Take 2 steps and call me in the morning: Prescribing physical activity through primary care

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Abstract

Objectives: Physical activity guidelines for older adults target high-intensity activities (i.e. increasing exercise), with less attention on low-intensity activities (i.e. reducing/interrupting sedentary behaviours) to improve health. Mobile health (mHealth) holds promise for engaging patients in self-management of chronic diseases. The purpose of this research was to prescribe physical activity of various intensities (i.e. sedentary through exercise) in primary care paired with mHealth for self-management.

Methods: Sixty older adults (55-75yr) were randomly assigned to four groups: one control, and three receiving mHealth kits plus prescription for a specific intensity of physical activity (exercise, sedentary or both). Clinical measures (anthropometrics, blood pressure, aerobic fitness, glucose, lipid profile) were conducted in a primary care office. During the 12-week intervention, participants remotely submitted measures for physical activity, blood pressure, body weight, and blood glucose. Six-months post-intervention, aerobic fitness was measured and interviews were conducted.

Results: Clinical and remotely submitted measures improved (p<0.05). Groups with a prescription including exercise demonstrated greater changes in home-monitored blood glucose than sedentary prescription alone (p<0.05). Following the intervention, gains made in aerobic fitness were maintained to six-months (p<0.05). Emergent themes from interviews included: mHealth for patient education and for creating social communities around health behaviours, as well as participant views of physical activity as medicine.

Conclusions: To our knowledge, this is the first report of sedentary behaviour prescription in primary care. Findings support the ongoing practice of measuring lifestyle-related risk factors (e.g. body weight status, blood pressure, cardiorespiratory fitness) in the primary care setting for chronic disease management and prevention. Novel results demonstrate clinical benefits of prescribing changes to sedentary behaviours among older men and women. Additionally, results support the physiological and behavioural benefits of pairing physical activity prescription with mHealth for self-monitoring among at-risk older adults.
Keywords

physical activity, sedentary behaviour, mHealth, older adult, mixed method, personalized medicine
Co-Authorship Statement

Melanie I. Stuckey participated in authorship for the articles included in chapter two ("Prescribing Physical Activity Through Primary Care: Does Activity Intensity Matter?") and chapter three ("Health Promotion Through Primary Care: Enhancing Self-Management with Activity Prescription and mHealth") by collaborating on study design, implementation, manuscript preparation and submission.

Robert J. Petrella participated in authorship for the articles included in chapter two ("Prescribing Physical Activity Through Primary Care: Does Activity Intensity Matter?"), chapter three ("Health Promotion Through Primary Care: Enhancing Self-Management with Activity Prescription and mHealth"), and chapter four ("Prescribing Physical Activity for Healthy Aging: Longitudinal Follow-Up and Mixed Method Analysis of a Primary Care Intervention") through approval of study design, implementation, data analysis, manuscript preparation and submission.
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Chapter 1

1 Introduction

Ontario’s older adults (>65 years) are living longer than previous generations, and generally with at least one chronic disease or condition.\(^1\) Older adults account for about 15% of the population of Ontario, and about half of health care spending.\(^1\) The Seniors Strategy for Ontario\(^1\) highlights the essential role of primary care in the management of complex and interrelated health and social issues for older adults.

Beyond provincial borders, global health systems are progressively being dominated by care for chronic conditions and non-communicable diseases. It is projected that in the coming decades deaths due to chronic conditions and non-communicable diseases like cardiovascular disease, cancer, and diabetes will account for nearly 60% of disease burden globally.\(^2\) Researchers and the medical community have long understood the importance of physical activity in promoting health.\(^3,4\) An active lifestyle is now understood to reduce both the morbidity and mortality of a wide range of chronic diseases, ranging from cancer (i.e. colon, breast) to cardiovascular disease, as well as protecting and promoting cognitive function.\(^5-7\) Insufficient levels of physical activity are responsible for six percent of global mortality, and are the fourth leading cause of death around the world.\(^8\)

1.1 Physical Activity

It is well established in the literature that physical activity is an important component of health and wellness, including primary and secondary prevention of chronic and non-communicable diseases. However, recent evidence indicates that 85% of Canadian adults are not meeting recommended guidelines for physical activity.\(^9,10\) Physically inactive lifestyles are the fourth leading cause of mortality, and contribute to over three million deaths globally each year.\(^11\) National Population Health Survey data from a representative
sample of Canadian older adults (aged >65 years) demonstrates an inverse relationship between physical activity participation and a number of chronic conditions, suggesting that older adults who are among the least physically active experience greater disease burden than their more active counterparts. Physical inactivity is a preventable risk factor for many lifestyle-related chronic conditions and diseases, and reducing physical inactivity represents a substantial opportunity for chronic disease prevention, health care cost savings, and improved quality of life. The World Health Organization’s guidelines for promoting physical activity among older adults reinforce the crucial role of regular engagement in physical activities for healthy and successful aging.

It is important to differentiate between physical activity, which is any bodily movement produced by skeletal muscles resulting in energy expenditure, and exercise, which is a subset of physical activity that is planned, structured, repetitive and for the purpose of improving or maintaining fitness. Despite their differences, and perhaps partially due to their overlapping constructs, the two terms are commonly, and incorrectly, used interchangeably in both the literature and clinical practice. For the purpose of this dissertation, physical activity will refer to the entire spectrum of daily activity behaviours.

**Figure 1.1 Continuum of Physical Activity Behaviours**

During waking hours, physical activities exist along a continuum which can be categorized by intensity and defined through metabolic equivalents (METs): ranging from low-intensity sedentary behaviours, such as sitting (i.e. <1.5 METs), through light physical activities, such as the incidental activities of daily living (i.e. 1.5-3.0 METs), to higher-intensity moderate- to vigorous-intensity physical activities (MVPA), such as
purposeful exercise (i.e. ≥3.0 METs) (Figure 1.1). Public health guidelines recommend 150 minutes of MVPA weekly, in bouts of a minimum of 10 minutes, in order to maintain good health. Meeting physical activity guidelines for MVPA can promote healthy body weight status and cardiometabolic markers such as blood pressure, triglycerides, low- and high-density lipoprotein cholesterol.

Due to the established health benefits of MVPA, these higher-intensity activities are typically targeted in physical activity interventions. However, Canadian adults spend three quarters of waking hours each day engaged in sedentary behaviours, while just three percent engaged in MVPA thus the proportion of time spent in sedentary behaviours dwarfs that spent in MVPA. While the health importance of MVPA is well established, recent evidence suggests that sedentary behaviour (e.g. activity done while sitting) also plays an important role in the development of chronic disease. Not surprisingly, recent studies have estimated that sedentary behaviour may reduce the life expectancy of Western nations by one to two years.

1.1.1 Sedentary Behaviour

Prolonged bouts of sedentary behaviours increase risk for lifestyle-related disease through adverse changes in cardiometabolic biomarkers (e.g. increased triglycerides, decreased high-density lipoprotein cholesterol), bone health (e.g. reduced bone mineral density), vascular health (e.g. peripheral vascular function, glucose tolerance), body weight status (e.g. obesity) and psychosocial health (e.g. quality of life, mental health, self-esteem). Importantly, these adverse outcomes are not offset by participation in MVPA, which is critical given that it is possible to accumulate high amounts of both sedentary behaviours and MVPA during a single day. Therefore, how we accumulate our physical activity throughout the day matters: interrupting sedentary time into smaller bouts is associated with better metabolic health.
Shifting behaviours from sedentary to light-intensity may reduce cardiometabolic risk,\textsuperscript{28,29} which has important implications for lifestyle interventions as this may be a more achievable behaviour to target than MVPA in part due to the substantial portion of daily living that Canadian adults spend in sedentary pursuits. It has been suggested that any brief and frequent muscular contraction throughout the day could be used to offset the molecular changes initiating metabolic disease caused by prolonged sedentary behaviours.\textsuperscript{21,32} Healy et al report that taking frequent (>600 breaks weekly), short (<5 minutes) breaks in sedentary time is associated with reduced markers of cardiometabolic risks, including waist circumference, body mass index, 2-hour plasma glucose and lipids.\textsuperscript{29} Dunstan et al have shown that simply standing up from a seated position every 20 minutes during the day can result in a reduction in markers of cardiometabolic risks in healthy adults.\textsuperscript{28}

Moreover, Katzmarzyk\textsuperscript{33} and van der Ploeg et al\textsuperscript{34} have reported decreased risk of all-cause mortality among individuals who spend more time standing than sitting. Specifically, van der Ploeg at al\textsuperscript{34} used Australian survey data to demonstrate that time spent standing has a beneficial effect on all-cause mortality, and that this is independent of sitting time, physical activity level and disease status. Similarly, Katzmarzyk\textsuperscript{33} used Canadian survey data to demonstrate a strong relationship between standing time and cumulative survival, indicating that among physically inactive adults greater time spent standing is associated with lower risk of mortality. Interestingly, this relationship was most apparent among the least active individuals, suggesting a dose-response relationship whereby individuals who spend the most amount of time sitting can have the greatest effect on mortality risk by standing more. Katzmarzyk equates this finding with the similar effect of exercise (MVPA) interventions, whereby improving the cardiorespiratory fitness among least fit individuals (e.g. improving from ‘poor’ to ‘fair’ rating) has the greatest effect on health status change.\textsuperscript{33}
However, to-date the relationship between time spent in sedentary behaviours and cardiometabolic health is observational, such that a cause and effect relationship remains to be established.\textsuperscript{35} Can we intervene to reduce sedentary time, and will this lead to improved health outcomes? Additionally, literature suggests that reducing sedentary time in addition to increasing MVPA may enhance the physiological benefits of modifying either behaviour independently.\textsuperscript{35} Yet there is a lack of evidence describing the clinical outcomes (i.e. effect on cardiometabolic markers) of intervening on both sedentary and exercise behaviours simultaneously.

### 1.1.2 Prescribing Physical Activity in Clinic

A written prescription holds symbolic meaning for patients, indicating that their health practitioner believes in the value of the behaviour for managing or promoting health.\textsuperscript{36} A health behaviour message (such as physical activity prescription) delivered by a healthcare provider may be an important stimulus for individual change.\textsuperscript{37} The Step Test and Exercise Prescription (STEP™) tool was designed to facilitate efficient, evidence-based physical fitness assessment and tailored exercise prescription in the primary care setting.\textsuperscript{38} Research employing STEP™ has demonstrated beneficial effects on aerobic fitness, exercise compliance, exercise self-efficacy, and cardiometabolic risk profile.\textsuperscript{39} Orrow et al\textsuperscript{40} identified STEP™ as a particularly effective tool for intervening on physical activity and fitness through primary care. Moreover, their systematic review and meta analysis of exercise (i.e. MVPA) prescription in primary care demonstrated that the practice improves both physical activity levels and cardiovascular health.\textsuperscript{40} However, 85\% of Canadian adults are not engaging in sufficient MVPA.\textsuperscript{17} This suggests that established approaches to exercise prescription may need to evolve to best meet the needs of patients and improve physical activity behaviours.

Sedentary behaviour and MVPA are distinct physical activity behaviours with distinct health outcomes.\textsuperscript{21-26} While the evidence base demonstrating efficacy of exercise
prescription is well established, literature reporting the clinical effect of prescribing changes to sedentary behaviours has yet to be established. Moreover, patients are less likely to receive sedentary behaviour counselling from their healthcare provider.\textsuperscript{41} Therefore, activity prescription targeting the low-intensity end of the physical activity continuum (namely, sedentary behaviours) is an emerging area of research.

1.2 mHealth

Mobile health (mHealth) is characterized by the use of mobile technologies in health care delivery. For example, the use of blood pressure monitors, glucometers, physical activity trackers (e.g. pedometers, accelerometers) and mobile communication devices (e.g. smartphones). mHealth technologies can promote patient engagement,\textsuperscript{42} which may be in part due to meaningful use and feedback for users. mHealth is a rapidly growing focus for chronic disease management and prevention,\textsuperscript{43} which is supported by the pervasive reach of these technologies across socioeconomic status and geographic region.\textsuperscript{44} mHealth facilitates access to individuals where they live, which could be leveraged to meet targets identified by the Senior Strategy for Ontario such as support for community and home care services.\textsuperscript{1} Ontario’s older adults, and their caregivers, seek information and services that facilitate opportunities to age-in-place and maintain independence.\textsuperscript{1} It is crucial that user-centered programs and services be developed and implemented to facilitate the adoption of healthy living behaviours now to promote healthy, independent aging.

Commonly, mHealth interventions are designed to increase health behaviours or improve disease management.\textsuperscript{45} Typically these interventions are conducted with individuals already experiencing symptoms of disease, such as diabetes, hypertension, and metabolic syndrome. It has been suggested that mHealth helps engage individuals in on-going self-management of prescribed physical activity behaviours for both disease management and prevention, in part through increased access to and perceived control over health services and knowledge.\textsuperscript{31,43,46–52} One of the key factors lending the potential of mHealth for
physical activity promotion is its ability to provide personalized and real-time feedback to users.\textsuperscript{45,53} This feature enables context-specific support for behaviour adoption, thereby enhancing learning and improving behavioural outcomes.\textsuperscript{53} While there is a substantial mismatch between the pace of technological advancement and scientific inquiry,\textsuperscript{45,53} the evidence for mHealth continues to emerge. However there is currently a gap in the literature describing the efficacy of mHealth for chronic disease prevention among apparently healthy older adults.

1.3 Research Plan

The literature for mHealth, exercise prescription, and physical activity behaviours demonstrates opportunities for advancement. Specifically, there is a lack of evidence reporting physical activity prescription of varying intensities (i.e. sedentary behaviour through MVPA) in the primary care setting as well as mHealth interventions among apparently healthy older adults. Previous research from our laboratory has implemented mHealth technologies paired with exercise prescription among adults with, or at risk for, metabolic syndrome in a rural setting.\textsuperscript{50,51,54-56} Building on this experience we aimed to conduct a physical activity prescription (both sedentary and MVPA) and mHealth intervention among apparently healthy, community-dwelling older men and women. Prior to this research there was a lack of evidence describing sedentary behaviour interventions through primary care as well as mHealth for prevention among apparently healthy older adults. We hypothesized that it would be feasible to conduct sedentary behaviour prescription (alone, or in conjunction with exercise) through the primary care setting, and that a group of healthy older adults would be willing to use mHealth to self-monitor for chronic disease prevention.

The overall aim of the present research was to address the previously identified gaps in mHealth and physical activity among a sample of older adults. This research was conducted in 2012. The intervention involved a convenience sample of 60 older adults
(55-75 years) who volunteered to participate. The total sample size was limited, pragmatically, due to the cost and availability of providing the mHealth technology kit to participants (described in chapter three). Data were collected in three phases: clinical testing, ongoing self-monitoring using mHealth, and post-intervention follow-up; and are presented through three papers. Results from the intervention are presented in chapters two through four: chapter two (Prescribing Physical Activity Through Primary Care) reports the clinical results; chapter three (mHealth and Self-Management) reports mHealth results; and chapter four (Longitudinal Follow-Up) reports post-intervention results with a focus on the participant experience.
1.4 References


15. CSEP. *Canadian physical activity guidelines for adults*. Ottawa: Canadian Society for Exercise Physiology; 2011.


Chapter 2

2 Prescribing Physical Activity Through Primary Care

A version of this chapter has previously been published:

2.1 Abstract

**Background**: Physical activity guidelines recommend engaging in moderate- and vigorous-intensity physical activity to elicit health benefits. Similarly, these higher intensity ranges for activity are typically targeted in healthy living interventions (i.e. exercise prescription). Comparatively less attention has been focused on changing lower intensity physical activity (i.e. sedentary activity) behaviours. The purpose of this study was to explore the effects of prescribing changes to physical activity of various intensities (i.e. sedentary through exercise) through the primary care setting.

**Methods**: Sixty older adults (aged 55 to 75 years; mean age 63 ± 5 years) volunteered to participate, and were randomly assigned to four groups: three receiving an activity prescription intervention targeting a specific intensity of physical activity (exercise, sedentary, or both), and one control group. During the 12-week intervention period participants followed personalized activity programs at home. Basic clinical measures (anthropometrics, blood pressure, aerobic fitness) and blood panel for assessing
cardiometabolic risk (glucose, lipid profile) were conducted at baseline (week 0) and follow-up (week 12) in a primary care office.

**Results:** There were no differences between groups at baseline ($p > 0.05$). The intervention changed clinical ($F_{(5,50)} = 20.458, p < 0.001, \eta^2 P = 0.672$) and blood panel measures ($F_{(5,50)} = 4.576, p = 0.002, \eta^2 P = 0.314$) of cardiometabolic health. Post hoc analyses indicted no differences between groups ($p > 0.05$).

**Conclusion:** Physical activity prescription of various intensities through the primary care setting improved cardiometabolic health status. To our knowledge, this is the first report of sedentary behaviour prescription (alone, or combined with exercise) in primary care. The findings support the ongoing practice of fitness assessment and physical activity prescription for chronic disease management and prevention.

**Keywords:** exercise prescription; sedentary prescription; primary care; chronic disease management; chronic disease prevention; Exercise Is Medicine
2.2 Introduction

North America is in the midst of a demographic shift toward an increasingly aged population. It is estimated that within 25 years, approximately one quarter of the population will be classified as older adults.\(^1\) Moreover, life expectancies in developed counties are increasing by two years every decade.\(^2\) Accompanying increased age is the increased prevalence of multiple chronic conditions.\(^3\) Chronic disease is more prevalent with advanced age; therefore, the demographic shift toward advanced age is of concern for the availability and sustainability of health care resources.\(^3,4\) In the years to come, it is projected that deaths due to chronic conditions and non-communicable diseases like cardiovascular disease, cancer, and diabetes will contribute to 70% of all deaths, which will account for nearly 60% of the disease burden globally.\(^5\) Novel interventions aimed at disease prevention are needed among the aging population.

It is well established in the literature that physical activity is an important component of health and wellness,\(^6\) including primary and secondary prevention of chronic and non-communicable diseases. Recent evidence indicates that 85% of Canadian adults and 97% of American adults are not meeting recommended guidelines for physical activity.\(^7,8\) Physically inactive lifestyles are the fourth leading cause of mortality, and contribute to >3 million deaths globally each year.\(^9\) Physical inactivity is a preventable risk factor for many lifestyle-related chronic conditions and diseases,\(^10\) and reducing physical inactivity represents a substantial opportunity for chronic disease prevention, health care cost savings, and improved quality of life.
Exercise Is Medicine® initiatives highlight the importance of prescribing activity through the primary care setting to manage health. A recent systematic review concluded that physical activity prescription in primary care significantly increases self-reported physical activity levels at 12 months, and has a positive, albeit non-significant, effect on cardiorespiratory fitness. The College of Family Physicians of Canada endorses the Step Test and Exercise Prescription (STEP™) tool as part of accredited continuing health education strategies for improving physical activity education among family physicians. Tools like STEP™ facilitate the measurement of aerobic fitness and prescription of physical activity by primary care physicians and allied health professionals in an office-based setting.

In addition to measuring exercise capacity and prescribing physical activity, mobile health technologies (mHealth) have demonstrated the potential for engaging individuals in ongoing self-management of activity behaviours and disease management. Moreover, among a sample of individuals with metabolic syndrome, it was suggested that mHealth tools improved awareness of lifestyle factors for overall health, which may affect clinical markers and risk factors for cardiovascular disease. Therefore, mHealth holds the potential for promoting health and preventing disease by addressing many of the costly and disabling factors that lead to chronic and non-communicable diseases, including access to care and knowledge about disease risk.
2.2.1 Physical Activity Intensity

Physical activity can occur across a spectrum of intensities, from lower intensity sedentary behaviours (such as reading and watching television) to higher intensity exercise behaviours (such as vigorous walking and playing sports). Currently, the best evidence suggests that adults and older adults should be accumulating 150 minutes of moderate- to high-intensity physical activity on a weekly basis, and that this activity should occur at a minimum of 10 minutes in any single bout.\textsuperscript{19,20} These higher intensity ranges for physical activity are typically targeted in healthy living interventions, as well as incorporated in established tools for exercise prescription through primary care settings. Comparatively little attention has been focused to date on changing lower intensity physical activity (i.e. sedentary) behaviours. Additionally, it has been suggested that individuals may compensate for engaging in a prescribed bout of exercise by reducing incidental (i.e. low-intensity) activities in other parts of their daily routine.\textsuperscript{21} That is, after participating in exercise, the individual may become less active for the remainder of the day—effectively increasing time spent engaged in sedentary pursuits.

There is a growing evidence base demonstrating that time spent being sedentary is a health risk, and a potentially important health behaviour to target through lifestyle interventions as the consequences of sedentary time are independent of the protective effects of higher intensity physical activity.\textsuperscript{22-28} Moreover, previous reports highlight the importance of interrupting prolonged periods of sedentary time to reduce cardiometabolic disease risk.\textsuperscript{29} It has been suggested that promoting reductions in sedentary time may be a more achievable behaviour to change through counselling in the primary care setting.
given that, compared with exercise behaviours, it requires smaller lifestyle changes to accomplish and may be more feasible to integrate into clinical practice than traditional exercise prescription. However, recent research has suggested that few attempts have been made to translate this evidence into clinical practice.

2.2.2 Objective
The purpose of this study was to explore the effect of prescribing various intensities of physical activity, in conjunction with an mHealth intervention for ongoing self-management, to elicit clinical changes for cardiometabolic risk. To the best of our knowledge, this intervention is the first study targeting both increases in exercise with reductions in sedentary behaviour in a single group of adult participants, thereby providing comprehensive counselling for the entire spectrum of physical activity intensities individuals typically engage in on a daily basis. Additionally, this study is the first to prescribe changes to sedentary behaviours through a primary care setting.

2.3 Method

2.3.1 Design
Previously, we conducted a pilot study using similar protocols (exercise prescription in conjunction with mHealth tools among a sample of older adults) over an eight-week period. Building on this experience, for the present study we were able to support 60
participants over a 12-week intervention period to explore the effect of prescribing various intensities of physical activity through primary care. The mHealth intervention is reported elsewhere.\textsuperscript{18} This study was conducted between April and December 2012 in Ontario, Canada.

2.3.2 Participants
Sixty community-dwelling men and women aged 55 to 75 years volunteered to participate in the intervention. Study flyers were posted in the community, and individuals were recruited through a primary care practice where they were approached by care practitioners during regularly scheduled clinic visits. We also queried the clinic database for potentially eligible patients. Exclusion criteria from previous STEP-based research interventions were followed, which included resting blood pressure $\geq 180/110$ mm Hg; type 1 diabetes; history of myocardial infarction, angioplasty, coronary artery bypass, or cerebrovascular ischemia; symptomatic congestive heart failure; atrial flutter; unstable angina; implanted pacemaker; second- or third-degree heart block; unstable pulmonary disease; unstable metabolic disease; use of medications known to affect heart rate (e.g. beta-blockers); started or changed dose of lipid lowering agent(s) within the previous three months; and any orthopedic condition restricting the ability to engage in physical activity. After screening for eligibility, participants were allocated to four groups based on a randomization schedule created using an online randomization tool (www.random.org/lists/). All subjects provided informed written consent as approved by Western University Health Sciences Research Ethics Board (Protocol No. 18700).
2.3.3 Intervention

This study involved four groups: three receiving an activity prescription intervention targeting a distinct intensity of physical activity along the activity spectrum, and one control group. Participants were not blinded to group allocation.

2.3.3.1 Control Group

The control (CT) group subjects (n = 15) completed clinic testing only, and did not receive additional intervention or restriction on their normal activity behaviours.

2.3.3.2 Exercise Group

The exercise (EX) group (n = 15) received a physical activity prescription targeting increases in high-intensity activity (i.e. exercise). The exercise prescription included training intensity (65% to 85% maximum heart rate) tailored to baseline aerobic fitness using the STEP™ tool, in conjunction with counselling based on public health guidelines for physical activity from the Canadian Society for Exercise Physiology and guided by the Fogg Behavior Model. Personalized home-based daily exercise programs were devised with each participant and a Canadian Society for Exercise Physiology Certified Exercise Physiologist® (CSEP-CEP) working toward public health guidelines for physical activity of ≥ 150 minutes of aerobic exercise weekly (in a minimum of 10-minutes bouts) at the individual target training intensity, and resistance training on ≥ two days of the week.
2.3.3.3  Sedentary Behaviour Group

The sedentary behaviour (SB) group (n = 14) received a physical activity prescription targeting decreases in low-intensity activities (i.e. sedentary behaviour). The sedentary prescription began with education about the importance of interrupting prolonged intervals (i.e. bouts > 20 minutes\textsuperscript{29}) of sedentary time, and counselling based on the goal of interrupting prolonged bouts was incorporated in a process guided by the Fogg Behavior Model.\textsuperscript{31,32} In the absence of clinical guidelines for sedentary behaviour prescription, personal activity programs were devised with each participant and a CSEP-CEP\textsuperscript{®} to identify three to five behaviours in the daily routine, during waking hours, in which the participant was likely to be inactive for > 20 minutes. Personalized strategies were devised to interrupt this time. Table 2.1 lists the strategies that participants identified during the counselling session with the CSEP-CEP\textsuperscript{®} for interrupting their sedentary time. The goal was to devise personal strategies to interrupt prolonged bouts of sedentary behaviour that the participant could engage in each day for the 12-week intervention period. Four categories or themes were identified from the participant-generated strategies, and the strategies are presented in Table 2.1 grouped by theme.

<table>
<thead>
<tr>
<th>Table 2.1 Strategies for Modifying Sedentary Behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interrupting prolonged sedentary time by adding movement on natural breaks:</td>
</tr>
<tr>
<td>▪ When I’m watching TV at night, I will do exercise at the end of each hour (lunges, push-ups, side leans)</td>
</tr>
<tr>
<td>▪ When I watch TV at night, I will do stair stepping on the commercial breaks</td>
</tr>
</tbody>
</table>
- When playing Scrabble on the computer, I will do counter push-ups after each word
- When I read the paper on the weekend, I will stand up between sections
- I will stand up between songs when playing the piano for the next 12 weeks
- I will do one cleaning chore (like vacuuming or dusting) at the end of a TV show I watch on the PVR [personal video recorder]
- I will walk up and down the stairs on commercial breaks when watching TV
- I will do a lap on the stairs after I check my email for the day
- When I am watching the evening news on TV, I will stand up during commercial breaks every night for the next 12 weeks
- On commercial breaks during TV I will take a moment to correct my posture, go get water in the kitchen, or do deep breathing exercises
- Between chapters while reading books, I will stand up and do 15-20 heel raises
- Do one lap of the stairs after each book chapter I read
- Stand up & do one lap of the stairs during each commercial break while I watch TV at night
- When I’m watching TV, I will stand up on commercial breaks, and walk up & down two flights of stairs
- When I’m reading a book, I will do 15-20 counter push-ups between each chapter
- When I’m watching TV, I will stand up on commercial breaks, and actually do the exercises from my physiotherapist

**Augmenting typically sedentary time with active options:**

- While ironing, I will do heel lifts (instead of standing still)
- While brewing coffee, I will do push-ups on the counter edge
**When I go for groceries, I will walk to the grocery store, or park in the furthest spot from the door if I have to drive (like in bad weather or when buying heavy things)**

**When doing errands, I will look for the farthest parking spot from the door I can find (to get in a few extra steps)**

**When at a mall and using the escalator, I will walk up it (instead of riding it)**

**Set the table outside the RV so that we eat meals out there instead (and have to carry the stuff outside)**

**Do counter push-ups while I wait for the oven to heat up, water to boil, or toast to pop**

**Use the stairs instead of an elevator (at work, in the mall, etc). When I can’t use the stairs, I will walk up the escalator**

**Adding in extra bouts of low-intensity activity:**

- I will use the “long route” when I walk my dog
- I will use the far bathroom (instead of the one in my room) every time I use the bathroom for the next 12 weeks
- I will walk a long route to the mailbox every day when I check the mail for the next 12 weeks
- I will ride my bike (instead of driving) to the bank every time I go to the bank for the next 12 weeks
- Walk to the trailer park & back each morning after I finish my morning coffee
- Take a long route to the mailbox to check the mail (like one lap around my apartment building)
- I will walk the driveway between glasses of wine at night
- Three times each day (in the morning, when I get home from work, and at night before
bed) I will do one-two minutes of stair stepping

- At lunch time at work, I will walk to a quiet room after I finish eating my lunch, to do 5-10 push-ups on a counter or wall, and then walk back
- On weekends (both Saturday & Sunday) I will go for a 20 minute walk around my neighbourhood
- Make more frequent trips down to the beach & back (instead of carrying everything with me in one trip)
- Play fetch with the dog outside (or be in the garden) for one hour each night after dinner

Setting timers to deliberately interrupt sedentary time:

- Set the timer on my microwave for 22:22 when watching TV or on the computer so that I have to get up every 22:22 to shut it off and reset it
- When I read, I will set a timer for 20 minutes so that I have to stand up and reset the timer
- Set the timer on my microwave for 30 minutes when I am doing any of the following four activities: reading, knitting, watching TV, doing puzzles
- When working on my computer at night, I will set my microwave timer for 20 minutes; and every time it goes off, I will walk back to the kitchen to re-set it, and then do 10 step-ups on the stairs before sitting back down at the computer
- When I’m working on puzzles, I will keep an eye on my watch and every 20 minutes I will stand up
2.3.3.4  Comprehensive Counselling Group

The comprehensive counselling (CC) group (n = 16) received a physical activity prescription targeting both increases in high-intensity (i.e. exercise) and decreases in low-intensity (i.e. sedentary behaviour) activities following the processes described above.

2.3.4  Measures

All groups completed baseline (week 0) and follow-up (week 12) clinic visits in a primary care setting. Primary measurements included basic clinical measures that could be conducted by health professionals or by self-management (anthropometrics, blood pressure, aerobic fitness), and secondary measurements included a blood panel available to primary care physicians for assessing cardiometabolic disease risk associated with overweight and obesity.

2.3.4.1  Primary Outcomes

2.3.4.1.1  Anthropometrics

Height (recorded to the nearest 0.5 cm) and weight (recorded to the nearest 0.1 kg) were measured with the subjects wearing light clothing but with their footwear removed, from which body mass index (BMI) was calculated. Waist circumference (WC) (recorded to the nearest 0.5 cm) was measured midway between the twelfth rib and the superior portion of the iliac crest on the right-hand side of the participant following normal exhalation.
2.3.4.1.2 Blood Pressure

Clinic blood pressure (BP) was measured with the subjects in a seated position, with the back supported and the left arm resting at heart height using an automatic cuff (BpTru®, Coquitlam, Canada). Three measures were conducted with a two-minute rest between measures. The average of the last two measures were recorded (to the nearest 1 mm Hg).

2.3.4.1.3 Cardiorespiratory Fitness

The self-paced submaximal stepping protocol from the STEP™ tool was used to predict functional aerobic fitness (maximum oxygen consumption, VO₂max). The protocol is described elsewhere.³⁰ Briefly, the stepping protocol involves a validated self-paced test from which post-exercise heart rate and the time to complete the test are entered, along with age, sex, and BMI, into a prediction equation for VO₂max.

2.3.4.2 Secondary Outcomes

A fasting (eight hours) blood draw was conducted in accordance with the usual standard of care, and specimens were analyzed by a local laboratory (Gamma-Dynacare, London, Canada). The blood panel included analysis of fasting glucose, total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol.

2.3.5 Statistical Analysis

Analyses were conducted on an IBM SPSS® Statistics Version 20 (Chicago, IL). Significance for all statistical tests was set at $p < 0.05$. An independent samples $t$-test was conducted to test the differences between the study sample and a representative sample of
Canadian adults from the Canadian Health Measures Survey. Repeated measures multivariate analysis of variance (MANOVA) were conducted for the primary analysis of basic clinic measures (anthropometrics, blood pressure, cardiorespiratory fitness) as well as for secondary analysis of the blood panel (fasting plasma glucose, cholesterol, triglycerides) to test for changes over time (baseline to follow-up clinic visits), with univariate analyses to determine which variables changed over time. Interactions were examined to test for the effect of group assignment over time. Data are presented as mean (± standard deviation) unless otherwise specified.

2.4 Results

2.4.1 Subject Characteristics

Figure 2.1 presents the flow of participants. The characteristics of the randomized participants are shown in Table 2.2. Participants’ mean age was 63 (± 5) years. Although no specific disease state or diagnosis was required for inclusion, participants were, on average, overweight or obese. The sample was no different from an age-matched representative sample of Canadian adults for anthropometrics (BMI, WC) or predicted aerobic capacity (VO₂max) (p = 0.911). Of the 60 participants, 59 (98.3%) completed the study. The reason for the loss to follow-up of the one subject could not be established, and data were excluded listwise from analysis. No adverse events were reported during the intervention.
Figure 2.1 Flow of Participants

Participant Pool (n=195)
• 153 Clinic Roster
• 42 Community

Excluded (n=135)
• 70 No Answers: Clinic Roster
• 46 Screen Failures: Clinic Roster
• 19 Screen Failures: Community

Enrolled (n=60)
• 37 Clinic Roster
• 23 Community

Analysed (n=59)
• 1 loss to follow-up
Table 2.2 Demographic and Clinical Characteristics of Participants at Baseline (n=60)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CT (n = 15)</th>
<th>SB (n = 14)</th>
<th>EX (n = 15)</th>
<th>CC (n = 16)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>62 (5)</td>
<td>63 (4)</td>
<td>63 (5)</td>
<td>62 (4)</td>
<td>0.979</td>
</tr>
<tr>
<td>Sex distribution (% female)</td>
<td>73</td>
<td>64</td>
<td>46</td>
<td>56</td>
<td>0.507</td>
</tr>
<tr>
<td><strong>Primary Measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>31.9 (5)</td>
<td>33.8 (4)</td>
<td>30.4 (5)</td>
<td>29.6 (6)</td>
<td>0.152</td>
</tr>
<tr>
<td>WC (cm)</td>
<td>105.7 (12)</td>
<td>114.1 (18)</td>
<td>107.8 (16)</td>
<td>98.9 (15)</td>
<td>0.060</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>129.5 (13)</td>
<td>130.3 (17)</td>
<td>131.1 (18)</td>
<td>121.4 (15)</td>
<td>0.295</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>81.1 (7)</td>
<td>80.1 (7)</td>
<td>79.8 (10)</td>
<td>76.8 (10)</td>
<td>0.549</td>
</tr>
<tr>
<td>VO₂max (mL/kg/min)</td>
<td>28.9 (8)</td>
<td>25.2 (5)</td>
<td>30.9 (9)</td>
<td>29.5 (5)</td>
<td>0.172</td>
</tr>
<tr>
<td><strong>Secondary Measures</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting glucose (mmol/L)</td>
<td>4.5 (0.4)</td>
<td>5.4 (1.5)</td>
<td>5.1 (1.3)</td>
<td>5.4 (1.5)</td>
<td>0.141</td>
</tr>
<tr>
<td>Total cholesterol (mmol/L)</td>
<td>4.9 (0.9)</td>
<td>4.7 (1.6)</td>
<td>5.1 (1.0)</td>
<td>5.5 (1.4)</td>
<td>0.284</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>1.3 (0.6)</td>
<td>1.6 (0.6)</td>
<td>1.7 (0.9)</td>
<td>1.3 (0.6)</td>
<td>0.249</td>
</tr>
<tr>
<td>LDL cholesterol (mmol/L)</td>
<td>2.7 (0.8)</td>
<td>2.4 (1.2)</td>
<td>2.9 (0.8)</td>
<td>3.3 (1.1)</td>
<td>0.084</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
<td>-------</td>
</tr>
<tr>
<td>HDL cholesterol (mmol/L)</td>
<td>1.6 (0.5)</td>
<td>1.6 (0.6)</td>
<td>1.4 (0.5)</td>
<td>1.6 (0.5)</td>
<td>0.763</td>
</tr>
</tbody>
</table>

**Abbreviations**: CT, Control group; SB, Sedentary group; EX, Exercise group; CC, Comprehensive group; BMI, body mass index; WC, waist circumference; BP, blood pressure; VO$_2$max, aerobic capacity; LDL, low-density lipoprotein; HDL, high-density lipoprotein; $p < 0.05$ denotes significant difference between groups.

### 2.4.2 Primary Outcomes
Primary analysis of this intervention included health status variables that can be measured by health practitioners or by individuals themselves for ongoing self-management. The difference in clinic measures was significant from baseline to follow-up ($F_{(5,50)} = 20.458$, $p < 0.01$, $\eta^2 = 0.672$). Post-hoc analysis using Tukey’s honestly significant difference correction indicated that this difference was not significant between groups ($p > 0.05$). Table 2.3 presents the univariate analyses, which determined statistically significant changes from baseline to follow-up for all groups in BMI, WC, diastolic BP, and VO$_2$max, with no change in systolic BP. Figure 2.2 shows the mean changes for primary measures over time, and Table 2.4 presents pairwise comparisons for primary outcomes from pre- to post-intervention.
Figure 2.2 Changes in Primary Markers

Note: * denotes statistically significant change ($p < 0.05$).
Table 2.3 Primary Analysis

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline (week 0)</th>
<th>Follow-up (week 12)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>31.1 (5.2)</td>
<td>30.6 (5.0)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>[29.8–32.5]</td>
<td>[29.4–32.0]</td>
<td></td>
</tr>
<tr>
<td>WC (cm)</td>
<td>105.4 (14.1)</td>
<td>101.1 (13.6)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>[102.0–109.3]</td>
<td>[97.8–104.9]</td>
<td></td>
</tr>
<tr>
<td>Systolic BP</td>
<td>127.8 (15.9)</td>
<td>125.3 (15.2)</td>
<td>0.135</td>
</tr>
<tr>
<td>(mm Hg)</td>
<td>[123.9–132.3]</td>
<td>[121.1–129.2]</td>
<td></td>
</tr>
<tr>
<td>Diastolic BP</td>
<td>79.1 (8.8)</td>
<td>75.7 (9.3)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>(mm Hg)</td>
<td>[76.9–81.6]</td>
<td>[73.2–78.1]</td>
<td></td>
</tr>
<tr>
<td>VO₂max (mL/kg/min)</td>
<td>29.0 (7.0)</td>
<td>31.7 (6.4)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td></td>
<td>[27.1–30.7]</td>
<td>[29.9–33.3]</td>
<td></td>
</tr>
</tbody>
</table>

Note: Data presented as mean (± standard deviation) with 95% confidence interval [lower bound–upper bound].

Abbreviations: BMI, body mass index; WC, waist circumference; BP, blood pressure; VO₂max, aerobic capacity; p<0.05 denotes significant difference.
Table 2.4 Pairwise Comparisons of Primary Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mean difference (standard error)</th>
<th>95% confidence interval [lower–upper bound]</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>-0.3 (0.2)</td>
<td>[-0.8 – 0.2]</td>
<td>0.190</td>
</tr>
<tr>
<td>SB</td>
<td>-0.7 (0.2)</td>
<td>[-1.1 – -0.2]</td>
<td>0.009</td>
</tr>
<tr>
<td>EX</td>
<td>-0.4 (0.2)</td>
<td>[-0.9 – 0.1]</td>
<td>0.079</td>
</tr>
<tr>
<td>CC</td>
<td>-0.4 (0.2)</td>
<td>[-0.9 – 0.0]</td>
<td>0.063</td>
</tr>
<tr>
<td><strong>WC (cm)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>-3.5 (1.4)</td>
<td>[-6.4 – -0.6]</td>
<td>0.018</td>
</tr>
<tr>
<td>SB</td>
<td>-4.8 (1.5)</td>
<td>[-7.8 – -1.8]</td>
<td>0.002</td>
</tr>
<tr>
<td>EX</td>
<td>-5.7 (1.4)</td>
<td>[-8.6 – -2.8]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CC</td>
<td>-3.0 (1.4)</td>
<td>[-5.8 – -0.2]</td>
<td>0.036</td>
</tr>
<tr>
<td><strong>Systolic BP (mm Hg)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>-6.8 (3.7)</td>
<td>[-14.2 – 0.6]</td>
<td>0.072</td>
</tr>
<tr>
<td>SB</td>
<td>-5.4 (3.78)</td>
<td>[-13.0 – 2.3]</td>
<td>0.168</td>
</tr>
<tr>
<td></td>
<td>EX</td>
<td></td>
<td></td>
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<tr>
<td>-------</td>
<td>---------</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>-6.4 (1.9)</td>
<td>[-10.1 - -2.7]</td>
<td>0.001</td>
</tr>
<tr>
<td>SB</td>
<td>-3.7 (1.9)</td>
<td>[-7.6 - 0.1]</td>
<td>0.058</td>
</tr>
<tr>
<td>EX</td>
<td>-3.7 (1.9)</td>
<td>[-7.4 - 0.1]</td>
<td>0.053</td>
</tr>
<tr>
<td>CC</td>
<td>-0.3 (1.8)</td>
<td>[-3.9 - 3.3]</td>
<td>0.863</td>
</tr>
<tr>
<td>VO\textsubscript{2}max (mL/kg/min)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>1.9 (0.7)</td>
<td>[0.5 - 3.4]</td>
<td>0.010</td>
</tr>
<tr>
<td>SB</td>
<td>2.9 (0.8)</td>
<td>[1.4 - 4.4]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>EX</td>
<td>2.1 (0.7)</td>
<td>[0.6 - 3.5]</td>
<td>0.006</td>
</tr>
<tr>
<td>CC</td>
<td>3.4 (0.7)</td>
<td>[1.9 - 4.7]</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Abbreviations: CT, Control group; SB, Sedentary group; EX, Exercise group; CC, Comprehensive group; BMI, body mass index; WC, waist circumference; BP, blood pressure; VO\textsubscript{2}max, aerobic capacity; \(p < 0.05\) denotes significant difference.
2.4.3 Secondary Outcomes

Secondary analysis of this intervention included markers for cardiometabolic risk available to a physician for assessing the health status of overweight and obese patients. The difference in blood panel measures was significant from baseline to follow-up ($F_{(5,50)} = 4.576, p = 0.002, \eta^2_P = 0.314$). Post-hoc analysis using Tukey’s honestly significant difference correction indicated that this difference was not significant between groups ($p > 0.05$). Table 2.5 presents the univariate analyses, which determined statistically significant changes from baseline to follow-up for all groups in fasting glucose, total cholesterol, and triglycerides, but no difference in HDL cholesterol or LDL cholesterol. Figure 2.3 shows the mean changes for secondary measures over time, and Table 2.6 presents pairwise comparisons for secondary outcomes from pre- to post-intervention.
Figure 2.3 Changes in Secondary Outcomes

*Note:* * denotes statistically significant change ($p < 0.05$).

### Table 2.5 Secondary Analysis

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline (week 0)</th>
<th>Follow-up (week 12)</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting glucose</td>
<td>5.1 (1.3) [4.8–5.4]</td>
<td>5.4 (1.1) [5.1–5.6]</td>
<td>0.005</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>5.1 (1.3) [4.7–5.4]</td>
<td>4.9 (1.2) [4.6–5.2]</td>
<td>0.039</td>
</tr>
<tr>
<td></td>
<td>Mean difference (standard error)</td>
<td>95% confidence interval</td>
<td>p value</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------</td>
<td>--------------------------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>lower–upper bound</td>
<td></td>
</tr>
<tr>
<td><strong>Triglycerides (mmol/L)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.5 (0.7)</td>
<td>[1.2–1.7]</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>1.3 (0.6)</td>
<td>[1.1–1.5]</td>
<td></td>
</tr>
<tr>
<td><strong>LDL cholesterol (mmol/L)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.9 (1.0)</td>
<td>[2.6–3.1]</td>
<td>0.313</td>
</tr>
<tr>
<td></td>
<td>2.8 (1.0)</td>
<td>[2.5–3.0]</td>
<td></td>
</tr>
<tr>
<td><strong>HDL cholesterol (mmol/L)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.6 (0.5)</td>
<td>[1.4–1.7]</td>
<td>0.407</td>
</tr>
<tr>
<td></td>
<td>1.5 (0.5)</td>
<td>[1.4–1.7]</td>
<td></td>
</tr>
</tbody>
</table>

*Note:* Data presented as mean (± standard deviation) with 95% confidence interval [lower bound–upper bound].

*Abbreviations:* LDL, low-density lipoprotein; HDL high-density lipoprotein; $P < 0.05$ denotes significant difference.

**Table 2.6 Pairwise Comparisons of Secondary Outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Mean difference (standard error)</th>
<th>95% confidence interval</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>lower–upper bound</td>
<td></td>
</tr>
<tr>
<td><strong>Fasting glucose (mmol/L)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>0.6 (0.2)</td>
<td>[0.3 – 1.0]</td>
<td>0.001</td>
</tr>
<tr>
<td>SB</td>
<td>0.3 (0.2)</td>
<td>[−0.1 – 0.7]</td>
<td>0.086</td>
</tr>
<tr>
<td></td>
<td>Total cholesterol (mmol/L)</td>
<td>Triglycerides (mmol/L)</td>
<td>LDL cholesterol (mmol/L)</td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------</td>
<td>------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td></td>
<td>EX</td>
<td>−0.1 (0.2)</td>
<td>[−0.5 – 0.3]</td>
</tr>
<tr>
<td></td>
<td>CC</td>
<td>0.2 (0.2)</td>
<td>[−0.1 – 0.5]</td>
</tr>
<tr>
<td></td>
<td>CT</td>
<td>−0.2 (0.1)</td>
<td>[−0.4 – 0.1]</td>
</tr>
<tr>
<td></td>
<td>SB</td>
<td>−0.2 (0.1)</td>
<td>[−0.5 – 0.0]</td>
</tr>
<tr>
<td></td>
<td>EX</td>
<td>−0.1 (0.1)</td>
<td>[−0.4 – 0.2]</td>
</tr>
<tr>
<td></td>
<td>CC</td>
<td>0.0 (0.1)</td>
<td>[−0.2 – 0.2]</td>
</tr>
</tbody>
</table>
### Discussion

Among the leading risks for mortality globally are high BP, blood glucose, body weight status, and physical inactivity.\(^{34}\) Best practice and evidence support intervening on cardiometabolic risk factors (e.g. elevated blood pressure, blood glucose, and body weight) prior to the development of chronic conditions such as hypertension, type 2 diabetes, and metabolic syndrome. Moreover, early identification and treatment with lifestyle modification has been advised for the prevention of hypertension, type 2 diabetes, and cardiovascular disease.\(^{35}\) In the present study, cardiometabolic risk factors were improved pre- to post-intervention.
2.5.1 Anthropometrics

On average, BMI decreased by 0.5 kg/m\(^2\) \((p < 0.05)\) but remained in the obese category post-intervention. The WC provides an assessment of body fat distribution, and better identifies patients at higher cardiometabolic risk than does BMI alone.\(^{36}\) Additionally, WC is an important indicator of diabetes, coronary heart disease, and mortality rate, independent of other clinical measures such as BP and blood markers like glucose and lipoproteins.\(^{36}\) In the present study, the mean reduction in WC across all groups was 4.3 cm \((p < 0.05)\). It has been suggested that a reduction in WC of ≥ 3.0 cm reduces cardiometabolic risk.\(^{36-38}\) Moreover, similar to other physical activity intervention studies, previous STEPTM interventions ranging from eight to 24 weeks have elicited reductions in WC of between 2.6 and 3.9 cm.\(^{16,17,34,35}\) Therefore, reductions in WC in the present study may be considered clinically meaningful.

2.5.2 Blood Pressure

Thompson et al\(^{39}\) suggest that following a 12-week physical activity intervention, normotensive patients could be expected to reduce systolic BP by 2.6 mm Hg and diastolic BP by 1.8 mm Hg. Mean changes in BP were similar across all groups, and although not statistically significant, changes in BP among the present study sample can be considered clinically relevant (2.5 mm Hg reduction in systolic BP, and 3.4 mm Hg reduction in diastolic BP).
2.5.3 Cardiorespiratory Fitness

In a recent systematic review of exercise prescription interventions delivered in the primary care setting, Orrow et al\textsuperscript{12} concluded that there was a small effect on aerobic fitness, which was primarily driven by a single intervention that employed the STEP\textsuperscript{TM} tool. The authors attributed this effect to the unique study characteristic of STEP\textsuperscript{TM} interventions, which is inclusion of a target training intensity (heart rate) in the prescription process. Previously published STEP\textsuperscript{TM} interventions, ranging between 8 weeks and 12 months in duration, have increased aerobic fitness 7% to 18%.\textsuperscript{30} In the current study, we observed an increase from baseline to follow-up of 8.5%, or 2.7 mL/kg/min \((p < 0.05)\), which is within the range reported by previous STEP\textsuperscript{TM} interventions.

2.5.4 Blood Panel

Clinical practice guidelines for managing and treating obesity recommend assessment of blood markers for cardiometabolic risk, including fasting plasma glucose, total cholesterol, triglycerides, and LDL and HDL cholesterol.\textsuperscript{40} Figure 2.3 shows the mean changes over time for blood panel measures from the present study. The sample was on average obese at baseline; however, blood panel markers were within normal or desired ranges. Despite this, most clinical markers showed statistically significant changes following the intervention. Although fasting glucose increased significantly from baseline to follow-up, this change may not be considered clinically meaningful given that the post-intervention average remained within normal values (3.6–6.0 mmol/L). Total cholesterol and triglycerides decreased following the intervention, and values both pre- and post-
intervention were within the clinically desired range (< 5.2 mmol/L and < 2.3 mmol/L, respectively). Similarly, the mean LDL and HDL cholesterol following the intervention remained unchanged and within clinically desired thresholds (< 3.0 mmol/L and > 1.0 mmol/L, respectively).

2.5.5 Physical Activity Behaviour

When prescribing lifestyle changes to manage metabolic risk, it is important to acknowledge the physiological difference between excess sitting and insufficient exercise.\textsuperscript{41} It has been suggested that prolonged intervals of sedentary time should be avoided to prevent increases in metabolic risk, and that any type of brief and frequent muscular contraction throughout the day could be used to offset the molecular changes of prolonged sedentary time and the signals causing metabolic disease.\textsuperscript{23,41} Independent of exercise, maintaining high levels of light-intensity activity throughout the day may be important for reducing metabolic risk factors. The health risks of prolonged intervals of sedentary activity in human and animal models are documented in the literature. A recent systematic review of sedentary time in humans concluded that prolonged intervals of sedentary behaviour may lead to undesirable changes in fasting glucose, HDL and LDL cholesterol, as well as triglycerides, which may help to explain associations that have been drawn between sedentary behaviour and chronic disease morbidity and mortality.\textsuperscript{41} In the present study, there was no difference in changes in fasting glucose and HDL and LDL cholesterol between groups ($p > 0.05$). This indicates that all groups, including the group receiving clinic testing only (CT group) changed similarly across the 12-week intervention period. Results are limited to the small sample in the present study, and may
be further influenced by the baseline characteristics of study participants being generally within clinically desirable (or normal) thresholds for these measures.

2.5.6 Prescribed Health Behaviours

There is evidence to suggest that a health behaviour message delivered by a health practitioner, such as through primary care, can be an important stimulus for individual change and adoption of prescribed health behaviours. Moreover, it has been suggested that a written exercise prescription holds symbolic meaning for patients by indicating that their health practitioner believes in the value of exercise for managing and promoting health. Health practitioners are in a unique position to educate patients about the importance of reducing, or interrupting, daily sedentary time. Previously it has been shown that more patients receive exercise counselling from their physician than counselling focused on reducing sedentary behaviour. Moreover, recent research has demonstrated that counselling for sedentary behaviours through the primary care setting is more likely to occur for obese patients, whereas exercise counselling is more likely to be conducted for younger patients, non-smokers, and patients with dyslipidemia. Results from the current study support the feasibility of counselling to change sedentary behaviours through the primary care setting.

In addition to the physiological difference between exercise and sedentary activity, health practitioners may also consider the complex nature of human behaviour when attempting to manage cardiometabolic risk with lifestyle modification. For example, individuals may
decrease non-exercise activities following a bout of exercise driven by the psychological belief that they are entitled to a rest following the energy expended during exercise.\textsuperscript{21} This may lead to an overall reduction in physical activity during non-exercise time, as there is evidence to suggest that individuals compensate by decreasing their routine activities during non-exercise activity.\textsuperscript{21} This supports the importance of prescribing activity across the range of intensities that an individual can participate in (i.e. sedentary through exercise, or comprehensive counselling).

However, counselling on the broad spectrum of activity intensities through the primary care setting may be too intensive to realize health benefits for patients. To the best of our knowledge, this is the first study to report a comprehensive counselling approach in a single group of adults. In pediatric psychology research, Epstein et al\textsuperscript{44} have explored a group-based comprehensive counselling approach reinforcing activity choices, decreased sedentary activities, or both. They found that the children in the sedentary group showed the best improvements in body weight status as compared with the exercise and combined groups. In their study, the authors suggested that multiple changes required in the combined group may have made it more difficult for participants to make individual exercise and sedentary changes, which may have diluted the intervention effect.\textsuperscript{44}

Similarly, in the present study individuals in the CC group, on average, showed the smallest improvements from pre- to post-intervention as compared to other intervention groups (Table 2.7). This may suggest that counselling for the range of activity intensities (e.g. sedentary, exercise) during a single clinic visit may be too intensive to realize changes. Future studies are warranted exploring the effect of staged comprehensive
counselling, where, instead of during a single visit, counselling for changes in activity behaviours progressively incorporates exercise and sedentary activities.

Table 2.7 Mean Changes by Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline (week 0)</th>
<th>Follow-up (week 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VO\textsubscript{2}max (mL/kg/min)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>28.93 (7.1)</td>
<td>30.87 (6.5)</td>
</tr>
<tr>
<td>SB</td>
<td>25.22 (5.3)</td>
<td>28.16 (5.4)</td>
</tr>
<tr>
<td>EX</td>
<td>30.85 (8.6)</td>
<td>32.93 (8.1)</td>
</tr>
<tr>
<td>CC</td>
<td>25.51 (5.1)</td>
<td>32.85 (5.9)</td>
</tr>
<tr>
<td>Body mass index (kg/m\textsuperscript{2})</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>31.92 (5.2)</td>
<td>31.61 (4.8)</td>
</tr>
<tr>
<td>SB</td>
<td>33.81 (4.3)</td>
<td>33.16 (4.3)</td>
</tr>
<tr>
<td>EX</td>
<td>30.36 (5.4)</td>
<td>29.95 (5.0)</td>
</tr>
<tr>
<td>CC</td>
<td>29.63 (5.9)</td>
<td>29.21 (5.9)</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Systolic BP (mm Hg)</td>
<td>Diastolic BP (mm Hg)</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>CT</td>
<td>105.67 (12.0)</td>
<td>102.13 (12.1)</td>
</tr>
<tr>
<td>SB</td>
<td>114.07 (17.5)</td>
<td>109.25 (16.7)</td>
</tr>
<tr>
<td>EX</td>
<td>107.83 (15.6)</td>
<td>102.13 (15.7)</td>
</tr>
<tr>
<td>CC</td>
<td>98.91 (14.6)</td>
<td>95.91 (13.2)</td>
</tr>
</tbody>
</table>

**Systolic BP (mm Hg)**

<table>
<thead>
<tr>
<th></th>
<th>CT</th>
<th>129.47 (13.9)</th>
<th>122.67 (13.9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB</td>
<td>130.29 (16.8)</td>
<td>124.93 (13.2)</td>
<td></td>
</tr>
<tr>
<td>EX</td>
<td>131.13 (18.1)</td>
<td>126.93 (17.3)</td>
<td></td>
</tr>
<tr>
<td>CC</td>
<td>121.44 (14.9)</td>
<td>127.31 (16.6)</td>
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</table>

**Diastolic BP (mm Hg)**

<table>
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<tr>
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<th>CT</th>
<th>81.13 (7.5)</th>
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<tbody>
<tr>
<td>SB</td>
<td>80.07 (7.1)</td>
<td>76.36 (10.2)</td>
<td></td>
</tr>
<tr>
<td>EX</td>
<td>79.80 (9.6)</td>
<td>76.13 (9.2)</td>
<td></td>
</tr>
<tr>
<td>CC</td>
<td>76.75 (10.4)</td>
<td>76.44 (9.5)</td>
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</table>

**Fasting glucose (mmol/L)**

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<tr>
<th></th>
<th>CT</th>
<th>4.48 (0.4)</th>
<th>5.05 (0.3)</th>
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<tbody>
<tr>
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<td>EX</td>
<td>CC</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td><strong>SB</strong></td>
<td>5.38 (1.5)</td>
<td>5.69 (1.6)</td>
<td>5.09 (1.3)</td>
</tr>
<tr>
<td><strong>EX</strong></td>
<td>4.69 (1.6)</td>
<td>4.45 (1.3)</td>
<td>5.09 (1.0)</td>
</tr>
<tr>
<td><strong>CC</strong></td>
<td>5.44 (1.5)</td>
<td>5.63 (1.1)</td>
<td>5.52 (1.4)</td>
</tr>
</tbody>
</table>

**Total cholesterol (mmol/L)**

<table>
<thead>
<tr>
<th></th>
<th>CT</th>
<th>SB</th>
<th>EX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CT</strong></td>
<td>4.85 (0.9)</td>
<td>4.71 (1.0)</td>
<td>5.09 (1.0)</td>
</tr>
<tr>
<td><strong>SB</strong></td>
<td>1.33 (0.6)</td>
<td>1.25 (0.6)</td>
<td>1.61 (0.6)</td>
</tr>
<tr>
<td><strong>EX</strong></td>
<td>1.68 (0.9)</td>
<td>1.53 (0.6)</td>
<td>1.68 (0.9)</td>
</tr>
<tr>
<td><strong>CC</strong></td>
<td>1.29 (0.6)</td>
<td>1.28 (0.6)</td>
<td>1.29 (0.6)</td>
</tr>
</tbody>
</table>

**Triglycerides (mmol/L)**

<table>
<thead>
<tr>
<th></th>
<th>CT</th>
<th>SB</th>
<th>EX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CT</strong></td>
<td>1.59 (0.4)</td>
<td>1.58 (0.4)</td>
<td>1.59 (0.4)</td>
</tr>
<tr>
<td><strong>SB</strong></td>
<td>1.55 (0.6)</td>
<td>1.54 (0.5)</td>
<td>1.55 (0.6)</td>
</tr>
</tbody>
</table>

**HDL cholesterol (mmol/L)**

<table>
<thead>
<tr>
<th></th>
<th>CT</th>
<th>SB</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CT</strong></td>
<td>1.59 (0.4)</td>
<td>1.58 (0.4)</td>
</tr>
<tr>
<td><strong>SB</strong></td>
<td>1.55 (0.6)</td>
<td>1.54 (0.5)</td>
</tr>
<tr>
<td></td>
<td>EX</td>
<td>1.47 (0.5)</td>
</tr>
<tr>
<td>-----</td>
<td>------</td>
<td>------------</td>
</tr>
<tr>
<td>EX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC</td>
<td>1.61 (0.5)</td>
<td>1.59 (0.5)</td>
</tr>
<tr>
<td></td>
<td>LDL cholesterol (mmol/L)</td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>2.66 (0.8)</td>
<td>2.56 (0.9)</td>
</tr>
<tr>
<td>SB</td>
<td>2.40 (1.2)</td>
<td>2.35 (1.0)</td>
</tr>
<tr>
<td>EX</td>
<td>2.85 (0.9)</td>
<td>2.88 (0.8)</td>
</tr>
<tr>
<td>CC</td>
<td>3.32 (1.1)</td>
<td>3.25 (1.1)</td>
</tr>
</tbody>
</table>

**Abbreviations:** CT, Control group; SB, Sedentary group; EX, Exercise group; CC, Comprehensive group; VO\textsubscript{2}max, functional aerobic capacity; BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

A health risk message delivered through the primary care setting can be a potent catalyst initiating physical activity–related health behaviour change.\textsuperscript{42} However, Pfeiffer et al.\textsuperscript{43} found no difference in self-reported activity level between written exercise prescription versus verbal exercise advice among a group of community-dwelling older adults, although their study was limited to recalled activity types and durations and did not assess physiological markers. Through the current study, we found statistically and clinically significant effects for clinical markers following a 12-week intervention period across both the control and treatment groups. These results further support the clinical
importance of measuring risk factors for lifestyle-related conditions through primary care. Although caution should be exercised in interpreting results from a single study, these findings could support the clinical utility of measuring and providing attention for managing cardiometabolic risk through the primary care setting as a potentially important treatment effect.

2.5.7 Placebo Effect

Findings from the present study demonstrate improvements from baseline to follow-up clinic visits across all groups. Participants were not blinded to group allocation and were aware of the purpose of the study from reading informed consent forms for participation. Often referred to as the placebo or Hawthorne effect, it has been widely accepted that an individual’s behaviour can be modified by the psychological awareness of being observed and included in an intervention, which is a nonspecific effect of participating in clinical research. It has been suggested that extra attention from researchers and clinicians through participation in an intervention applies to both treatment and control arms, and that psychological and social factors from participation may overestimate the treatment effect for both types of participant groups.\textsuperscript{45} Anecdotally, multiple participants in the CT group of the present study reported at follow-up (week 12) clinic testing that they had initiated dietary and activity changes to their lifestyles since the baseline clinic testing visit. The present study was not designed to record and control for this effect. Results from the present study support the clinical utility of measuring lifestyle-related disease risk factors through the primary care setting.
2.5.8 Strengths and Limitations

Exclusion criteria restricted participation of individuals using medication that would alter heart rate (e.g. beta-blockers), as heart rate response to activity was essential to the measure of aerobic capacity used in the present study. However, individuals with high blood pressure, a common effect of high body weight status and unhealthy physical activity behaviours, were eligible to participate in the current study. Excluding individuals who were at high risk of cardiovascular complications would inhibit the ability to detect changes in health markers over a 12-week intervention period.

The short intervention period (12 weeks) may have further inhibited our ability to detect changes among intervention groups that might have emerged over a longer time period. Results from the present study help to demonstrate the clinical value of tailoring activity behaviour counselling to various intensities (i.e. ranging from sedentary behaviour through exercise), as changing sedentary behaviours may have implications for cardiometabolic risk. Moreover, the results imply that enhancing an individual’s understanding of disease risk, such as measuring cardiometabolic risk through the primary care setting, may be an important stimulus for change. The results from the present study can be used to help inform the design of future investigations of prescribing various intensities of physical activity through the primary care setting.
Participants received personal activity programming tailored to baseline cardiorespiratory fitness. Individual differences in prescribed activities were not controlled for. Objective measures of physical activity (via pedometer) during the 12-week intervention period are reported elsewhere. The present analysis did not include a measure of physical activity level. This study explored the effect of prescribing activities of different intensities on clinical outcome measures that would typically be collected in the primary care setting.

Previously there has been a gap in the literature reporting sedentary behaviour interventions that include cardiometabolic measures to assess change in clinical outcomes of cardiometabolic risk. The primary strength of this study stems from the fact that it is the first study to present clinical results pertaining to sedentary behaviour prescription, alone and in conjunction with exercise prescription, in the primary care setting. The results, although limited to the small sample size, could help to inform future interventions aimed at decreasing sedentary time as well as the development of practice guidelines for the counselling and prescription of sedentary behaviours by health practitioners. Moreover, findings from the present study may be used to draw inferences about expected treatment outcomes, and may be of value in the design of future investigations prescribing various intensities of physical activity through the primary care setting. Future exploratory analyses may be warranted to describe characteristics of individuals who responded to the present physical activity intervention; however, the current study was not powered for this analysis. An understanding of these characteristics may help clinicians identify individuals who are most likely to respond to intervention.
2.5.9 Conclusion

The present study investigated the effect of prescribing various intensities of physical activity through the primary care setting on cardiometabolic risk factors. Changes in primary and secondary outcomes of cardiometabolic health status were statistically significant and clinically meaningful, with no difference between groups. Novel results demonstrate clinical benefits of prescribing changes to low-intensity physical activities (i.e. sedentary behaviours) for older men and women. Moreover, findings support the ongoing practice of measuring lifestyle-related disease risk factors (e.g. body weight status, blood pressure, cardiorespiratory fitness) in the primary care setting for chronic disease management and prevention.
2.6 References


20. CSEP. *Canadian physical activity guidelines for older adults*. Ottawa: Canadian Society for Exercise Physiology;2011.


Chapter 3

3 mHealth and Self Management

A version of this chapter has previously been published:

3.1 Abstract

Background: It is well established in the literature that regular participation in physical activity is effective for chronic disease management and prevention. Remote monitoring technologies (i.e. mHealth) hold promise for engaging patients in self-management of many chronic diseases. The purpose of this study was to test the effectiveness of an mHealth study with tailored physical activity prescription targeting changes in various intensities of physical activity (e.g. exercise, sedentary behaviour, or both) for improving physiological and behavioural markers of lifestyle-related disease risk.

Methods: Forty-five older adults (aged 55 to 75 years; mean age 63 ± 5 years) were randomly assigned to receive a personal activity program targeting changes to either daily exercise, sedentary behaviour, or both. All participants received an mHealth technology kit including smartphone, blood pressure monitor, glucometer, and pedometer. Participants engaged in physical activity programming at home during the 12-week intervention period and submitted physical activity (steps/day), blood pressure (mm Hg),
body weight (kg), and blood glucose (mmol/L) measures remotely using study-provided devices.

**Results:** There were no differences between groups at baseline ($p > 0.05$). The intervention had a significant effect ($F_{(10,488)} = 2.947, p = 0.001, \eta^2_P = 0.057$), with similar changes across all groups for physical activity, body weight, and blood pressure ($p > 0.05$). Changes in blood glucose were significantly different between groups, with groups prescribed high-intensity activity (i.e. exercise) demonstrating greater reductions in blood glucose than the group prescribed changes to sedentary behaviour alone ($p < 0.05$).

**Conclusions:** Findings demonstrate the utility of pairing mHealth technologies with activity prescription for prevention of lifestyle-related chronic diseases among an at-risk group of older men and women. Results support the novel approach of prescribing changes to sedentary behaviours (alone, and in conjunction with exercise) to reduce risk of developing lifestyle-related chronic conditions.

**Keywords:** mobile health; exercise prescription; sedentary behaviour; primary care; chronic disease prevention; exercise is medicine.


3.2 Introduction

It has been well established in the literature that regular participation in physical activities is effective for managing and preventing many chronic and non-communicable diseases. Despite this, developed countries continue to report that adults and older adults are not meeting public health guidelines for physical activity.\(^1,2\) Interventions aimed at improving physical activity behaviours typically target increases in high-intensity activities such as exercise. However, there is a growing body of evidence to suggest that time spent being sedentary is a distinct health risk and a potentially important behaviour to target through physical activity interventions.\(^3\text{-}^6\) Predominantly inactive lifestyles present substantial consequences for public health around the globe.\(^7\)

In developed countries, individuals are living longer than previous generations, yet there is a disparity between longevity and healthy, independent living; increased life expectancies are not matched with fewer years of disability and ill health.\(^8\) Moreover, global health systems are progressively being dominated by care for chronic conditions and non-communicable diseases.\(^9,10\) As the number of patients continues to grow and the health care resources continue to strain, engaging patients in self-management may be an effective strategy for disease prevention and management.

3.2.1 Physical Activity Prescription

Evidence suggests that the delivery of a health risk message by a health professional can initiate and promote patient adoption of healthy lifestyle behaviours.\(^11\) A written exercise
prescription expresses symbolic meaning that a health professional values the role of exercise for managing and promoting health. The importance of prescribing activity through the primary care setting to manage cardiometabolic risk is further underscored by Exercise Is Medicine® initiatives. Moreover, physical activity prescription through the primary care setting has been shown to significantly increase physical activity levels as well as have a positive effect on cardiorespiratory fitness. Health professionals are in a unique position to educate patients about the importance of interrupting sedentary activities as well as the health benefits of exercising. However, it has previously been demonstrated that patients are more likely to receive exercise counselling than sedentary behaviour counselling from their physician. As we become increasingly aware of the health risks of prolonged sedentary behaviours, novel interventions are needed that target sedentary activities as well as exercise behaviours.

3.2.2 Remote Monitoring

The use of mobile communication devices in the health landscape, commonly referred to as mobile health (mHealth), enables remote monitoring of individuals. The use of mobile phones is pervasive around the world, and leveraging the utility and accessibility of mobile technologies holds much potential for health behaviour interventions. Currently there are an estimated 6.9 billion mobile phone subscribers globally, and 2.1 billion smartphone (i.e. broadband-enabled phone) subscriptions globally. Comparatively fewer individuals are using landlines and the Internet at home (1.2 billion and 696 million, respectively), which are platforms that have previously been leveraged for delivering health behaviour interventions (i.e. electronic, or eHealth). In North America,
98% of Americans and 75% of Canadians are mobile phone subscribers.\textsuperscript{18} Therefore, the availability of mHealth for rich, complex, and frequent data sharing and self-monitoring supports its utility for the modification of various health behaviours,\textsuperscript{19} and the prevalence of mobile phones both in North America and around the world support the growing value of mHealth interventions in the global health landscape. Moreover, mHealth technologies involving smartphones are a rapidly expanding focus of preventive care for chronic disease management.\textsuperscript{20}

Remote monitoring technologies have been cited for improving health by improving access to information and services, providing care not otherwise deliverable and enhancing care delivery.\textsuperscript{21} Pilot work from our research group has demonstrated the efficacy of self-monitoring using remote technologies to manage body weight, blood pressure, and blood glucose among adults with metabolic syndrome, and it was suggested that the mHealth tools provided to study participants improved awareness of lifestyle factors for overall health to effect clinical markers and risk factors for cardiometabolic disease.\textsuperscript{22,23} Moreover, the remote monitoring in these studies has improved participants’ overall sense of well-being, and provided a sense of security to participants during an eight-week healthy living intervention.\textsuperscript{23} The mHealth evidence base predominantly focuses on diseased populations (e.g. individuals who are diabetic, hypertensive, or obese), and limited information is available describing the effect of mHealth on apparently healthy populations for the purpose of disease prevention. Leveraging the utility of mHealth, the purpose of this study was to prescribe changes to a range of physical activity intensities (i.e. exercise, sedentary, or both) using tailored activity
prescription to improve clinical and behavioural markers of lifestyle-related cardiometabolic risk among a sample of older adults.

3.3 Method

3.3.1 Design
Previously, we have piloted similar protocols (exercise prescription in conjunction with remote self-management tools) over an eight-week period. Building on this experience, for the present study we were able to feasibly support 45 participants with the remote monitoring technologies over a 12-week intervention period. This study was conducted between April and December 2012.

3.3.2 Participants
A convenience sample of 45 community-dwelling men and women aged 55 to 75 years volunteered to participate in the intervention. Individuals were generally healthy, with no diagnosis (e.g. hypertensive, diabetic, obese) required for inclusion. Participants were recruited through study advertisements posted in the community as well as enrolment through a local primary care setting. Exclusion criteria were followed from similar interventions previously conducted by our group that facilitate safe participation in a physical activity intervention: resting blood pressure $\geq 180/110$ mm Hg; type 1 diabetes; history of myocardial infarction, angioplasty, coronary artery bypass, or cerebrovascular
ischemia; symptomatic congestive heart failure; atrial flutter; unstable angina; implanted pacemaker; second- or third-degree heart block; unstable pulmonary disease; unstable metabolic disease; use of medications known to affect heart rate (e.g. beta-blockers); started or changed dose of lipid lowering agent(s) within the previous three months; and any orthopedic condition restricting the ability to engage in physical activity. After screening for eligibility, participants were divided into three groups based on a randomization schedule created using an online randomization tool (www.random.org/lists/). All subjects provided informed written consent as approved by Western University Health Sciences Research Ethics Board (Protocol No. 18700).

3.3.3 Intervention

3.3.3.1 Groups

Participants were randomized at recruitment into three intervention groups: (1) exercise (EX), in which participants received a physical activity prescription targeting increases in high-intensity activity (i.e. exercise); (2) sedentary behaviour (SB), in which participants received a physical activity prescription targeting reductions and interruptions in low-intensity daily activity (i.e. sedentary behaviour); and (3) comprehensive (CC), in which participants received an activity prescription targeting both increases in high-intensity activity (i.e. exercise) and reductions in low-intensity activity (i.e. sedentary behaviour). Further details regarding the activity prescription process are reported elsewhere.14
3.3.3.2 Technology Kit

A technology kit containing mHealth devices for home self-monitoring was loaned to participants in all three groups free of charge for the duration of the 12-week intervention. Participants were provided with a smartphone (BlackBerry™ Curve 8530), Bluetooth-enabled blood pressure monitor (A&D Medical, No. UA-767PBT), Glucometer (Lifescan One Touch Ultra 2™) with Polymap wireless adaptor (PWR-08-03), and a pedometer (Omron No. HJ-150). Participants used their own weight scales for measuring body weight. All Bluetooth-compatible devices were paired with a unique study-provided smartphone. An application linking measures to a secure study database (Healthanyhwere™, Biosign Technologies Inc., Thornhill, Ontario, Canada) was installed on the smartphone to manage health measures. The smartphone transmitted data to the study database in real time, interfaced participants with research personnel, and allowed participants to monitor their personal health indicators.

3.3.3.2.1 Data Transmission and Security

When participants measured blood pressure and glucose, the reading was automatically sent to their smartphone via the Bluetooth connection. Measures for body weight and physical activity were manually entered by participants into their smartphone. The smartphone transmitted measures through a wireless network to the study database. Each submitted measure automatically updated the participant’s profile on the server in real-time. The study database was hosted on Healthanywhere servers, which is a secure repository for the participant’s study-related health information. Data security protocols are available elsewhere. Data of 500 MB per month were enabled for 12 months on each smartphone, which included roaming to allow participants to travel within North
America. If participants traveled outside the data coverage area, measures were stored at the time of measurement and automatically updated to the server, via smartphone, upon return to the data coverage area.

### 3.3.4 Measures

Physical activity (steps) was measured daily. Body weight (kg) was measured once weekly using the participant’s own weight scale. Blood pressure (mm Hg) was measured in a seated position three times weekly (two weekdays and one weekend day) upon waking. Fasting blood glucose (mmol/L) was measured once weekly. Participants were instructed on proper measurement technique and device use at baseline. Additionally, they were provided with a hardcopy troubleshooting guide and contact information for study personnel for further questions regarding either device operation or measurement procedures.

### 3.3.5 Statistical Analysis

Analyses were conducted in IBM SPSS® Statistics Version 20 (IBM, Chicago, IL). Blood pressure and physical activity measures were each averaged to a single weekly reading for analysis. A minimum of two submitted measures were required to compute the weekly average value. Missing values varied from 0% to 11% of cases across the five variables (physical activity, body weight, systolic blood pressure, diastolic blood pressure, and blood glucose) spanning the 12-week intervention. Regression with variables of age, sex, and group assignment was used to test that missing values were
missing completely at random. Multiple imputation (five sets) was used to replace missing values for analysis, and the imputed data files were used for parametric analyses. Significance for all statistical tests was set at $p < 0.05$. Repeated measures of multivariate analysis of variance (MANOVA) were conducted to test the effect of the intervention on changes in remotely submitted measures over time. Univariate analyses were examined to test for effects of group assignment over time. Data are presented as mean ($\pm$ standard deviation) unless otherwise specified.

### 3.4 Results

#### 3.4.1 Subject Characteristics

Figure 3.1 presents the flow of participants. Forty-five volunteers (25 women and 20 men) completed the 12-week intervention. The mean age of the sample was 63 ($\pm$ 5) years. Sample characteristics are presented in Table 3.1. There were no differences between groups at baseline for demographic (age, sex) or physiological markers (blood pressure, fasting plasma glucose).14
Figure 3.1 Flow of Participants

Participant Pool (n=195)
- 153 Clinic Roster
- 42 Community

Excluded (n=135)
- 70 No Answers: Clinic Roster
- 46 Screen Failures: Clinic Roster
- 19 Screen Failures: Community

Enrolled (n=60)
- 37 Clinic Roster
- 23 Community

Randomized to mHealth Intervention (n=45)
- 14 SB group
- 15 EX group
- 16 CC group
### Table 3.1 Sample Characteristics (n=45)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SB (n = 14)</th>
<th>EX (n = 15)</th>
<th>CC (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
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<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>63 (4)</td>
<td>63 (5)</td>
<td>62 (4)</td>
</tr>
<tr>
<td>Sex distribution (% female)</td>
<td>64</td>
<td>46</td>
<td>56</td>
</tr>
<tr>
<td>Clinical Measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>33.8 (4)</td>
<td>30.4 (5)</td>
<td>29.6 (6)</td>
</tr>
<tr>
<td>WC (cm)</td>
<td>114.1 (18)</td>
<td>107.8 (16)</td>
<td>98.9 (15)</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>130.3 (17)</td>
<td>131.1 (18)</td>
<td>121.4 (15)</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>80.1 (7)</td>
<td>79.8 (10)</td>
<td>76.8 (10)</td>
</tr>
<tr>
<td>Fasting glucose (mmol/L)</td>
<td>5.4 (1.5)</td>
<td>5.1 (1.3)</td>
<td>5.4 (1.5)</td>
</tr>
</tbody>
</table>

*Abbreviations:* SB, Sedentary group; EX, Exercise group; CC, Comprehensive group; BMI, body mass index; WC, waist circumference; BP, blood pressure.

### 3.4.2 Outcomes

The mean change in remotely submitted home-monitored variables is presented in Table 3.2. The multivariate analysis of variance revealed a significant effect of the intervention
during the 12-week home-monitoring period \( (F_{(10,488)} = 2.947, p = 0.001, \eta^2 = 0.057) \).

Univariate comparisons using Greenhouse-Geisser correction indicated no difference in changes between groups for physical activity \( (F_{(2,247)} = 1.615, p = 0.201, \eta^2 = 0.013) \), body weight \( (F_{(2,247)} = 2.147, p = 0.119, \eta^2 = 0.017) \), or blood pressure (systolic, \( F_{(2,247)} = 1.260, p = 0.286, \eta^2 = 0.010 \); diastolic, \( F_{(2,247)} = 0.520, p = 0.595, \eta^2 = 0.004 \)).

Table 3.2 Mean Change in Self-Monitored Measures Over Time

<table>
<thead>
<tr>
<th></th>
<th>Mean difference (standard error)</th>
<th>95% confidence interval [lower–upper bound]</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical activity (steps/day)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SB</td>
<td>460 (375)</td>
<td>([-278 – 1199])</td>
<td>0.22</td>
</tr>
<tr>
<td>EX</td>
<td>(-76 (364))</td>
<td>([-792 – 640])</td>
<td>0.84</td>
</tr>
<tr>
<td>CC</td>
<td>(-454 (345))</td>
<td>([-1134 – 225])</td>
<td>0.19</td>
</tr>
<tr>
<td>Body weight (kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SB</td>
<td>(-0.8 (1.3))</td>
<td>([-3.3 – 1.7])</td>
<td>0.52</td>
</tr>
<tr>
<td>EX</td>
<td>2.8 (1.2)</td>
<td>([0.4 – 5.3])</td>
<td>0.02</td>
</tr>
<tr>
<td>CC</td>
<td>0.7 (1.2)</td>
<td>([-1.6 – 3.0])</td>
<td>0.54</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SB</td>
<td>EX</td>
<td>CC</td>
</tr>
<tr>
<td>----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>SB</td>
<td>−3 (1)</td>
<td>[−5 − 0]</td>
<td>0.06</td>
</tr>
<tr>
<td>EX</td>
<td>−6 (1)</td>
<td>[−8 −3]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CC</td>
<td>−5 (1)</td>
<td>[−7 −2]</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

**Diastolic BP (mm Hg)**

<table>
<thead>
<tr>
<th></th>
<th>SB</th>
<th>EX</th>
<th>CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB</td>
<td>−4 (1)</td>
<td>[−6 −3]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>EX</td>
<td>−4 (1)</td>
<td>[−5 −2]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CC</td>
<td>−4 (1)</td>
<td>[−6 −3]</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

**Blood glucose (mmol/L)**

<table>
<thead>
<tr>
<th></th>
<th>SB</th>
<th>EX</th>
<th>CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB</td>
<td>−0.1 (0.1)</td>
<td>[−0.4 − 0.2]</td>
<td>0.51</td>
</tr>
<tr>
<td>EX</td>
<td>−0.4 (0.1)</td>
<td>[−0.7 −0.2]</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CC</td>
<td>−0.8 (0.1)</td>
<td>[−1.0 −0.5]</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

**Abbreviations**: SB, Sedentary group; EX, Exercise group; CC, Comprehensive group; BP, blood pressure; $p < 0.05$ denotes significance.

Changes were significantly different between groups for fasting blood glucose ($F_{(2,247)} = 5.978, p = 0.003, \eta^2 = 0.046$). Post-hoc analysis using Tukey’s honestly significant difference revealed no difference in change in blood glucose between the EX and CC groups ($p > 0.05$); however, there was a difference between the SB and CC groups ($p <$
0.05) as well as the SB and EX groups ($p < 0.05$). Mean remotely submitted weekly measures are listed in Table 3.3. Mean changes by group are presented in Figures 3.2 to 3.5.

**Figure 3.2 Change in Physical Activity by Group**
Figure 3.3 Change in Body Weight by Group

Note: * denotes statistical difference ($p < 0.05$) between groups.

![Body Weight Graph](image1)

Figure 3.4 Change in Blood Pressure by Group

Note: * denotes statistical difference ($p < 0.05$) between groups.

![Systolic Blood Pressure Graph](image2) ![Diastolic Blood Pressure Graph](image3)
Figure 3.5 Change in Blood Glucose by Group

*Note: * denotes statistical difference ($P < 0.05$) between groups.

![Fasting Blood Glucose](image)

Table 3.3 Average Weekly Readings by Intervention Group

<table>
<thead>
<tr>
<th>Physical activity (steps/day)</th>
<th>SB</th>
<th>EX</th>
<th>CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>6343 (3325)</td>
<td>9258 (5412)</td>
<td>9194 (3306)</td>
</tr>
<tr>
<td>Week 2</td>
<td>6759 (3572)</td>
<td>9458 (4304)</td>
<td>9688 (3961)</td>
</tr>
<tr>
<td>Week 3</td>
<td>6865 (4258)</td>
<td>9913 (5159)</td>
<td>9214 (4067)</td>
</tr>
<tr>
<td>Week 4</td>
<td>6536 (3674)</td>
<td>9913 (5415)</td>
<td>9198 (3455)</td>
</tr>
<tr>
<td>Week 5</td>
<td>6719 (3576)</td>
<td>9960 (5850)</td>
<td>9802 (3954)</td>
</tr>
<tr>
<td>Week</td>
<td>SB</td>
<td>EX</td>
<td>CC</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>--------</td>
<td>--------</td>
</tr>
<tr>
<td>6</td>
<td>7068 (3776)</td>
<td>9961 (5487)</td>
<td>9069 (2979)</td>
</tr>
<tr>
<td>7</td>
<td>7243 (3506)</td>
<td>9838 (4210)</td>
<td>9119 (3524)</td>
</tr>
<tr>
<td>8</td>
<td>6671 (3278)</td>
<td>9002 (4691)</td>
<td>9029 (3364)</td>
</tr>
<tr>
<td>9</td>
<td>6877 (3808)</td>
<td>9382 (4651)</td>
<td>8931 (3110)</td>
</tr>
<tr>
<td>10</td>
<td>8090 (5452)</td>
<td>9746 (4903)</td>
<td>9315 (3830)</td>
</tr>
<tr>
<td>11</td>
<td>6906 (4366)</td>
<td>9130 (5285)</td>
<td>9084 (3573)</td>
</tr>
<tr>
<td>12</td>
<td>6809 (3624)</td>
<td>9195 (6094)</td>
<td>8762 (3578)</td>
</tr>
</tbody>
</table>

**Body weight (kg)**

<table>
<thead>
<tr>
<th>Week</th>
<th>SB</th>
<th>EX</th>
<th>CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>97.1 (20.2)</td>
<td>82.3 (18.2)</td>
<td>83.5 (17.0)</td>
</tr>
<tr>
<td>2</td>
<td>96.2 (20.0)</td>
<td>82.6 (17.5)</td>
<td>81.6 (17.5)</td>
</tr>
<tr>
<td>3</td>
<td>96.7 (20.1)</td>
<td>82.4 (17.4)</td>
<td>83.2 (16.5)</td>
</tr>
<tr>
<td>4</td>
<td>98.3 (18.6)</td>
<td>82.0 (17.3)</td>
<td>81.5 (17.2)</td>
</tr>
<tr>
<td>5</td>
<td>95.4 (19.2)</td>
<td>82.2 (17.6)</td>
<td>84.1 (17.0)</td>
</tr>
<tr>
<td>6</td>
<td>96.9 (19.6)</td>
<td>79.4 (14.4)</td>
<td>82.3 (15.7)</td>
</tr>
<tr>
<td>7</td>
<td>91.8 (12.0)</td>
<td>80.8 (17.0)</td>
<td>81.8 (15.8)</td>
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<tr>
<td>8</td>
<td>96.5 (19.1)</td>
<td>81.3 (17.0)</td>
<td>81.6 (17.5)</td>
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<td>9</td>
<td>90.7 (11.9)</td>
<td>79.1 (14.8)</td>
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<td>10</td>
<td>97.1 (17.7)</td>
<td>82.1 (11.7)</td>
<td>81.3 (17.4)</td>
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<tr>
<td>Week</td>
<td>SB</td>
<td>EX</td>
<td>CC</td>
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</tr>
<tr>
<td>11</td>
<td>95.0 (19.4)</td>
<td>81.4 (10.6)</td>
<td>80.3 (16.4)</td>
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<tr>
<td>12</td>
<td>96.4 (18.6)</td>
<td>85.4 (13.1)</td>
<td>84.3 (15.4)</td>
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**Systolic blood pressure (mm Hg)**

<table>
<thead>
<tr>
<th>Week</th>
<th>SB</th>
<th>EX</th>
<th>CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>135 (19)</td>
<td>129 (16)</td>
<td>131 (13)</td>
</tr>
<tr>
<td>2</td>
<td>133 (16)</td>
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<td>3</td>
<td>131 (12)</td>
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<td>124 (13)</td>
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<td>4</td>
<td>131 (13)</td>
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<td>12</td>
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**Diastolic blood pressure (mm Hg)**

<table>
<thead>
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<th>EX</th>
<th>CC</th>
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<tbody>
<tr>
<td>1</td>
<td>86 (9)</td>
<td>81 (9)</td>
<td>83 (10)</td>
</tr>
<tr>
<td>Week</td>
<td>SB</td>
<td>EX</td>
<td>CC</td>
</tr>
<tr>
<td>-------</td>
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<tr>
<td>1</td>
<td>6.6 (1.4)</td>
<td>6.6 (1.4)</td>
<td>6.7 (1.7)</td>
</tr>
<tr>
<td>2</td>
<td>6.3 (1.6)</td>
<td>6.1 (1.0)</td>
<td>5.9 (0.7)</td>
</tr>
<tr>
<td>3</td>
<td>6.1 (1.2)</td>
<td>6.3 (1.3)</td>
<td>6.0 (0.9)</td>
</tr>
<tr>
<td>4</td>
<td>6.4 (1.3)</td>
<td>6.4 (1.4)</td>
<td>6.1 (1.2)</td>
</tr>
<tr>
<td>5</td>
<td>6.3 (1.4)</td>
<td>6.0 (0.8)</td>
<td>6.0 (1.0)</td>
</tr>
<tr>
<td>6</td>
<td>6.3 (1.1)</td>
<td>6.0 (0.9)</td>
<td>6.1 (1.0)</td>
</tr>
<tr>
<td>Week</td>
<td>SB (0.9)</td>
<td>EX (0.8)</td>
<td>CC (1.3)</td>
</tr>
<tr>
<td>-------</td>
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</tr>
<tr>
<td>Week 1</td>
<td>6.2</td>
<td>6.1</td>
<td>6.3</td>
</tr>
<tr>
<td>Week 2</td>
<td>6.2</td>
<td>5.9</td>
<td>5.9</td>
</tr>
<tr>
<td>Week 3</td>
<td>6.2</td>
<td>6.0</td>
<td>6.2</td>
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<tr>
<td>Week 4</td>
<td>6.4</td>
<td>6.2</td>
<td>5.8</td>
</tr>
<tr>
<td>Week 5</td>
<td>6.2</td>
<td>6.1</td>
<td>5.6</td>
</tr>
<tr>
<td>Week 6</td>
<td>6.5</td>
<td>6.2</td>
<td>5.9</td>
</tr>
</tbody>
</table>

Note: Participants submitted weekly readings remotely using mHealth technology kit. This table lists the values of submitted readings by intervention group for the 12-week remote monitoring and physical activity intervention.

Abbreviations: SB, Sedentary group; EX, Exercise group; CC, Comprehensive group.

### 3.5 Discussion

This study examined the effect of pairing mHealth tools for home self-monitoring with personalized activity prescriptions targeting various intensities of physical activity (sedentary, exercise, or both) to remotely manage health and cardiometabolic risk. Changes in home-monitored measures were significant during the 12-week intervention. Across all three groups, changes in physical activity, body weight, and blood pressure were similar, whereas change in blood glucose was significantly better for the groups that were prescribed exercise. Results are novel in that they demonstrate that prescribing physical activity in conjunction with mHealth devices for ongoing self-monitoring holds...
promise for changing lifestyle-related disease risk among at-risk, but otherwise healthy, older men and women.

### 3.5.1 Physical Activity

At week one, all groups had received, and it is assumed initiated, their physical activity prescriptions for this intervention. Although significance was not achieved \((p < 0.05)\), the EX and CC groups tended to engage in more steps per day than the SB group during the course of the intervention (Table 3.3), indicating that the groups engaging in prescriptions that included higher intensity physical activity (EX and CC groups) accumulated more steps per day. In the present study the SB group incrementally improved daily physical activity by increasing the average steps per day from week one to 12 \((p > 0.05)\). The gradual increase in daily activity of the group prescribed changes to low-intensity physical activity only (SB group) suggests that prescribing changes to sedentary behaviours may lead to progressive increases in daily activity behaviours. Moreover, an early sedentary behaviour intervention among community-dwelling older adults by Gardiner et al.\(^{24}\) determined that individuals educated about sedentary time increased their light- and moderate- to vigorous-intensity physical activity as measured by accelerometer. Although the present study used a less sophisticated device for measuring daily physical activity, the results are promising and further demonstrate the benefit of pedometers as an mHealth tool for increasing physical activity levels.
3.5.2 Body Weight

Body weight status is an indication of lifestyle-related disease risk. This study was designed to educate patients about their body weight (e.g. ongoing self-measurement). Changes in home-monitored body weight varied across groups from reduction in the SB group \((p > 0.05)\), to increases in the EX \((p < 0.05)\) and CC groups \((p > 0.05)\) (Table 3.2). A meta-analysis of walking interventions without a dietary component concluded that healthy adults may reduce body weight by 0.05 kg per week of intervention.\(^{25}\) In the current study, across all groups the average home-monitored body weight increased marginally from week one to 12 \((p > 0.05)\), which may demonstrate that the physical activity prescription and mHealth tools were on average not effective at managing body weight status as compared with a pedometer-based walking intervention alone. However, although not statistically significant, results are promising in that they may support the novel approach of prescribing changes to sedentary behaviours for weight management.

3.5.3 Blood Pressure

Although the majority of mHealth interventions that involve remote self-monitoring of blood pressure include a population of hypertensive patients, a systematic review of pedometer-based physical activity interventions including individuals who were predominantly normotensive at baseline concluded that clinic systolic and diastolic blood pressure could decrease by 3.8 mm Hg and 0.3 mm Hg, respectively.\(^{26}\) It has also been suggested that normotensive individuals engaged in 12-week physical activity intervention, without an mHealth component, may reduce systolic blood pressure by 2.6 mm Hg and diastolic blood pressure by 1.8 mm Hg.\(^{27}\) In the present study, mean home-
monitored systolic blood pressure was reduced by 4.2 mm Hg and diastolic blood pressure by 4.0 mm Hg (Table 3.3), with reductions in systolic and diastolic blood pressure significant across all groups (Table 3.2). Moreover, these improvements are greater than previously identified for physical activity and mHealth interventions among normotensive patients. Therefore, changes in systolic and diastolic blood pressure also may be considered clinically meaningful across all groups in the present study.

3.5.4 Blood Glucose

At baseline, participants in our sample had, on average, fasting blood glucose within clinically desirable thresholds (3.6–6.0 mmol/L). It has been suggested that glucose-normal individuals could be expected to reduce their fasting plasma glucose by 0.03 mmol/L following a physical activity intervention.\(^{26}\) In our sample, reduction in home-monitored blood glucose ranged between 0.1 mmol/L for the SB group \((p > 0.05)\) and 0.8 mmol/L for the CC group \((p < 0.05)\) (Table 3.2). Mean changes in blood glucose were significant for the groups prescribed higher intensity activity (EX and CC groups). Results support the effectiveness of prescribing exercise to manage blood glucose as well as using mHealth devices for self-monitoring blood glucose among glucose normal individuals.

3.5.5 mHealth

mHealth technologies can be used to assist both health professionals and patients in evidence-based self-management care and prevention.\(^{20}\) Previous research has shown that
remote monitoring technologies enable participants to share in the responsibility for their own health, while also providing a new understanding of their overall health and physical fitness. In the present study, the smartphone portal allowed participants to submit measures to the study database, communicate with study personnel, and self-monitor indicators of health status. Results of the participant’s acceptance of and experience using the mHealth technology kit employed in the present study for remote self-management are presented elsewhere.

It has been suggested that the value of telemedicine for the management of chronic conditions is weak and even contradictory. Free et al found that mHealth interventions aiming to change physical activity behaviours (with and without dietary intervention) led to a small clinical benefit or none at all. However, studies included in their systematic review were predominantly based on text messaging protocols, which is a single functionality of mobile phones. Furthermore, there is an abundance of literature reporting the use of this limited functionality of mobile phones, and a Cochrane Systematic Review concluded that there is little evidence to support the effectiveness of mobile messaging services (i.e. texting, or short message service) for chronic disease prevention. In contrast, smartphones allow for the diverse use of mobile technologies, including pairing with peripheral devices to allow for measurement of multiple health parameters (e.g. body weight, blood glucose, blood pressure). Recently, it was suggested that the effect of mHealth interventions is hampered by the limited use of messaging functionalities only, which has restricted the ability to draw evidence-based conclusions about the effectiveness of smartphones on various health behaviours.
Failure to implement telemedicine interventions commonly descends from the technology’s acceptance, financing, application policy, and legislation for use in practice. Using widely available devices may help to improve implementation of findings from remote health monitoring studies into clinical practice. However, the cost of supplying these devices to individuals is immense. For example, in the present study the cost of the devices included in the technology kit as well as the data plan enabled on each smartphone for the 12-week intervention was approximately $34,000 (25 technology kits at $1000 each, data plan subscription for the 25 smartphones at $9000). Future researchers may wish to examine the feasibility of using devices that subjects already have access to, thereby reducing costs and limiting duplication in technology. Moreover, leveraging devices individuals are familiar with using may enhance adherence to the self-management and remote monitoring protocols, potentially further enhancing the clinical effect.

3.5.6 Strengths and Limitations

mHealth has the potential to promote health and prevent disease by addressing many of the costly and disabling factors that lead to chronic and non-communicable diseases, including access to care and knowledge about disease risk. To date, mHealth interventions have primarily involved individuals already experiencing symptoms of disease (e.g. diabetes, hypertension, obesity). The present study explored the effect of mHealth technologies in conjunction with prescribed changes to various intensities of
physical activity (i.e. sedentary, exercise, or both) to improve risk factors for preventing various lifestyle-related chronic conditions. Among the present sample of typical, community-dwelling older men and women, the mHealth intervention involving physical activity prescription effectively improved behavioural and physiological risk factors for chronic disease among all three groups.

Recruitment advertisements indicated the use of smartphones as well as other self-management technologies in the present study. Therefore, it is likely that individuals with low motivation for the use of mHealth technologies would not have volunteered. Participants’ baseline comfort with using mHealth devices could potentially impact behavioural and clinical outcomes. The present investigation was not designed to control for familiarity with technology. However, all participants were trained individually at baseline to ensure that they knew how to use the devices. Additionally, individuals interested in learning to use the technologies may have been more inclined to change their behaviours compared with those who did not volunteer to participate in the intervention. All participants who enrolled in the study completed the 12-week intervention, which suggests that the present sample may be more highly motivated than the average clinic population.

The findings reported here are limited to the small sample of highly motivated individuals who volunteered for the present study. The primary factor limiting sample size was the cost of providing the mHealth component of the intervention. Future
research is warranted to further demonstrate the efficacy of mobile technologies for chronic disease prevention among a sample of healthy individuals. Additionally, exploratory analyses may be warranted to determine characteristics of individuals most likely to respond to an mHealth behavioural intervention.

3.5.7 Conclusion

This study explored the effect of pairing mHealth with a physical activity prescription for changing physiological and behavioural markers of lifestyle-related chronic disease risk. The results support the effectiveness of home health monitoring for self-management of health risk. Moreover, findings suggest that prescribing changes to sedentary behaviours may be an effective strategy for chronic disease prevention. To the best of our knowledge, this is the first mHealth study involving prescribed changes to sedentary behaviours (alone, and in conjunction with exercise) to manage and prevent lifestyle-related chronic conditions among a cohort of healthy, older adults. More research is needed to further explore the effect of mHealth for preventing the development of lifestyle-related chronic disease among at-risk individuals.
3.6 References


Chapter 4

4 Longitudinal Follow-Up

A version of this chapter has previously been published:

4.1 Abstract

**Background:** There is a shortage of literature describing the experience of individuals who have participated in a physical activity and mobile health (mHealth) intervention. Many physical activity interventions are of short duration and do not report long-term changes in clinical measures or adoption of prescribed health behaviours. Previously, we have reported the clinical and behavioural outcomes from the first phase of a physical activity prescription and mHealth intervention delivered through the primary care setting. The purpose of this next phase was to perform a longitudinal follow-up six-months post-intervention.

**Methods:** Mixed methods analysis including repeated measures ANOVA of functional aerobic capacity (VO$_2$max) at pre-intervention, post-intervention, and follow-up clinic visits, and whole text analysis of semi-structured interviews discussing the participant experience in a health behaviour intervention.
**Results:** Twenty participants, mean age 63 ± 5 years, participated. Gains made in VO$_2$\textsubscript{max} were maintained at 6 months ($p < 0.05$). Participants reported engaging in sustained and routine physical activity, yet some identified a need for additional support to adopt the prescribed health behaviours. Emergent themes included the desire for short-term mHealth intervention to educate individuals about prescribed health behaviours without need for ongoing management by clinicians, leveraging mHealth to build social networks around prescribed health behaviours and to connect individuals to build a sense of community, and participant views of physical activity as medicine.

**Conclusions:** The present study investigated both the long-term adoption of physical activity behaviours as well as the participant experience in a physical activity and mHealth intervention. Findings from the current study may be used to inform the development of user-centered lifestyle interventions.

**Keywords:** mixed methods; mobile health; activity prescription; healthy aging; disease prevention; Exercise Is Medicine
4.2 Introduction

Health systems around the world are progressively being dominated by the need to care for chronic conditions and non-communicable diseases. In the years to come, it is projected that deaths due to chronic and non-communicable disease will account for nearly 60% of disease burden globally. Simultaneously, life expectancies in developed countries are increasing by approximately two years each decade. The prevalence of chronic conditions increases with advanced age. Therefore, a disparity remains between longevity and independent healthy living. It is crucial that user-centered programs and services be developed and implemented to facilitate the adoption of healthy living behaviours now to promote healthy, independent aging.

4.2.1 Physical Activity

It is well reported in the literature that physically active lifestyles promote health and healthy aging. However, the majority of North American adults are not meeting minimum physical activity levels recommended in public health guidelines. Physical inactivity is the fourth leading cause of death, and each year contributes to more than three million deaths around the world. Health messages delivered in the primary care setting can be a catalyst for change. A written prescription represents the value a health practitioner (e.g. physician) places on exercise for managing and promoting health. Moreover, the global expansion of Exercise Is Medicine® initiatives demonstrate the widespread acceptance of the prescription of exercise to manage and prevent lifestyle-related diseases.
4.2.2 mHealth

There is a growing body of evidence reporting the power and utility of mobile communication devices in the health landscape (i.e. mobile health [mHealth]). The worldwide omnipresence of mobile communication devices supports the availability of mHealth for comprehensive and frequent data sharing.\textsuperscript{16,17} Mobile technologies are becoming a focus for chronic disease management and prevention, and reportedly improve access to information and services, provide care that is not otherwise deliverable, and increase care delivery.\textsuperscript{18,19} Therefore, mHealth holds the potential to engage patients in ongoing treatment for and self-management of their health.

4.2.3 Research Paradigm

Pragmatic approaches to research leverage the strengths of quantitative and qualitative research paradigms in an effort to consider multiple perspectives and viewpoints in a unified approach. This methodology is often referred to as triangulation, and focuses on a mixture, or balance, of qualitative and quantitative research paradigms.\textsuperscript{20} Understanding the experience of individuals who have participated in research investigating the implementation of prescribed changes in health behaviours is fundamental to designing future interventions, programs, and services that respond to patient needs. Leveraging the experience of individuals to develop better systems is at the core of user-centered design.\textsuperscript{21} However, there has been a shortage of information describing the experience of individuals who have participated in a physical activity and mHealth intervention.
4.2.4 Objective

Previously, we have reported the clinical and behavioural outcomes from the first phase of a physical activity prescription and mHealth intervention delivered through the primary care setting.\textsuperscript{12,22} Briefly, the 12-week intervention elicited significant changes in anthropometrics (body mass index, waist circumference), functional aerobic capacity (predicted maximum oxygen consumption [VO\textsubscript{2}\text{max}]), and clinical markers for cardiometabolic risk (blood pressure, glucose, cholesterol),\textsuperscript{12} as well as self-monitored measures of physiological and behavioural risk factors for cardiovascular disease (physical activity, blood pressure, blood glucose, body weight).\textsuperscript{22} The purpose of this next phase was two-fold: (1) determine if improvements made through the 12-week intervention phase were maintained long-term by measuring a clinical marker of cardiometabolic health risk (functional aerobic capacity) at six months post-intervention; and (2) discuss with participants their experience in a behavioural health intervention to elicit themes describing the participant experience in a program aimed to modify lifestyle using activity prescription and mHealth.

4.3 Method

4.3.1 Design

Individuals enrolled in the 12-week intervention were invited to complete a longitudinal follow-up visit 6 months post-intervention. The intervention is described elsewhere.\textsuperscript{12,22} Briefly, participants were randomized into four groups based on the prescribed level of
physical activity intensity: no prescription (control), increasing high-intensity activity (i.e. exercise), reducing low-intensity activity (i.e. sedentary behaviour), or both (increasing exercise and reducing sedentary behaviour). Participants in the three groups receiving an activity prescription at baseline also received a technology kit of mHealth devices for home self-monitoring of risk factors associated with cardiometabolic disease, including blood pressure, blood glucose, body weight, and physical activity. During the pre-intervention visit (week 0) the activity prescription included counselling with a Certified Exercise Physiologist (CSEP-CEP®) and a personalized activity program. At the post-intervention visit (week 12), all participants were provided with a written prescription indicating their VO$_2$max, target training heart rate, and amount of activity required to meet physical activity guidelines (Figure 4.1). Participants were not informed during the 12-week visit that they would be contacted six months later for a longitudinal follow-up visit.
Figure 4.1 Standardized Prescription Form from the Step Test and Exercise Prescription (STEP™) Tool

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At the follow-up visit (after 36 weeks), participants completed the submaximal self-paced functional aerobic capacity test from the Step Test and Exercise Prescription (STEP™)\textsuperscript{24-26} tool as well as engaged in a semi-structured interview discussing their experience in the mHealth and physical activity intervention.
4.3.2 Participants
Sixty older men and women (aged 55 to 75 years) volunteered for the 12-week intervention. They were invited to attend the follow-up visit using their preferred method of communication (e.g. email, telephone). Two attempts were made to contact each participant for this follow-up visit. Exclusion criteria from the first phase were followed, which are reported elsewhere. All subjects provided informed written consent as approved by Western University Health Sciences Research Ethics Board (Protocol No. 18700).

4.3.3 Statistical Analysis
4.3.3.1 Quantitative Analysis
Previously, we found no difference between groups for functional aerobic capacity (VO$_{2\text{max}}$) during the 12-week intervention phase. A dependent samples $t$-test was conducted to test for differences in VO$_{2\text{max}}$ between participants who completed follow-up (36-week) testing and participants who completed post-intervention (12-week) testing only. Repeated measures ANOVA was conducted for the primary outcome (VO$_{2\text{max}}$). Analyses were conducted in IBM SPSS® Statistics Version 20 (Chicago, IL). Data are presented as mean ($\pm$ standard deviation).

4.3.3.2 Qualitative Analysis
Interviews were digitally recorded and manually transcribed by the first author. Member checking was conducted by reading the transcript back to the participant to confirm that it
reflected the message and tone that the participant intended to convey. Whole text analysis was conducted to interpret participant responses. Data were managed in Microsoft Excel® for Mac 2011.

4.4 Results

4.4.1 Participants
Of the 60 participants invited to participate, 30 (50%) did not respond to the invitation, four declined (7%), and 26 (43%) were interested. Twenty participants (12 women and 8 men) volunteered to participate in the longitudinal follow-up visit. The mean age of participants at follow-up was 63 ± 5 years.

4.4.2 Quantitative Results
The average functional aerobic capacity of the sample across the 3 clinic visits are presented in Table 4.1. There was no difference in VO$_{2\text{max}}$ between participants who completed the longitudinal follow-up visit and those who did not participate ($p = 0.250$).

There was a significant change in aerobic capacity ($F_{(2,38)} = 13.645, p<0.01, \eta^2 = 0.418$). Post-hoc analysis using a Greenhouse-Geisser correction indicated that the difference was significant between pre-intervention (week 0) and post-intervention (week 12) visits, with no difference between post-intervention and follow-up (after 36 weeks) visits (Figure 4.2). The unpublished standard error associated with VO$_{2\text{max}}$ calculation from the
STEP™ tool is 1.35. Therefore, gains made through the intervention (12 weeks) and sustained to follow-up (36 weeks) may be considered significant. Results from the current study are promising, given that longitudinal follow-up from previous STEP™-based interventions have demonstrated that gains made in VO₂max at six months were maintained to ≥ 12 months.¹³

Table 4.1 Average Aerobic Capacity Across 3 Clinic Visits (n=20)

<table>
<thead>
<tr>
<th>Clinic visit</th>
<th>VO₂max (ml/kg/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 0</td>
<td>29.91 ± 7.94</td>
</tr>
<tr>
<td>After 12 weeks</td>
<td>33.02 ± 6.46</td>
</tr>
<tr>
<td>After 36 weeks</td>
<td>33.59 ± 6.99</td>
</tr>
</tbody>
</table>

*Note:* Data presented as mean ± standard deviation.

*Abbreviation:* VO₂max, functional aerobic capacity (maximum oxygen consumption).

Figure 4.2 Aerobic Capacity Across 3 Clinic Visits (n=20)

*Note:* * denotes statistical difference (p < 0.05).
4.4.3 Qualitative Results

4.4.3.1 Activity Prescription

The physical activity prescription portion of the intervention is described elsewhere. Briefly, at baseline participants in the intervention groups were provided with personalized activity programming through a written activity prescription. At 12 weeks all participants received a written prescription identifying their predicted aerobic capacity (VO$_2$max), corresponding fitness level, and information regarding their target training intensity, frequency, type, and time (Figure 4.1).

At the longitudinal follow-up, participants were asked if they had continued doing their activity prescription from the intervention after their final clinic visit (six months...
Representative quotations of participants’ responses are listed in Table 4.2. The responses suggested that most participants who did continue their activity prescription adapted it to their evolving activity preferences and lifestyle needs to maintain health benefits. Moreover, participants reported that they had successfully incorporated healthy physical activity behaviours into their daily routines. However, some participants reported obstacles to engaging in sustained healthy activity behaviours following the 12-week intervention period. Common themes for not continuing with their personal activity prescription included weather/seasonal, lack of purpose after the study ended, and medical reasons preventing engagement in activity.

Table 4.2 Participants’ Comments About the Activity Prescription

<table>
<thead>
<tr>
<th>Quotation</th>
<th>Participant Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I would say that I do it regularly, but it’s altered in terms of the exercise I’m doing. I’ve sort of evolved.”</td>
<td>61-year-old man</td>
</tr>
<tr>
<td>“I just go day-by-day. It depends on what I have on the agenda… I have my events and my outings, and I plan [activity] around them.”</td>
<td>65-year-old woman</td>
</tr>
<tr>
<td>“Yes. Just continue to do what I’m doing at the gym: my walking, working with the weights, going on the treadmill, not to sit too long.”</td>
<td>62-year-old man</td>
</tr>
<tr>
<td>“It’s just a commitment to myself to do activity everyday like we planned [in the study]. It’s really the commitment to myself, determination to stay in shape.”</td>
<td>57-year-old woman</td>
</tr>
<tr>
<td>“Yeah, I did in the summertime. Just wintertime, sometimes I go to the YMCA and work with the”</td>
<td></td>
</tr>
</tbody>
</table>
machine, but not walking [outside]. In the summer I will go and do it again.” (59-year-old man)

“I found it very helpful, you know. I think it gave us a purpose to do it. It was a useful tool and we tried to keep up, but I don’t think we’re keeping up as much because you’re not sort of checking-in and putting in the numbers [self-monitoring] and that. We had more of a purpose while we were doing the study.” (63-year-old couple)

“I would need someone to keep track of me. The accountability.” (59-year-old woman)

“I have not been doing the walking like I should as my knee has been hurting all winter. I have given it a good rest and it’s getting better. Looking forward to getting back in shape.” (67-year-old woman)

### 4.4.3.2 mHealth

In addition to the physical activity prescription, the intervention also included an mHealth component (described elsewhere). Briefly, participants were provided with a technology kit including a smartphone, blood pressure monitor, glucometer, pedometer, and weight scale to submit health measures remotely during the 12-week intervention. At the longitudinal follow-up, participants were asked about their experience using the technology kit, and if they would like to use any of the devices on an ongoing basis. Representative quotations of participants’ responses are listed in Table 4.3.
Table 4.3 Participants' Comments About mHealth

<table>
<thead>
<tr>
<th>Quote</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I found it quite helpful, really. I went out and got my own blood pressure cuff. I already had a pedometer. I weigh myself when I go to the gym, probably once a week. I have a glucometer now, and it’s helpful because times when I think it’s going to be high it’s not. So I’ve got my own everything now. I just monitor them. If I find out my sugar’s high, I think about what I had to eat. Then I know not to eat it again, or eat less of it.”</td>
<td>62-year-old man</td>
</tr>
<tr>
<td>“Very helpful, I found. Encouraging to see good blood pressure, sugar glucose go down. Using it would be good. I would use it if I had it—maybe not every day. I might buy them myself. I thought about getting a blood pressure thing, but I don’t want to get too addicted to it though, that’s the thing. “Self-management”: I’d never thought of it like that before [the study].”</td>
<td>57-year-old woman</td>
</tr>
<tr>
<td>“I did buy the pedometer after the study. I already had a blood pressure machine. I didn’t bother with the glucose. I log measures about a month before my annual check-up. For the pedometer, I don’t log it but I make sure each day I do a decent amount.”</td>
<td>73-year-old woman</td>
</tr>
<tr>
<td>“I enjoyed the pedometer. It gave me motivation to try and outdo the number of steps. Even my neighbor wanted to know how many steps we did together on walks. I also liked finding the correlation between doing the activities and sleeping much better at night. That was a really good correlation—I liked that! Even when I went [on vacation] I did my exercise because they had an exercise room.”</td>
<td>65-year-old woman</td>
</tr>
<tr>
<td>“I think the most important thing is the pedometer. This is the BEST device. You can talk about</td>
<td></td>
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</table>
all kinds of other things, but this one is the best because you know what you did and you’re always trying to compete and to keep it up and set a goal and then just go for it.” (68-year-old woman)

“No, it wasn’t a burden for me. It just makes you aware of your blood pressure and blood sugars. I thought mine were levels that were fine anyway. But you know, it just gives it to you right there [on device screen]. Somebody who had issues, it might be more important for them because they can see it [measures] there clearly. Whereas I’m fortunate to not have issues. So, you know. I really enjoyed the pedometer—it was the one! The blood pressure and sugars, you know. I really liked that pedometer.” (65-year-old woman)

“It was helpful, yeah. It was a little bit hard, but helpful. At first I start, and yeah, had a little bit problems. But after like 2 weeks it was easy.” (59-year-old man)

“It was a burden. I found that I would get upset. I don’t know why, but anytime I have to do anything that just raises my tension or stress, you know. It definitely isn’t good for my blood pressure! The other parts were fine, like sending in blood sugar, I guess. I do take my blood sugar every day so it’s not a big deal. But if it didn’t go right the first time I took it, then I’d do it again and the machine would beep. There was a delay in the machine—it didn’t happen instantly, so I was worried. And the same thing when I recorded my steps: sometimes it didn’t seem like it went through. But I found out it did, so I ended up sending it in a couple of times. So there are those hassles. But if someone HAD to use it, it would be okay.” (68-year-old woman)

“I think it was helpful. Prior to that I wouldn’t be able to tell you what my heart rate normally is. And now I know the range it’s in, as well as my blood glucose and weight. Probably before the study if someone asked me what my weight was I’d just say I really don’t know. Because my
readings were so consistent through the study, it was good to have that period of time, but I
don’t think I would continue to use it just because they are so consistent. You know, now when I
go to my physician I have an expectation—so being able to kind of monitor, I’ve got a
benchmark now” (54-year-old man)

“I was encouraged by having it all measured. My workouts are a lot harder now that I know. I
feel good about pushing hard now because of it. I guess it’s that old adage in business: what
doesn’t get measured doesn’t get done. You need that feedback.” (61-year-old man)

“I think the [self-monitoring feedback] was really valuable: it shows us that we did it, and this is
where we are now.” (63-year-old couple)

“I was interested in the subject—myself!—and general health. And I didn’t know a lot about my
glucose, which it turns out is pretty flat and regular so that’s good. I thought it was a pretty
useful tool. I think the feedback is good. I should be monitoring my blood pressure a little more
because I tend to get readings, like, all over the place. When I went to the doctor last month,
those were the best [blood pressure] readings I’ve had in years.” (61-year-old man)

The responses indicated that the participants enjoyed learning how to use the technology
for self-management, did or would like to continue using the devices, and that they
typically found some devices more appropriate to their health and lifestyle needs than
others. Specifically, the pedometer was most commonly reported as a useful device for
self-monitoring. However, participants with multiple health concerns were interested in
sustained use of additional devices, such as the blood pressure and blood glucose
monitors and the weight scale. Few participants reported interest in using the smartphone for ongoing self-monitoring of health measures.

Among this older adult sample, for some participants the technology kit was their first introduction to a smartphone and to mHealth devices. Participants were asked about their experience learning to use these devices. Most responses indicated that learning to use the devices was easy, and that using the devices was unobtrusive to their daily routines. However the few participants who struggled with the technology kit shared details of their experience identifying various challenges, which included the usability of the various devices in the kit as well as device integration with the health application used to manage submitted measures. The participants also reported that using the technology during the intervention period was sufficient to provide them with a more comprehensive understanding of their health, which suggests that mHealth devices may have a role in educating individuals without the need for ongoing clinician-supported intervention. Participants reported that using the mobile technology kit for self-management was especially useful due to the instant feedback. Figure 4.3 demonstrates the instant feedback available through the smartphone application, which displays graphical and tabular results for the participants to view. Tables reported each submitted measure, and graphs displayed trends in submitted measures over time. Individual tables and graphs were generated in real time for each measure (physical activity, blood pressure, blood glucose, and body weight). Additionally, participants had access to all their wirelessly submitted measures during the course of the intervention. Some participants reported sharing this information with their personal healthcare team (e.g. primary and allied
health professionals), and some participants capitalized on the graphs and figures generated as well as their experience in taking and submitting measures to learn about and manage their health.

**Figure 4.3 Graphical Feedback for Self-Monitoring**

![Graphs of Pedometer Trend, Blood Pressure Trend, Blood Glucose Trends, and Body Weight Trend]

### 4.4.3.3 Education About Health

Beyond the two principal components of the intervention (activity prescription and mHealth), there was interest in assessing how participating in this intervention educated the participants about health and activity behaviours. During the interview, participants were asked if there was something specific that they learned during the intervention that they continue to use in their daily life on an ongoing basis. Representative quotations of
participants’ responses are listed in Table 4.4. Interview responses indicated that
participants now have an understanding of their personal activity behaviours relative to
evidence-based guidelines. Moreover, the physical activity counseling process was cited
as a beneficial learning experience for individuals by enhancing their knowledge of and
confidence with physical activity and exercise.

Table 4.4 Participants' Comments About Health Education

<table>
<thead>
<tr>
<th>Comments</th>
<th>Age</th>
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</thead>
<tbody>
<tr>
<td>“I think for me, and probably for both of us, it’s just an awareness of knowing what we need to do. It was recommended when we started to get the 10,000 steps. So that’s really the benchmark we use. I think the whole program gave both of us a better awareness. We used to go for walks, but now we’re more aware of going a little further and going a little faster.”</td>
<td>63-year-old couple</td>
</tr>
<tr>
<td>“I learned that you’ve got to get that activity in every day.”</td>
<td>67-year-old woman</td>
</tr>
<tr>
<td>“I probably take the stairs more at work. Just integrate more. Or if I’m working at my desk I’ll get up and instead of having coffee in the kitchen on my floor I’ll go up 2 floors and get a coffee on the other floor.”</td>
<td>58-year-old woman</td>
</tr>
<tr>
<td>“It was the fact that 10,000 steps is a good target. And I wear the pedometer. And if I haven’t done the 10,000 steps in the day, I know why. And most of the time when I haven’t, I haven’t been idle: I’m on my feet, I’m ironing, I’m cooking—so, active in that sense. In fact, when I’ve read a book I think, ‘Oh darn it, I have to get up and get moving!’”</td>
<td>64-year-old woman</td>
</tr>
<tr>
<td>“Well, actually, I think the talk we had about how to exercise, and particularly the weight lifting,</td>
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</tbody>
</table>
I found really, really helpful. And I’ve used it a lot. The strategies and techniques and pointers you pointed out. The way we talked about it. And just doing it regularly, I guess. I think really for the first time in my life it’s not a chore. I’m not looking for excuses anymore. A more measured approach, you know what I mean. And that, I guess, comes from really a lifestyle change instead of sort of saying something like I’m going to lose weight or exercise for 6 weeks. I just got into the routine of making it part of my day, and now it is.” (61-year-old man)

4.4.3.4 Exercise as Medicine

The participants’ comments during the interviews illustrated their perceptions of exercise and activity as a form of medical treatment, perhaps because the intervention was initiated in the primary care setting, or because the participants in the intervention groups were measuring markers of health at home for the 12-week intervention period.

Representative quotations of participants’ responses are listed in Table 4.5; specific references to exercise as medicine are italicized.

Table 4.5 Participants’ Comments About Exercise as Medicine

*Note:* Specific references to exercise as medicine are italicized.

“I should tell you too, that my blood sugar has gone way down. They say that *exercise is good for managing it.* And since the study it’s gone down to a lower level where I don’t have to worry about it anymore. So that’s good.” (68-year-old woman)
“Because you feel better—that’s probably my motivation.” (57-year-old woman)

“I learned that when I thought I was taking sufficient exercise I wasn’t: that the time I was on the treadmill for wasn’t enough. Some days I was only at 5 [thousand steps], and I got on the treadmill and thought, ‘I don’t care how long it takes me, I’m going to get that 10 in’ or as close as I can. Before the study, if my time on the treadmill got interrupted I would just let it go. But now I know I need to go back down and do more time to finish it.” (73-year-old woman)

“My doctor actually told me that if I wasn’t doing what I’m doing now I would have high blood pressure and diabetes because they run in the family. He told me to keep doing what I’m doing because I’m looking after myself and really medicating myself with exercise.” (57-year-old woman)

4.4.3.5 Building Community and Social Networks

At the follow-up visit we learned that some participants were in common social networks outside the study. Group participation and networking was not an intentional component of this intervention. However, participants commented on the value of building a sense of social network or community through mHealth devices and participating in activities with health professionals and with other individuals. Representative quotations of participants’ responses are listed in Table 4.6.
Table 4.6 Participants' Comments About Building Community and Social Networks

<table>
<thead>
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<th>Comment</th>
<th>Age, Gender</th>
</tr>
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<tbody>
<tr>
<td>“I would like to be informed. Like if you find out about a new food or something that’s good, just to send out an email to everyone to share it.” (58-year-old woman)</td>
<td></td>
</tr>
<tr>
<td>“My friend came into the study too, and it was nice to have someone to talk to about it, understand why you were doing it and had the same motivations...” (65-year-old woman)</td>
<td></td>
</tr>
<tr>
<td>“Just knowing other people were in the study was fun. Whenever we’d chat we’d say, ‘So, how many steps have you done?’ A bit of a competition. So that was good. It was fun.” (64-year-old woman)</td>
<td></td>
</tr>
<tr>
<td>“My physical activity actually impacts my wife’s. Because a number of times of doing those walks, she’s doing those walks with me.” (62-year-old man)</td>
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4.5 Discussion

The purpose of this mixed methods study was both to assess long-term changes in aerobic fitness following a 12-week physical activity and mHealth intervention and to gain a better understanding of the participants’ experience in a health behaviour intervention. Understanding the lived experience of individuals may enhance the design of future interventions, programs, and services by focusing on a user-centered approach. Moreover, testing the long-term clinical improvements helps to support the importance of assessing cardiorespiratory fitness in the primary care setting for chronic disease management and prevention.
Previously it has been suggested that, independent of the type of intervention, there is a tendency for behaviours to return to baseline following intervention.\textsuperscript{28} Aerobic capacity (VO\textsubscript{2}max) reduces in as little as three weeks without continued training.\textsuperscript{29} However, previous STEP\textsuperscript{TM}-based interventions have reported that gains made in aerobic capacity at six months were maintained \geq 12 months.\textsuperscript{13} Quantitative results from the present study demonstrate that gains made in functional aerobic capacity through the intervention were maintained to six months. Results are promising in that they demonstrate long-term adoption of behaviours prescribed through the physical activity intervention.

Quantitative results should be interpreted with caution due to the small sample size. Only one third of the participants from the 12-week intervention participated in the long-term follow-up measure of functional aerobic capacity. Participants were not informed at the end of the 12-week intervention that they would be contacted again in 6 months to participate in a follow-up visit. Therefore, it is perhaps not surprising that half of the original sample did not respond to the attempts to contact for this phase of the study. However, there was no difference in aerobic capacity post-intervention between participants who chose to participate in the follow-up and participants who did not choose to participate. Results demonstrate the maintenance of functional aerobic capacity 6 months following intervention, which may support the clinical utility of providing a written physical activity prescription through the primary care setting to help individuals maintain healthy living behaviours. These results support evidence-based approaches to exercise prescription through primary care, such as Exercise Is Medicine\textsuperscript{®}.\textsuperscript{15}
Although weather, illness, and lack of accountability are commonly reported reasons for not engaging in physical activities, what is interesting from the current study is that these reasons remained barriers to participation even after individuals received a written exercise prescription and completed a 12-week physical activity intervention. In contrast, previously it had been suggested that receiving a written prescription for physical activity from a health care professional can be a catalyst for change.\textsuperscript{13,14} Future studies may wish to consider phase-out periods following the intervention during which individuals receive additional programming and guidance to help facilitate a successful transition out of the study and into incorporating sustained healthy behaviours in their daily routine.

Adherence to self-report of health measures via mobile device decreases over time.\textsuperscript{30} Similarly, a theme that emerged in the present study was that using mHealth devices for a period of time was acceptable, but that long-term use was not desired by all. Thus, mobile devices may have benefit as educational tools for short-term intervention to initiate behaviour changes without the demand for ongoing support. Future investigations need to explore if a short-term intervention period using mHealth tools to initiate treatment programs and prescribed health behaviours is sufficient for sustaining adoption of healthy behaviours and management of disease risk. This approach may be supported by clinicians, as it has the potential to shift the responsibility for ongoing management and prevention to the patient.
Physical activity interventions that are designed to reflect the needs of the target population must incorporate an understanding of the lived experiences of the participants. From a user-centered design approach, it is the combination of theory, user needs, and the evidence base that contributes to the design of responsive programs and services.\textsuperscript{21} Previous research has shown that remote monitoring technologies enable participants to share in responsibility for their own health, while also providing a new understanding of their overall health and physical fitness,\textsuperscript{31} which is further supported by results from the present study. Moreover, although some individuals were able to incorporate prescribed physical activity behaviours into their daily routines, others identified a need for more assistance to adopt a healthy, active lifestyle.

\section*{4.5.1 Conclusion}
The present study investigated both the long-term adoption of physical activity behaviours as well as the participant experience in a physical activity and mHealth intervention. The intervention improved functional aerobic capacity (VO\textsubscript{2}max), which was maintained long-term. Although many participants reported engaging in sustained and routine physical activities following initial intervention, some reported a need for continued support to adopt the prescribed health behaviours. Barriers that prevented sustained engagement in physically active lifestyles included health problems, weather, and a lack of purpose following the study. The sample of older adults enjoyed the mHealth component, reported new awareness of evidence-based guidelines for healthy active living following the intervention, and indicated that ongoing self-monitoring would be best using devices specific to their health needs and personal preferences.
Emergent themes included the need for short-term mHealth intervention to educate individuals about prescribed health behaviours without entailing ongoing support or management by clinicians, that mHealth could be used as a platform to build social networks around prescribed health behaviours to connect individuals and build a sense of community, as well as participants’ views of physical activity as a form of health risk management. Findings from the current study can be used to inform the development of user-centered lifestyle interventions.
4.6 References


8. CSEP. *Canadian physical activity guidelines for older adults.* Ottawa: Canadian Society for Exercise Physiology;2011.


10. Tudor-Locke C, Brashear MM, Johnson WD, Katzmarzyk PT. Acceleromter profiles of physical activity and inactivity in normal weight, overweight and obese


Chapter 5

5 Discussion

In developed countries, adults are living longer than previous generations.\(^1\) Currently, this increased life expectancy is paired with increased prevalence of chronic conditions.\(^2,3\) For centuries we have understood the importance of physical activity in promoting health.\(^4,5\) Despite this, only 13% of Canada’s older adults engage in sufficient levels of physical activity.\(^6\) Physical inactivity is a preventable risk factor for many chronic conditions including cardiovascular disease, diabetes, cancer, hypertension, obesity, depression and osteoporosis.\(^7\) Older adults are at greater risk for sedentary lifestyles,\(^8\) and Canadian adults over 60 years of age accumulate more sedentary behaviour than their younger counterparts, regardless of sex.\(^6\) This suggests that older adults are at increased risk for the health consequences of a sedentary lifestyle. Therefore, interventions aimed at changing physical activity behaviours among this population are warranted.

5.1 Intervening on Physical Activity Behaviours

Interrupting prolonged sedentary time, such as by standing up, may be a feasible approach for intervention, and may be a reasonable alternative to prolonged sitting especially among physically inactive individuals.\(^9\) While both sitting and standing seem like simple behaviours, they are in fact distinct behaviours.\(^9\) Compared to increasing time spent engaged in moderate- to vigorous-intensity physical activity (MVPA), reducing sedentary time is conceptually an easier behaviour to change. This may contribute to successful intervention approaches and be more effective at changing behaviours than exercise or combined approaches. However, this is an area of research that is still developing.

A recent systematic review by Prince et al\(^{10}\) examined the effect of physical activity interventions on sedentary behaviours. Results demonstrated that changing behaviours
along the activity spectrum (sedentary through MVPA) can result in small, yet significant, reductions in sedentary time: approximately 20 minutes less per day.\textsuperscript{10} Interestingly, interventions targeting both sedentary and MVPA can result in even more substantial reductions in sedentary time: approximately 35 minutes/day less sedentary time.\textsuperscript{10} These results demonstrate that interventions designed to include physical activity behaviour change of any intensity (sedentary through MVPA) would be expected to result in reduced sedentary time. However, it should be noted that the studies included in this systematic review predominantly focused on changing sitting time at work, not sedentary lifestyles in the free-living environment. Moreover, the authors highlight that the quality of studies to-date is “moderate” due to small numbers and large heterogeneity. Therefore results should be interpreted with caution, but are promising in that they suggest that intervening on physical activity behaviours may have a positive effect on sedentary lifestyles.

Since the time my research was submitted for publication, one report of a similar study design was published by Kozey Keadle et al\textsuperscript{11} who found that combining exercise training with reductions in sedentary behaviour did not result in greater improvements in cardiometabolic health markers as compared to exercise alone. Their study was a controlled exercise trial where participants in exercise groups (either alone, or in conjunction with sedentary behaviour reductions) engaged in supervised exercise sessions for 200 minutes per week. Participants in sedentary behaviour groups (alone or combined with exercise) engaged in weekly face-to-face counselling sessions with research assistants to review daily activity profiles, set goals, and plan to overcome barriers. Despite the high intensity of the intervention (i.e. supervised exercise and weekly counselling), no differences were found between groups for metabolic outcomes.\textsuperscript{11} Their results corroborate the clinical findings from my research, presented in chapter two.
Shifting behaviours from sedentary to relatively higher-intensity physical activities like light activity or MVPA has important health implications. For example, each 30-minute bout of sedentary time reallocated to another intensity of physical activity (e.g. light, MVPA) improves cardiometabolic biomarkers such as waist circumference, high density lipoprotein cholesterol, triglycerides and insulin.\textsuperscript{12} This suggests that changes to daily activity behaviours, from sedentary to any higher intensity, can result in clinically meaningful changes to health outcomes. Results from systematic reviews of physical activity interventions suggest that individuals who change sedentary behaviours are likely to reallocate this time to higher-intensity physical activities, specifically MVPA.\textsuperscript{10,13} The demonstrated health effects of interrupting sedentary time underscore the potential importance of promoting reductions in sedentary time as a public health message in the years to come.

\textbf{5.2 Physical Activity Prescription}

A systematic review and meta-analysis of physical activity promotion interventions through primary care concluded that initiatives can significantly improve self-reported physical activity levels, and have a positive impact on cardiorespiratory fitness.\textsuperscript{14} The authors identified one study, which employed the STEP\textsuperscript{TM} tool, as driving the effect on cardiorespiratory fitness. STEP\textsuperscript{TM} is a clinical tool that includes a brief self-paced sub-maximal stepping protocol followed by exercise prescription tailored to predicted aerobic fitness. The tool has been validated for clinical use among adults 18-85 years\textsuperscript{15,16} as well as for self-administration.\textsuperscript{17} Previously, we completed a review of published exercise interventions utilizing the STEP\textsuperscript{TM} tool, which concluded that interventions employing STEP\textsuperscript{TM} have demonstrated beneficial effects on aerobic fitness, exercise compliance, exercise self-efficacy, and risk factors associated with cardiovascular disease.\textsuperscript{18} Therefore, based on existing evidence, STEP\textsuperscript{TM} is an effective clinical tool to assess aerobic fitness and provide individualized exercise prescription.\textsuperscript{18}
Results from the present research further demonstrate the clinical utility of the STEPTM tool for measuring and prescribing physical activity. Anecdotal reports from participants indicate that the prospect of undergoing the stepping test portion of STEPTM at the post-intervention (12-week) visit was a driving force to initiate behaviour change. The effort of exertion required for the stepping test plus the knowledge of results was, in some cases, an impetus for change. For example, participants reported engaging in specific exercise behaviours (e.g. brisk walking, stair climbing at work and home) and nutrition behaviours (e.g. initiating a diet) to prepare for the subsequent stepping test in clinic. While the present research was not designed to control for this effect, it does support the treatment value of measuring fitness in clinic. As one participant identified at follow-up, “…I guess it’s that old adage in business: what doesn’t get measured doesn’t get done…” (61 year-old male, reported in chapter three). Results from previous literature combined with the current research demonstrate the importance of measuring health risk markers and suggest that this act of measurement may be a catalyst for change.

5.3 mHealth

A combination of rapid technological development paired with public demand for increased value in health services underscore the importance of developing and adopting personalized approaches in medicine and health care delivery.19 It has been suggested that health technologies and patients’ drive to use them will continue to transform health care practices.19 Therefore research employing tools like mHealth may continue to develop and demonstrate clinical utility.

Recently, Bond et al20 reported an mHealth and sedentary behaviour intervention aimed at breaking up prolonged bouts of sedentary time among a sample of obese adults. They utilized an app to prompt breaks for three, six, or 12 minutes in duration related to length of sedentary time (30, 60, or 120 minute bouts, respectively). Results demonstrated significant reductions in sedentary time using the mHealth prompt.20 Additionally,
participants engaged in more light activity and MVPA during the breaks. Bond et al concluded that mHealth prompts can be used to initiate short, frequent breaks in prolonged sedentary behaviours.\textsuperscript{20} Results are promising as they demonstrate the potential value of mHealth for prompting change in physical activity behaviours.

The mHealth research design for the present projects was informed by pilot work from Stuckey et al,\textsuperscript{21,22} which tested the mHealth protocols among a sample of rural adults with metabolic syndrome. These protocols were utilized in the same population for a 12-month intervention focused on reducing blood pressure using mHealth paired with exercise prescription, which resulted in significant reductions in systolic blood pressure, but no difference between participants who used the mHealth kit versus those who logged measures using a paper journal.\textsuperscript{23} Results from that intervention suggest that it may be the process of ongoing measurement of personal health markers, and not the tool (i.e. paper log, mHealth) that may be the most important factor in managing health and preventing disease. Similarly, mHealth results from my research (presented in chapter three) demonstrate that among a sample of older adults motivated to volunteer for an mHealth study, the tools were equally effective among all groups. Moreover, qualitative results (presented in chapter four) highlight the participant views of selecting devices and approaches unique to individual needs and circumstances to promote adoption of prescribed behaviours. Personalized and tailored approaches to intervention may be ideal in designing optimal treatment therapies for patients.

5.4 Limitations

Quantitative results from the present research should be interpreted with caution due to the small sample size. Kozey Keadle et al\textsuperscript{11} recently reported a similar intervention design as reported here in chapters two and three, and employed the same sample size (n=60, 15 per group). Results from both reports may be used to inform the design of future interventions.
Although designed as a clinical aid, our research group has used the STEP™ tool widely in similar research. For the present projects we used predicted aerobic capacity measured through STEP™ as an outcome measure. Recently it was suggested that the tool is best used for clinical application to guide health professionals in tailored exercise prescription.\textsuperscript{15} Moreover, it was identified that STEP™ systematically over-predicts aerobic capacity as compared to a traditional laboratory-based VO\textsubscript{2,max} testing protocol, which suggests that it may not be a strong outcome measure to use. However, the tool has been shown to be sensitive to change,\textsuperscript{16} and was used in the present projects to assess change over time through the clinical intervention.

The present research provided pedometers to participants to encourage self-monitoring of physical activity behaviours. More sophisticated devices exist for measuring physical activity behaviours (e.g. accelerometers, inclinometers) and may be considered for use in future research. However, participants in the present research overwhelmingly reported their enjoyment of using the pedometers to self-monitor daily physical activity (chapter four). These qualitative results support the clinical value of using pedometers for participant satisfaction and adherence.

Participants from the present research may have been highly motivated, as there was a very high retention rate (98\% (n=59/60) completed the 12 week intervention). Therefore results may be limited in their application to future research among a broader, perhaps less motivated, clinical population. Analyses are warranted to describe characteristics of participants who responded well to the present intervention to identify individuals who may respond to future physical activity and mHealth interventions. These insights could enhance personalized approaches to intervention, whereby groups of populations with a greater likelihood of responding to a particular treatment approach could be identified.\textsuperscript{19}
This knowledge would allow for tailoring of therapeutic interventions to participant needs and characteristics.

5.5 Clinical Implications

“Health care today is in a crisis as it is expensive, reactive, inefficient, and focused largely on one-size-fits-all treatments. An answer is personalized, predictive, preventive, and participatory medicine.” It has been suggested that personalized medicine can: contribute to the shift from reactive health services to preventive services (e.g. early intervention through lifestyle changes and disease-monitoring options to reduce risk of adverse health outcomes); help select optimal therapies (e.g. using risk markers to assist clinical decision making and reduce trial-and-error prescribing of behaviours); increase patient adherence to treatment (e.g. personalized therapies which are more effective may enhance engagement); improve quality of life through fewer adverse events; and reduce health care costs through increased efficiency. The quantitative and qualitative results from the present research suggest that personalized, tailored approaches to interventions may be a valuable focus for clinicians.

Personalized medicine can be considered as delivering the ideal intervention for the patient at the optimal point in time to enhance their personal health outcomes. Traditionally, the phrase ‘personalized medicine’ tends to focus on tailoring health services and interventions based on genetic variables, and to-date the literature has focused on insights and advancements gained through gene mapping. The common thread among reports is that personalized medicine is relevant in selecting the ideal treatment for patients. In this sense, the term can also be applied to healthy living interventions, such as physical activity promotion and mHealth tools: selecting the right application for the right patient at the right time to create the best outcome. The research reported in chapters two through four highlight this effect: tailoring the physical activity targets to the individual’s abilities and desires, whether it be sedentary behaviour,
exercise behaviours or both; and selecting the tools to best enhance the individual’s understanding of their health and ongoing self-management, such as pedometers, smartphone apps, and devices to measure clinical markers (e.g. blood pressure or blood glucose monitors).

Providing personalized care includes addressing patient needs, outcomes and preferences, and facilitating informed decision making for both clinicians and patients around comparative interventions. Personalized health care has the capacity to increase the efficiency of the health care system by improving quality, accessibility and affordability. Personalized approaches may offer even more substantial effects for managing chronic and complex conditions, therefore they may prove to be clinically meaningful for older adults living with multiple chronic conditions. It has been suggested that the benefit of personalized care is knowing what interventions are successful, understanding why, and applying that knowledge to address patient needs. It could also be argued that this is the basis of clinical decision-making. To assist clinicians in selecting optimal interventions, more research is needed to identify patients most likely to respond favourably to interventions such as physical activity prescription or mHealth for ongoing self-management.

5.6 Research Directions

Building on results from the current research, we identified an opportunity to take the exercise testing and prescription protocol (i.e. STEPTM) out of the clinical setting and into the community. Preliminary work exploring the safety of administering STEPTM in a community location demonstrated safety and highlighted potential for self-administration. Bridging this evidence with previous studies validating STEPTM for non-clinical use (i.e. home use) we have been working to develop a health application (app) which incorporates self-administration of STEPTM. These initiatives enrich the ability to scale cardiorespiratory fitness measurement and personalized physical activity
prescription from clinical application to self-use, which could be leveraged for personalized medicine. Moving forward, clinicians may wish to introduce patients to tools like STEP™ for ongoing self-management and education.

Research is warranted to identify personal variables that distinguish between responders and non-responders to intervention. For example, including analysis by demographic and clinical variables that distinguish highly responsive participants from minimally responsive participants. This information may help clinicians identify patients who are most likely to benefit from therapeutic intervention.

Personalized approaches to medicine and health care pose challenges for research interventions. Specifically, when patients choose the intervention they are exposed to, how do we determine the effect of the intervention? Perhaps for behavioural interventions, patient choice may be the key variable of interest: can informed selection of intervention exposure lead to clinically meaningful outcomes? For the present research, this participant-centered variable was observed -anecdotally- among the control group. Participants were motivated to volunteer for a physical activity intervention, and even without receiving additional intervention were determined to make changes to perform better post-intervention (chapter two).

5.7 Conclusion

Healthy physical activity behaviours, which include regular bouts of MVPA and frequent interruptions in sedentary time, are integral to lifestyle-related disease prevention and management. Clinicians can prescribe changes to physical activity, and there is growing interest in targeting prescribed reductions for sedentary behaviours. Among a sample of community-dwelling older men and women, the present research demonstrated the importance of measuring markers for lifestyle related disease risk in clinic (chapter two)
as well as the utility of mHealth for managing markers of disease risk (chapter three). Participants identified the value of mHealth for patient education and creating social connections (chapter four). Additionally, clinical physical activity prescription underscored the role for and patient understanding of physical activity for managing health (chapter four). Results of the physical activity prescription intervention were maintained long-term without additional intervention (chapter four), which demonstrates scalability of this approach. To enhance scalability, we have since explored options for community-based physical activity prescription\textsuperscript{26} as well as options for self-administration of exercise testing and personalized physical activity prescription.\textsuperscript{17} Future research will need to explore the role of participant choice in selecting therapeutic intervention to enhance the effect of personalized medicine.
5.8 References


Appendices

Appendix A Research Ethics Approval

Use of Human Participants - Ethics Approval Notice

**Principal Investigator:**

**Review Number:** 18700

**Review Level:** Full Board

**Approved Local Adult Participants:** 150

**Protocol Title:** A multi-center, prospective, randomized study To determine the effects of Exercise Managed Intervention Study (ARTEMIS Study): Health-E Steps Pilot Study

**Department & Institution:** Schulich School of Medicine and Dentistry/Family Medicine, University of Western Ontario

**Sponsor:** Canadian Institutes of Health Research

**Ethics Approval Date:** March 06, 2012

**Ethics Expiry Date:** December 31, 2012

**Documents Reviewed & Approved & Documents Received for Information:**

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<td>(including instruments noted in section 8.1)</td>
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This is to notify you that the University of Western Ontario Health Sciences Research Ethics Board (HSREB) which is organized and operates according to the TRI-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced study on the approval date noted above. The membership of this HSREB also complies with the membership requirements for REB’s as defined in Division 3 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.

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

The Chair of the HSREB is [Name]. UWO HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000540.

Signature

**Ethics Officer to Contact for Further Information**

[Contact Information]

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

The University of Western Ontario
Office of Research Ethics
Appendix B Letter of Information for Intervention

ARTEMIS-STEP™ Study

Letter of Information

Investigators: Robert J Petrella, MD, PhD; Melanie Stuckey, PhD (candidate); Emily Knight, MPT/PhD (student)

Introduction

You have expressed interest in participating in a research study investigating the impact of lifestyle changes on clinical and health measures like blood pressure, blood glucose, physical fitness, physical activity and wellbeing. You have spoken with research personnel over the phone to discuss the nature of this study, your potential eligibility to participate, and to schedule this first (of two) study visits. You are being invited to participate in this study. It is important that you read this description of the study and your role in it to help you decide if you would like to volunteer to participate.

Who can participate?

- In order to be eligible to participate, you must be between 55 and 75 years of age.
- Your body mass index must be 27.0 kg/m² or higher. Body mass index is a calculation of your height-to-weight ratio, and is determined by your family doctor. (We do not require that you know your body mass index.)
- You must be willing to participate in this study for 12 consecutive weeks.
- You must have read this letter of information about the nature and risks of participating.

Your decision to participate is completely voluntary. If you chose to participate, you will provide your consent on the final page of this letter of information.
Purpose of the Study

An increasingly sedentary and obese Canadian population has caused an epidemic of lifestyle-related chronic conditions and diseases like high blood pressure and Type 2 diabetes. Changes in blood pressure and blood glucose results in physiological changes in the cardiovascular system that can be identified very early in the laboratory (for example, through a simple blood test) and can be used to signal improvement with effective treatments to manage lifestyle-related conditions and diseases. Recent studies have shown that lifestyle interventions targeting physical activity are effective in lowering high blood pressure, improving physiological cardiovascular functioning and reducing cardiac disease.

This study will look at the use of remote monitoring technologies (like smartphones and Bluetooth-enabled devices) as well as telephone counseling support to deliver a healthy living intervention for patients at-risk for developing lifestyle-related diseases and conditions.

Length and Size of the Study

This study involves 100 people from London and surrounding areas in southwestern Ontario. Each person will participate for 12 weeks.

Study Tests and Procedures

Screening – You have been asked a few questions over the phone to determine your eligibility to participate, and to ensure that participating in a healthy living intervention is safe and appropriate for you. During that phone call, you were scheduled to attend your two study visits, which is why you are here today.
Study Visits – If you chose to participate in this study, you will be asked to complete two visits (one today, and one 12 weeks from today) in London, Ontario. Each study visit will include a questionnaire that asks you about your physical activity and wellbeing, a stepping fitness test, and a blood draw. It is anticipated that these visits will last approximately 45-90 minutes.

The stepping test consists of stepping up and down on a standardized set of steps 20 times at a pace that is comfortable for you. This is a predictive test of your maximum exercise ability, which will allow us to provide you with an estimate of how efficiently your heart and lungs can circulate oxygen (known as aerobic capacity or “VO₂ max”). If you consent, you will get to take home a record of this measure as well for your own information.

For the blood draw, 20-30 cc (about 2-3 tablespoons) of blood will be drawn which will be used to measure your cholesterol, blood glucose and markers of your metabolism. You will be asked to fast for 8 hours prior to this test, but can drink water during these 8 hours. Results from this test will also be sent to your family doctor.

Before you begin your first visit as part of this study, you will be randomly selected (like the flip of a coin) to be in one of four study groups. This means that you will be assigned to participate in one of the four groups based on what side of the coin you are on. For this study, there is one Control Group and three Intervention Groups. What is involved to participate for each group is explained below. If you are assigned to the Intervention Groups you will be expected to participate in an activity program designed for you by an exercise specialist (CSEP-CEP®) on most days of the week for the entire 12-weeks of this study. Your personal activity program may include aerobic activities (for example, walking, riding a bike, running, swimming), resistance training activities (for example, lifting weights, push-ups, sit-ups, squats) and being more active during your daily routine.
(for example, using stairs, walking to the store, standing while watching television or listening to music). The activity program designed for you will depend on your fitness level and activity preferences.

1. Control Group – You will be required to attend two visits (today is the first visit). At each visit you will complete the stepping test as well as the blood draw, and will receive a copy of your estimated VO$_2$max (from the stepping test), and a copy of the results from the blood draw will be sent to your family physician. For the 12-weeks between your two study visits you will be expected to carry on with your typical daily routine. This means we are not asking you to do anything extra during the 12 weeks between visits. However, should you become sick (i.e. seek out medical care or require hospitalization) we would ask that you inform the study team at your convenience so that we can consider if it is safe for you to continue with the study and complete your second clinic visit.

2. Intervention Groups – You will be required to attend two visits (today is the first visit). At each visit you will complete the stepping test as well as the blood draw, and will receive a copy of your estimated VO$_2$max (from the stepping test), and a copy of the results from the blood draw will be sent to your family physician. During this first visit you will receive an activity prescription from an exercise specialist (Canadian Society for Exercise Physiology Certified Exercise Physiologist®), which you will be encouraged to participate in during the study period (12 weeks). You will be required to submit regular measures that you can take from home and submit wirelessly using a Blackberry® smartphone. The measures include:

- Taking a blood sugar reading from a finger-prick glucometer device one time per week.
- Measuring your blood pressure at home using a home blood pressure monitoring device three times per week.
- Wearing a pedometer to measure the number of steps you take per day.

We will provide you with all the technology (the smartphone and other wireless devices) that are part of this study as well as show you how to use them. You are expected to
return these study materials when you are finished participating in this study. Throughout
the study, you will also have access to a specialist to ask questions about your devices at
anytime. At the end of the 12 weeks, you will return to your family health team’s office
for your second (final) clinic visit.

**Ongoing Contact for Intervention Groups** – Throughout the study, participants in the
*Intervention Groups* may be contacted over the phone—during appointments scheduled at
your convenience—by someone involved with the research study (for example, your
personal exercise specialist or a research assistant) to check in on your physical activity
program and other measures, and to provide you with general support for any questions
or concerns you may have. Should any of the readings you submit wirelessly be
abnormal, the readings will be screened by a healthcare professional and you may be
contacted should it be deemed necessary for your health. You will also have the freedom
to speak with your personal exercise specialist at any point during the 12 weeks.

**Risks of Participating**

When blood samples are taken, you may feel some discomfort, develop some bruising, or
in very rare cases develop a minor infection. Standardized sterilized techniques will be
used by a trained specialist to minimize any risk. You may also feel faint or nauseous.
The specialist performing the blood draw is trained to deal with such situations.

The clinic and home blood pressure monitoring cuffs used to measure blood pressure
may cause some mild discomfort, bruising or red blood spots on the arm where the cuff is
applied. There is a risk of pain when pricking your finger for the home blood glucose
monitoring. Also, there is risk of infection during home blood glucose monitoring if
proper hygiene and cleanliness are not followed. However, at your first clinic visit you
will receive hands-on training from study personnel as well as written instructions for
your reference about proper use of the equipment. You will also be able to contact study
personnel throughout the duration of the study if you have questions or concerns about the proper use of any of the equipment provided to you for your participation.

The stepping test requires mild to moderate exertion by you, which may be uncomfortable. As a result, you may feel some of the symptoms of exercise (see below). If you develop any chest pain during the stepping test you must report this immediately to the study personnel.

There is no known health risk associated with you becoming physically active under the supervision of a trained health professional. Exercise is associated with increased awareness of breathing, muscle pain, sweating and fatigue. These symptoms should resolve on stopping exercise and become less noticeable as your fitness improves. There is a small risk of injury with any form of exercise, however choosing activities that are familiar such as walking minimizes these risks.

**Benefits of Participating**

Participation in this study may be of no direct benefit to you. Positive changes in physical activity are an accepted strategy for controlling high blood glucose and treating high blood pressure: Increasing physical activity helps to manage lifestyle-related chronic conditions and diseases. Through participating in this study you may benefit from possible improvement in your glucose levels and blood pressure profile. Also, improved lifestyle habits may benefit many other aspects of your health and wellbeing.
Compensation and Costs

You will not be paid to take part in this study. You will not be required to pay for any of the services associated with participating in this study. All study materials will be provided to you at no cost during the study period.

Alternatives to Participating

This study is completely voluntary, and you are not required to participate. Your healthcare from your family health team will not be affected by your participation in this study. If you choose to participate, you are free to withdraw from the study at any time and you will not be required to submit any future information to the study personnel. (Any data provided during the course of your participation will be retained.) If you withdraw you will be required to return the technology kit that had been loaned to you for the duration of your participation in this study.

Voluntary Participation— Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at anytime with no effect on your future care.

Contact Persons

If during the course of this study you have any questions or concerns about this research study you may contact:

1. Dr Robert Petrella at [contact information]
2. Melanie Stuckey at [contact information]
3. Emily Knight at [contact information]
If you have any questions about the conduct of this study or your rights as a research participant or the conduct of the study you may contact:

The Office of Research Ethics at 519-661-3036 or ethics@uwo.ca

Dr. David Hill, Scientific Director, Lawson Health Research Institute at 519-667-6649.

Confidentiality

The information you provide by participating in this study will be stored in a secure laboratory at Parkwood Hospital. At no time will you be identified by name during the course of data analysis or publication, as all participant data is number coded. The number code master list will be kept by Dr Robert Petrella in his secure office within the laboratory at the Aging, Rehabilitation and Geriatric Care Research Centre at Parkwood Hospital.

Representatives of the University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. You do not waive any legal rights by consenting to participate in this study.

You are encouraged to keep a copy of this information letter for your records.
ARTEMIS-STEP™ Study

Informed Consent to Participate

I ______________________ have read the letter of information, have had the

(your name)
nature of the study explained to me, and I agree to participate. And all questions have

been answered to my satisfaction.

________________________________________
Participant Signature

Date

________________________________________
Name of Person Conducting
Initials
Date

Consent

☐ I would like results from this study shared with my family physician.

Family physician contact information:

Name: __________________________________________

Clinic Location: __________________________________

Phone Number: _________________________________

Fax Number: _________________________________
Appendix C Letter of Information for Follow-Up

ARTEMIS-STEP™ Study: Follow-Up

Letter of Information

Investigators: Robert J Petrella, MD, PhD; Melanie Stuckey, PhD (candidate); Emily Knight, MPT/PhD (student)

Introduction

Six months ago you completed the ARTEMIS-STEP™ study with us. We spoke with you over the phone or email, and booked this appointment for you to come in today to complete a follow-up visit. You are being invited to participate in this part of the study. It is important that you read this description of the part of the study and your role in it to help you decide if you would like to volunteer to participate.

Who can participate?

• In order to be eligible to participate, you must have completed the 12-weeks of the ARTEMIS-STEP™ Study.
• You must have read this letter of information about the nature and risks of participating.

Your decision to participate is completely voluntary. If you choose to participate, you will provide your consent on the final page of this letter of information.
Purpose of this Visit

We are interested to know more about your experience participating in a healthy living intervention (that is, the ARTEMIS-STEP™ Study) as well has how your fitness has changed over the last 6 months since your most recent clinic visit with us. This part of the study will look at how fitness changes over time in people, just like you, who have recently participated in a healthy living intervention. It will also look into what it’s like to participate in a healthy living intervention. For example, what you learned through participating, and how you suggest designing future studies based on your experience.

Length and Size of the Study

This study involves the 100 people who participated in the ARTEMIS-STEP™ Study 6 months ago. Each person who volunteers will participate in this phase one time for approximately 1 hour (that is, today’s visit).

Procedures

Participating in this visit involves completing the same stepping test that you did during the ARTEMIS-STEP™ Study, as well as answering up to 4 questions about your experience participating in this study. You are able to choose if you would like to complete both portions of this visit (that is the stepping test as well as the interview), or only 1 portion (either the stepping test or the interview). You will have an opportunity on the last page of this document to indicate which part(s) of this visit you would like to participate in.

Stepping Test - The stepping test consists of stepping up and down on a standardized set of steps 20 times at a pace that is comfortable for you. This is a predictive test of your maximum exercise ability, which will allow us to provide you with an estimate of how efficiently your heart and lungs can circulate oxygen (known as aerobic capacity or
“VO\textsubscript{2max}”). If you consent, you will get to take home a record of this measure as well for your own information. Like the previous 2 study visits you completed, prior to completing this stepping test we will need to measure your height, weight and blood pressure. This portion of the visit should last less than 10 minutes.

**Interview** – The interview involves up to 4 questions designed to help us better understand your experience participating in the ARTEMIS-STEP\textsuperscript{TM} Study. These questions include topics like what you learned through participating that you use still use in your daily life 6 months later, and your opinions about using technology to help with physical activity. It is anticipated that this portion of the visit will last less than 20 minutes. This interview will be audio recorded to help us ensure that we have captured the information you share accurately. During this interview, no personally identifying information will be asked (like your name, job, contact information, etc), and any personally identifying information you share will be removed from the audio recording after the interview.

**Risks of Participating**

The stepping test requires mild to moderate exertion by you, which may be uncomfortable. As a result, you may feel some of the symptoms of exercise (see below). If you develop any chest pain during the stepping test you must report this immediately to the study personnel.

There is some risk that you may feel vulnerable discussing your experience in the study. Please remember that answering questions about your experience in the study is completely voluntary. If you do not feel comfortable answering these questions, you are free to stop at any time and will not be required to provide a reason for doing so.
Benefits of Participating

Participation in this study may be of no direct benefit to you.

Compensation and Costs

You will not be paid to take part in this study. You will not be required to pay for any of the services associated with participating in this study. You will be provided with complimentary parking during your study visit today at Parkwood Hospital.

Alternatives to Participating

This study is completely voluntary, and you are not required to participate. If you choose to participate, you are free to withdraw from the study at any time and you will not be required to submit any future information to the study personnel. (Any data provided during the course of your participation will be retained.)

Voluntary Participation— Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at anytime with no effect on your future health care.

Contact Persons

If during the course of this study you have any questions or concerns about this research study you may contact:

4. Dr Robert Petrella at [removed]
5. Melanie Stuckey at [removed]
6. Emily Knight at [removed]
If you have any questions about the conduct of this study or your rights as a research participant or the conduct of the study you may contact:

Dr. David Hill, Scientific Director, Lawson Health Research Institute at [redacted].

Confidentiality

During this visit, we will audio record the interview portion of this visit. This audio recording is not intended to include personal identifying information (like your name, job, address, etc). Any personally identifying information like this that you may share will be removed from the audio recording after the interview is finished. The information you provide by participating in this study will be stored in a secure laboratory at Parkwood Hospital. At no time will you be identified by name during the course of data analysis or publication, as all participant data is number coded. The number code master list will be kept by Dr Robert Petrella in his secure office within the laboratory at the Aging, Rehabilitation and Geriatric Care Research Centre at Parkwood Hospital. Representatives of the University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. You do not waive any legal rights by signing the consent form.

You are encouraged to keep a copy of this information letter for your records.
ARTEMIS-STEP™ Study: Follow-Up

Informed Consent to Participate

I ____________________________ have read the letter of information, have (your name) had the nature of the study explained to me, and I agree to participate. And all questions have been answered to my satisfaction.

☐ I consent to completing the stepping test portion of this visit.

☐ I consent to participating in the interview portion of this visit, and understand that that the answers I provide during the interview portion of this visit will be audio recorded.

☐ I do not consent to participating in the interview portion of this visit.

__________________________  ______________________
Participant Signature      Date

__________________________
Name of Person Conducting Consent

__________________________  ______________________
Signature of Person Conducting Consent      Date
# Curriculum Vitae

<table>
<thead>
<tr>
<th>Name</th>
<th>Emily Knight</th>
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<tbody>
<tr>
<td><strong>Post-secondary Education and Degrees</strong></td>
<td></td>
</tr>
<tr>
<td>University of Winnipeg</td>
<td>Winnipeg, Manitoba, Canada</td>
</tr>
<tr>
<td>2005-2008 BSc</td>
<td></td>
</tr>
<tr>
<td>University of Western Ontario</td>
<td>London, Ontario, Canada</td>
</tr>
<tr>
<td>2011- PhD(c) Health &amp; Rehabilitation Sciences</td>
<td></td>
</tr>
<tr>
<td>University of Western Ontario</td>
<td>London, Ontario, Canada</td>
</tr>
<tr>
<td>2013- Master of Physical Therapy student</td>
<td></td>
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<tr>
<td><strong>Honours and Awards</strong></td>
<td></td>
</tr>
<tr>
<td>Canadian Institutes of Health Research (CIHR) Doctoral Research Award</td>
<td>2012-2015</td>
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<tr>
<td>Ontario Research Coalition Early Researcher Award</td>
<td>2012-2013</td>
</tr>
<tr>
<td>University of Western Ontario Graduate Thesis Research Award</td>
<td>2013</td>
</tr>
<tr>
<td>Canadian Institutes of Health Research (CIHR) Frederick Banting and Charles Best Canada Graduate Scholarship Master’s Award</td>
<td>2011</td>
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<tr>
<td><strong>Related Work Experience</strong></td>
<td></td>
</tr>
<tr>
<td>Instructor Retirement Research Association</td>
<td>2014-2015</td>
</tr>
<tr>
<td>Teaching Assistant Western University School of Physical Therapy</td>
<td>2011</td>
</tr>
</tbody>
</table>
Research Assistant
Lawson Health Research Institute
Aging, Rehabilitation and Geriatric Care Research Centre
2011-2012

Research Coordinator
Children’s Hospital of Eastern Ontario Research Institute
Healthy Active Living and Obesity Research Group
2009-2010

Research Assistant
Children’s Hospital of Eastern Ontario Research Institute
Healthy Active Living and Obesity Research Group
2008-2009

Publications


Knight E., Petrella RJ. (2013). Implementing Evidence-Based Exercise Prescription Services in the Community. *Health & Fitness Journal of Canada*. 6(1); 78-81. ISSN 1920-6216.


Larouche, R., Lloyd, M., Knight, E., Tremblay, MS. (2011). Relationship between active school transport and body mass index of children in Grades 4-6: Results from the Canadian Assessment of Physical Literacy (CAPL) pilot testing. *Pediatric Exercise Science*, (23); 322-330.

Active Healthy Kids Canada. Healthy Habits Start Earlier Than You Think. The Active Healthy Kids Canada Report Card on Physical Activity for Children and Youth. 2010; Toronto, ON.

**Presentations**

*invited


Knight E, Stuckey MI, Petrella RJ. (2013). What intensity of physical activity should we be prescribing to manage weight-related health risk? Aging, Rehabilitation and Geriatric Care / Faculty of Health Sciences Joint Research Symposium. London, ON. February 1.


Knowledge Translation (2013) Physiotherapy Foundation of Canada: Video interview for a not-for-profit fundraising agency promoting research in physical therapy http://www.youtube.com/watch?feature=player_detailpage&v=_xC8jdrT1TM

(2013) Physiotherapy Practice: Interview in the official magazine of the Canadian Physiotherapy Association promoting research in physical therapy. Winter 2013, Volume 3, Number 1, Page 30 http://www.physiotherapy.ca/Practice-Resources/Publications/Physiotherapy-Practice.aspx?id=23

(2012) Museum School Tour, Lawson Health Research Institute Aging, Rehabilitation & Geriatric Care Research Centre (ARGC); London, ON: Organized a tour of the ARGC for forty grade eight students from Jack Chambers Public School as part of the Museum School Tour initiative. Directed graduate students and staff from the ARGC in creating & delivering demonstrations and active learning stations for students to learn about ongoing research projects and be exposed to the research process. Activities included learning about heart rate variability, gait and cognition as well as ultrasound and arterial compliance. (December 6 2012)

(2012) TD Discovery Day in Health Sciences, Lawson Health Research Institute; London, ON: Facilitated the “Exercise and Brain” workshop in the ARGC at Parkwood Hospital as part of the Discovery Days initiative from the Canadian Medical Hall of Fame. Over 360 students and teachers were introduced to what it’s like to be a health professional and careers in the health sciences. (May 4 2012)