exercise and technology on the risk factor status of individuals with MetS. ARTEMIS is a 12 month study examining technology versus usual care in rural and urban populations with MetS. The outcome measures in

ARTEMIS include BP, weight, WC, body mass index (BMI), VO_2max, resting heart rate (RHR), stage of change model developed by Prochaska and Diclemente (1983), vascular function (flow mediated dilation, arterial compliance and distensibility, vascular conductance and resistance), muscle sympathetic nerve activity, heart rate variability, blood composition (low density lipoprotein cholesterol [LDL], HDL, glucose, catecholamines, triglycerides, estrogen, HgbA1C, insulin, hs-CRP), behavioural changes (QOL, self-efficacy, decisional balance, diabetes self-care activities), and satisfaction/comfort with technology. The present study was the first 6 months of the exercise intervention component of ARTEMIS, evaluating the effects of a 6 month aerobic exercise program on the BP, fitness (VO_2max), and QOL in individuals with MetS. All participants had BP measurements, fitness evaluation, and QOL questionnaires before the study, halfway through the study (at 3 months) and upon completion of the study at 6 months. No nutritional guidance was given aside from providing and encouraging the use of the Canada's Food Guide (Health Canada, 2007) in attempt to isolate the effect of the aerobic exercise. All participants were provided with a Blackberry™ (BlackBerry™ Curve 8300), home BP monitor (A & D Medical #UA-767PBT), and pedometer (Omron # HJ-150) for self-monitoring as part of the overall ARTEMIS study.

All visits were conducted at the Gateway Rural Health Research Institute in Seaforth, Ontario between November 2009 and December 2010. Gateway is a collection of rooms dedicated to research within the family health team primary care clinic in Seaforth. Participants arrived at the clinic fasted and without caffeine for 12 hours and were directed to Gateway by the family health team secretary at baseline (V0), 3 months into the study (V1) and 6 months into the study (V2).

The ARTEMIS study was approved by the University of Western Ontario REB #15828 and study was funded by Canadian Institutes of Health Research Grant #CCT-83029, Heart and Stroke Foundation of Canada # PG-07-0364, and by the Canadian Diabetes Association.

Measurement of blood pressure and anthropometrics

Resting brachial BP and heart rate (HR) were measured in the supine position by a trained health care professional with an automated sphygmomanometer (BpTRU™) on the left arm. Three measures were taken, each 2 minutes apart (Quinn et al., 2010). Recorded BP was measured as the average of SBP in the final two readings over the average of DBP in the final two readings. If the final two readings were greater than 5 mmHg apart, a fourth BP measurement was made and the last three readings of SBP and DBP were averaged for the participant's resting BP.

Anthropometrics were then measured and included each participant's weight, height, and WC. Weight (kg) was measured with a standard scale without shoes in the clothing worn by the participant at each visit. Height (cm) was measured without shoes at baseline and used throughout the study. WC (cm) was measured at each visit according to the National Institutes of Health measuring tape position for waist (abdominal) circumference, just above the uppermost lateral border of the iliac crest (National Heart, Lung, and Blood Institute, 1998).

MetS risk factors were measured at each visit; HDL, triglycerides and blood glucose were measured by a blood draw after a half hour rest. Blood analysis was completed by Gamma Dynacare Medical Laboratories, Brampton, Ontario. MetS risk factors were classified using the cut offs from the NCEP ATP III definition of MetS. We chose to use this definition because it was designed for clinical use and is a widely used definition of MetS in North America.

Step Test and Exercise Prescription

After at least one hour of rest (in which vascular measures were completed), the participant completed a submaximal aerobic fitness stepping test which is the first component of the STEP™ protocol (Petrella et al., 2001). The test was administered in a private, quiet room. The test consisted of stepping up and down a step measuring 20 cm high (includes both of the 2 steps, each 9.5cm), base is 40 cm wide and 60 cm deep. Participants were instructed to complete 20 steps at a pace they considered to be moderate. HR was measured before and after the step test. The time required to complete the test (seconds) and HR (beats per minute; bpm) after completion were used to predict maximal oxygen consumption (see Appendix A for VO_2max calculation and ratings).

After calculation of predicted VO_2max, participants were given individualized exercise prescriptions (second component of STEP™) to increase their weekly aerobic and resistance exercise over the 3 months between study visits. The exercise prescription included providing the participant with a training HR, duration of aerobic exercise, types of aerobic exercise, and types/frequency of resistance exercise based on American College of Sports Medicine (ACSM) standards (American College of Sports Medicine et al., 2010). Training HR reflected the participant's VO_2max score rating of either poor, fair, good, or excellent with the training HR of 70%, 75%, 80%, or 85% of max HR respectively. Max HR was calculated as 220-age (years) (American College of Sports Medicine et al., 2010). Participants were instructed on how to take their radial pulse in 10 seconds and were encouraged to take and record their pulse during their daily exercise bouts. Duration of exercise ranged from 10 minutes of daily aerobic exercise building up to 60 minutes of accumulated daily aerobic exercise. Frequency of aerobic exercise was set at everyday (5-7 days per week) for each participant, regardless of VO_2max rating. Types of aerobic exercises prescribed were individualized to the participant to suit their needs; examples included, but were not limited to biking, walking, jogging, swimming, and hiking. Resistance exercise frequency ranged from one to three times per week with repetitions and sets increasing with fitness.

The final component of the individualized exercise prescription in the STEP™ protocol included a goal setting portion where the participant was assisted in setting two to three physical activity or health-related goals to be completed upon returning for the next visit. Goals were encouraged by using the SMART framework (specific, measurable, attainable, realistic, and timely) in addition to the inclusion of potential barriers and solutions (see Appendix B for exercise prescription, goals, and resistance sheets) (Schut & Stam, 1994).

Quality of Life

After completion of STEP™, participants completed a QOL questionnaire, QOL was measured using the Short Form-36 (SF-36) questionnaire (Ware & Sherbourne, 1992). The SF-36 has 36 questions and is divided into eight dimensions of QOL: physical functioning, role-physical, role-emotional, bodily pain, vitality, mental health, social functioning and general health. Raw scores are transformed using the guidelines developed by Medical Outcomes Trust and are then converted to a score out of 100 (0 being having extremely poor QOL for a particular dimension, and 100 being having extremely good QOL for a particular dimension). The SF-36 has proven validity and reliability (Mchorney, Ware, & Raczek, 1993; Mchorney, Ware, Lu, & Sherbourne, 1994) and was self-administered by the participants the way it was constructed to be administered (Ware & Sherbourne, 1992).

Technologies/Pedometer

Each participant completed a 2 hour technology education session at baseline to ensure they were familiar with how to use each device. Manuals for each device were provided as well as a contact sheet for each participant should they require any technical assistance throughout the study.

The Blackberry™ (BlackBerry™ Curve 8300) was used as a data hub for BP measures which were sent wirelessly via a Bluetooth™ device connected to the BP monitor (A & D Medical #UA-767PBT). Pedometer steps were manually entered into the Blackberry™. Measurements were automatically transferred to a secure online database (Healthanywhere™) where they could be monitored by researchers.

BP was measured on the left arm every Tuesday, Thursday and Sunday morning before breakfast by the participant using the provided BP monitor. When taking the measurement, participants were instructed to be in a seated position with feet flat on the ground, back supported, left arm supported and at a slight angle with palm up, in a room free of distractions (Campbell et al., 2010). BP measures were then sent wirelessly to the Blackberry™.

Steps per day were recorded at the end of each day on the provided pedometer (Omron # HJ-150) and manually entered into the Blackberry™ before going bed. Pedometers had a 7 day memory so steps could be entered for previous days if missed. Participants were also provided with an activity log on their Blackberry™ where they could enter their daily physical activity and HR from a list of personalized and pre-selected activities. Pedometer data was analyzed as weeks 1-12 vs. weeks 13-24 to see if the STEP™ increased steps from the first 3 months of the study to the last 3 months.

Once data was entered or sent to the Blackberry™, all data could be reviewed and/or retrieved at any time by research personnel on a password protected website (Healthanywhere™, IgeaCare Inc.).

Statistical Analysis

Differences between V0, V1 and V2 were analyzed for each variable using a repeated measures multivariate analysis of variance (MANOVA) as well as paired *t*-tests to compare home versus clinic data. Partial eta squared (η^2_p) was used to display the variability accounted for in the treatment effect, unique to this study interaction. All statistical analysis was done with PSAW (version 18, SPSS Inc., Chicago, IL), accessed through the University of Western Ontario VLab, and significance was set at $p<0.05$. All values are presented as mean±SD.

2.3 Results

A total of 211 individuals were contacted for this study, 128 were deemed eligible and 61 were randomly assigned to the STEP™ and technology group. Ineligibility was due to the failure to meet inclusion/exclusion criteria or individuals made initial contact with the researchers, but failed to return calls or emails to determine eligibility. Fifty five of the 61 participants recruited completed all three study visits. Six participants dropped out of the study after baseline. Reasons for drop-out included no time (n = 2), too much burden (n = 2), not feeling monitored (n = 1) and unknown (n = 1). Values missing completely at random were imputed using last outcome carried forward (n = 2).

Participant Characteristics

At V0, the 55 participants had a mean age of 56.9±10.1 years and 70.9% were female. Table 2.1 outlines the baseline characteristics of the participants. Seventeen participants were on BP medication before starting the study and did not change the dosage or start a new medication throughout the intervention period; the majority of BP medications were angiotensin-converting enzyme inhibitors. Another seven participants changed, started, or stopped using BP medication during the study in which case a separate ANOVA was run (two participants changed BP medication after V0, three participants started using BP medication after V0, and two participants stopped using BP medications after V0) to see if the pattern of change matched clinical BP. Average clinical SBP and DBP were 143.4±18.3 mmHg and 88.1±10.3 mmHg at V0, respectively, and RHR was 67.7±9.4 bpm (Table 2.1). At-home BP was averaged during the week following V0 and was 130.8±15.9 mmHg for SBP and 83.9±10.2 mmHg for DBP (Table 2.1). Average WC, weight and BMI at V0 were 106.6±12.6 cm, 91.7±16.5 kg and 32.8±5.2 kg/m^2, respectively (Table 2.1). All variables had equal sample sizes at each visit (n = 55).

At baseline, participants had an average of 2.9 MetS risk factors which did not significantly decrease throughout the study [$F(1, 54) = 1.50$, *n.s*]. The majority of participants had two risk factors (36.4%), followed by three (29.1%) and four (23.6%) risk factors and a small number with one (5.5%) and five (5.5%) risk factors. The most prevalent risk factors were waist circumference and BP followed by HDL and triglycerides with a small portion of the sample meeting the fasted blood glucose risk factor cut-off for MetS (Table 2.2).

Effects of STEP^{TM} on clinical blood pressure, fitness, and anthropometrics at 3 and 6 months

At V2, STEP^{TM} had a significant effect on clinical BP, whereby, clinical SBP decreased from 143.4±18.3 mmHg at V0 to 138.2±16.6 mmHg at V1 [$F(1, 54) = 4.84, p<0.05, \eta^2_p = 0.082$] and to 132.7±13.0 mmHg at V2 [$F(1, 54) = 7.55, p<0.05, \eta^2_p = 0.123$] (Figure 2.1), for a total decrease of 10.7 mmHg. Clinical DBP showed a significant decrease from

88.1±10.3 mmHg at baseline to 84±10.3 mmHg at V1 [$F(1, 54) = 12.20, p<0.05, \eta^2_p = 0.184$] and continued to decrease to 81.3±9.4 mmHg at V2 [$F(1, 54) = 6.16, p<0.05, \eta^2_p = 0.102$], for a total decrease of 6.8 mmHg.

A separate analysis was run excluding individuals who had changed, started, or stopped their BP medication throughout the study ($n = 48$). This analysis was the same as previously mentioned aside from a loss in significance from V1 to V2 for clinical DBP ($p = 0.054$).

Predicted VO_2max showed a significant increase from V0 to V1, [$F(1, 54) = 8.78, p<0.05, \eta^2_p = 0.140$] (30.7±7.3 ml/kg/min vs. 32.3±7.4 ml/kg/min, respectively; Figure 2.2) and remained elevated at V2. There was no change seen in RHR from V0 to V1, [$F(1, 54) = 1.31$, *n.s.*], or from V1 to V2, [$F(1, 54) = 2.77$, *n.s*]. There was however, a significant change in RHR from V0 to V2, [$F(1, 54) = 8.03, p<0.05, \eta^2_p = 0.129$] (67.7±9.4 bpm vs. 64.7±9.2 bpm, respectively).

Average weight decreased significantly from 91.7±16.5 kg at V0 to 90.2±16.0 kg at V1, [$F(1, 54) = 19.02, p<0.05, \eta^2_p = 0.260$], and remained significantly lower than baseline following 6 months of training (V2, [$F(1, 54) = 1.95$, *n.s.*]; Figure 2.3). The average change in BMI followed the pattern of change in weight with a significant decrease from V0 to V1, [$F(1, 54) = 19.09, p<0.05, \eta^2_p = 0.261$] (32.8±5.2 kg/m^2 vs. 32.3±4.9 kg/m^2) and remained low at V2 [$F(1, 54) = 2.03$, *n.s.*] (Figure 2.3). WC however showed a continuous decrease throughout the study. WC decreased from106.6±12.6 cm at V0 to 104.4±12.0 cm at V1, [$F(1, 54) = 7.55, p<0.05, \eta^2_p = 0.123$] to 100.4±14.3 cm at V2, [$F(1, 54) = 6.39, p<0.05, \eta^2_p = 0.106$] (Figure 2.3).

Effects of STEP^{TM} on at-home blood pressure and pedometer steps

At-home SBP significantly decreased from V0 to V1, [$F(1, 54) = 6.78, p<0.05, \eta^2_p = 0.112$] (130.8±15.9 mmHg vs. 126.7±13.0 mmHg, respectively decreasing 4.1 mmHg) and remained low at V2 [$F(1, 54) = 3.68$, *n.s.*]. At-home DBP decreased from 83.9±10.2 mmHg at V0 to 81.6±9.3 mmHg at V1, [$F(1, 54) = 5.68, p<0.05, \eta^2_p = 0.095$], and continued to decrease to 79.6±9.5 mmHg at V2, [$F(1, 54) = 7.65, p<0.05, \eta^2_p = 0.124$] (Figure 2.4), decreasing 4.3 mmHg. At-home BP was significantly lower than clinical BP for each visit except for V2 where there was no significant difference between at-home and clinical DBP, [$t(54) = 1.568$, *n.s.*].

A separate analysis was run excluding individuals who had changed, started, or stopped their BP medication throughout the study ($n = 48$). This analysis found a significant decrease in at-home SBP from baseline to V2 only, [$F(1, 47) = 11.54, p<0.05, \eta^2_p = 0.197$] (129.5±15.5 mmHg vs. 124.3±13.1 mmHg, respectively), while at-home DBP showed a significant decrease from V1 to V2, [$F(1, 47) = 5.97, p<0.05, \eta^2_p = 0.113$] (81.61±9.3 mmHg vs. 79.7±9.3 mmHg, respectively).

Daily physical activity, measured with pedometers as steps per day showed a significant increase in the average number of steps per day in weeks 1 through 12 with 7940.9±2781.6 steps/day increasing to 8475.7±2627.5 steps/day in weeks 13-24, [$t(54) = 2.857, p<0.05$] (Figure. 2.5).

Effects of STEP™ on quality of life

There was no significant change in the QOL SF-36 questionnaire as a whole [$F(16, 36) = 1.598$, *n.s.*]. However, looking at the specific domains of the SF-36, there were significant improvements in the areas of vitality, mental health, and general health. Vitality increased from a score of 59.3±18.8% at baseline to 64.8±16.4% at V1, [$F(1, 51) = 6.03, p<0.05, \eta^2_p = 0.106$], and remained elevated at V2. Improvements in mental health followed a similar pattern, with a score of 79.0±13.6% at V0 increasing to 83.6±11.6% at V1, [$F(1, 51) = 9.52, p<0.05, \eta^2_p = 0.157$], and no increase from V1 to V2. General health increased from V0 to V2 [71.7±16.3% vs. 77.5±13.4%, respectively, $F(1, 51) = 13.31, p<0.05, \eta^2_p = 0.207$], but not at V1 (Figure 2.6). Sample sizes for each domain were equal ($n = 52$). If a questionnaire or a score within a domain were missing completely at random, the SF-36 for that individual was not used (this occurred in only three participants).

Table 2.1. Participant baseline characteristics

	Mean ± SD
Age (year)	56.9 ± 10.1
Clinical SBP (mmHg)	143.4 ± 18.3*
Clinical DBP (mmHg)	88.1 ± 10.3*
At-home SBP (mmHg)	130.8 ± 15.9
At-home DBP (mmHg)	83.9 ± 10.2
Resting heart rate (bpm)	67.7 ± 9.4
VO_2max (ml/kg/min)	30.7 ± 7.3
Waist circumference (cm)	106.6 ± 12.6
Weight (kg)	91.7 ± 16.5
BMI (kg/m^2)	32.8 ± 5.2

n = 55, * significantly higher than at-home BP measures. $p<0.05$.

Table 2.2. Participant MetS risk factor distribution at baseline

MetS Risk Factors	Number of participants with risk factor
Waist circumference	47
Blood pressure	47
Blood glucose	8
HDL	33
Triglycerides	23

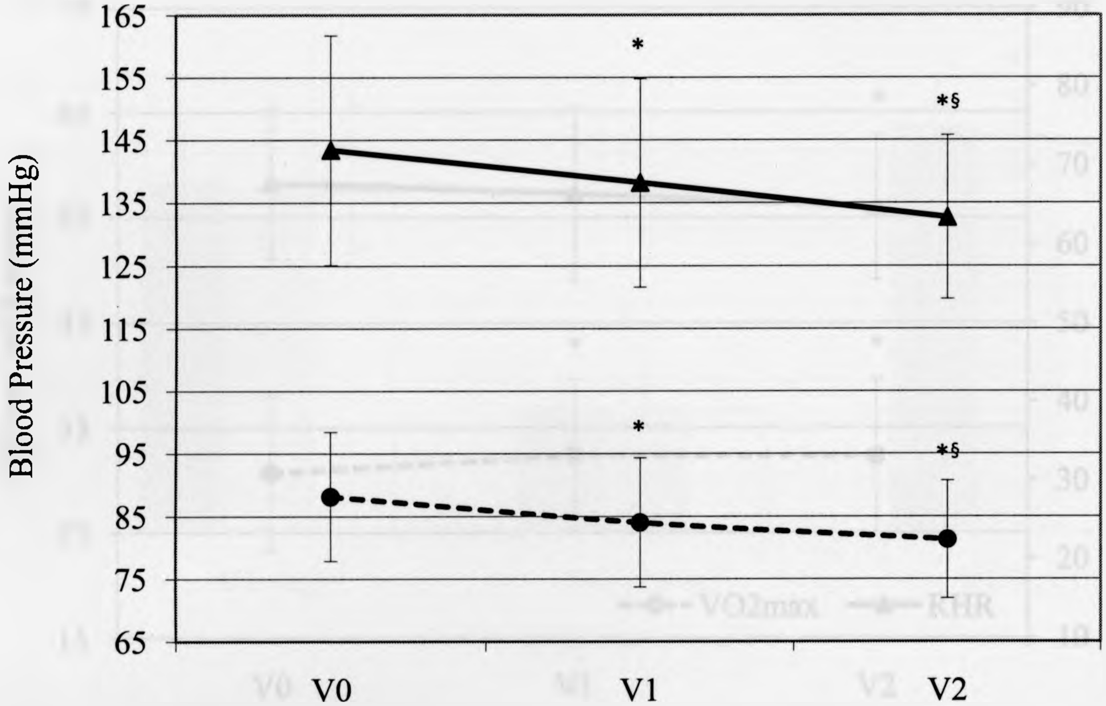

Figure 2.1 Clinical BP changes over 6 months. Solid line represents SBP and dotted line represents DBP. All values are means±SD. * significant difference from V0. § significant difference from V1. $p<0.05$.

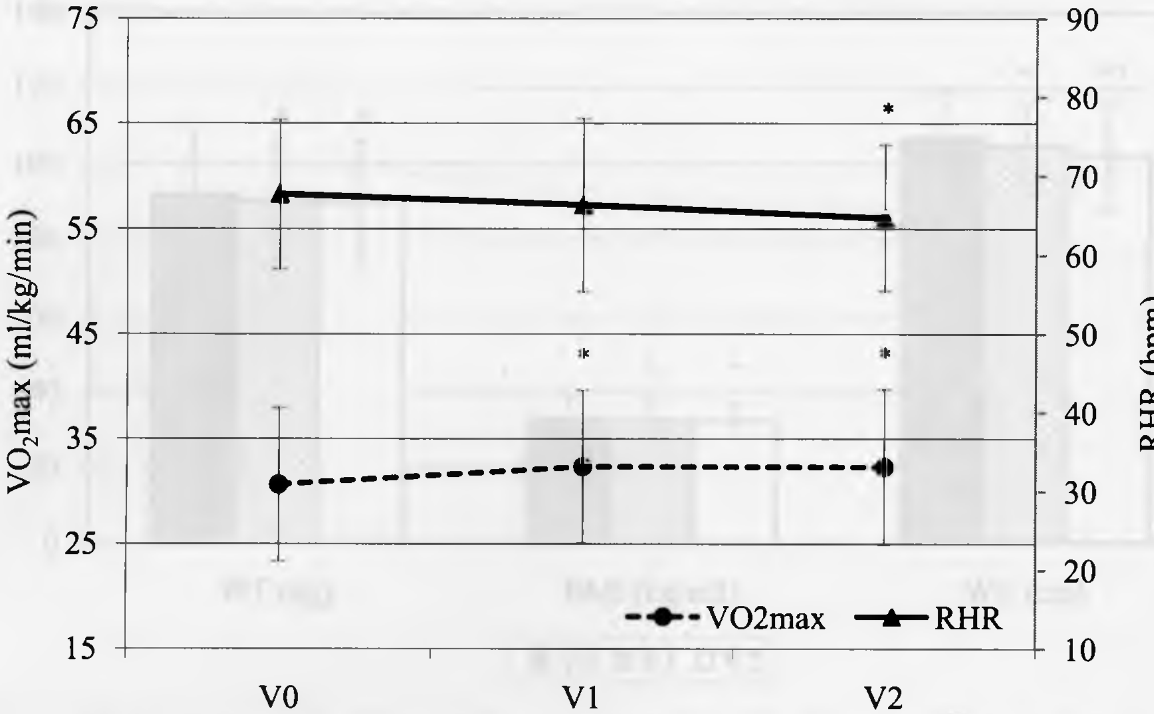

Figure 2.2. VO_2max and RHR changes over 6 months. Solid line represents VO_2max and the dotted line represents RHR on the secondary (right hand) axis. All values are means±SD. * significant difference from V0. $p<0.05$.

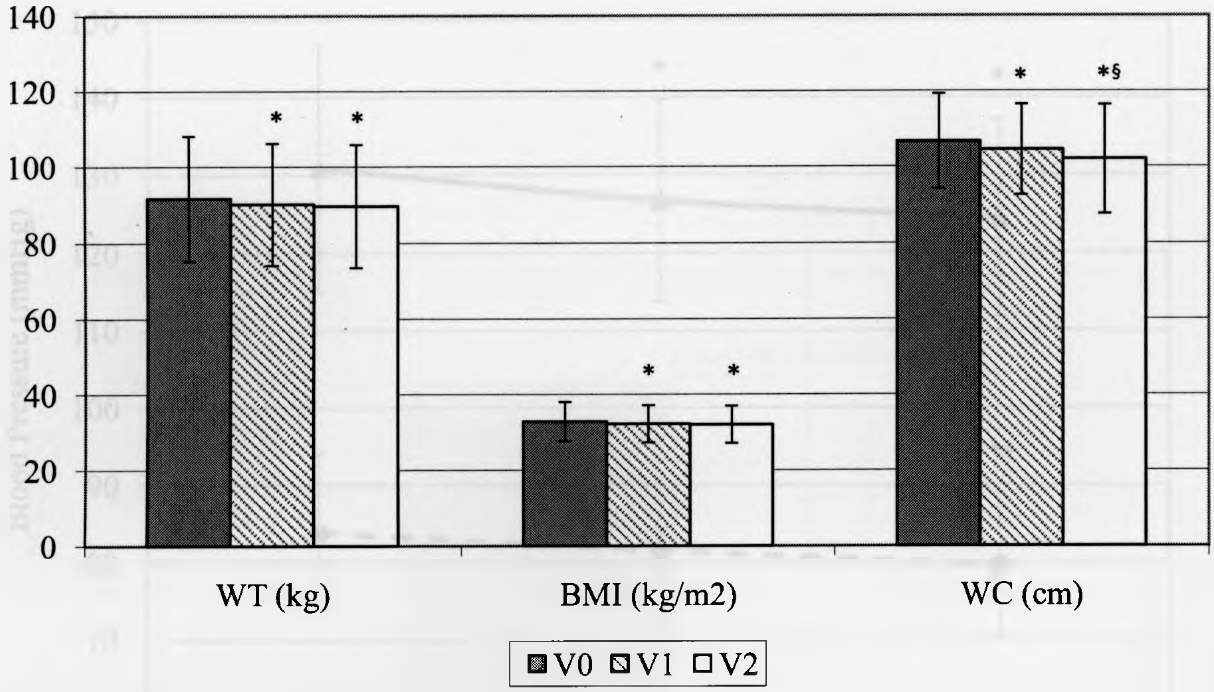

Figure 2.3. Change in anthropometrics over 6 months. WT; weight, BMI; body mass index, WC; waist circumference. All values are means±SD. * significant difference from V0. § significant difference from V1. $p<0.05$.

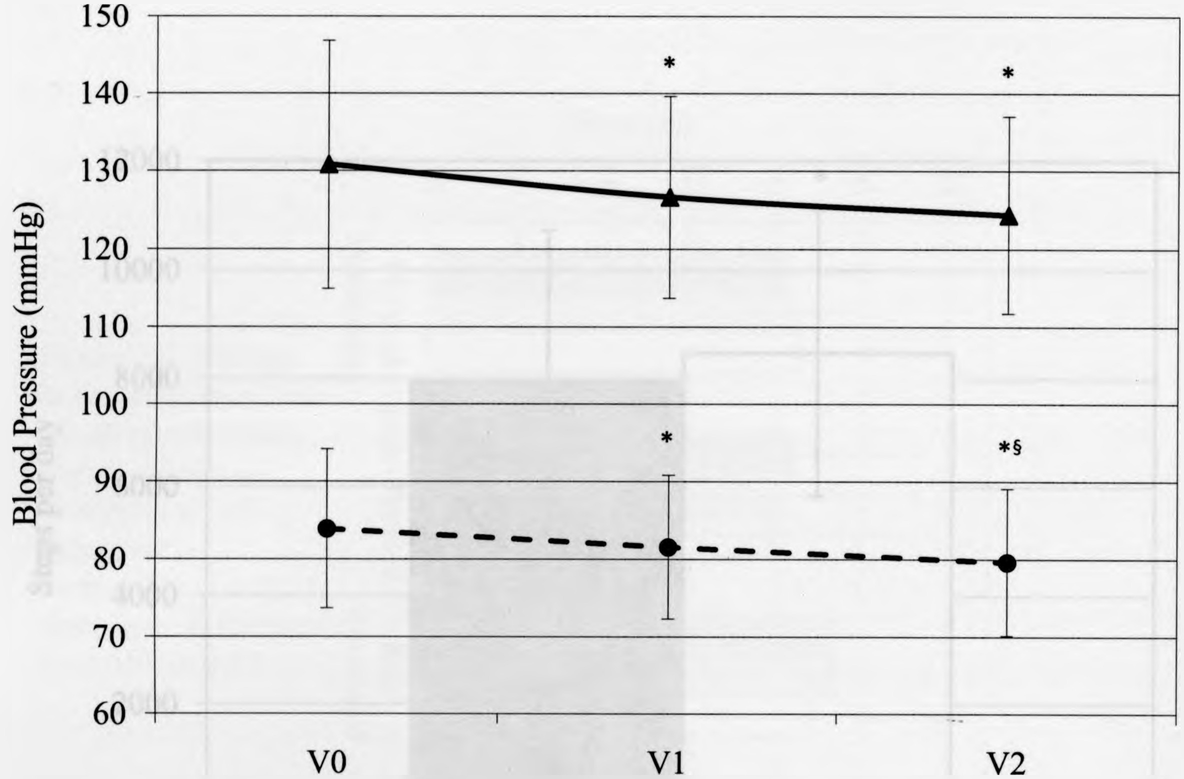

Figure 2.4. At-home BP changes over 6 months. Solid line represents SBP and dotted line represents DBP. All values are means±SD. * significant difference from V0. § significant difference from V1. $p<0.05$.

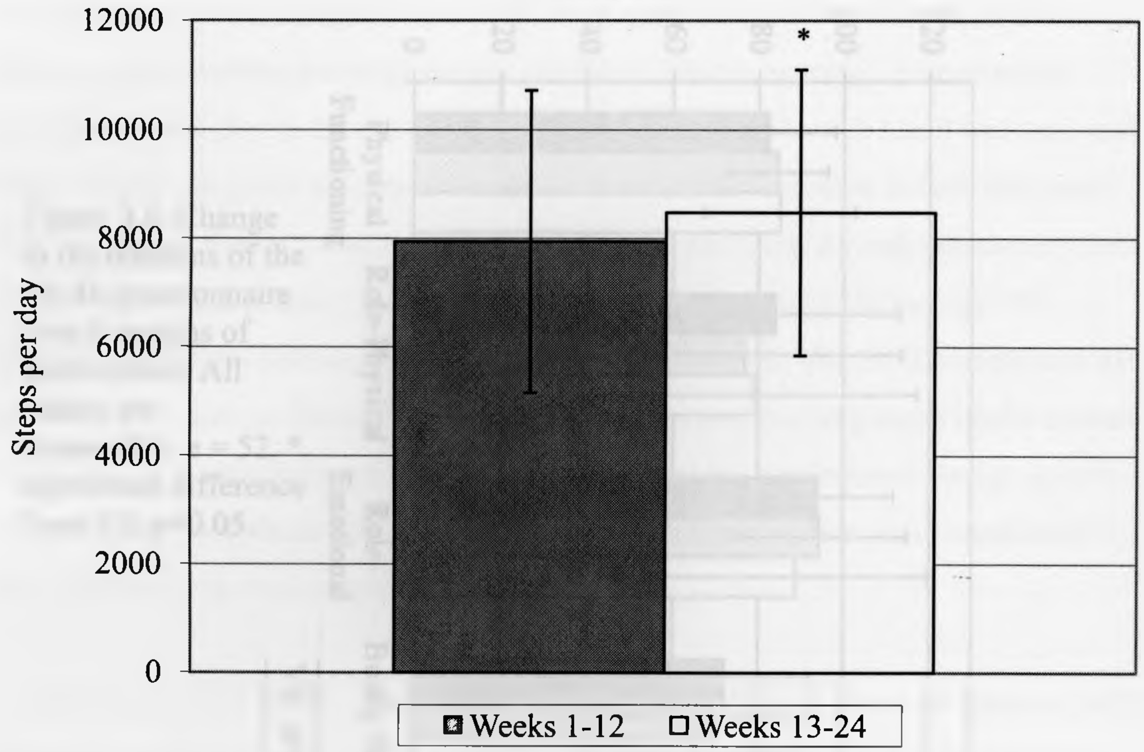

Figure 2.5. Change in pedometer steps from weeks 1-12 to weeks 13-24 of intervention. All values are means±SD. * significant difference from weeks 1-12. $p<0.05$.

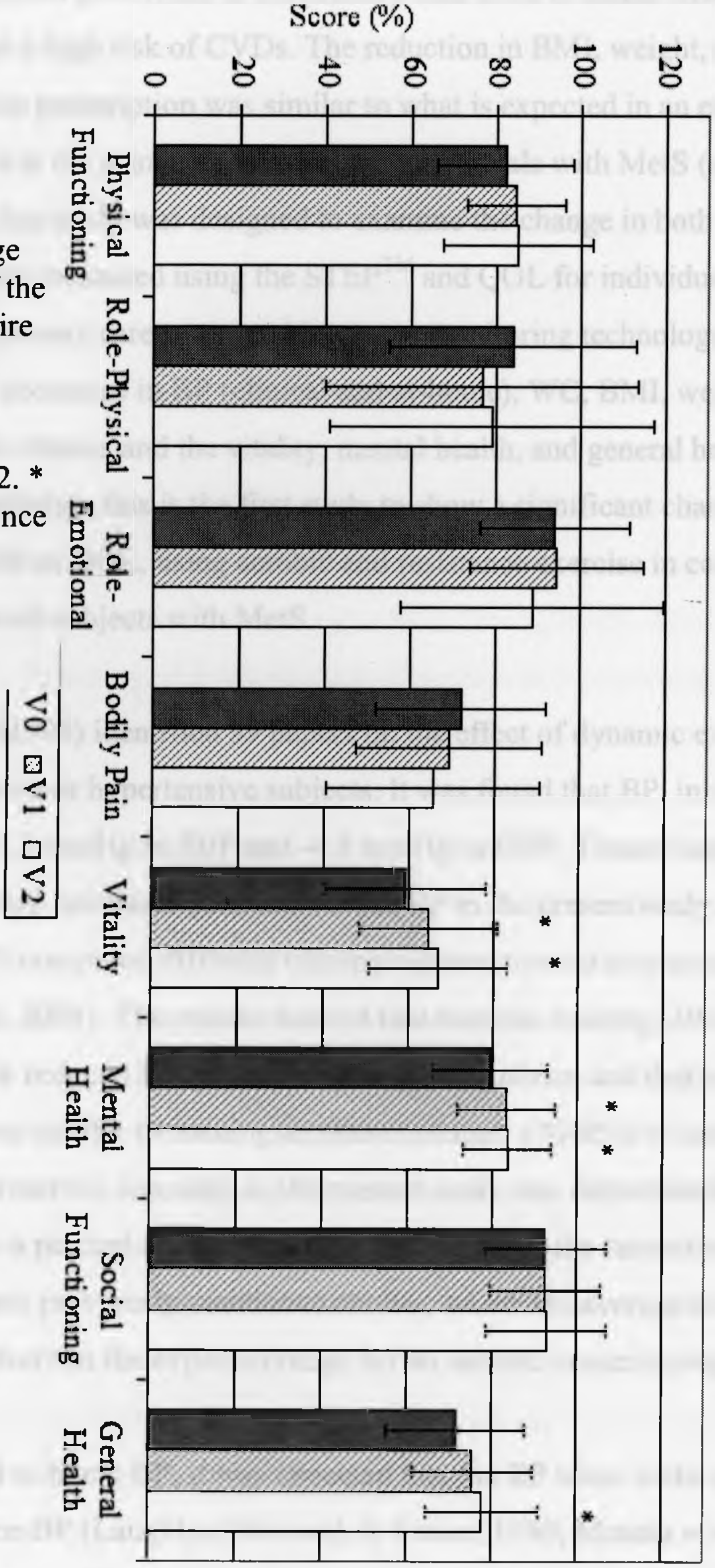

Figure 2.6. Change in the domains of the SF-36 questionnaire over 6 months of intervention. All values are means±SD. n = 52. * significant difference from V0. p<0.05.

2.4 Discussion

This study illustrates the effects of a 6 month aerobic-based, technology supported physical activity program prescribed at the primary care level to adults from rural Ontario with MetS who are at a high risk of CVDs. The reduction in BMI, weight, and WC following this exercise prescription was similar to what is expected in an exercise prescription provided at the primary care level for individuals with MetS (Aizawa et al., 2009). Specifically, this study was designed to examine the change in both SBP and DBP, as well as fitness measured using the STEP™ and QOL for individuals at risk for T2D and CVD in a primary care setting with remote monitoring technology. We observed significant decreases in BP (clinical and at-home), WC, BMI, weight and RHR, as well as increases in fitness and the vitality, mental health, and general health domains in QOL. To our knowledge, this is the first study to show a significant change in both SBP and DBP as wells as QOL, using aerobic and resistance exercise in combination with technology in rural subjects with MetS.

A review by Fagard (1993) identified 39 papers on the effect of dynamic exercise on BP in healthy normotensive or hypertensive subjects. It was found that BP, in response to training, decreased -5.3 mmHg in SBP and -4.8 mmHg in DBP. These changes are very similar to the significant decreases seen in at-home BP in the present study. Another meta-analysis in 2001 compared different training regimes to treat or prevent hypertension (Fagard, 2001). The results showed that exercise training, 30-60 minutes, on most days of the week reduced BP, particularly in hypertensives, and that training at a moderate intensity was similar to training at a hard intensity (40-85% of net maximal exercise or VO_2max reserve). Intensity in the present study was determined through predicted VO_2max as a percent of maximal HR. The results of the current study are in agreement with the two previously mentioned studies, where the average decrease in home SBP and DBP were in the expected range for an aerobic exercise program.

Comparing clinic and at-home BP, it was expected that the BP taken at the clinic would be higher than at-home BP (Laughlin, Sherrard, & Fisher, 1980; Mancia et al., 2007). However, the lack of a significant decrease in at-home SBP between V1 and V2, compared to clinic SBP, could potentially be due to familiarisation of the participants to the clinical testing procedure at V2 and therefore resulting in decreased clinic SBP (Felmeden, Lip, Beevers, & Beevers, 2000). This would imply that our intervention did not continue to have an effect on at-home SBP post 3 months but rather maintained the reduction achieved half-way through the intervention.

In contrast to our findings, Church et al. (2007) found that overweight or obese women with elevated BP did not experience a change in BP with increases in exercise levels. They did however, see a significant improvement in VO_2max following 6 months of supervised exercise training. The authors mentioned that the lack of change in BP seen in their study was likely due to their participants being asked not to change any of their lifestyle habits outside of the study. While the women in the Church et al. study were not classified as having MetS, their baseline values provide evidence that, on average, they possessed the necessary risk factors to be diagnosed as having MetS. Although we did not offer any lifestyle advice apart from increasing exercise and providing Canada's Food Guide, our participants may have been motivated to live healthier lifestyles in accordance to their individualized exercise programs and goal setting.

The results of the present study support improvements in VO_2max after 3 months of aerobic training, the increase of which was maintained (but not further augmented) with an additional 3 months of training. Other studies that reported a continued increase in fitness with exercise training have used supervised, scheduled exercise training sessions or classes (Carroll et al., 2007; Church et al., 2007) rather than physical activity prescribed to an individual. Individuals with MetS experience similar changes in VO_2max with training as those without MetS (Katzmarzyk et al., 2003) and therefore absence of an increase in VO_2max post 3 months seen in our population may be attributed to the lack of continued increase in the intensity of their activities (Church et al., 2007). However, the STEP™ with home-monitoring technology was able to maintain the improved fitness of our participants throughout the remainder of the study. One study that used exercise counselling versus exercise training showed an increase in 6 month fitness levels (measures in METs) in both control and intervention groups from baseline thereby supports the use of counselling within the STEP™ intervention (Dunn et al., 1997). The results of the present study also showed an increase in VO_2max at V1 from V0.

Confirming our results of a decrease in both SBP and DBP at V1, a review by Hagberg et al. (2000) found that reductions in BP could be observed early in an exercise intervention. Specifically, reductions in both SBP and DBP could be evident after only 1 to 10 weeks of aerobic training in hypertensive adults. However, Hagberg et al. also found that SBP has been shown to progressively decrease over the length of the training period (1-20 weeks) while DBP shows a decrease in the first 1-10 weeks of an exercise training program with a lack of a decrease seen in weeks 11-20. This time course of improvement was opposite to what we found in our at-home BP readings. While decreased BP with increased exercise has been shown to be consistent in individuals with MetS (Carroll et al., 2007; Katzmarzyk et al., 2003), we observed a continuous improvement in at-home DBP while SBP declined early in the intervention and remained suppressed following 6 months of intervention. This could be attributed to the fact that VO_2max also did not continue to improve post 3 months and SBP may follow the change in fitness more closely than DBP. Carroll et al. (2007) found an increase in VO_2max with their exercise intervention for MetS (+1.66 ml/kg/min) very similar to the increase seen in the present study (+1.6 ml/kg/min), yet Carroll et al. saw a significant decrease in DBP only at 3 months. The data from Hagberg et al. (2000) was collected on individuals with hypertension (BP ≥140/90 mmHg) and therefore may explain why they expected a prolonged decrease in SBP. Since the participants in the present study were not required to have hypertension (at V0, 63.6% of participants were hypertensive in clinic and 57.2% were hypertensive at-home [at-home hypertension classified as SBP ≥135 mmHg or DBP ≥85] according to the 2010 CHEP recommendations; Campbell et al., 2010), the reduction of SBP might not be continuous with training since hypertensive individuals experience a greater decrease in BP with exercise training than normotensive or pre-hypertensive individuals (Fagard, 1993).

The addition of the technology to the present study provided the participants with home monitoring devices that allowed for feedback on their exercise habits with respect to the changes in their BP and pedometer steps. The improvement seen in at-home BP in our participants is consistent with other studies that have used a cell-phone or internet in combination with exercise counselling to promote improved BP (Park et al., 2009). However, another study using only remote BP monitoring and no exercise counselling also found a decrease in BP over time (4 months) (Logan et al., 2007). There were, however, coaching messages sent automatically to the mobile phone after every reading that encouraged participants to follow a healthy lifestyle if a BP reading was above their individual goal. These messages, as well as the fact that the individual treatment of a participant was at the discretion of their own attending physician, may have attributed to the decrease in BP as much as the use of the technology itself. In the present study we did not provide detailed activity changes or counselling to participants between visits if there was a lack of improvement in BP.

The slight change in weight, and in turn BMI, was normal as current research has found modest weight loss in lifestyle modifications that promote physical activity without supervised exercise training (Jakicic et al., 2011; Ross & Bradshaw, 2009). In the present study, there was no dietary prescription or changes made to the dietary habits of the participants. Had there been a diet or caloric restriction in the present study, a greater change in weight beyond 3 months of the intervention may have been expected (Aizawa et al., 2009; Jakicic, 2009). However, a significant improvement in the WC of the participants throughout the 6 months of our intervention was observed, a finding which is somewhat more important for MetS risk factor reduction than weight or BMI. Abdominal obesity, measured by WC, is a risk factor of MetS as well as a strong predictor of heart disease on its own (Alberti, Zimmet, & Shaw, 2006). The importance of abdominal obesity and its relationship to CVD and T2D is portrayed in the International Diabetes Federation definition of MetS, which was designed for clinical use, where an increased WC is a risk factor an individual must possess in order to be diagnosed as having MetS (Alberti et al., 2006).

With respect to QOL, the significant increases in the domains of vitality, mental health, and general health with the STEP™ are encouraging. A similar study that used an exercise intervention in a rural population of women with MetS also found significant improvements in physical function, vitality, mental health and general health using the SF-36 QOL questionnaire (Oh et al., 2010). The intervention used in the Oh et al. (2010) study included supervised exercise and diet that the STEP™ did not, therefore, the similar increases seen with the STEP™ intervention may suggest that the lack of supervised exercise does not decrease an individual's perception of their general health.

There are limitations to the present study. First, the results of the intervention were not compared to a control group and therefore there is potential that the results are due to regression to the mean in addition to the effect of the intervention itself. Second, due to our study design being mostly pragmatic, individuals who started, stopped or changed their medication throughout the study were not excluded from the analysis and may have contributed to changes seen in BP throughout the study. However, this design allows for greater generalizability of our study since changes in BP medication are relatively common amongst older adults, as seen in our subjects where medication changes were at the discretion of their own physicians. Third, dietary changes were not monitored throughout the study and therefore it is not known if any of our participants experienced a change in BP, WC or weight mainly due to a decrease in caloric or sodium intake rather than an increase in the physical activity. Participants were not instructed to change their dietary habits throughout the study aside from being provided with the Canadian Food Guide (Health Canada, 2007) and therefore, it was assumed that any changes to diet were minor. Fourth, not all of the participants used the technology to the same degree. Participants were reminded throughout the study by automatic short message service reminders to perform their BP readings and enter their pedometer steps according to the given schedule. On occasion, study researchers would contact a participant to confirm that technical issues were not the reason behind multiple missed readings; however compliance with the technology was not forced throughout the study and no individuals were withdrawn from the study for lack of compliance. Fifth, pedometers were the only means of tracking the exercise performed by the participants and therefore may have missed activities that were not recorded by the pedometer such as swimming, biking and aerobic machines such as the elliptical. Participants were provided with an activity log application on their Blackberry™ where they could record their daily activities (aerobic and resistance), however activity log data remains to be analyzed. Sixth, staff turnover in this study may have led to potential variations in measurement techniques of the primary and secondary outcome measures. Seventh, the somewhat small sample size may have resulted in Type I error. Our sample size calculation was performed based on an estimation of a 5.3 mmHg reduction in SBP. Lastly, the use of technology in conjunction with the STEP™ showed improved BP in this study, however it is unknown if the exercise prescription at the primary care level, the technology in rural care, or better management of BP by subjects' physicians during the study was the main cause of improved BP.

2.5 Conclusion and implication

In conclusion, this study has demonstrated that, in rural populations with MetS, an aerobic based exercise program using STEP™ at the primary care level in conjunction with at-home monitoring improved resting BP, fitness, QOL, weight, BMI and WC at 3 months and continued to improve DBP and WC into 6 months. Further studies in ARTEMIS will be to determine if the STEP™ in combination with technology is as effective in a control group of the same population without the use of technology. Since a lifestyle modification that includes exercise and a healthy diet are the first line of therapy for individuals at risk for CVD and T2D, future studies will improve the transition of implementing additional resources into primary care for these modifications to take place.

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Appendix A.

Step Test VO_2max Calculation and Ratings

Patient Data

Sex male = 1 female = 2	________	
Age	________	years
Weight	________	kg
Time required for Step Test	________	seconds
Heart rate after Step Test	________	beats/min

Calculations

Step 1: (1511 / time) * weight / heart rate =

Step 2: (_____* 0.124) – (age * 0.032) – (sex * 0.633) + 3.9 =

Step 3: (_____* 1000) / weight = VO_2max

	Age	VO_2max(ml/kg/min)	Rating	Heart Rate Prescription
Female	18-29	≤ 31	Poor	70% of max HR
	18-29	32-34	Fair	75% of max HR
	18-29	35-37	Good	80% of max HR
	18-29	≥ 38	Excellent	85% of max HR
Male	18-29	≤ 37	Poor	70% of max HR
	18-29	38-41	Fair	75% of max HR
	18-29	42-44	Good	80% of max HR
	18-29	≥ 45	Excellent	85% of max HR
Female	30-39	≤ 29	Poor	70% of max HR
	30-39	30-32	Fair	75% of max HR
	30-39	33-35	Good	80% of max HR
	30-39	≥ 36	Excellent	85% of max HR
Male	30-39	≤ 35	Poor	70% of max HR
	30-39	36-39	Fair	75% of max HR
	30-39	40-42	Good	80% of max HR
	30-39	≥ 43	Excellent	85% of max HR
Female	40-49	≤ 27	Poor	70% of max HR
	40-49	28-30	Fair	75% of max HR
	40-49	31-32	Good	80% of max HR
	40-49	≥ 33	Excellent	85% of max HR
Male	40-49	≤ 33	Poor	70% of max HR
	40-49	34-37	Fair	75% of max HR
	40-49	38-40	Good	80% of max HR
	40-49	≥ 41	Excellent	85% of max HR
Female	50-59	≤ 24	Poor	70% of max HR
	50-59	25-27	Fair	75% of max HR
	50-59	28-29	Good	80% of max HR
	50-59	≥ 30	Excellent	85% of max HR
Male	50-59	≤ 30	Poor	70% of max HR
	50-59	31-34	Fair	75% of max HR
	50-59	35-37	Good	80% of max HR
	50-59	≥ 38	Excellent	85% of max HR
Female	60+	≤ 23	Poor	70% of max HR
	60+	24-25	Fair	75% of max HR
	60+	26-27	Good	80% of max HR
	60+	≥ 28	Excellent	85% of max HR
Male	60+	≤ 26	Poor	70% of max HR
	60+	27-30	Fair	75% of max HR
	60+	31-34	Good	80% of max HR
	60+	≥ 35	Excellent	85% of max HR

Appendix B.

ARTEMIS – Fitness Test Results and Prescription

Results and Exercise Prescription Participant ID:______

VO_2max Score	
VO_2max Rating	
Training Heart Rate (bpm)	
Training Heart Rate (10 seconds)	
Target Aerobic Exercise Duration	
Target Aerobic Exercise Frequency	
Types of Aerobic Exercises	
Types of Resistance Training Exercises	

Definitions

VO_2max – This is a measure of your cardiorespiratory fitness. It is a score of how well your heart, lungs, and muscles work together, the higher the number is, the more fit you are, you can become more fit by increasing your aerobic physical activity. Some examples of aerobic physical activity include walking, swimming, or shovelling the driveway.

Training Heart Rate – In order to improve your fitness, it is important to check your heart rate during physical activity. This training heart rate has been prescribed specifically for you based on your exercise results. The easiest way to check your pulse is to count how many times you feel your heart beat in 10 seconds.

Participant Goals/Barriers/Solutions

Write down 2-3 physical activity or health related goals that you want to achieve. Remember to make them specific, measurable, attainable, realistic, and timely. For each goal, identify barriers that will prevent you from reaching your goal. Barriers can be things that you cannot control, such as the weather. For each barrier, identify how you plan to overcome that barrier. For example, you might overcome bad weather by choosing to walk up and down the stairs in your home.

Goal # 1 →	Barriers →	Solutions
Goal # 2 →	Barriers →	Solutions
Goal # 3 →	Barriers →	Solutions

Activity Level: Sedentary

Do each activity two times per week.

1 set, and 12 repetitions of each:

1) Wall push ups
2) Sit to stands
3) Abdominal exercises
4) Calf raises

Activity Level: Somewhat Active

Do each activity two times per week.

2 sets, and 12 repetitions of each:

1) Wall push ups
2) Sit to stands
3) Abdominal exercises
4) Calf raises

Activity Level: Moderately Active

Do each activity two or three times per week.

3 sets, and 12 repetitions of each:

1) Wall push ups
2) Sit to stands
3) Abdominal exercises
4) Calf raises

2 sets, and 12 repetitions of each:

5) Lunges
6) Bicep Curls
7) Tricep Dips

Activity Level: Active

Do each activity three times per week.

3 sets, and 12 repetitions of each:

1) Wall push ups
2) Sit to stands
3) Abdominal exercises
4) Calf raises
5) Lunges
6) Bicep Curls
7) Tricep Dips

Certificate of Ethics Approval

Office of Research Ethics

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Western

Use of Human Subjects - Ethics Approval Notice

Principal Investigator: Dr. R.J. Petrella
Review Number: 15828 **Review Level:** Full Board
Review Date: January 13, 2009
Protocol Title: A multi-centre, prospective, Randomized study To determine the effects of Exercise Managed Intervention (ARTEMIStudy).
Department and Institution: Geriatric Medicine, Parkwood Hospital
Sponsor: CIHR-CANADIAN INSTITUTE OF HEALTH RESEARCH
Ethics Approval Date: March 10, 2009 **Expiry Date:** December 31, 2012
Documents Reviewed and Approved: UWO Protocol, Letter of information & consent form dated December 7/08, Poster Ad and Newspaper Ad both dated December/08
Documents Received for Information:

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the UWO Updated Approval Request Form.

During the course of the research, no deviations from, or changes to, the protocol or consent form may be initiated without prior written approval from the HSREB except when necessary to eliminate immediate hazards to the subject or when the change(s) involve only logistical or administrative aspects of the study (e.g. change of monitor, telephone number). Expedited review of minor change(s) in ongoing studies will be considered. Subjects must receive a copy of the signed information/consent documentation.

Investigators must promptly also report to the HSREB:

a) changes increasing the risk to the participant(s) and/or affecting significantly the conduct of the study;
b) all adverse and unexpected experiences or events that are both serious and unexpected;
c) new information that may adversely affect the safety of the subjects or the conduct of the study.

If these changes/adverse events require a change to the information/consent documentation, and/or recruitment advertisement, the newly revised information/consent documentation, and/or advertisement, must be submitted to this office for approval.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

Chair of HSREB: Dr. Joseph Gilbert

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cc: ORE File
LHRI