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DIABETES AND TECHNOLOGY FOR INCREASED ACTIVITY (DaTA)

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ABSTRACT

Physical inactivity is a primary target for prevention of cardiovascular disease and type 2 diabetes. Rural Canadians are at increased risk of metabolic syndrome - a clustering of risk factors preceding these conditions. This study investigated feasibility and effectiveness of a stage-matched physical activity intervention using novel self-monitoring technologies in rural adults with metabolic syndrome. Adherence to self-monitoring protocols was >94%. Stage of change increased by 1 stage ($p=0.001$). Physical activity increased from 5579 ± 1964 steps/day at week 1 to 7818 ± 4235 steps/day at week 8 ($p=0.02$). VO_{2max} increased by 17% ($p<0.05$). BMI decreased from 33.1 to 32.7 ($p=0.016$). Participants were comfortable using the technology, found it easy-to-use, of low burden, and perceived it positively. This pilot study shows that this stage-matched technology intervention for increased physical activity was feasible and effective in high-risk adults in rural Ontario.

KEYWORDS: Metabolic syndrome, stages of change, physical activity, cardiovascular risk factors, technology, rural health

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CHAPTER 1 – INTRODUCTION

1.1 Introduction

Metabolic syndrome represents a state of metabolic dysfunction within the human body. When regulation of glucose, lipids, and blood pressure is disrupted severe consequences can result. Having metabolic syndrome increases the likelihood of developing type 2 diabetes by 7-fold and doubles the risk of cardiovascular disease (Ballantyne et al., 2008; Wilson, D'Agostino, Parise, Sullivan, & Meigs, 2005). In Canada cardiovascular disease accounts for 30% of annual deaths– that's equivalent to one Canadian every seven minutes (Statistics Canada, 2009).

Metabolic syndrome often leads to type 2 diabetes. Microvascular complications including neuropathy, retinopathy, and nephropathy are not uncommon in this disease and may lead to amputations, blindness, and kidney failure (Fowler, 2008). Type 2 diabetes also increases your chances of dying from a major cardiovascular event (Almdal, Scharling, Jensen, & Vestergaard, 2004; Huxley, Barzi, & Woodward, 2006; Sanmartin & Gilmore, 2005). It is estimated that about 80% of diabetics die from cardiovascular disease (Canadian Diabetes Association, 2010).

Although metabolic syndrome is widespread across Canada there exists clear disparity between urban and rural populations. It is estimated that 14.4% of Canadians over the age of 18 suffer from this condition (Brien & Katzmarzyk, 2006). Canadians living in rural or remote regions are much more likely to have metabolic syndrome, and thus, experience the consequences of this condition, than their urban counterparts (Ardern & Katmarzyk, 2007). Rural communities have significantly limited access to health care resources compared to their urban counterparts. For example, in 2004 only 9.4% of physicians were located in rural communities though 21.4% of the population resided in these non-urban areas (Pong & Pitblado, 2006). Since rural Canadians are particularly vulnerable to metabolic syndrome, type 2 diabetes, and the subsequent cardiovascular complications of these conditions this project aims to address the needs of this underserved high risk population. These include improved access to quality care and primary prevention of cardiovascular disease and type 2 diabetes.

Metabolic syndrome is largely preventable because it is attributable to physical inactivity and unhealthy dietary habits (Allbright et al., 2005; American Diabetes Association, 2004; Ford, Kohl, Mokdad, & Ajani, 2005). Physical inactivity has been identified as a primary modifiable risk factor for the development of cardiovascular disease, coronary artery disease, hypertension, obesity, metabolic syndrome, and the development of type 2 diabetes (Department of Health and Human Services, 2007; Paffenbarger & Hyde, 1984). Some evidence suggests that up to 1 in every 10 deaths in the United States is caused by physical inactivity (Danaei et al., 2009).

Aerobic and resistance training exercise interventions are effective methods of preventing and managing metabolic syndrome and decreasing risk of developing cardiovascular disease (Department of Health and Human Services, 2007; Diabetes Prevention Program Research Group, 2002; Grundy et al., 2002; Hayes & Kriska, 2008; Paffenbarger & Hyde, 1984). Exercise can reverse the problems of metabolic syndrome such as glucose intolerance, hypertension, dyslipidemia, and abdominal obesity (Bo et al., 2007; Brien, Janssen & Katzmazyk, 2007; Durstine et al., 2001; Kelley, Kelley & Tran, 2005; Khan et al., 2009; Ohkawara, Tanaka, Miyachi, Ishikawa-Takata, & Tabata, 2007).

In general, behaviour modification is complicated and difficult; exercise is no exception. Despite attempts to encourage physically active living through health promotion campaigns (ParticipACTION) and resources (Canada's Physical Activity

Guide) millions of Canadians remain sedentary (Health Canada, 2002). Information on how to be physically active is available but it often takes more to get people moving. Becoming physically active is as much a psycho-social process as a physical one, and therefore researchers have drawn from the field of behaviour change psychology to help design more effective physical activity interventions (Marcus et al., 2000).

One widely accepted theoretical approach to changing exercise behaviour is the Transtheoretical Model of behaviour change. Created by Prochaska and DiClemente in the late 1970's, this paradigm looks at behaviour change as an individualized process taking place within the context of the individual and their environmental circumstances (Prochaska, 1979). Interventions based on the Transtheoretical Model take stock of each participant's reality in terms of their stage of change (readiness to change) and then apply the most appropriate processes of change to help modify their self-efficacy, decisional balance, and target behaviour (Prochaska, 2005).

This approach has been found to improve adherence to short-term regular physical activity. For example, in the PACE randomized controlled trial, Calfas and colleagues (1995) showed that 52% of the intervention group adopted regular physical activity (were in the action stage) compared to only 12% of the control group after 6 weeks. Meta-analysis also shows positive short-term results of physical activity interventions based on this model with 11/15 studies demonstrating significant improvements in physical activity in the intervention group compared with control (Adams & White, 2003). The Transtheoretical Model is also used by Canadian Society for Exercise Physiology fitness professionals when making exercise recommendations (Canadian Society for Exercise Physiology, 2004).

In the primary health care setting, exercise prescription research has become increasingly prevalent (Aittasolo, Miilunpalo, Stahl, & Kukkonen-Harjula, 2006; Kerse, Elley, Robinson, & Arroll, 2005; Little et al., 2004). Most of these studies are targeted toward sedentary adults with no specific health condition or disease making it difficult to generalize the results to those with metabolic syndrome. There is also heterogeneity among study designs, as some are grounded in the Theory of Planned Action, the 5A framework for health counselling, parts of the Transtheoretical Model, or simply modelled after other research studies. The wide variety of study designs and interventions makes it difficult to compare studies that have been done to one another.

A handful of studies have looked at the effects of exercise on health in a metabolic syndrome population. Lifestyle interventions targeting both diet and exercise in this population include the Diabetes Prevention Program, the Finnish Diabetes Prevention Study, and the Staged Nutrition and Activity Counselling (SNAC) study. The Diabetes Prevention Program intervention focused on diet, exercise, and behaviour modification skills as separate components, with an emphasis on self-esteem, empowerment, and social support (Diabetes Prevention Program Research Group, 1999). Participants received education on several behavioural skills. These include self-monitoring, goal-setting, stimulus control, problem solving, and relapse prevention. The Finnish Diabetes Prevention Study provided one-on-one nutritional counselling and a general exercise prescription for aerobic and resistance training exercise for all participants (Eriksson et al., 1999). Results of both studies showed that lifestyle intervention decreased the incidence of type 2 diabetes in this high-risk population by ~58% compared to control.

The SNAC study was a 24-week randomized controlled trial investigating the impact of an individually tailored exercise and nutrition intervention on cardiovascular risk factors in a metabolic syndrome population. Based on the Transtheoretical Model, the intervention included the STEP^{TM} test exercise prescription and a tailored Mediterranean-style diet. The STEP^{TM} test exercise prescription was designed as a practical method to assess individual aerobic fitness levels and provide stage-matched exercise counselling and prescription within the context of the primary care setting (Petrella & Wight, 2000; Petrella, Koval, Cunningham, & Paterson, 2003). Results of the trial showed significant improvements in waist circumference, diastolic and systolic blood pressure, fasting blood glucose, weight, BMI, resting heart rate, total cholesterol, and LDL cholesterol levels in metabolic syndrome patients compared to baseline (Aizawa, Shoemaker, Overend, & Petrella, 2009). It is unknown whether dietary changes or changes in physical activity were the driving force behind these positive results.

1.2 Statement of the problem

The purpose of this study was to determine the feasibility and effectiveness of this multi-dimensional approach for increasing physical activity in rural adults with metabolic syndrome. Feasibility was assessed as adherence to the self-monitoring protocols by study participants as well as self-reported comfort, ease-of-use, perception, and burden of the technology from the DaTA Study Technology Experience Survey. Effectiveness was assessed as the impact of the intervention on stage of change for physical activity as well as physical activity, cardiorespiratory fitness, and cardiovascular risk factors.

Independent variables include the self-monitoring protocols, the parameters of the stage-matched STEP^{TM} test exercise prescription (frequency, intensity, type, and time for exercise), and processes of change. Dependent variables include adherence to self-monitoring, acceptance of the technology, stage of change, VO_{2max}, steps/day, and cardiovascular risk factors (triglycerides, LDL cholesterol, HDL cholesterol, systolic and diastolic blood pressure, waist circumference, weight, BMI, fasting blood glucose, HbA1c, and C-reactive protein).

1.3 Hypotheses

The primary hypotheses were that using the combined technology of self-monitoring devices, Blackberry™ cell phones, and Bluetooth wireless technology to implement a physical activity intervention targeting high-risk rural participants would be feasible and effective. Previous studies have shown variable adherence of rates of 34%-66% for technology-based behaviour change interventions in high risk populations (Faridi et al., 2008; Patrick et al., 2009). Therefore it was hypothesized that rural adults with metabolic syndrome given an intervention that includes a stage-matched STEP™ test exercise prescription and advanced technology self-monitoring tools will complete 50% of their planned self-monitoring readings over 2 months. It was hypothesized that participants would find the technology acceptable in terms of comfort, ease-of-use, perception, and burden. It was hypothesized that stage of change will increase, leading to improvements in physical activity, VO_{2max}, and cardiovascular risk factors.

1.4 Delimitations

The scope of this study was within the bounds of its geographical location. The study was conducted in the small rural town of Seaforth, Ontario, which may or may not be representative of all rural areas of Canada.

1.5 Limitations

Limitations of the study include the short duration of the intervention which was due to funding for the Blackberry™ phone plans and HealthAnywhere™ database management. The study was also underpowered due to the limited number of available Blackberrys™. Patients were required to come to the clinic during the morning or early afternoon, perhaps eliminating potential participants that were unable to attend during those times.

1.6 Assumptions

This study made several assumptions. First of all, it was assumed that Seaforth and surrounding area is representative of rural Canadian communities. Secondly, it was assumed that having a spouse or family member in the study would not affect the results of the intervention. The study did not assume that participants had any former knowledge or training on home-monitoring devices or Blackberry™ cell phones. We did not expect participants to have prior knowledge or experience with exercise other than walking.

1.7 Operational definitions

Metabolic Syndrome – Defined by the presence of 3 of the following criteria: waist circumference $\geq$ 102 cm in males and $\geq$ 88 cm in females), high triglycerides ($\geq$ 1.7 mmol/L), low HDL cholesterol ($\leq$ 1.03 mmol/L in males and $\leq$ 1.29 mmol/L in females), elevated blood pressure (systolic blood pressure $\geq$ 130 mmHg or diastolic $\geq$ 85 mmHg), and impaired fasting glucose ($\geq$ 5.6 mmol/L) (National Heart, Lung, and Blood Institute, 2001).

Type 2 diabetes – impaired fasting glucose $\geq$ 7.0 mmol/L or serum HbA1c $\geq$7%

Cardiovascular disease – a disease affecting the large or small blood vessels or the heart. This includes macrovascular diseases such as heart attack, stroke, cardiac arrest, angina, and coronary artery disease, as well as diseases of the microvasculature such as neuropathy, nephropathy, and retinopathy.

Stages of change – Stage of readiness to change physical activity behaviour.

Pre-contemplation – the individual is not considering making a change in a given behaviour

Contemplation – the individual is aware of the pros and cons of making a given behaviour change but has not made a decision to change; considering making a change in the next month

Preparation – the individual has decided that they want to make a change in their behaviour and is planning to take action within the next week

Action – the individual is in the process of changing their behaviour and has done so for less than 3 months

Maintenance – the individual has made a successful change for at least 3 months

Termination – the individual has made a successful change and no longer experiences any temptation to relapse and has 100% self-efficacy

Mediator – a variable that explains the relationship between an independent and dependent variable

Cardiorespiratory/aerobic fitness – one's ability to collect oxygen and deliver it to working tissues. Measured in terms of maximal aerobic capacity (VO_{2max}).

Rural – A geographic area with low population density and wide open spaces

Self-monitoring device – A pedometer, home-blood pressure monitor, glucometer, or Blackberry™ smart phone

CHAPTER TWO – LITERATURE REVIEW

2.1 Metabolic syndrome

Originally coined "Syndrome X" by Reaven in 1988, metabolic syndrome describes a condition of metabolic dysfunction characterized by the presence of several risk factors for developing cardiovascular disease and type 2 diabetes. Until recently there have been multiple clinical definitions for metabolic syndrome. This lack of standardization makes it difficult to compare studies using different criteria for metabolic syndrome due to increased heterogeneity among patients who fall below or above the cut points for particular risk factors.

As of October, 2009, an individual who has 3 out of 5 specific cardiovascular risk factors is classified as having the metabolic syndrome. These 5 elements include increased waist circumference (population-specific), elevated triglycerides ($\geq$ 1.7 mmol/L), low HDL cholesterol levels ($\leq$ 1.03 mmol/L in males and $\leq$ 1.30 mmol/L in females), high blood pressure (systolic blood pressure $\geq$ 130 mmHg and/or diastolic blood pressure $\geq$ 85 mmHg), and fasting blood glucose levels $\geq$ 5.6 mmol/L. This universal definition redefines waist circumference as specific to the population rather than the one-size fits-all approach previously used. This is important because some populations have a slighter build than others and those at risk may not be identified using European values. For Canadians of European descent the cut off points for waist circumference are $\geq$102 cm for males and $\geq$88 cm for females (Alberti et al., 2009). The current study uses the guidelines established by the National Cholesterol Education Program Adult Treatment Panel III prior to the publication of the current consensus statement (National Heart, Lung, and Blood Institute, 2001). Specifically, the inclusion criteria used in this study include two (rather than three) of the risk factors included in the current definition.

2.2 Complications of metabolic syndrome

Metabolic syndrome is a wide-spread and largely undiagnosed disease. In Canada, it is estimated that at least 14.4% of adults have metabolic syndrome (Brien & Katzmarzyk, 2006). Thousands more are likely unaware that they have metabolic syndrome until it progresses into a disease with acute complications like type 2 diabetes and/or cardiovascular disease. In 2001 a large screening study estimated that at least 2.2% of the Canadian population had undiagnosed type 2 diabetes and another 3.5% had glucose intolerance. Rates may be higher, as only 25% of patients with fasting blood glucose >5.5 mmol/L returned for a venous blood test and of the patients who did attend their blood test, only 50% returned for an oral glucose tolerance test (Leiter at al., 2001).

Individually the five components of metabolic syndrome predict cardiovascular disease. For example abdominal obesity is a significant independent risk factor for future cardiovascular events in men and women (de Koning, Merchant, Pogue, & Anand, 2007; Lakka, Lakka, Tuomilehto, & Salonen, 2002). Hypertension, high serum triglycerides, and low HDL cholesterol have also been shown to be significant contributors to cardiovascular risk (Pencina, D'Agostino, Larson, Massaro, & Vason, 2009). In combination, these risk factors represent an even greater risk of cardiovascular disease.

2.2.1 Type 2 diabetes

Metabolic syndrome often progresses into type 2 diabetes if left untreated. In 2005 Wilson et al. followed 2549 participants in the Framingham Heart Study over 8 years. The results show that those with metabolic syndrome at baseline were 6.9 times more likely to develop type 2 diabetes than those who did not (RR= 6.92 for men and 6.90 for women) (Wilson, D'Agostino, Parise, Sullivan, & Meigs, 2005). In 2008 the ARIC study found that metabolic syndrome risk factors predicted 81% of all incident cases of type 2 diabetes over 9 years (Ballantyne et al., 2008). Not only does metabolic syndrome increase the likelihood of developing type 2 diabetes, but it is also a preventable condition in most cases.

Metabolic syndrome represents a critical point in the progression of metabolic dysfunction. If treated with exercise and proper nutrition, it can be reversed more often than not. Left untreated, the disease will likely progress into type 2 diabetes. Type 2 diabetics are at higher risk of acute cardiovascular events such as myocardial infarction, coronary artery disease, and stroke than their non-diabetic counterparts. The most recent Canadian statistics indicate that 19.8% of Canadians with diabetes have cardiovascular disease compared to only 4.0% of non-diabetics (Sanmartin & Gilmore, 2005). This is consistent with studies from around the world. Results from 20-year follow-up of the Copenhagen City Heart Study estimate the relative risk of myocardial infarction or stroke to be 1.7-2.7 in women and 3.5-4.6 in men with type 2 diabetes compared to age-matched controls (Almdal, Scharling, Jensen, & Vestergaard, 2004). Type 2 diabetics are also more likely to suffer fatal coronary heart disease than healthy controls (5.4% versus 1.6%) (Huxley, Barzi, & Woodward, 2006). The consequences of allowing metabolic syndrome to progress into type 2 diabetes can be severe and should be prevented if possible.

2.2.1.1 Microvascular complications of type 2 diabetes

Diabetes increases the risk of developing chronic cardiovascular complications at the microvascular level including retinopathy, nephropathy, and neuropathy (Fowler, 2008). These conditions may lead to serious consequences including blindness, kidney failure, ulcers, and even amputations.

Nephrology is the branch of medicine concerned with the kidneys (nephrology, 2010). Diabetic nephropathy is the leading cause of kidney failure in the United States (Fowler, 2008). Kidney function appears to decline with increased duration of diabetes. The United Kingdom Prospective Diabetes Study investigated the development and progression of nephropathy in 5097 type 2 diabetics over 15 years. Prevalence of various stages of nephropathy was found to increase over time from 7.3% at diagnosis to 28.0% after 15 years of living with type 2 diabetes. Additionally 14 people eventually required renal replacement therapy and 17 patients died due to renal disease during the course of the study (Adler et al., 2003).

Diabetic hyperglycermia is associated with microvascular disease of the eye. Retinopathy can take several forms including spots on the eye and the growth of extra retinal capillaries. Unfortunately it can lead to partial or complete blindness (Fowler 2008). Metabolic syndrome is associated with increased chances of developing retinopathy (OR=2.23, 95% CI, 1.69-2.95) but not independently of diabetes. In a large cross-sectional study Keenan et al. (2009) found that incidence of retinopathy is also associated with the number of metabolic syndrome components an individual has. With only one risk factor present the odds ratio of developing retinopathy was 1.08 but with five risk factors it increased to 5.31 ($p < 0.001$ for trend). Retinopathy is more prevalent in type 2 diabetes than metabolic syndrome but as discussed previously, many individuals with metabolic syndrome will develop type 2 diabetes, putting themselves at greater risk of retinopathy.

Diabetic neuropathy according to the American Diabetes Association is any signs and/or symptoms of peripheral nerve damage not attributable to a particular cause (American Diabetes Association, 2007). Neuropathy can cause poor circulation, ulcers, and impair wound healing. It is estimated that about 80% of all foot amputations that happen after injury or ulcer are caused by nerve damage due to hyperglycaemia (Fowler, 2008). For those with type 2 diabetes this is a brutal consequence of a largely preventable condition.

Components of the metabolic syndrome that are shared by type 2 diabetes are associated with an increased risk of neuropathy. In particular, high levels of HbA1c and fasting blood glucose are indicative of future neuropathy and its complications. Several cross-sectional studies have shown a significant correlation between hyperglycaemia and neuropathy in type 2 diabetics that meet the criteria for metabolic syndrome (Hsu, Yen, Liou, Wang, & Chen, 2009; McClean, Andrews, & McElnay, 2005; MetaScreen Writing Committee, 2006). No high quality epidemicological studies were found investigating the prevalence and risk of neuropathy in metabolic syndrome alone.

2.2.3.2 Macrovascular Disease

Cardiovascular disease is the number one cause of death in the United States (Rosamond et al., 2008). Metabolic syndrome contributes to this death toll because it represents a state of metabolic dysfunction that increases cardiovascular risk. Meta-analysis of 21 prospective studies between 1966 and 2005 shows evidence that metabolic syndrome increases the relative risk of developing cardiovascular disease compared with individuals who do not have metabolic syndrome (RR=1.52; 95% CI. 1.26-1.87) (Galassi, Reynolds, & He, 2006).

Myocardial infarction and angina pectoris represent the most common diseases of the coronary arteries. Commonly known as a heart attack, myocardial infarction happens when arterial plaque causes a blockage in one of the coronary arteries. The majority of coronary blockages (55-60%) occur when a vulnerable plaque breaks off upstream and subsequently gets lodged in a section of the coronary vessel that has severe plaque build up and a narrow lumen (Virmani, Burke, Farb, & Kolodgie, 2006). The myocardium (heart muscle) requires oxygen to contract so when one of the arteries that supply the heart with oxygen becomes blocked, the heart cannot keep working at full capacity or for long. Even with immediate medical attention irreversible damage to part or all of the myocardium can result. Angina is a condition characterized by the symptoms of myocardial infarction but is caused by reduced delivery of oxygen to the heart due to narrowing of the coronary blood vessels rather than a complete blockage. Symptoms are usually relieved by using nitro-glycerine, a powerful vasodilator which widens the blood vessels and permits more oxygen to reach the heart.

Overall, coronary heart disease represents >50% of all cardiovascular events in men and women less than 75 years of age (Rosamond et al., 2008). Metabolic syndrome has been associated with an increased risk of myocardial infarction and vice versa. In 2009 a clinical study in Nepal found that 26.19% of patients diagnosed with acute myocardial infarction also had metabolic syndrome. The researchers also found that the presence of metabolic syndrome was significantly greater among younger patients (ages 40-49) than in older patients, with a prevalence of 75% (Pandey et al., 2009).

In 2008 the ARIC study compared 12,089 individuals with and without metabolic syndrome at baseline and 9 year follow up. Comparing those with metabolic syndrome to those without, the hazard ratio of developing incident coronary heart disease was found to be 1.46 (95% CI, 1.23-1.74) for men and 2.05 (95% CI, 1.59-2.64) for women (Ballantyne et al., 2008). As these results show, metabolic syndrome is often a precursor to serious cardiovascular events.

It is estimated that every 40 seconds an adult in the United States has a stroke (Rosamond et al., 2008). Metabolic syndrome is associated with an increased risk of experiencing an acute stroke. Recent meta-analysis of 13 prospective cohort studies from the United States and China shows when comparing those with metabolic syndrome to those who do not, the age-adjusted relative risk of having a stroke is 1.61 (95% CI, 1.48-1.75) (Li et al., 2008). Independently 9/13 of these studies showed a significant increased relative risk of stroke in metabolic syndrome individuals (Li et al., 2008).

2.3 Prevalence in rural Canada

Metabolic syndrome is prevalent in rural areas of Canada. In 2006 Brien and colleagues estimated the overall prevalence of metabolic syndrome in Canada to be about 14.4% (17.5% in men and 11.2% in women) based on a sample of 12,881 adults across 10 provinces who completed the Canadian Heart Health Surveys between 1986 and 1992 (Brien & Katzmarzyk, 2006). Ardern and Katmarzyk found that there were significant differences between provinces, with the highest rates of metabolic syndrome occurring in the Atlantic provinces (16.6% in P.E.I., 18.0% in NS, 20.7% in NB, and 22.8% in NFLD). Prevalence of metabolic syndrome was lowest in British Columbia (12.8%) (Ardern & Katmarzyk, 2007). This suggests a regional trend in which individuals living in the predominately rural areas of Canada are more likely to have metabolic syndrome than those who live in urban areas. Evidence from another study supports this evidence, showing that rural Canadians are much more likely to have metabolic syndrome and/or undiagnosed type 2 diabetes than city-dwellers (Leiter et al., 2001).

Rural Canadians are also at increased risk of the individual risk factors that make up the metabolic syndrome. A report published by the Canadian Institute for Health Information (2006) shows that living in rural Canada is independently associated with elevated risk of being overweight or obese, hypertensive, and/or diabetic. Dyslipidemia and hypertension are prevalent risk factors in the Ontario adult population. In a large retrospective cohort study of 46,322 patients South-western Ontario, Canada, the prevalence of hypertension and dyslipidemia was 17.6% and 12.3%, respectively (Petrella & Merikle, 2008).

In 2006, Shields & Tjepkema estimated that 23% of Canadian adults were obese and another 36% were overweight. Regional trends in obesity parallel those of metabolic syndrome from Ardern & Katzmarzyk (2007), with the highest proportion of obese adults in Newfoundland (34%) and the smallest in British Columbia (18%). In Ontario it is estimated that 21% of urbanites are obese compared to 28% of non-city dwellers. Also of note is that the obesity rate of the Greater Toronto Area is only 16% which is much lower than the provincial average (Shields & Tjepkema, 2006).

2.4 Benefits of exercise on metabolic syndrome

Physical inactivity has been identified as a primary modifiable risk factor for the development of metabolic syndrome, type 2 diabetes, and the cardiovascular complications that accompany these diseases (Department of Health and Human Services, 2007; Diabetes Prevention Program Research Group, 2002; Grundy et al., 2002; Hayes & Kriska, 2008; Paffenbarger & Hyde, 1984). Evidence shows that adults who are sedentary are at increased risk of developing metabolic syndrome than adults who engage in 150 min/week or more of moderate to vigorous physical activity (OR=1.90, 95% CI, 1.22-2.97) (Ford, Kohl, Mokdad, & Ajani, 2005).

Physical activity is known to produce many general health benefits (for a review see Warburton, Nicol, & Bredin, 2006) as well as physiological improvements in the risk factors that contribute to metabolic syndrome (Bo et al., 2007; Brien, Janssen & Katzmarzyk, 2007). Exercise can improve blood lipid profiles (Durstine et al., 2001; Kelley, Kelley & Tran, 2005), lower blood pressure (Khan et al., 2009), and decrease abdominal fat (Ohkawara, Tanaka, Miyachi, Ishikawa-Takata, & Tabata, 2007). Strong evidence shows that exercise is associated with a decrease in overall risk of cardiovascular morbidity and mortality (Paffenbarger & Hyde, 1984; Sandrock, Schulze, Schmitz, Dickhuth, & Schmidt-Trucksaess, 2008).

Lifestyle interventions specifically targeting high-risk individuals with metabolic syndrome have shown promising results. The Diabetes Prevention Program study, a large randomized controlled trial in the United States, found that lifestyle intervention including physical activity counselling reduced the incidence of type 2 diabetes by 58% (95% CI, 48-66%) compared to control (Diabetes Prevention Program Research Group, 2002). In 2005 Orchard and colleagues reported resolution rates of metabolic syndrome for participants in the Diabetes Prevention Program. Of participants who had metabolic syndrome at baseline, 38% of the lifestyle group and 18% of the placebo group had reversed their condition at 3 years. These results support the use of lifestyle intervention to treat metabolic syndrome.

A second randomized controlled trial, the Finnish Diabetes Prevention Study, also showed that lifestyle changes can improve cardiovascular risk factors and reverse metabolic syndrome. Along with healthy eating advice, participants in the intervention group received individually tailored exercise instruction. After three years the healthy lifestyle group improved their metabolic syndrome profile and reduced their incidence of type 2 diabetes 58% more than the control group (Tuomilheto et al., 2001). Lifestyle interventions focusing on diet and exercise behaviours have shown promise for preventing type 2 diabetes and reversing metabolic syndrome.

It has been recognized that changing human behaviour is a complex process and that even the best exercise intervention won't work unless you actually do it. Thus, using a behaviour change model to inform an exercise or lifestyle intervention is essential for success.

2.5 Transtheoretical model-based exercise interventions & the metabolic syndrome

2.5.1 The transtheoretical model & exercise behaviour change

The Transtheoretical Model proposes three major constructs of behaviour change: stages of change (Table 1), processes of change (Table 2), and the mediators between them (Prochaska, Redding, Harlow, Rossi, & Velicer, 1994). **Stages of change** represent different psychological states of preparedness to change a particular habit; they act as the dependent variable in the model. **Processes of change** are the thoughts and actions that help or lead individuals to make changes in their behaviour; these are the independent variables. Different processes of change tend to be used at different stages of change (Prochaska & DiClemente, 1983; Prochaska, 2005). Processes of change also influence decisional balance, self-efficacy/temptation, and the target behaviour. **Mediators** are variables that explain the relationship between an independent variable (like processes of change) and a dependent variable (stage of change). In the Transtheoretical Model mediating variables include decisional balance, self-efficacy/temptations, and target behaviours. Decisional balance involves the weighing the pros and cons of continuing a behaviour and/or adopting a new behaviour. Generally as an individual goes through the stages of change pros of changing their behaviour increase and cons decrease (Prochaska, Redding, Harlow, Rossi, & Velicer, 1994). Self-efficacy represents an individual's situation-specific confidence that they will be able to make a particular change in behaviour and overcome temptation, the salience of cues to engage in the problem behaviour. As a person starts to successfully change their behaviour, their confidence in being able to continue and overcome temptations improves (Prochaska & DiClemente, 1982). Finally, target behaviours are measures of how successfully an individual is adopting (or quitting) a particular behaviour. Each of these mediators predicts stage progression which is the outcome of interest in the Transtheoretical Model (Prochaska, Redding, Harlow, Rossi, & Velicer, 1994). *Figure 1* shows the relationship between the processes of change, self-efficacy/temptation, decisional balance, and the stages of change.

Table 1

Stages of Change for Physical Activity in the Transtheoretical Model

Stage of Change	Description
Pre-contemplation	The individual is not contemplating making a change in physical activity behaviour
Contemplation	The individual is aware of the pros and cons of changing physical activity behaviour but is "on the fence" about making a change
Preparation	Pros of changing physical activity behaviour outweigh cons. The individual has decided to make a change and is planning to take action within the next month
Action	The individual is now increasing their physically activity or has been engaging in regular physical activity for less than 3 months
Maintenance	The individual has been regularly physically active for at least 3 months
*Termination	The individual has 0 temptation and 100% self-efficacy regarding their physical activity behaviour (rare)

Note: Termination Stage is not included in the early versions of the model, is rare in real life, and not used in most interventions.

Table 2

Processes of Change for Physical Activity from the Transtheoretical Model

Process of Change	Description
Consciousness-raising	Involves increased awareness of the consequences of being physically inactive and the benefits of becoming physically active.
Dramatic Relief	Involves emotional arousal about one's current behaviour and relief that can come from changing.
Environmental Re-evaluation	Involves assessing one's current social environment and how becoming physically active would impact that environment.
Self Re-evaluation	Involves re-assessing one's image and empowering oneself to make changes.
Self Liberation	The belief that one can change and the commitment to act on that belief.
Social Liberation	Changes in the social environment that make it easier to behave in a particular way. (i.e. laws prohibiting smoking indoors may help you quit smoking)
Reinforcement Management	Involves the systematic use of reinforcements for taking steps in the right direction.
Helping Relationships	Involves positive and supportive relationships that encourage one's physical activity journey.
Counter-conditioning	Involves substituting healthy behaviours for unhealthy ones.
Stimulus Control	Involves modifying one's environment to increase cues for positive behaviours and decrease cues for negative behaviours.

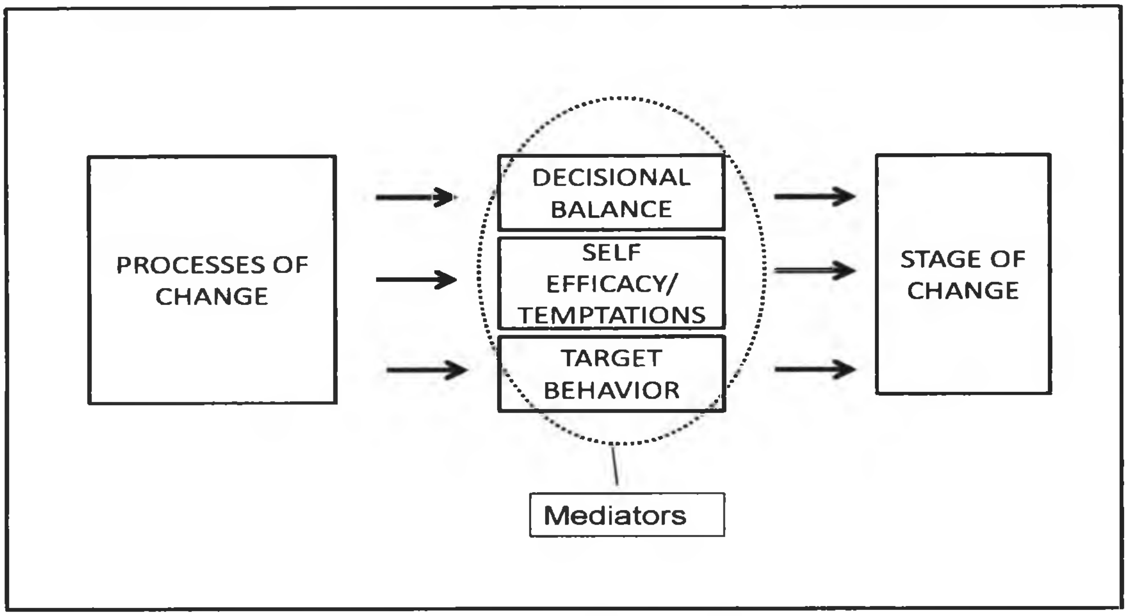

Figure 1. The Transtheoretical Model of Behaviour Change

2.5.2 Effectiveness of exercise interventions using a transtheoretical approach

Although originally used to describe non-exercise behaviours, the Transtheoretical Model of behaviour change is now commonly applied to exercise adoption, adherence, and maintenance. It has become a useful model to develop and implement exercise interventions and programs tailored to individuals' needs. This is done by first assessing an individual's stage of change for physical activity. Then stage-matched exercise recommendations that use the most appropriate processes of change for that stage are given. Processes of change are thought to facilitate changes in self-efficacy, decisional balance, and target behaviour which in turn facilitate progressions in stage of change (*Figure 1*).

The literature suggests that short-term stage-matched physical activity interventions are effective (Adams & White, 2003). One of the most successful exercise interventions based on the Transtheoretical Model is the Physician-based Assessment and Counselling for Exercise (PACE) study. Calfas and colleagues applied the Transtheoretical Model to a sample of sedentary patients (mean age 39.4) with Hepatitis B in a primary care setting. Patients' stage of change was assessed using an 11-item questionnaire designed for the PACE study. Those in the pre-contemplation stage were asked to consider the personal benefits of being physically active and encouraged to think about starting a program. Patients in the contemplation group worked with their physician to establish a physical activity goal, come up with ways to overcome barriers, and identify helping relationships. Finally, patients who were currently active were provided with verbal reinforcement and discussed strategies to prevent relapse. After 6 weeks 52% of the contemplators in the intervention group moved from the contemplation stage to the action stage compared to only 12% of the control group. Self-reported physical activity increased by 10 min/week in the control group and 40 min/week in the intervention group. Accelerometer data confirmed a 33% increase in the intervention group and a slight decrease in the control group. The PACE study showed that physical activity interventions tailored to individuals' stage of change can be effective in the short-term in a young sedentary population (Calfas et al., 1996).

Long-term benefits of a physical activity intervention based on the Transtheoretical Model have not been confirmed. In 2005 the PACE study was repeated in the Netherlands over a one-year period. This randomized controlled trial enrolled and randomized 358 patients to either usual care or the PACE intervention. Results showed no significant differences between groups in progression of stage of change or increases in physical activity levels. However, both the usual care and the PACE participants did significantly increase their overall physical activity, suggesting that physical activity counselling is effective whether it is included as part of usual care or as part of the PACE protocol (van Sluijs et al., 2005). It is also important to remember that the Transtheoretical Model is not a linear paradigm – according to Prochaska & DiClemente (1983), the stages of change are dynamic and often involve many failed attempts before successful change is adopted. Long-term interventions are more susceptible to stage regression (relapse) than short-term programs, which may explain why short-term interventions appear more successful.

The STEP™ test exercise prescription is grounded in the Transtheoretical Model. Stages of change are assessed initially, and exercise counselling and prescription based on ACSM guidelines are tailored to individuals' stage of change and fitness level. Stage-matched written activities are also provided to individuals. These activities address processes of change appropriate to each stage and aim to facilitate improvements in decisional balance, self-efficacy, skills for coping with temptation, and physical activity levels. The major advantage of the STEP™ test exercise prescription over previous protocols grounded in the Transtheoretical Model is that it also provides a valid and reliable estimate of maximal aerobic fitness. This information is essential to provide a tailored exercise prescription that is appropriate for the individual's current physical fitness. The STEP™ test integrates the psycho-social aspects of behaviour modification with the physiological aspects of exercise prescription (Petrella, Koval, Cunningham, & Patterson, 2001; Petrella, Koval, Cunningham, & Patterson, 2003; Petrella & Wight, 2000).

2.5.3 Exercise interventions using a transtheoretical model approach for metabolic syndrome

Diabetes prevention research focusing on lifestyle changes including physical activity has infrequently used the Transtheoretical Model. Two of the most famous diabetes prevention studies, the Diabetes Prevention Program and the Finnish Diabetes Prevention Study, provided education and training on behaviour modification skills but lacked vigorous theoretical backing for these strategies. The Diabetes Prevention Program enlisted the aid of specialists with prior training in nutrition, exercise, or behaviour modification to deliver the content of their program. Topics covered for behaviour modification were self-monitoring, goal-setting, stimulus control, problem solving, and relapse prevention. Despite the fact that this combines ideas from several paradigms, the authors only make reference to motivational interviewing (The Diabetes Prevention Program Research Group, 1999). The Finnish Diabetes Prevention Study on the other hand doesn't mention any specific theoretical approach to their lifestyle intervention (Eriksson et al., 1999).

The Staged Nutrition and Activity Counselling trial (SNAC) is a precursor to the current study. This trial examined the effectiveness of a STEP™ test exercise prescription and a staged Mediterranean diet on cardiovascular function and structure in patients with metabolic syndrome and/or hypertension. This study used the Stage of Change for Physical Activity Questionnaire, as well as a staging algorithm for the Mediterranean diet with subsequent stage-appropriate counselling and prescription for diet and exercise from their physician. The SNAC intervention had positive effects on metabolic syndrome components: fasting blood glucose, waist circumference, LDL cholesterol, and blood pressure decreased significantly ($p < 0.05$) (Aizawa, Shoemaker, Overend, & Petrella, 2009).

A similar trial has recently been initiated in Kingston, Ontario. In 2009 Ross and colleagues described the methods and design of a large randomized trial comparing a stage-matched Mediterranean diet and physical activity intervention to usual care in a high-risk obese population. This research differs from the SNAC study because it does not measure physical fitness or use the STEP™ test exercise prescription. Results are not yet available.

To our knowledge there has not been a study investigating the impact of a STEP™ test exercise prescription intervention without dietary intervention on a rural metabolic syndrome population.

2.5.4 The STEP™ Test Exercise Prescription

The STEP™ test exercise prescription began as a self-paced stepping protocol. The self-paced stepping test comes out of the work of several faculty members at the University of Western Ontario. In the late 1990's a randomized trial was conducted to validate a self-paced stepping test at normal and fast stepping speed as a predictive submaximal test for VO_{2max} in community-dwelling older adults. The results of the stepping test were compared to direct measurement of VO_{2max} from a commonly used maximal treadmill test. The results showed that performing the test at normal and fast speeds yielded the same results. Correlation of predicted VO_{2max} was high (0.96) between the self-paced stepping test and the maximal treadmill test with direct measurement of VO_{2max} (Petrella, Koval, Cunningham, & Paterson, 1998). The self-paced stepping test was found to be reliable and valid for predicting maximal aerobic capacity in older adults (Petrella, Koval, Cunningham, & Paterson, 2001).

It is also a practical and feasible test to perform in clinical practice (Petrella & Wight, 2000). In 2003 a randomized controlled trial was preformed to assess the potential benefits of using the self-paced stepping test combined with stage-matched exercise prescription (referred to as the STEP™ test exercise prescription, or STEP™). After 1 year, VO_{2max} increased by 14% in the STEP™ group compared with 3% in the control group ($p<0.001$). Exercise self-efficacy was significantly higher in the STEP™ group compared with control (32% versus 22% increase, respectively). The STEP™ group also dropped their systolic blood pressure by 7.3% and BMI by 7.4%, whereas the control group experienced no significant changes in these outcomes (Petrella, Koval, Cunningham, & Paterson, 2003). These results show that the STEP™ test is effective in facilitating increases in cardiorespiratory fitness through increased physical activity.

2.6 Patient self-monitoring and technology

Self-monitoring technology has been available to the public for several years. Advances in technology have improved access to self-monitoring devices including home blood pressure monitors, glucometers, pedometers, and heart rate monitors. Self-monitoring of blood glucose is an effective tool for increasing glucose control (Poolsup, Sukomboon, & Rattanasookchit, 2009). Likewise, self-monitoring of home-blood pressure has been recommended to help enhance blood pressure control in hypertensive patients (McManus et al., 2008). Physical activity interventions often rely on self-monitoring of physical activity using pedometers. Pedometers are widely available and have high convergent validity with other measures of physical activity including accelerometers (mean $r = 0.86$) and self-reported walking or running distances (Tudor-Locke, Williams, Reis, & Pluto, 2002). A recent meta-analysis by Bravata et al. (2007) shows that pedometer-based physical activity interventions helped participants increase daily physical activity by at least 2100 steps/day. The evidence shows that using self-monitoring devices can improve health outcomes and physical activity.

2.6.1 Cell phone technology for health interventions

Access to advanced communications technology has improved drastically over the last 20 years. The majority of Canadians have home access to the internet and a cell phone on hand at all times. Cell phones are lightweight, portable, and have a variety of functions such as text messaging, email, internet, and Bluetooth capabilities that make them a versatile technological tool, ideal for interventions fusing technology and self-monitoring for health.

Health interventions using cell phones have used built-in reminders, automated or real-time text-messages, and automatic data transfer using Bluetooth wireless technology. Recent studies have employed cell phones for everything from improving sunscreen use (Armstrong et al., 2009) to quitting smoking (Obermayer, Riley, Asif, & Jersino, 2009; Whittaker et al., 2009) and losing weight (Patrick et al., 2009) with varying degrees of success.

Cell phone technology has been used to enhance blood pressure control in hypertensive patients. Park, Kim, and Kim (2009) implemented an 8-week quasi-experimental trial of blood pressure self-monitoring study using two-way cell phone SMS text messaging and an interactive website in 49 obese hypertensive adults. Participants were instructed to monitor their blood pressure at their convenience and were given automatic feedback via SMS text messaging or a website. Weekly tailored recommendations were provided electronically by a study nurse. Results showed significant decreases in systolic blood pressure (-9.1 mmHg) and diastolic blood pressure (-7.2 mmHg) in the treatment group, with no changes in the control group.

Cell phones have showed promise for enhancing glucose control in hyperglycaemic patients. In 2005 Farmer and colleagues described a real-time telehealth system centered on data transmission to and from a mobile phone. This system was targeted to diabetic populations whose primary self-monitoring outcome is blood glucose. Patients were monitored by a data management system that sends alerts when patients were above or below pre-set glucose levels or missed readings. Cho, Lee, Lim, Kwon, and Yoon (2009) demonstrated the effectiveness of the Diabetes Phone, a specialized cell phone capable of functioning as a glucometer and a cell phone, in lowering HbA1c levels over 3 months in middle-aged type 2 diabetics. The NICHE study in Connecticut, United States, studied the feasibility of using cell phones paired with self-monitoring devices to improve glucose control and physical activity in type 2 diabetics. In this randomized pilot study, 15 participants monitored their blood glucose using glucometers and their daily physical activity via pedometers while 15 participants received usual care. Data was transferred wirelessly to their cell phones and then to the study database in real time. Results of the NICHE trial showed that the use of these technologies was feasible but adherence varied considerably across participants from 100% (n=2) to 0% (n=5) (Faridi et al., 2008). This suggests that interventions combining self-monitoring and cell phone technology can be effective but may depend on individual factors like motivation and readiness to change behaviour.

Cell phone and internet technologies have also been employed to increase physical activity in sedentary adults. Hurling et al. (2007) investigated the impact of a cell phone and web-based behaviour change system for increasing physical activity in middle-aged sedentary adults. Participants in the intervention group wore accelerometers and received automated dialogue therapy via SMS text messaging to help identify barriers and offer solutions. They reported physical activity on the research program website weekly and could opt to send reminders for physical activity via text or email for the upcoming week. After 9 weeks the intervention group was active for 138 min/week more than the control group according to accelerometer data.

2.6.2 Applications to Metabolic Syndrome

Treatment recommendations for metabolic syndrome patients include making lifestyle changes like exercising more. Evidence shows that making behavioural changes is extremely challenging. In fact, Prochaska & DiClemente found that even those who successfully quit smoking failed multiple times before making a successful change Prochaska and DiClemente, 1983). Having social support, being motivated, and being ready to change contribute tremendously to successfully adopting regular physical activity (Prochaska & DiClemente, 1982).

Blackberry™ smart phones combined with remote health monitoring tools have the potential to facilitate the processes of change. One of the ways it might do this is by providing patients with physiological feedback regarding the impacts of their behaviours on their health. For example, having a glass of wine late in the evening will show up as elevated blood glucose levels before bed. Theoretically, this is a form of consciousness raising, one of the processes of change from the Transtheoretical model. Automated reminders also serve to increase awareness about decisions on a day-to-day basis and may help individuals make different choices or think differently about the consequences of their choices. Having constant support and reminders may also help keep people motivated toward reaching their goals.

Cell phone-based interventions targeting physical activity in a metabolic syndrome population have not been done. Past studies show that interventions combining cell-phone and self-monitoring technologies are promising for blood glucose and blood pressure control, as well as increasing physical activity and promoting weight loss. The current study will integrate all of these components with a STEP^{TM} test exercise prescription intervention targeting a rural metabolic syndrome population.

2.6.3 Potential benefits for remote & rural populations

Incidence of metabolic syndrome is prevalent in rural areas of Canada which tend to have a high numbers of patients without family doctors. Rural and remote communities have significantly limited access to health care resources compared to their urban counterparts. In 2004 only 9.4% of physicians were located in rural communities though 21.4% of the population resides in these non-urban areas (Pong & Pitblado, 2006). It has also been shown that living in a rural or non-metropolitan area can increase wait times and lower your chances of receiving specialized care from a cardiologist after an acute myocardial infarction compared to those living in metropolitan centres (Hassan et al., 2009).

Technology has been cited as a potential solution to improve access to health care in rural Canada. In 2002 the Government of Canada issued the Romanow report which recommended that the federal government establish a Rural and Remote Access Fund to support new initiatives for health care delivery to people in remote and rural communities. This report highlighted the potential for technology to help bridge the gap between rural populations and health care access (Romanow, 2002, pp.159-169).

Using cell phone and home-based self-monitoring technologies is a cost-effective and novel way to improve access to care and address issues of health care provider shortages and an aging population (Celler, Lovell, & Chan, 1999). Qualitative analysis from a study in Northern Ontario shows that using video technology to provide health care to patients in rural Canada can increase patients' sense of security, improve care, and significantly reduce the emotional and financial burdens of travelling to city centres for health care (Sevean, Dampier, Spadoni, Strickland, & Pilatske, 2009). Another study from Northern Ontario implemented a home telehealth unit with peripheral self-monitoring devices for multiple chronic conditions in frail older adults. The home care unit collected data from the peripheral monitoring devices and transmitted it to a secure server via telephone wires or the internet. Qualitative data at 1 year suggested that the majority of the patients were highly satisfied with the system. They found it easy-to-use and useful, and it provided patients with a sense of security (Liddy et al., 2009).

The literature shows good acceptance of telehealth systems in rural and remote communities in Ontario. To our knowledge there have not been any studies using Blackberry™ smart phones combined with Bluetooth-enabled self-monitoring devices in a rural adult population with metabolic syndrome.

2.7 Summary

Metabolic syndrome increases the risk of a host of cardiovascular events and complications. Rural patients are at increased risk of metabolic syndrome and reduced access to health resources. Evidence shows that regular exercise improves cardiovascular risk factors. Home self-monitoring and cell-phone technology have the potential to enhance patient adherence and support during an exercise intervention. Improved compliance to the intervention and physiological feedback may improve patient outcomes. The Transtheoretical Model provides a theoretical basis for the STEP™ test exercise prescription which has been effective in increasing physical activity and aerobic fitness in a metabolic syndrome population. The Diabetes and Technology for Increased Activity (DaTA) study is a multi-faceted exercise intervention targeting metabolic syndrome patients in rural Canada. This 2-month pilot project is the first study integrating the STEP™ test exercise prescription with self-monitoring devices, Blackberry™ smart phones, and Bluetooth technology. This is also the first study to apply such an approach to a physical activity intervention in a rural metabolic syndrome population.

CHAPTER THREE – METHODOLOGY

3.1 Study design

We conducted a pre-post pilot study to evaluate the feasibility and effectiveness of using Blackberry™ and Bluetooth self-monitoring technologies during a stage-matched STEP™ test exercise prescription in rural patients with metabolic syndrome. Feasibility was assessed as adherence to the self-monitoring protocols and participant perception of the technology in terms of comfort, ease of use, perception, and burden. Effectiveness of the intervention was assessed in terms of stage of change for physical activity and improvements in physical activity, fitness, and cardiovascular risk factors.

Participants came to the Gateway Rural Health Research Institute for clinic visits at baseline, 1 month, and 2 months (study end). At each clinic visit blood samples were collected for measurement of blood lipids, HbA1c, and C-reactive protein. A complete physical examination that included measurements of weight, height, and waist circumference was completed. Participants completed the Stages of Change for Physical Activity Questionnaire (Marcus, Selby, Niaura, & Rossi, 1992) at each visit and the DaTA Study Technology Experience Survey at visit 2 and visit 3. The STEP™ test was completed at each visit followed by goal setting and a stage-matched exercise prescription. Participants received a stage-matched activity booklet addressing self-efficacy, decisional balance, and stage-appropriate processes of change.

At baseline participants were given several self-monitoring devices: a Blackberry™ smart phone, a Bluetooth-enabled glucometer and automated home blood pressure monitor, as well as a pedometer and blood glucose test strips. Training was provided on all devices at this visit. Self-monitored glucose measurements were to be submitted twice daily: once before breakfast and again before going to bed. Pedometer data was entered manually at the end of each day. Home blood pressure readings were to be collected 3 times/week as follows: Sunday, Tuesday, and Thursday. The Stages of Change for Physical Activity Questionnaire was sent to the participants' Blackberrys™ every week. Blood glucose measurements from the glucometer and blood pressure measurements from the home blood pressure monitor were wirelessly transferred to the patient's Blackberry™. Pedometer data was entered manually. All patient data was then submitted in real time from the Blackberry™ Smart phones to a secure, encrypted database supplied by HealthAnywhere™ and managed by Sykes Canada.

3.2 Study population

3.2.1 Inclusion and exclusion criteria

Participants (n=25) included 18 females and 6 males living in rural communities surrounding Seaforth, Ontario. They were between the ages of 28 and 72 years old and had two or more symptoms of metabolic syndrome. This included high risk patients with elevated blood glucose, high blood pressure, elevated cholesterol and/or triglycerides, low HDL cholesterol, high waist circumference, or obesity.

Participants were excluded from the study if they had uncontrolled or severe hypertension (systolic $\geq$ 180mmHg or diastolic $\geq$ 110mmHg), type 1 diabetes, a history of cardiovascular disease or angina, symptomatic congestive heart failure, unstable pulmonary disease, or second to third degree heart block. Patients on medications known to affect heart rate or other medications that might cause a co-intervention effect were also excluded. Additionally those who had started or changed dose of a lipid-lowering agent within the last 3 months were not included. Individuals with pacemakers, unstable metabolic disease (e.g. thyroid disease), or orthopaedic or rheumatologic problems that could impair exercise ability were not included. Lastly, patients with a history of problems with drugs or alcohol, and those with emotional, cognitive, or psychiatric problems were also excluded.

3.2.2 Recruitment

Patients were recruited using an advertisement in the local newspaper in Seaforth, Ontario, Canada. From there word-of-mouth was highly effective in recruiting patients for the study.

3.3 Study intervention

All clinic visits took place at the Gateway Rural Health Research Institute in Seaforth, Ontario, Canada. Stage-matched STEP™ test exercise prescription was performed by a certified Kinesiologist. Stage of change was assessed using the Stage of Change for Physical Activity Questionnaire (Marcus, Selby, Niaura, & Rossi, 1992). Participants' current cardiorespiratory fitness level was assessed using the self-paced submaximal aerobic fitness STEP™ test (Petrella, Koval, Cunningham, & Paterson, 2001). The STEP™ test is a timed self-paced stepping test that involves stepping up and down two 20 cm tall steps at a normal pace. Participants' predicted maximal aerobic capacity is calculated using the equation: $VO_2max = (((1511/time) \times (weight/heart\ rate)) \times 0.124) - (age \times 0.032) - (sex \times 0.633) + 3.9$, where heart rate is in seconds, weight is in kilograms, and female = 2, male = 1. Normative data is then used to place participants in a fitness category (low, fair, Average, good, or high). Fitness level, stage of change for physical activity, and exercise counseling are then used to prescribe appropriate exercise to the individual.

During counseling participants were asked questions about their activity preferences and current activities to come up with an appropriate exercise prescription tailored to their unique fitness level, abilities, and needs. Exercise prescription followed the ACSM guidelines (American College of Sports Medicine, 2000). The FITT principles of frequency, intensity, type, and time were used to specify the amount and type of exercise to be done each week. An exercise heart rate of 70-85% of age-predicted maximal heart rate was also given to the patient. Patients set physical activity goals including a pedometer goal for the next 4 weeks using the SMART principles of goal-setting (Specific, Measurable, Attainable, Realistic, and Timely). An ultimate goal of 10,000 steps/day was recommended to the patients (Tudor-Locke & Bassett, 2004). It was also advised that patients should see what their regular steps/day were and then strive to improve by 1000 steps/day which represents a more attainable goal for some individuals. Participants also received a booklet of activities to work on at home that corresponded to their stage of change.

Counselling was individualized for each participant according to their stage of change and their fitness level in order to provide the best intervention for each person. For example, for a participant in the contemplation stage for physical activity with a fitness rating of "Fair", counselling focused on processes of change such as consciousness raising, self reevaluation, and self-liberation. Examples of consciousness raising include increasing the participant's awareness of the benefits (pros) of becoming physically active, recognition of perceived barriers and potential solutions to overcome them, and recognition of current behavioural patterns. Self-reevaluation involves thinking about how being physically active might improve your life and how continuing to be inactive may be detrimental. Lastly, self-liberation involves making a commitment to change one's behaviour. This often occurs after a person has decided that the pros of changing outweigh the cons and marks the transition from the contemplation stage to the preparation stage. Importantly, individuals in different stages of change for physical activity received a stage-appropriate intervention, focusing on the processes of change appropriate for them.

For the technology portion of the intervention each patient received a DaTA kit containing several technological devices: a Blackberry™ Smart phone with a 2 month data plan, a pedometer, a Bluetooth-enabled glucometer, and a home blood pressure monitor. Blood glucose test strips, instructions, and a handout on troubleshooting were also provided. Participants received training and instruction on each of the devices and when to measure each variable. They were also provided with contact information in case they had concerns or problems before their next clinic visit.

3.4 Outcome measures

3.4.1 Adherence

Adherence was measured as the average percentage of readings actually received out of the total possible number of readings expected from each participant. Participants received an automatic reminder on their Blackberry™ smart phone every time a reading was scheduled to be taken. Blood glucose was measured twice each day: once while fasted before breakfast and once before bed. Blood glucose measurements were taken using a Bluetooth-enabled One Touch glucometer and corresponding test strips (Lifescan One Touch Ultra2 and Polymap wireless adaptor PWR-08-03). Data from the glucometers was automatically transferred to the participant's Blackberry™ Smart phone via Bluetooth connection and then sent to the secure HealthAnywhere™ database. Blood pressure and resting heart rate was taken 3 times per week: Sunday, Tuesday, and Thursday. Patients were instructed to sit down in a quiet place where they could rest their left arm at chest level, put the blood pressure cuff on, and sit quietly for 3-5 minutes before taking their reading. Measurements were taken using a home blood pressure monitor (A & D Medical #UA-767PBT). Data were sent via Bluetooth technology from the monitor to the Blackberry™ cell phone and sent to the HealthAnywhere™ database in real-time. Daily physical activity was measured as steps/day using a pedometer (Omeron # HJ-150). Patients received an automated reminder from their Blackberry™ at the end of the day instructing them to manually enter their steps for the day. Bluetooth-enabled pedometers were unavailable at the time of the study. Weight was also entered manually by the patients once a week.

3.4.2 DaTA Study Technology Experience Data

Participants' perceptions of the technology were assessed using the DaTA Study Technology Experience Survey. Participants were asked to complete the survey at visit 2 and visit 3 to the research clinic. The survey consisted of 28 questions and assessed previous technology experience, comfort level, ease of use, perception, and burden of using the technology.

3.4.3 Effectiveness

The primary outcome of effectiveness of the intervention was stage of change for physical activity. Secondary outcomes of effectiveness included physical activity, fitness, and cardiovascular risk factors. Stage of change was measured using the self-reported Stage of Change for Physical Activity Questionnaire on visit 1 versus visits 2 and 3 as part of the STEP™ test protocol. Stage of change was also measured weekly on the participants' Blackberry™ smart phone to provide feedback to the participants about their progress. Changes in physical activity were quantified as mean steps/day during week 1 compared to weeks 4 and 8 of the intervention. Changes in fitness were measured as predicted VO_{2max} using the STEP™ test protocol on visit 1 compared to visits 2 and 3. Changes in cardiovascular risk factors included comparisons of the following variables at visit 1, visit 2, and visit 3: serum triglycerides, HDL-cholesterol, LDL-cholesterol, total cholesterol, weight, waist circumference, BMI, systolic and diastolic blood pressure, and C-reactive protein.

3.5 Data Management and statistical analysis

3.5.1 Data management

Despite the fact that this was a small pilot study, the amount of data collected was very large. All self-monitoring outcome data was encrypted and automatically transferred from patient Blackberrys™ to a HealthAnywhere™ database using Secure Socket Layer protocols and signed certificates. Data was transferred exclusively over secured links and messages did not contain any personal identification information. HealthAnywhere™ is an Ontario-based company designed for secure handling, transmission, and storage of confidential patient information. HealthAnywhere™ provides a web-based interface that services queries and operations that result in the addition of new patient records or adds to existing records. Messages transmitted between the HealthAnywhere™ server and participants' Blackberrys™ follow the guidelines for Health Level Seven (HL7) domain Common Message Element Types (CMETs). "Level Seven" refers to the applications level of the International Standards Organization (ISO) model of communications for Open Systems Interconnection. This is the level that interfaces directly to and performs application services (hl7.org, 2010). HealthAnywhere™ uses the HL7 domain to transform input from the Blackberry™ Smart phones into electronic patient health records on the secure HealthAnywhere™ database. The company complies with the Health Insurance Portability and Accountability Act which protects personal health information. Personal patient information is guaranteed to be secure and is not transmitted with the data captured from self-monitoring devices. Patients provided consent to transmit their Secure Socket Layer (SSL) encrypted data to HealthAnywhere™ firewall-protected server. Server access is restricted to authorized personnel at the hosting center. Only authorized logins are permitted using Secure Shell (SSH) encrypted tunnel with a valid username and password.

HealthAnywhere™ provides secure database access to health care professionals with a valid user ID and password. Access and use is restricted to authorized personnel who must be authenticated via Java-based authentication libraries. The health care professional portal allows clinical administrators to manage patient information and regulate clinician and patient accounts within their clinician team. Clinicians are only able to view patient information for the patients belonging to their specific database, protecting patient confidentiality.

Clinic data were collected on the case report form for each patient and securely stored in binders at the Gateway Rural Health Research Institute in Seaforth, Ontario, Canada.

3.5.2 Statistical analysis

A one-way repeated measures ANOVA was conducted to compare clinical outcomes at baseline, 1 month, and 2 month visits, and for self-monitoring data at weeks 1, 4, and 8. Post-hoc analysis using a Bonferroni correction was performed to assess differences between groups when the ANOVA showed statistically significant differences between the groups. A paired t-test was used to compare results of the DaTA Study Technology Experience Survey at 1 month and 2 months of study intervention. Statistical significance was set at $p < 0.05$ and all analyses were performed using SPSS. Adherence to self-monitoring protocols was calculated by manually picking out missed data points from the uploaded data file. Self-monitoring data that was entered between the hours of midnight and 5am was considered as data from the previous calendar day. Missing data were handled using the last outcome carried forward approach.

3.6 Ethics Approval

The study was approved by the Health Sciences Research Ethics Board of the University of Western Ontario and by the Clinical Research Impact Committee at Parkwood Hospital, London, Ontario.

CHAPTER FOUR – RESULTS

4.1 Study population and demographics

A total of 25 adults between the ages of 28-72 (mean age 57 ± 9) were recruited for the study. One patient withdrew from the study after 1 week due to an unrelated medical problem. All remaining participants completed the study. Participant baseline characteristics are presented in Table 3. At baseline, participants fulfilled the criteria for metabolic syndrome. Additionally, 25% of the participants were type 2 diabetics.

4.2 Feasibility

4.2.1 Adherence

Adherence to self-monitoring protocols was high.

Table 4

Participant Adherence to Self-monitoring Protocols during the 2 Month DaTA Study

Self-monitoring Variable	Adherence (%)
Pedometer (daily)	97.7
Blood Glucose (am)	95.3
Blood Glucose (pm)	94.6
Weight (weekly)	98.4
Blood Pressure (3x/week)	97.4

Notes: Values represent percentage of required readings submitted. Superfluous data points submitted by participants were not included in the analysis of adherence to the self-monitoring protocol. Participants that completed fewer or more than 8 weeks of the intervention were assessed using the total number of data points expected for the entire duration of their enrolment.

4.2.2 DaTA Study Technology Experience Survey

Results of the DaTA Study Technology Experience Survey showed no significant changes from Visit 2 to Visit 3. Table 5 provides a summary of the survey data. Scores on the DaTA Study Technology Experience Survey indicate that patients had infrequently used monitoring devices prior to the study. Comfort level of using the devices was high, with the mean values for each devices ranging between 3 ("agree") and 4 ("strongly agree"). Participants found the Blackberry™ display screen easy to read, and study instructions easy to understand. Overall, participant acceptability of the technology was high and perceived burden was low. Most patients reported that it took < 20 min to perform the self-monitoring each day. There were no significant differences between responses at V2 and V3.

Table 5

Responses from the DaTA Technology Experience Survey at 1 month and 2 months

Question	V2	V3
1. Currently use a Personal computer (%)	87.5	87.5
2. Currently use Internet (%)	70.8	79.2
3. Currently use Cell phone (%)	50	58.3
4. Currently use a PDA (%)	20.8	16.7
5. Currently use an Mp3 Player (%)	4.2	4.2
6. Currently use a Game system (%)	4.2	0
7. Currently watch Television (%)	58.3	66.7
8. Currently listen to the Radio (%)	75	75
9. How often have you previously used a PDA, Blackberry™ or similar device?	1.33 ± 0.87	1.46 ± 1.06
10. How often have you previously used a blood pressure cuff at home?	2.29 ± 1.33	2.25 ± 1.29
11. How often have you previously used a blood glucose monitor at home?	1.83 ± 1.34	1.88 ± 1.33
12. How often have you previously used a pedometer (step counter) at home?	1.70 ± 0.95	1.54 ± 0.93
13. I am comfortable using a Blackberry™ to complete the study.	3.75 ± 0.44	3.58 ± 0.78
14. I am comfortable using a blood glucose monitor to complete the study.	3.96 ± 0.20	3.79 ± 0.66
15. I am comfortable using a blood pressure monitor to complete the study.	3.83 ± 0.48	3.67 ± 0.87

16. I am comfortable using a pedometer to complete the study.	4.00 ± 0	3.83 ± 0.64
17. I am comfortable using a heart rate monitor to complete the study.	3.83 ± 0.38	3.75 ± 0.68
18. The display screen on the Blackberry™ was easy to read.	3.79 ± 0.41	3.63 ± 0.65
19. The instructions were easy to understand.	3.71 ± 0.55	3.50 ± 0.66
20. The devices did not cause me any physical discomfort.	3.54 ± 0.72	3.83 ± 0.38
21. The self-monitoring events were easily scheduled into my daily activities.	3.54 ± 0.66	3.54 ± 0.59
22. When I had technical problems with the devices, the problem was resolved within 24h.	3.60 ± 0.50	3.75 ± 0.44
23. Participation in this self-monitoring program gave me a sense of security.	3.43 ± 0.51	3.58 ± 0.50
24. Use of the self-monitoring technology helped me adopt new practices that improved my well being.	3.42 ± 0.72	3.83 ± 0.38
25. Managing the technology used in the DaTA study took too much time in my day.	1.38 ± 0.58	1.25 ± 0.44
26. Managing the technology used in the DaTA study interfered with other activities of daily living.	1.46 ± 0.59	1.33 ± 0.48
27. How much time did using the DaTA study technologies require per day?	1.00 ± 0	1.08 ± 0.28

Notes: The first 8 items were yes/no questions; they are expressed as the percentage of responders who checked "yes". All other values are means ± standard deviation. Questions 9-12 were measured on a 4-point scale from 1 to 4 with: 1 = never, 2 = rarely, 3 = sometimes, and 4 = frequently. Items 13-26 were measured on a 4-point scale from 1 to 4 with: 1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree. Question 27 was measured as follows: 1 = <20 min, 2 = 20-40min, 3 = 40-60min, and 4 = >60min.

<u>4.3 Effectiveness</u>

4.3.1 Stage of Change

A Chi Square non-parametric test was performed to assess differences in stage of change at V1, V2, and V3 (Table 6). Mean stage of change increased from 3.8 ± 1.1 to 4.6 ± 0.5

from baseline to V3. This result was statistically significant (p=0.001) and represents an overall shift from the Preparation stage to the Action stage of the Transtheoretical Model in the study participants (*Figure 2*).

Table 6

Frequency of stages of change at V1, V2, and V3 in the DaTA study

Stage	V1	V2	V3
Contemplation (2)	3	0	0
Preparation (3)	8	3	1
Action (4)	3	3	3
Maintenance (5)	10	18	20

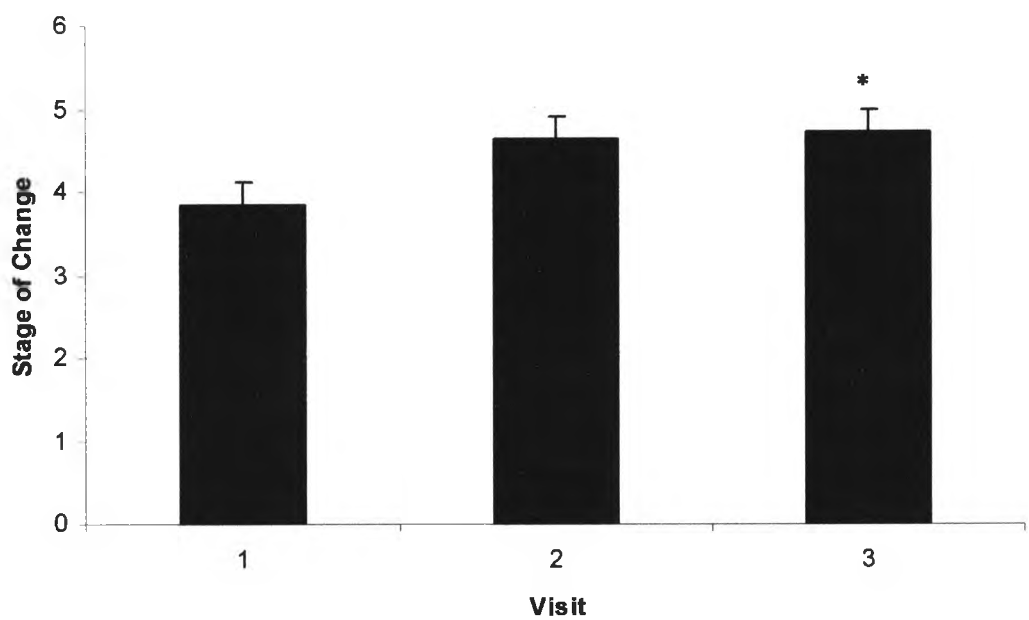

Figure 2. Mean Stage of Change at baseline, 1 month (Visit 2), and 2 months (Visit 3) of the DaTA Study. Stage of change was measured using the Stage of Change for Physical Activity Questionnaire. Scoring is as

follows: 1 = pre-contemplation, 2 = contemplation, 3 = preparation, 4 = action, and 5 = maintenance. All values are means ± standard error. *Indicates significant change from baseline value.

4.3.2 Physical Activity

Mean steps per day increased significantly from week 1 to week 8. As seen in *Figure 3*, participants walked an average of 5579 ± 1964 steps/day during the first week of the study and this increased to 7818 ± 4235 steps/day during week 8 of the study ($p=0.02$). Mean steps/day during week 1, week 4, and week 8 were calculated to reduce the effects of day-to-day variation in physical activity and provide a more reliable estimate of average steps/day.

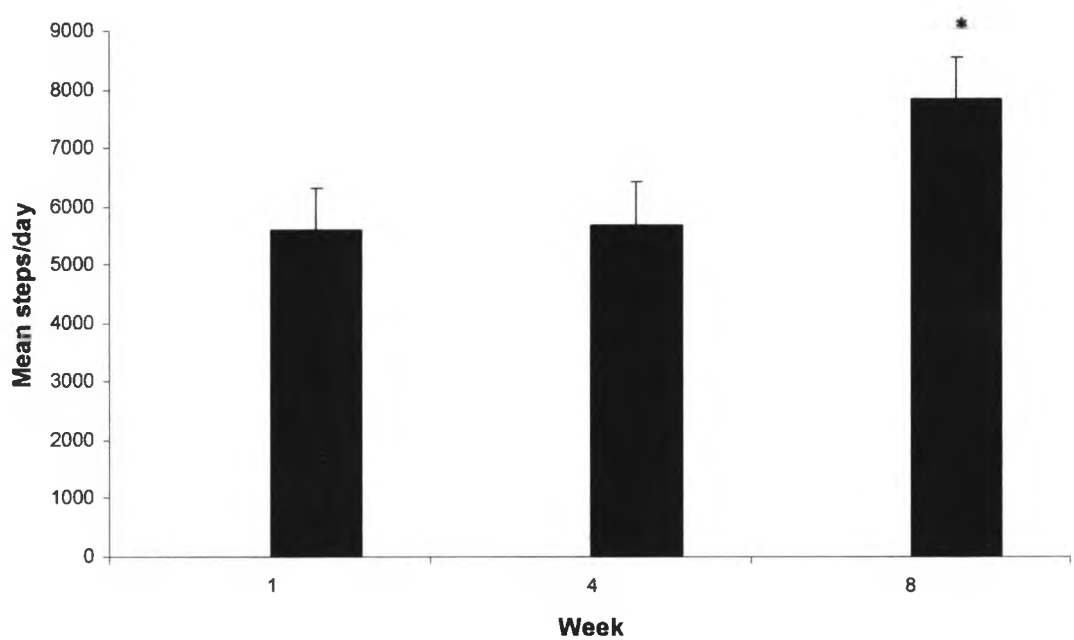

Figure 3. Steps/day during Week 1, 4, and 8 of Participation in the DaTA Study. Mean steps/day for each participant were calculated using pedometer data submitted during the first 7 days, days 22-29 (week 4), and days 49-56 (week 8) following study commencement. Values are group means ± standard error. *Indicates a statistically significant difference compared to week 1.

4.3.3 Cardiorespiratory Fitness

All patients were able to complete the STEP™ test. Time to complete the STEP™ test decreased significantly from baseline to V3 (2 months). The mean difference in time to completion between baseline and V3 was 14.3 s (95% CI, 6.7-21.9, $p<0.05$) (*Figure 4*). Predicted VO_{2max} increased significantly from 29.5 ± 5.6 $mL/kg/min^{-1}$ at baseline to 34.6 ± 7.0 $mL/kg/min^{-1}$ at 2 months, ($p<0.05$). Mean difference between baseline and 2 month predicted VO_{2max} was 5.1 $mL/kg/min^{-1}$ (95% CI, 2.5 ± 7.7 $mL/kg/min^{-1}$, $p<0.05$). This can be seen in *Figure 5*. Rating of perceived exertion (RPE) on the modified Borg scale did not change. No significant changes in resting or post-exercise heart rate were found (*Figure 6*).

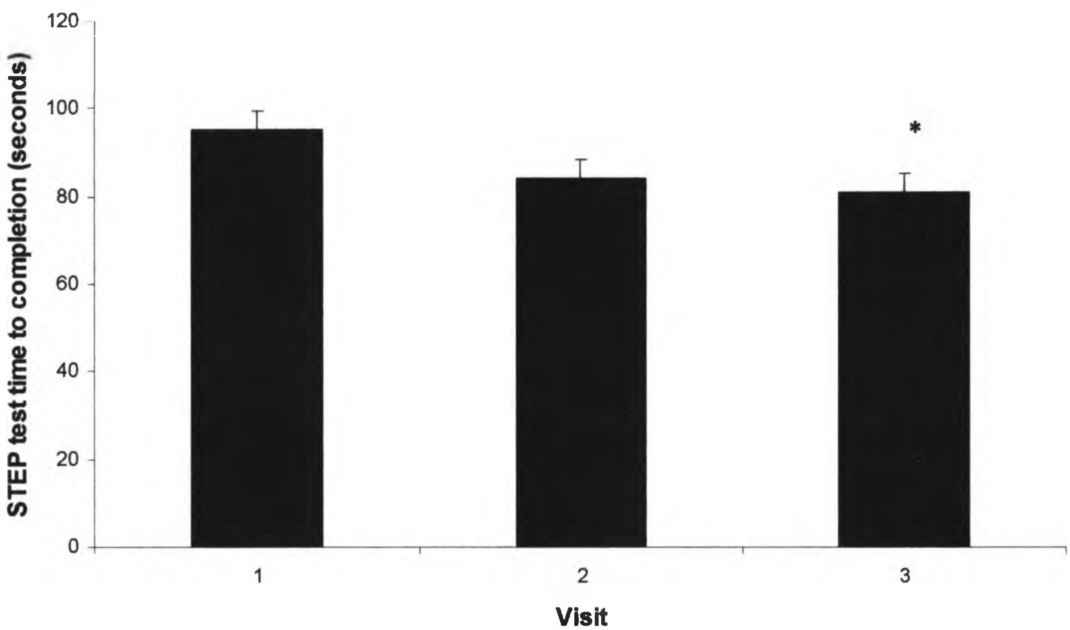

Figure 4. STEP™ Test Time-to-completion at Baseline, 1 month, and 2 months. Values are means ± standard error. *Indicates a statistically significant difference compared to baseline.

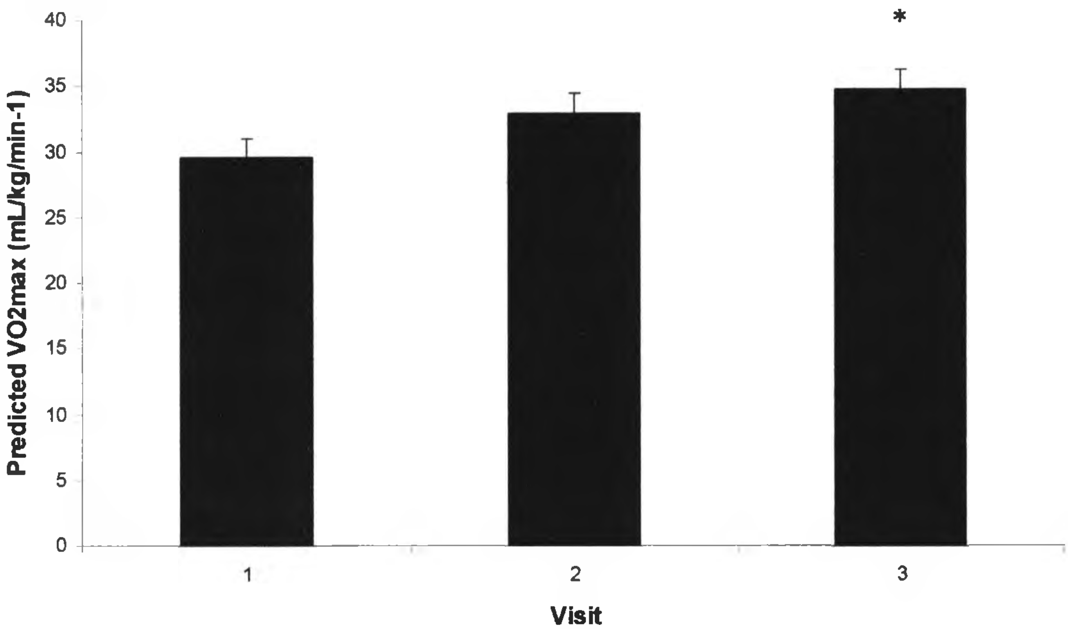

Figure 5. STEP™ Test Predicted VO_{2max} at Baseline, 1 month, and 2 months. Values are means ± standard error. *Indicates a significant difference compared to baseline.

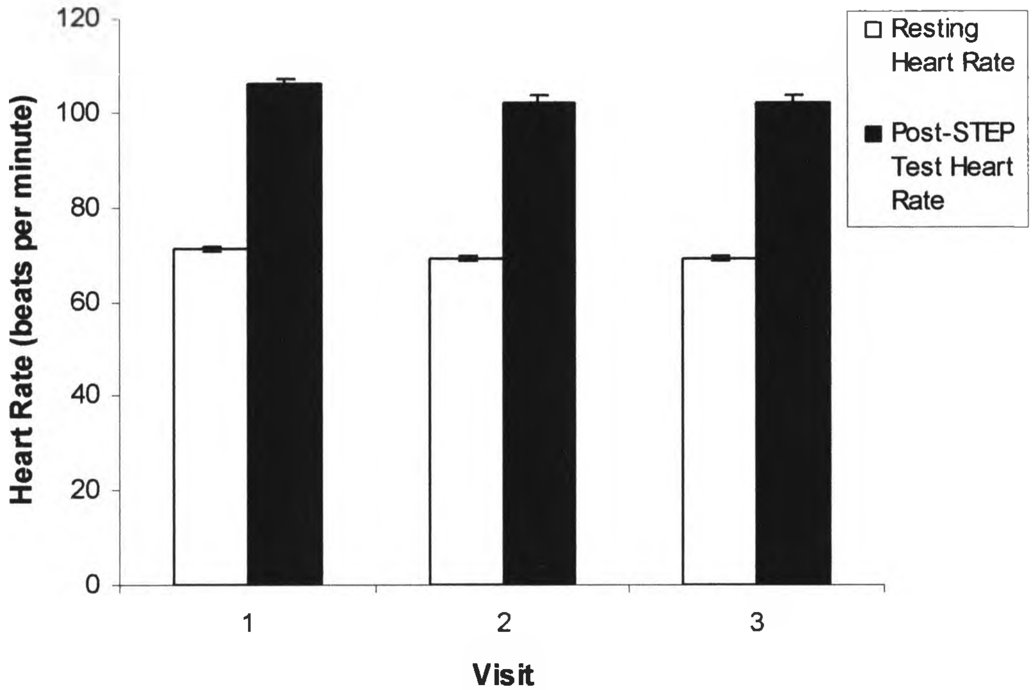

Figure 6. STEP^{TM} Test Resting and Post-exercise Heart Rate at Baseline, 1 month, and 2 months. All values are means ± standard error.

4.3.4 Cardiovascular risk factors

4.3.4.1 Self-monitoring

Daily morning glucose dropped significantly after the first week due to the discovery of type 2 diabetes in one patient. Daily evening blood glucose did not change significantly during the 2 month intervention. A slight negative linear relationship between morning and evening blood glucose was evident (*Figure 7*).

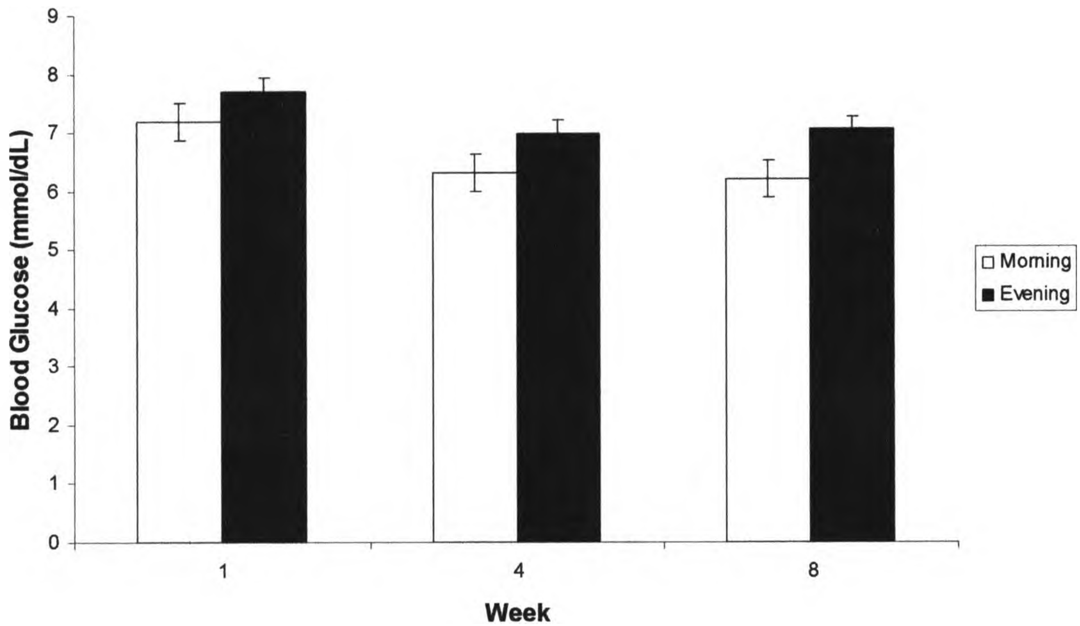

Figure 7. Mean Blood Glucose Levels collected via Home Self-monitoring Technologies at 1 week, 4 weeks, and 8 weeks.

Figure 8 shows body weight over the 8 week study. No significant changes in body weight occurred.

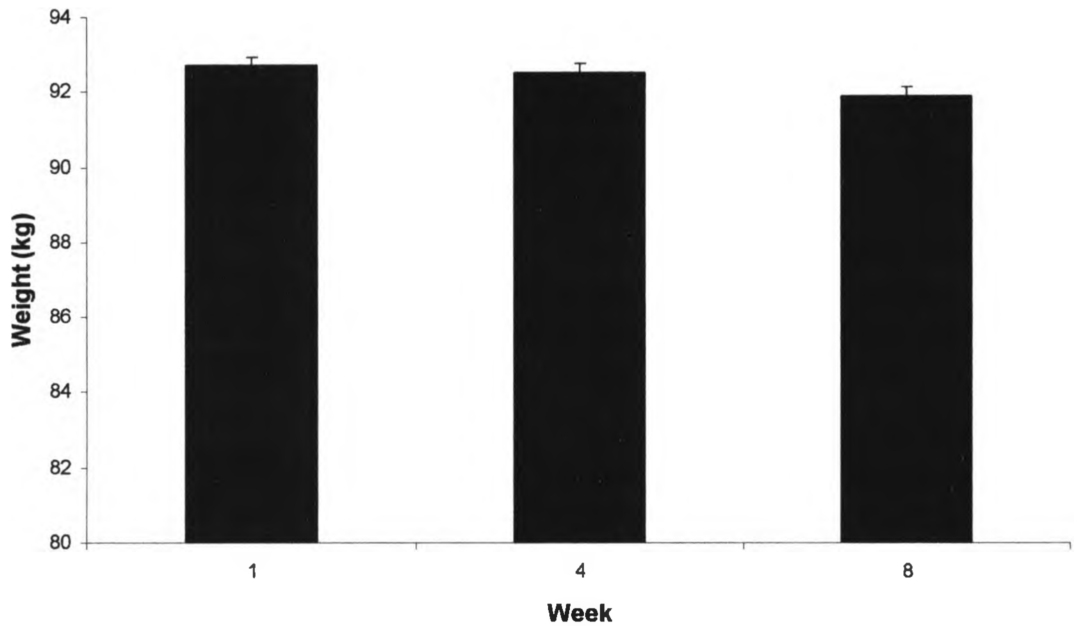

Figure 8. Self-monitored Body Weight of Participants at Week 1, 4 and 8. Weight was measured in kilograms using the same scale of each participant's choosing. Values were entered manually into the Blackberry™ by the participants and transferred in real time to the Health Anywhere e-health database. Values are means ± standard error over 7 days.

Self-monitored resting diastolic and systolic blood pressure did not change significantly during the study. Results are displayed below in *Figure 9*.

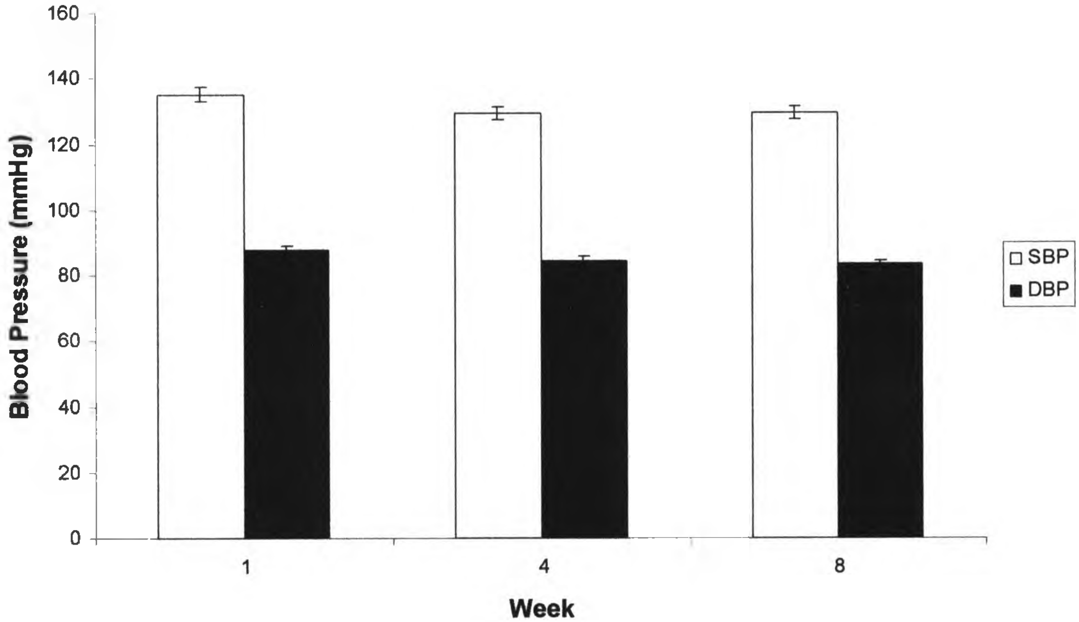

Figure 9. Self-monitored Systolic (SBP) and Diastolic (DBP) Blood Pressure at 1 week, 4 weeks, and 8 weeks of the DaTA study. Systolic and diastolic blood pressure is measured in mmHg. Each week represents the group mean over 3 readings/week.

4.3.4.2 Clinic data

Table 7 summarizes the changes in clinical outcomes during the DaTA study. BMI decreased significantly from 33.1 ± 4.4 kg/m ^{2} at baseline to 32.8 ± 4.3 kg/m^2 at 1 month. These changes from baseline remained significant at 2 months. No other significant changes occurred. Diastolic blood pressure decreased from 84 ± 9 mmHg at baseline to 80 ± 13 mmHg, ($p = 0.06$). Blood glucose was 6.0 ± 2.4 mmol/L at baseline and 5.63 ± 1.4 mmol/L at 2 months, ($p = 0.522$). Total cholesterol was 5.48 ± 1.3 mmol/L at baseline and 5.19 ± 1.1 mmol/L at 2 months, ($p = 0.069$). No change was seen in waist circumference, HbA1c levels, triglycerides, HDL cholesterol, LDL cholesterol, total cholesterol, or systolic blood pressure.

Table 7

Cardiovascular Risk Factors at baseline, 1 month, and 2 months of the DaTA Study

Outcome	V1		V2		V3		F-Value	P-value
	Mean	SD	Mean	SD	Mean	SD		
Glucose (mmol/L)	6.0	2.4	5.6	1.4	5.6	1.4	0.66	0.522
HbA1c (%)	6.0	1.0	6.0	1.0	6.0	1.0	1.495	0.235
HDL Cholesterol (mmol/L)	1.3	0.3	1.4	0.4	1.4	0.4	0.161	0.852
LDL Cholesterol (mmol/L)	3.4	1.2	3.2	1.1	3.1	1.1	0.228	0.797
HDL Cholesterol (mmol/L)	1.3	0.3	1.3	0.41	1.4	0.4	0.226	0.796
Total Serum Cholesterol (mmol/L)	5.5	1.3	5.3	1.1	5.2	1.1	2.827	0.069
Triglycerides (mmol/L)	1.8	1.3	1.7	1.3	1.7	1.2	1.887	0.163
C-Reactive Protein (mmol/L)	4.0	2.3	4.0	2.3	3.5	2.2	1.243	0.298
Waist circumference (cm)	112	9	108	11	108	12	1.578	0.222
BMI (kg/m^2)	33.1	4.4	*32.8	4.3	*32.7	4.3	4.568	0.016
Systolic BP (mmHg)	141	9	137	13	139	19	0.405	0.669
Diastolic BP (mmHg)	84	9	79	10	80	13	2.993	0.06

Note: F-values and p-values were calculated using a repeated measures ANOVA. *Indicates that there was a significant difference from baseline.

4.4 Adverse events

One participant withdrew from the study within the first week due to an unrelated medical problem. There were no other adverse events to report.

CHAPTER FIVE – DISCUSSION

5.1 Overall findings

The results of the DaTA pilot study show that the technology is a feasible and effective intervention delivery method in a population of high risk rural adults. The use of this technological approach encourages adherence to self-monitoring of blood pressure, heart rate, blood glucose, and daily physical activity. The results support our original hypotheses that compliance to self-monitoring protocols would be at least 50% and that participants would have positive views of the technology, finding it comfortable, easy-to-use, and of low burden.

Stage of change changed significantly with an overall shift from the preparatory stage to the action stage. This indicates an increased readiness to be physically active and shows that the technology-based intervention was effective in motivating participants to increase their physical activity. Participants increased their physical activity and improved predicted VO_{2max} Contrary to expectations, few significant changes in cardiovascular risk factors occurred from baseline to 2 months. BMI decreased significantly while no other changes were seen. This may reflect the low number of participants in enrolled in the study (low power) or the short duration of the study intervention.

The DaTA study showed that self-monitoring devices paired with data management and adherence reminders via Blackberry™ cell phone are acceptable and effective in assisting participant adherence to a stage-matched STEP™ test exercise prescription intervention over 2 months. The intervention helped participants increase their physical activity behaviour and improve their aerobic fitness. A longer study is planned to assess the long-term effectiveness of this intervention in reducing cardiovascular risk factors in a rural population with metabolic syndrome.

5.2 Feasibility

Our initial hypothesis that patient adherence would be 50% was supported by the study results. Adherence to self-monitoring protocols was high (>94% for all readings), reflecting the strong acceptability of the technology to the participants. Results from the DaTA Study Technology Experience Survey show that the majority of study participants agreed or strongly agreed that the technology devices were easy to use and understand, and that they were comfortable using them for the study (Table 6).

Our study findings also show that middle-aged adults in rural Ontario are open to learning how to use new technology. The mean age of our sample was 57 and only 50% of the participants were currently using a cell phone. Results from the DaTA Technology Experience Survey show that participants had infrequently used the self-monitoring devices or a Blackberry™ in the past but were comfortable using the pedometer, blood pressure monitor, glucometer, and Blackberry™ during the study.

Most participants found that the self-monitoring did not require more than 20 min/day and was easy to schedule into their daily activities (Table 6). Participants perceived the technology as being helpful in helping them adopt new habits that were beneficial to their wellbeing. The majority of participants also disagreed or strongly disagreed that using the technology took up too much time or interfered with other activities.

Previous studies using at-home monitoring devices support these findings. In 2008, Liddy and colleagues performed a pilot study in a semi-rural area of North-eastern Ontario investigating the feasibility and acceptance of a telehealth monitoring system for patients with multiple chronic diseases. In this study a variety of self-monitoring devices including a blood pressure monitor and a glucometer connected to a telehealth unit that collected and transferred patient data to a secure web-based server using patients' telephone lines. Patient information could then be accessed and reviewed by the patients' health care providers. This is similar to the technological design of the DaTA study except we employ the use of a Blackberry™ smart phone instead of a telehealth unit. Since cell phones are now popular devices with a variety of functions, it is thought that this may be more practical and cost-effective for patients than a single-use device. Results of this study showed that patients were "overwhelmingly positive toward home health monitoring" and that the majority of patients found the technology useful and easy to use (Liddy et al., 2008).

Overall, the findings of the study show that pairing the STEP™ test exercise intervention with self-monitoring and Blackberry™ technologies was feasible. High adherence to the self-monitoring protocols suggests high participant motivation to improve physical activity and health. This is supported by the significant improvements made in physical activity and cardiorespiratory fitness over the 2 month study. Furthermore, the technology was acceptable and easy-to-use for participants. Positive perceptions and high adherence to self-monitoring protocols shows that the intervention is feasible and provides support for initiating a larger randomized controlled trial.

5.3 Effectiveness

5.3.1 Stages of Change

Stage of change for physical activity represents an individual's psychological readiness to change their physical activity behaviour (Prochaska & DiClemente, 1982). Mean baseline stage of change was high for the participants in our study, likely reflecting the fact that volunteers are generally highly motivated. The baseline mean score of 3.8 falls between the preparation stage (3) and the action stage (4). At baseline ten participants had already been exercising for at least 3 months (maintenance stage), while eight were in the preparation stage, three were contemplators, and three were in the action stage. On average, participants increased their stage of change by almost 1 stage by the end of the study. This was a major finding ($p=0.001$), demonstrating that the intervention was effective in increasing participants' readiness for physical activity. Participants who were in the maintenance stage at baseline remained there (experienced no change), while those in the contemplation, preparation, and action stages progressed at least one stage, if not two. The results also showed that nobody relapsed into a previous stage of change. According to Prochaska & DiClemente (1982) relapse-prevention is a key focus of the maintenance stage, though it can happen (and often does) at any stage. Most participants (23/24) were in the action or maintenance stage at the end of two months, indicating that the intervention was successful in improving participants' readiness to be physically active. This is supported by the participants' significant increase in steps/day and cardiorespiratory fitness during the study.

Previous physical activity trials have showed good short-term results regarding stage of change progression in sedentary adults. Calfas et al. (1996) showed that a Transtheoretical Model approach to increasing physical activity can be effective in facilitating increased physical activity readiness. In their 6-week randomized trial, 52% of participants in the intervention group became regularly physically active by the end of the trial compared to 12% of the control group. A review by Hutchinson et al. (2008) also reports positive changes in stage of change in 18/24 short-term (< 6 months) physical activity interventions based on the Transtheoretical Model.

To date few studies have applied a Transtheoretical Model-based exercise intervention to a metabolic syndrome population. The SNAC study used the STEP™ test exercise prescription in a sample of high-risk adults with pre-diabetes and/or pre-hypertension but did not report data for stage of change as it was not the primary focus of the study (Aizawa, Shoemaker, Overend, & Petrella, 2009). The current study shows that an intervention pairing the STEP™ test exercise prescription with self-monitoring and Blackberry™ smart phone technology results in stage progression in metabolic syndrome adults in rural Ontario. The results also suggest that the intervention may be helpful in preventing stage regression (relapse).

5.3.2 Physical activity & cardiorespiratory fitness

Physical activity increased significantly from baseline to V3 (2 months) in the current study. Mean steps per day increased from 5579 ± 1964 steps/day during the first week of the study to 7818 ± 4235 steps/day during week 8, ($p = 0.02$). These findings align with those from other studies. In a systematic review of the literature pedometer use was found to increase physical activity by an average of 2491 steps/day compared to non-pedometer control (Bravata et al., 2007).

Although significant increases in steps/day were achieved by the participants in this study they were well under the 10,000 steps/day recommended (Government of Ontario, 2010; Tudor-Locke & Bassett, 2004). 10,000 steps is equivalent to about 8 km (5 miles) and public health documents insist that it should be easy to achieve with an active lifestyle (City of Ottawa, 2004; Government of Ontario, 2010). A systematic review by Bravata et al. highlights the effectiveness of pedometers and having a goal of 10,000 step/day for helping people increase their daily physical activity despite the reality that few people actually achieve that many steps (Bravata et al., 2007). Furthermore changes in steps/day in the current study had a moderate effect size, despite not meeting the goal of 10,000 steps/day.

The DaTA intervention improved participants' pedometer-measured physical activity. Mean daily steps increased by 41% from week 1 to week 8. This is well above the mean 26% increase in steps/day found by Bravata et al. (2007). Some participants in our study did achieve the goal of 10,000 steps/day though this may not reflect the typical response of metabolic syndrome patients since volunteers are generally more motivated than non-volunteers. Nevertheless, the intervention successfully helped patients increase their walking behaviour in the short-term.

Individual exercise prescriptions were tailored to include other activities along with walking. Several participants took part in other physical activities that are not conducive to pedometer monitoring. Activities such as cycling, swimming, resistance training, and even vibration machine exercise were performed by some of our participants. Walking was the most accessible and preferred mode of physical activity and the pedometer captured that data in a cost-effective and reliable manner. In retrospect, an exercise journal or accelerometer may have been an effective way to capture non-walking data which may have had an impact on study outcomes.

Although pedometer data is self-reported, the literature supports the use of pedometers as a reliable and valid measurement of physical activity (Tudor-Locke, Williams, Reis, & Pluto, 2002). Improvements in predicted VO_{2max} also suggest that physical activity increased over the course of the study. For example, aerobic fitness increased significantly despite an insignificant change in weight. This is also important because VO_{2max} can be improved simply by losing weight. Since our participants did not lose a significant amount of weight, the improvements in fitness are not caused by weight loss but rather by increased physical activity.

Aerobic fitness is an important indicator of cardiovascular health and has been associated with decreased risk of cardiovascular disease and all-cause mortality (Myers, Prakash, & Froelicher, 2002). Metabolic syndrome is associated with poor aerobic fitness (Brien, Janssen, & Katzmarzyk, 2007). Aerobic fitness declines with age, largely due to disuse. Generally as people age they become more sedentary, but there is also physiological decline of the cardiovascular system with age regardless of physical activity levels (Hawkins & Wiswell, 2003). Endurance capacity generally decreases by 10% per decade after age 30 (Heath, Hagberg, Ehsani, & Holloszy, 1981). There is a great deal of variability in aerobic capacity due to genetics, physical activity levels, gender, age, and lean body mass. Typically untrained sedentary adults have a maximal aerobic capacity ranging anywhere from 15.0 $mL/kg/min^{-1}$ to 32 $mL/kg/min^{-1}$ (Huang, Gibson, Tran, & Osness, 2005). This agrees with the findings from our study which show baseline mean VO_{2max} values of 29.5 ± 5.6 $mL/kg/min^{-1}$ for middle-aged adults. Aerobic training can improve aerobic fitness regardless of age. Improving aerobic fitness can reduce age-associated declines in aerobic capacity. Studies show that aging athletes lose aerobic fitness at a rate of 5-7% per decade as opposed to10% experienced by the average healthy individual (Hawkins & Wiswell, 2003). The training effect of exercise slows the structural and functional changes of the heart and vascular system that occur with aging, and help preserve cardiac output. Work capacity declines with age because of reduced oxygen delivery to the tissues and working muscles (Astrand, 1956).

The STEP™ test results show that aerobic fitness improved significantly over the 2 month study. As shown in *Figure 7* predicted VO_{2max} increased 17.2% over 2 months, from 29.5 ± 5.6 mL/kg/min^{-1} at baseline to 34.6 ± 7.0 mL/kg/min^{-1} at 2 months, ($p<0.05$). Short term exercise training studies have been shown to improve aerobic fitness in at-risk populations. Baynard at al. (2009) studied obese individuals performing 10 days of treadmill walking at 70-75% of maximal aerobic capacity. This brief intervention resulted in a modest increase of 5% in mean aerobic capacity from 24.6 ± 1.2 mL/kg/min^{-1} to 26.0 ± 1.1 mL/kg/min^{-1}.

Improvements in aerobic fitness happen as a result of physiological adaptations to exercise. Short-term exercise training improves insulin sensitivity and glucose metabolism. Toledo et al., 2008 demonstrated that an improvement in VO_{2max} by 12 ± 1.6% ($\rho < 0.05$) over 4 months of moderate-intensity exercise in type 2 diabetics was accompanied by significant increases in mitochondrial density within skeletal muscle (67 ± 17%, $p < 0.01$). Insulin sensitivity also improved by 59 ± 21% ($p <0.05$). A recent study showed that 7 days of 60 min of aerobic exercise training at ~70% of VO_{2max} produces significant improvements in insulin action with no change in fasting glucose levels in obese type 2 diabetics (Kirwan, Soloman, Wojita, Staten, & Holloszy, 2009). This suggests that although we did not see significant changes in blood glucose levels during our intervention, it is possible that improvements in insulin action occurred but were not measured.

Measurement error may also be a factor. One limitation of the procedure is that VO_{2max} is dependent on exercise heart rate which is calculated from a 15 s palpation of the radial artery rather than by an electronic heart rate monitor. There may also be a learning effect resulting from repeated performance of the test.

5.3.3 Cardiovascular risk factors

A significant reduction in BMI occurred despite no changes in self-monitored weight and waist circumference. No other changes in cardiovascular risk factors occurred from baseline to 2 months. This is contrary to our initial hypothesis that there would be moderate changes in cardiovascular risk factors from participation in the DaTA study.

5.3.3.1 Abdominal Adiposity

Waist circumference is an acceptable surrogate marker of abdominal obesity and one criterion for diagnosing metabolic syndrome. While waist circumference decreased from 112 ± 9 cm to 108 ± 8 cm this was not a statistically significant finding. These values are still above the cut-off values for metabolic syndrome. A waist circumference ≥ 102 cm in women or ≥ 88 cm in men is considered high-risk (National Heart, Lung, and Blood Institute, 2001). To lose another 6-20 cm around the midsection, participants might need more than two months of physically active living. There is a dose-response relationship between aerobic exercise volume and decreases in abdominal fat (Ohkawara, Tanaka, Miyachi, Ishikawa-Takata, & Tabata, 2007). This suggests that the participants in our study may have seen better results with further increases in physical activity volume.

Although visceral fat is a risk factor for cardiovascular disease, there is evidence that improving fitness levels improves cardiovascular risk factors such as triglycerides, HDL cholesterol, and blood pressure, irrespective of visceral fat levels. Lee and colleagues (2008) performed a systematic review, finding that for a given waist circumference individuals with high aerobic fitness had lower triglycerides and higher HDL cholesterol levels than those with lower aerobic fitness, ($p < 0.05$). Blood pressure was also higher in less fit individuals than more fit individuals with the same amount of abdominal fat.

Self-monitored weight did not change significantly during the 2 month intervention. This may be due to the short duration of the intervention. In a meta-analysis of physical activity interventions using pedometers (with no concurrent dietary interventions), there was a strong linear relationship between intervention duration and weight change. Meta-regression results showed a mean weight loss of 0.05 kg/week, or 1 lb every 10 weeks (Richardson et al., 2008). While this is a very slow rate of weight loss, there are still health benefits to be gained from increased physical activity regardless of changes in weight.

Physiological benefits can be seen from moderate-intensity training interventions lasting only 7 days in length (Kirwan, Soloman, Wojita, Staten, & Holloszy, 2009). Though patients with high waist circumference are still at cardiovascular risk, being physically active improves their overall risk profile. Individuals are not always aware of the physiological improvements in their bodies and may get frustrated from lack of visible progress. While weight loss and changes in body composition are important, they take longer to accomplish. Thus physiological monitoring, fitness testing, and progressive exercise prescription with goal setting can be helpful catalysts of long-term behaviour changes with respect to physical activity since they emphasize positive changes other than weight loss.

5.4 Limitations

The primary limitation of the current study is the lack of statistical power due to a small sample size. However since the overall purpose of this pilot study was to assess the feasibility and effectiveness of the intervention for a larger randomized controlled trial, sufficient power was not expected. Another limitation to the study is the short duration. It was proposed that 2 months was the minimum amount of time necessary to see changes in physical activity, aerobic fitness, and several cardiovascular risk factors. Evidence suggests that short-term exercise interventions have higher adherence rates than long-term interventions so potentially the results of the current study are not applicable to a longer-term intervention. Another limitation is that the DaTA Study Technology Experience Survey was created for this study and lacks the methodological rigour of a validated questionnaire. However, as a feasibility study, we were interested in collecting feedback. Physical activity other than pedometer-measured walking was not collected during the study. Although steps/day increased significantly it is likely that additional exercise contributed to the increases in aerobic fitness that resulted from the 2 month intervention. In the future capturing total energy expenditure and physical activity should be considered. Having another device such as an accelerometer would be beneficial in capturing non-walking/running type activity in future studies. Although our patients met inclusion criteria the low subject number and self-selection of volunteers may have resulted in a sample characteristic of the lower end of the high cardiovascular risk continuum. That being said, this is a pilot study to assess the feasibility and effectiveness of this intervention in preparation for a larger trial. No participant was in the pre-contemplation stage at baseline. Unfortunately it is extremely difficult to recruit people who are not even considering becoming physically active for a physical activity intervention. This reduces the generalizability of the study, as it is unknown if those in the pre-contemplation stage will respond the same way to the intervention as those who are contemplating or preparing for changes in their physical activity behaviour.

5.5 Conclusions

The results of this two month pilot study suggest that this novel intervention is a feasible and effective method of implementing a physical activity intervention. As we hypothesized, participant adherence to the intervention was >50% at ~94% for all self-monitoring readings. Participants were comfortable using the technology, found it easy-to-use, and did not perceive the technology to be a substantial burden in their everyday lives. Participants had positive perceptions of the technology and found it helpful. The DaTA study was effective in increasing physical activity readiness (stage of change) and behaviour (steps/day), as well as physical fitness (VO_{2max}). We had hypothesized that participants would experience moderate improvements in cardiovascular risk factors over the two month intervention but the only significant change was a decrease in BMI. Overall the results of this study show that this physical activity intervention combining the STEP™ test exercise prescription with self-monitoring and Blackberry™ smart phone technology is feasible and effective in increasing physical activity, stage of change, and aerobic fitness.

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APPENDIX 1 – 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 **Revision Number:** 3
Review Date: October 08, 2009 **Review Level:** Expedited
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: October 20, 2009 **Expiry Date:** December 31, 2012
Documents Reviewed and Approved: Revised co-investigators (add S. Shapiro & remove E. Russel-Minda). Revised Letters of Information and Consent Forms - Gateway dated 09Oct2009; UWO dated 09Oct2009.
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 revision(s) or amendment(s) 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

Ethics Officer to Contact for Further Information			
☐ Janice Sutherland (jsutherl@uwo.ca)	☑ Elizabeth Wambolt (ewambolt@uwo.ca)	☐ Grace Kelly (grace.kelly@uwo.ca)	☐ Denise Grafton (dgrafton@uwo.ca)

This is an official document. Please retain the original in your files.

cc: ORE File
LHRI

APPENDIX II

STEP TEST EXERCISE PRESCRIPTION

Patient ID

Patient Initials

Date of Visit (day/month/year)

STEP TEST

Blood Pressure (BP-TRU™). Take 3 [setting is for every 2 minutes] TIME COLLECTED: ________________

A) ___ / ___ mmHg

B) ___ / ___ mmHg

C) ___ / ___ mmHg

Average of B and C is: ___ / ___ mmHg

Resting Heart Rate: ___ bpm

Able to complete?

☐ 1 = Yes ☐ 2 = No

If NO, number of steps completed: ___

Reasons for stopping

☐ 1 = Fatigue

☐ 2 = Musculoskeletal (i.e. joint pain)

☐ 3 = Cardiovascular (i.e. chest pain)

☐ 4 = Muscle Pain

☐ 5 = Other, specify: ________________________________

Heart Rate (after test): ___ bpm

Time: ___ : ___ . ___ min sec 1/100 ___ . ___ sec

Borg Score: ___ . ___

$VO_{2\ max}$ ___ . ___ ml/kg/min

Training Heart Rate ___ bpm

Training Heart Rate ___ beats in 10 sec

APPENDIX III

DATA TECHNOLOGY EXPERIENCE SURVEY

Patient Initials: ☐☐☐ Visit: ☐ Date: ☐ ☐ ☐

First Mid. Last S= screen, V1 or V2 DD/MM/YY

Technology Usage: What technology do you currently use? Please check boxes all that apply:

☐ 1. Personal computer
☐ 2. Internet
☐ 3. Cell phone
☐ 4. PDA
☐ 5. Mp3 player
☐ 6. Game system
☐ 7. Television
☐ 8. Radio

Previous experience: Please check the box that applies and rate your previous experience with the DaTA study technology. On a scale of 1 to 4 with: **1 = never, 2 = rarely, 3 = sometimes, 4 = frequently.**

9. Have you previously used a PDA, Blackberry or similar device?
1. ☐ 2. ☐ 3. ☐ 4. ☐

10. Have you previously used a blood pressure cuff to monitor your own blood pressure?

1. ☐ 2. ☐ 3. ☐ 4. ☐

11. Have you previously used a blood glucose monitor to measure your own blood glucose level?

1. ☐ 2. ☐ 3. ☐ 4. ☐

12. Have you previously used a pedometer (step counter) to monitor your own daily activity level?
1. ☐ 2. ☐ 3. ☐ 4. ☐

Comfort level: Please check the box that applies and rate the following statements by adding the number to the box. On a scale of 1 to 4 where: **1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree.**

13. I am comfortable using a Blackberry to complete the study.
1. ☐ 2. ☐ 3. ☐ 4. ☐

14. I am comfortable using a blood glucose monitor to complete the study.
1. ☐ 2. ☐ 3. ☐ 4. ☐

15. I am comfortable using a blood pressure monitor to complete the study.
1. ☐ 2. ☐ 3. ☐ 4. ☐

16. I am comfortable using a pedometer to complete the study.
1. ☐ 2. ☐ 3. ☐ 4. ☐

Patient Initials: ☐☐☐ Visit: ☐ Date: ☐ ☐ ☐

First Mid. Last S= screen, V1 or V2 DD/MM/YY

17. I am comfortable using a heart rate monitor to complete the study.
1. ☐ 2. ☐ 3. ☐ 4. ☐

Ease of use: Please check the box that applies and rate the following statements. On a scale of 1 to 4 where **1 = strongly disagree, 2 = disagree, 3 = agree, and 4 =strongly agree**.

18. The display screen on the Blackberry was easy to read.
1. ☐ 2. ☐ 3. ☐ 4. ☐

19. The instructions were easy to understand.
1. ☐ 2. ☐ 3. ☐ 4. ☐

20. The use of the devices in the DaTA study did not cause me any physical discomfort. (Provide list below).
1. ☐ 2. ☐ 3. ☐ 4. ☐

21. The self-monitoring events were easily scheduled into my daily activities.
1. ☐ 2. ☐ 3. ☐ 4. ☐

22. When I had technical problems with the devices, the problem was resolved within 24 hours.
1. ☐ 2. ☐ 3. ☐ 4. ☐

Perception: Please check the box that applies and rate the following statements. On a scale of 1 to 4 where: **1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree.**

23. Participation in this self-monitoring program gave me a sense of security.
1. ☐ 2. ☐ 3. ☐ 4. ☐

24. Use of the self-monitoring technology helped me adopt new practices that improved my well being.
1. ☐ 2. ☐ 3. ☐ 4. ☐

Burden: Please check the box that applies and rate the following statements. On a scale from 1 to 4 where: **1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree.**

25. Managing the technology used in the DaTA study took too much time in my day.
1. ☐ 2. ☐ 3. ☐ 4. ☐

26. Managing the technology used in the DaTA study interfered with other activities of daily living.
1. ☐ 2. ☐ 3. ☐ 4. ☐

27. How much time did using the DaTA study technologies require per day? Please **check one** box.
1. < 20 mins. ☐ 2. 20 to 40 mins. ☐ 3. 40 to 60 mins. ☐ 4. > 60 mins. ☐

28. Provide a list of discomfort (s):____

____

APPENDIX IV

STAGES OF CHANGE FOR

PHYSICAL ACTIVITY QUESTIONNAIRE

Patient ID | Patient Initials | Date of Visit (day/month/year)

STAGE OF CHANGE: Physical Activity

Physical activity or exercise = walking briskly, heavy housework, jogging, digging in the garden, climbing stairs or any other physical activity where the exertion is similar to these

Regular physical activity or exercise = accumulating 30 minutes or more in the above activities most (5 or more) days of the week

For example, you could:

1. Take *ONE* 30-minute walk OR
2. Take *THREE* 10-minute walks OR
3. Do 10 minutes of heavy housework + 10 minutes of walking + 10 minutes of digging in the garden.

For **each** question below please mark YES or NO

1 I am not currently ***physically active*** and no plans to change ☐ 1 = Yes ☐ 2 = No
(ie. no walking briskly, heavy housework, jogging, digging in the garden, climbing stairs or any other physical activity where the exertion is similar to these).
`If yes, Give PA Step 1`

2 I intend to become ***more physically active*** in the next month ☐ 1 = Yes ☐ 2 = No
`If yes, Give PA Step 2`

3 I intend to become ***more physically active*** in the next week ☐ 1 = Yes ☐ 2 = No
`If yes, Give PA Step 3`

4 I have been ***regularly physically active*** but only less than 3 months ☐ 1 = Yes ☐ 2 = No
`If yes, Give PA Step 4`

5 I have been ***regularly physically active*** in the past for a period at least 3 months ☐ 1 = Yes ☐ 2 = No
`If yes, Give PA Step 5`

Physical Activity Stage: ______________________

To be completed by study office ONLY

`Physical Activity Stage: 1 2 3 4 5`

APPENDIX V

ACTIVITIES FOR THOSE WHO ARE

THINKING ABOUT BECOMING PHYSICALLY ACTIVE

STEP TWO:

ACTIVITIES FOR PEOPLE WHO ARE THINKING ABOUT BECOMING PHYSICALLY ACTIVE

ACTIVITIES FOR PEOPLE WHO ARE THINKING ABOUT BECOMING PHYSICALLY ACTIVE

Your doctor has asked you to complete this set of activities based on the questionnaire you completed regarding your intention to become physically active OR you have completed the STEP ONE activities and are ready to move on to STEP TWO.

We know that people go through different 'STEPS' in the process of changing their behaviour. While many people think about becoming physically active, it is not always easy to get started, so we suggest that you do it in STEPS.

There are FIVE STEPS in the behaviour change process and you are currently at STEP TWO for Physical Activity. The following activities are designed to make it easier for you to move from STEP TWO to STEP THREE.

At the moment some or all of the following probably apply to you:

- You are considering trying to become physically active
- You are not sure you can do it but are slowly feeling more confident
- Temptations not to become physically active are still high
- The 'Pros' of changing are about the same as the 'Cons'

Complete the Activities on the following pages and if you are ready to move on to STEP THREE then ask the Study Coordinator or your doctor for the STEP THREE activities at your next visit.

ACTIVITY ONE

PROS AND CONS OF BECOMING PHYSICALLY ACTIVE

This activity will help you decide whether or not you want to start becoming physically active.

On the next page, write down your reasons for (PROS) choosing to become physically active and reasons against (CONS) choosing to become physically active.

Spend some time thinking about these reasons and try to be as honest as possible with yourself. Think about things like:

- Your energy level
- Your health
- Your social life]
- Your time commitments
- What your friends and family think
- How you feel about yourself
- How you cope with stress and frustration
- What problems/barriers you may have to overcome
- Your weight

Once you have written down your Pros and Cons give them a 'weighting; between 1 and 3 where:

1 = not very important to me
2 = important to me
3 = very important to me

At the end of the activity think about whether or not you want to become physically active.

PROS for becoming Physically Active	Weighting

CONS for becoming Physically Active	Weighting

If you have more Pros and/or you have weighted most of them 2 or 3 then you are ready to move on to STEP 3. If you more Cons and/or you have weighted most of them 2 or 3 go on to the next activity.

ACTIVITY TWO

PHYSICAL ACTIVITY BARRIERS

What keeps you from being more physically active? Maybe you're too busy at work. Or perhaps your kids or other loved ones need you and they come first.

Brainstorm all the reasons you are not more physically active. Nothin is too big or too small. Just write down all the things that come to mind. Some examples are given below to help you get started.

My Barriers to Becoming Physically Active

Not enough time
Too out of shape
Don't like to sweat

Now, review your physical activity barriers. Which one is the biggest obstacle? List it on the first line below. Prioritize the rest of your barriers from biggest to smallest.

1. ______________________ 6. ______________________

2. ______________________ 7. ______________________

3. ______________________ 8. ______________________

4. ______________________ 9. ______________________

5. ______________________ 10. ______________________

Pick one barrier and come up with ways to get around it. Be creative! List your ideas below.

____

____

Now pick one of your ideas and try it for a week. If after a week it didn't work, try another strategy. Keep trying new ideas until you find some that help you overcome your barriers.

ACTIVITY THREE

PERSONAL TIME STUDY

Do you really know how you spend your time every day? This page will help you find where you might be able to fit in more physical activity. Write in all your activities for each four hour block of time in the chart below. In each four hour block, add up the minutes you were active and put this in the "active" column. Subtract you 'active' minutes from 240 minutes (the total amount of minutes in four hours) to get your 'inactive' time. At the end of the day, total the number of minutes that you were active and inactive. Keep this sheet with you, in an easy to use place, and write things down as you go. Record your activities for one week day and one weekend day to see how differently you spend your time. Use a separate sheet for each day.

WEEK DAY

Time Slot	Tasks/Activities	Active (minutes)	Inactive (minutes)
Example: 12:01-4pm	Washed dishes, 10 min; watched TV, 90 min; walked to mall, 15 min; met friend for coffee, 35 min; walked home, 15 min; napped, 60 min; talked on phone, 15 min	30 min	210 min
Midnight – 4am			
4:01am-8am			
8:01am-noon			
12:01pm-4pm			
4:01pm-8pm			
8:01pm – midnight			
	TOTAL TIME		

WEEKEND DAY

Time Slot	Tasks/Activities	Active (minutes)	Inactive (minutes)
Example: 12:01-4pm	Washed dishes, 10 min; watched TV, 90 min; walked to mall, 15 min; met friend for coffee, 35 min; walked home, 15 min; napped, 60 min; talked on phone, 15 min	30 min	210 min
Midnight – 4am			
4:01am-8am			
8:01am-noon			
12:01pm-4pm			
4:01pm-8pm			
8:01pm – midnight			
	TOTAL TIME		

Now go back and find time within your day when you can fit in more physical activity. Write the times below:

____

____

____

ACTIVITY FOUR

KEEPING TRACK OF THOUGHTS

Use this worksheet to record the number of times you think about doing some physical activity. Simply place a check mark in a box in the right hand column in Section 1. If you actually carried out your thoughts and did some physical activity, place a checkmark in the right column in Section 2.

Keeping track of your thoughts can help you start moving toward a physically active lifestyle.

Section 1

You thought about doing some	□□□□□□□□□□□□□
physical activity	□□□□□□□□□□□□□
	□□□□□□□□□□□□□
	□□□□□□□□□□□□□
	□□□□□□□□□□□□□
	□□□□□□□□□□□□□

Section 2

You actually did some	□□□□□□□□□□□□□
physical activity	□□□□□□□□□□□□□
	□□□□□□□□□□□□□
	□□□□□□□□□□□□□
	□□□□□□□□□□□□□
	□□□□□□□□□□□□□

How do you feel?

Are you ready to start making changes to your physical activity habits? If so, ask your doctor or the study coordinator for the STEP 3 activities at your next visit. If not, discuss the above activities with your doctor at your next visit.