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Facilitating Access and Adherence to Exercise in People with Type 2 Diabetes

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Facilitating Access and Adherence to Exercise in People with Type 2 Diabetes

by

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Abstract

Exercise is a key component in the management of type 2 diabetes. It improves blood glucose control and quality of life, and reduces cardiovascular events and mortality. Despite the strong evidence demonstrating protective effects of exercise in type 2 diabetes, much of this population remains inactive, and many of those who begin an exercise program do not continue long-term. Finding strategies to support the adoption and long-term adherence to exercise is a valuable endeavor.

The aim of this thesis was to examine the effectiveness of motivational interviewing, a potential facilitator to behaviour change and maintenance, together with an examination of pre-exercise stress testing which has been identified as a plausible barrier to supervised exercise programs. This was accomplished through a variety of methods within three distinct studies. These included a systematic review and meta-analysis of motivational interviewing in weight loss interventions, a randomized controlled trial on the effectiveness of motivational interviewing-based counselling to promote maintenance of exercise after the completion of a supervised exercise program, and finally a data linkage study examining the utility of pre-exercise stress testing within a retrospective cohort from a real-world supervised exercise program.

The results of the first two studies gave support to use of motivational interviewing as a strategy to improve the effectiveness of weight loss interventions and as an approach to help promote the maintenance of physical activity after a supervised exercise program. In the examination of the use of pre-exercise stress testing, we discovered that the rate of cardiovascular outcomes was low, and that in the few cases where referral for pre-exercise stress testing resulted in a change in care, the patients had multiple cardiac risk factors. These results

suggest that improved pre-exercise risk stratification might help identify the small subset of patients with type 2 diabetes likely to benefit from pre-exercise stress testing, thereby streamlining the process prior to the initiation of a supervised exercise program.

Within supervised exercise programs, implementing strategies that employ effective facilitators, as well as reduce barriers such as unnecessary testing, may help improve participation and long-term adherence to exercise in people with type 2 diabetes.

Preface

Statement of contributions

The following manuscripts, which have been authored as part of this program of research, have been published, are under review, or to be submitted. Where Marni Jane Armstrong (MJA) has not retained copyright over the published material, written permission for reproduction of the articles in their entirety has been obtained from the publisher and co-authors.

1) Marni J. Armstrong, Tony A. Mottershead, Paul E. Ronksley, Ronald J. Sigal, Tavis S. Campbell, Brenda R. Hemmelgarn. Motivational interviewing to improve weight loss in overweight and/or obese patients: a systematic review and meta-analysis of randomized controlled trials. *Obesity Reviews* 2011; Sep; 12(9):709-23.

Author contributions are as follows: MJA contributed to the conception and design of the project, collected and analyzed the data, and drafted, reviewed and edited the manuscript. TAM contributed to the conception and design of the project, collected and analyzed the data, reviewed and edited the manuscript. RJS, TSC, and BRH contributed to the conception and design of the project, contributed to the discussion, reviewed, and edited the manuscript. PER assisted with data analysis and contributed to the discussion, reviewed and edited the manuscript.

2) Marni J. Armstrong, Tavis S. Campbell, Steve Doucette, Adriane M. Lewin, Farah Khandwala, S. Nicole Culos-Reed, Ronald J. Sigal. Motivational Interviewing-Based Counselling Promotes the Maintenance of Physical Activity in People with Type 2 Diabetes: a Pilot Randomized Controlled Trial. *Diabetes Care (Under Review).*

Author contributions are as follows: MJA led the conception and design of the project, delivered the intervention, analyzed the data, and drafted, reviewed and edited the manuscript. RJS, TSC, and SNCR contributed to the conception and design of the project, contributed to the discussion, reviewed, and edited the manuscript. SD, AML and FK assisted with data analysis and contributed to the discussion, reviewed and edited the manuscript.

3) Marni J. Armstrong, Ronald J. Sigal. Examining pre-exercise screening using exercise stress testing in people with diabetes: a data linkage study (*To be submitted*).

Author contributions are as follows: MJA led the conception and design of the project, obtained the data, analyzed the data, and drafted, reviewed and edited the manuscript. RJS contributed to the conception and design of the project, contributed to the discussion, reviewed, and edited the manuscript.

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A sincere thanks to my family, as well as my family of friends, who have encouraged and supported me throughout this process. Finally, to my husband-to-be Evan, for your unwavering support and sense of humor through this entire endeavour, and most specifically for helping me see what a privilege and honor it is to have the opportunity to complete graduate training.

Dedication

To my parents,

The ones who taught me to never stop questioning and to whom I owe so much.

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List of Symbols, Abbreviations and Nomenclature

Symbol	Definition
APPROACH	Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease
BMI	Body mass index
BP	Blood pressure
CABG	Coronary artery bypass graft
CAD	Coronary artery disease
CI	Confidence interval
CPG	Clinical practice guidelines
CV	Cardiovascular
CVD	Cardiovascular disease
ECG	Electrocardiogram
GLTEQ	Godin Leisure Time Exercise Questionnaire
HbA1c	Hemoglobin A1c
ICD-10-CA	International Classification of Diseases, Tenth revision, Canada
MCS	Mental composite score
METs	Metabolic equivalents
MI	Myocardial infarction
MInt	Motivational interviewing
MITI	Motivational interviewing treatment integrity code
MPI	Myocardial perfusion imaging
MVPA	Moderate to vigorous physical activity

PA	Physical activity
PCI	Percutaneous coronary intervention
PCS	Physical composite score
PHN	Provincial health number
PRISMA	Preferred reporting items for systematic reviews and meta-analyses
SC	Standard care
SD	Standard deviation
SF-12	Medical outcomes study 12-item short-form
SMD	Standardized mean difference
T2D	Type 2 diabetes
WMD	Weighted mean difference

Chapter One: **Introduction and Overview of Thesis**

Type 2 diabetes is a serious condition with potentially devastating complications that affects many Canadians. Obesity, sedentary lifestyle, and genetic factors are important risk factors for development of type 2 diabetes. “Physical activity” defined as “bodily movement produced by the contraction of skeletal muscle that results in energy expenditure beyond resting expenditure’’ is used interchangeably with ‘‘exercise’’ which is defined as ‘‘a subset of physical activity that is planned, structured, repetitive, and done with the intention of developing physical fitness (i.e., cardiovascular, strength, and flexibility training)’’.[1] Physical activity is a cornerstone in the management of this condition as it improves morbidity and mortality. Accordingly, many health care systems have invested in the implementation of supervised exercise programs with the intention of risk reduction and reducing the burden of type 2 diabetes. People with type 2 diabetes are substantially less likely to meet physical activity guidelines compared with the general population and many of those with type 2 diabetes who begin an exercise program do not continue the behaviour long-term. The overarching intent of this program of research is to explore issues of access and adherence to exercise in people with type 2 diabetes by evaluating certain identified facilitators and barriers to supervised exercise programs.

How to effectively increase participation and adherence to exercise programs in people with type 2 diabetes remains unclear. There is a pressing need to explore possible strategies that might increase the likelihood that an individual will participate, adhere to, and maintain an exercise program. The goals of this thesis are to: 1) explore the use of motivational interviewing as a potential facilitator in health behaviour change, and 2) to explore the usefulness of electrocardiogram (ECG) exercise stress testing for pre-exercise screening in people with type 2 diabetes, which has been identified as a barrier to supervised exercise programs. Figure 1 illustrates this relationship and outlines the conceptual model upon which this thesis is based.

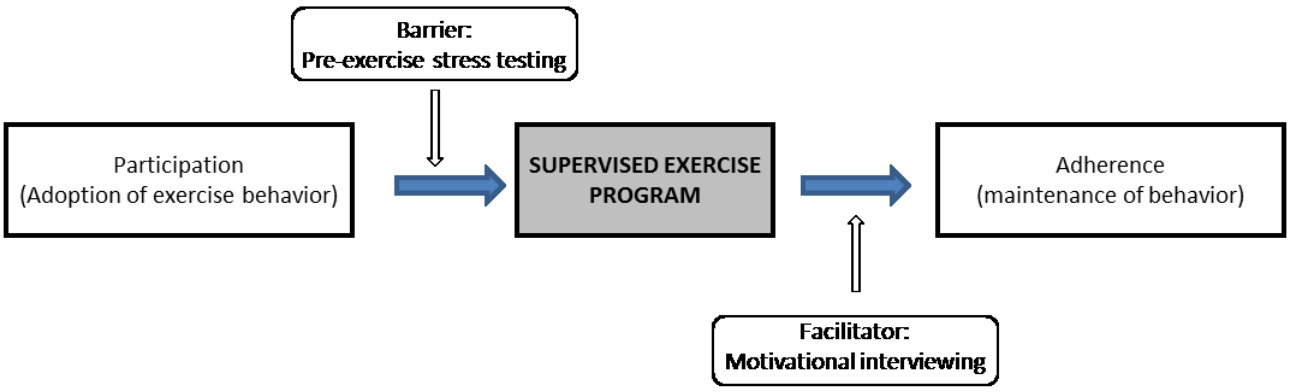

Figure 1.1 Conceptual model of thesis

Within this thesis we will examine a potential barrier (pre-exercise stress testing) and a potential facilitator (motivational interviewing), that may each mediate the likelihood of a patient participating and adhering to a supervised exercise program. This will be accomplished through three studies that each examine a facilitator or barrier within this model. The three studies include:

A) A systematic review and meta-analysis of motivational interviewing to improve weight loss in overweight and/or obese patients. This will provide an indication of the state of the evidence on motivational interviewing within the clinical context of behaviour change for weight management. This review encompasses studies that have evaluated motivational interviewing for weight management (both diet and physical activity) in overweight/ obese populations which also included people with type 2 diabetes.

B) A randomized controlled trial evaluating the use of motivational interviewing to promote exercise maintenance in patients with type 2 diabetes. This evaluation will offer novel insight into the effectiveness of motivational interviewing used specifically for promoting maintenance of exercise behaviours within a clinical setting.

C) An evaluation of the utility of ECG exercise stress testing in people with type 2 diabetes for pre-exercise screening. The need for pre-exercise stress testing was identified as a barrier to participation in the exercise program in the recruitment stage of Study B. This study will provide valuable data on the yield of pre-exercise stress testing in a real-world clinical example.

Through the use of varying methodologies, these three studies will work to inform evidence-based approaches in the delivery of supervised exercise programs for people with type 2 diabetes. Specifically, they will shed light on two key challenges within front-line practice; improving and streamlining access, as well as strategies to improve adherence and sustained behaviour change.

This thesis is divided into seven chapters. The rationale of this thesis is described by an overview of the literature in two specific contexts: the clinical basis for this study (Chapter 2), and the facilitation of health behaviour change with an emphasis on motivational interviewing (Chapter 3). Chapters 4-6 will provide the findings of the three studies in the form of original research papers (one published, one under review, one prepared for submission). Finally, Chapter 7 will provide a summary of the implications, recommendations, and future directions based on this work.

Chapter Two: **Clinical Context**

2.1 Introduction

This program of research undertaken in this thesis is centered on the medical condition of diabetes mellitus, with a specific focus on type 2 diabetes. This chapter provides an overview of the clinical context for this study underscoring the role of exercise in the management of type 2 diabetes.

2.2 Diabetes mellitus

Diabetes mellitus, commonly referred to as diabetes, has been a health concern for thousands of years, with the ancient Indians (circa 600 BCE) being well aware of this condition as they tested for "sweet urine disease", by determining if ants were attracted to a person's urine.[2] Diabetes refers to several diseases characterized by chronically elevated blood glucose levels due to defects in insulin secretion and/or insulin action in the body. Currently, the Canadian Diabetes Association[3] recommends the use of any of the following four criteria for diagnosing diabetes: 1) fasting plasma glucose $\geq$ 7.0 mmol/L, 2) hemoglobin A1c (HbA1c) value of 6.5% or higher, 3) two-hour plasma glucose of $\geq$ 11.1 mmol/L during an oral glucose tolerance test using 75 grams of glucose, or 4) random plasma glucose of $\geq$ 11.1 mmol/L in the presence of typical symptoms of hyperglycemia. Diabetes has become a growing national and international public health burden. The incidence and prevalence have risen dramatically over the past decades. Globally, the International Diabetes Federation has now estimated that 382 million people, or 8.3% of the world's population, is living with diabetes and this number is expected to rise by 55% by 2035.[4] Here in Canada, a similar situation exists with an estimated 6.8% of the adult population diagnosed with diabetes and indications that this number will continue to grow.[5] Rising obesity rates, sedentary lifestyles, an aging population, and changes in the ethnic mix of new immigrants have and will continue to drive these increases.

Of those individuals diagnosed with diabetes, the vast majority (90-95%) are diagnosed with type 2 diabetes.[5] In type 2 diabetes there is some endogenous insulin secretion, and varying degrees of insulin resistance, such that insulin secretion is insufficient to maintain normal glucose levels. In the absence of optimal metabolic control, diabetes can lead to numerous vascular complications including retinopathy, neuropathy and cardiovascular diseases.[6] Based on information from the National Diabetes Surveillance System,[5] diabetes remains the leading cause of blindness, end-stage renal failure and non-traumatic amputation in Canadian adults. Individuals with diabetes are over three times more likely to be hospitalized with cardiovascular disease than individuals without diabetes,[5] with many patients with diabetes succumbing to complications of ischemic heart disease or stroke. As a result, diabetes is extraordinarily costly to our society both in terms of direct costs to the medical system and indirect cost of disability and premature death.[7] In Canada, it is predicted that the economic impact of the disease in Canada will jump from $12.2 billion annually in 2010 to $16.9 billion annually by 2020.[8] In Alberta, the economic burden of diabetes was estimated to be $1.1 billion in 2010 (measured in 2009 dollars), and this cost is expected to increase by 43% over the next decade to $1.6 billion by 2020.[8] The direct cost of diabetes now accounts for about 3.5% of public healthcare spending in Canada and this share is likely to continue rising given the expected increase in the number of people living with diabetes in Canada.[8]

2.3 Type 2 diabetes and exercise

Exercise (planned, structured physical activity) is a key component in the management of diabetes. Extensive evidence has now established that participation in regular exercise by people with type 2 diabetes (e.g. achieving 150 minutes of moderate-to- vigorous aerobic exercise per week as recommended by guidelines) improves blood glucose control and reduces diabetic

complications, along with favorable effects on cardiovascular events, mortality and quality of life.[9-12] Large cohort studies[13-17] have demonstrated that in people with type 2 diabetes, higher aerobic fitness and/or regular physical activity are associated with reductions in cardiovascular and overall mortality of 39-70% over 15 to 20 years of follow-up, even after adjustment for other cardiovascular disease risk factors. In one large cohort study, being physically unfit (i.e. unable to achieve 8.8 METs on a treadmill test) carried a similar excess risk of mortality to that of cigarette smoking.[16] Metabolic Equivalents (METs) are commonly used to express the intensity of physical activities, with one MET is defined as the energy cost of sitting quietly and is equivalent to a caloric consumption of 1kcal/kg/hour. In a cohort of 2,196 men with diabetes, Church et al.[16] reported that for each 1-MET increase in exercise capacity there was a 26% lower risk of death in a model including body mass index (BMI) and other clinical variables. Clearly, achieving a more active population of people with type 2 diabetes would substantially reduce health-care burden and expenditure.

International diabetes guidelines consistently call for exercise as a central element of diabetes management. For example, the Canadian Diabetes Association 2013 Clinical Practice Guidelines[12] recommend that people with diabetes "accumulate 150 minutes of moderate-to-vigorous aerobic exercise per week, spread over at least 3 days per week, with no more than 2 consecutive days without exercise" and "perform resistance training 2-3 times per week". While exercise can help people with diabetes achieve a variety of benefits, most notable are the reductions in many of the metabolic and cardiovascular risks associated with diabetes. Large randomized trials[18-20] and systematic reviews of smaller trials[21-23] have found that exercise programs involving aerobic exercise (e.g., walking or jogging) and resistance exercise (e.g.,

weight lifting) cause significant improvements in glycemic control in patients with type 2 diabetes, with a combination of both types of exercise being most beneficial.

Several key trials[18-20] have demonstrated strong evidence for the combination of both aerobic and resistance training and the value of supervised exercise training. In the Diabetes Aerobic and Resistance Exercise (DARE) trial, by Sigal and colleagues[18], 251 sedentary adults with type 2 diabetes were randomized to aerobic training, resistance training, combined training, or waiting-list control. The group randomized to perform both aerobic and resistance training had an absolute decrease in HbA1c of 0.97% versus control, more than twice the decline observed in the groups randomized to either type of exercise alone. This clinically significant improvement, if maintained, would be expected to reduce the risk of diabetic complications significantly, considering that a 1% absolute decrement in HbA1c is associated with a 15-20% relative risk reduction for major cardiovascular events[24], and a 25-40% reduction in risk of diabetes-related microvascular complications: eye, kidney and neurological disease.[25,26] In the Health benefits of Aerobic and Resistance Training in type 2 Diabetes (HART-D) trial,[19] 262 patients with type 2 diabetes were randomized to three times weekly aerobic training, resistance training, both types of training or control. Unlike the DARE trial, the combined group performed smaller amounts of aerobic and resistance exercise so total weekly exercise time was about the same among the three groups, and no efforts were made to minimize dietary or medication co-intervention. The absolute reduction in HbA1c in HART-D was statistically significant compared to control only in the combined group (-0.34%). In addition to the greatest HbA1c reduction, the combined group also had the most decreases in hypoglycemic medication. This trial provided additional support for combined aerobic and resistance exercise rather than either type of exercise alone,

even if total exercise time was held constant. The exercise training in both the DARE and HART-D trials were supervised by exercise staff.

Although supervised exercise programs can be labour intensive, another large study has demonstrated that supervised exercise programs provide benefit over less-resource intensive and unsupervised interventions such as exercise counselling or physical activity advice. In the Italian Diabetes and Exercise Study (IDES), Balducci and colleagues[20] demonstrated that a twice-weekly, supervised, facility-based combined aerobic and resistance exercise had significant incremental benefits beyond those of exercise counselling alone in terms of promotion of exercise, improvement of HbA1c levels and cardiovascular risk profiles. Further to this finding, a systematic review and meta-analysis by Umpierre and colleagues,[23] evaluated the use of physical activity advice only or structured exercise training on change in HbA1c in people with type 2 diabetes. It was demonstrated that structured exercise interventions were associated with a greater decline in HbA1c when compared to trials using physical activity advice alone (-0.67 vs. -0.16, respectively).

These findings provide support for the supervised, facility-based exercise training to become part of standard, evidence-based therapy for type 2 diabetes. Consequently, the current Canadian Diabetes Association 2013 Clinical Practice Guidelines[12] suggest that structured exercise programs supervised by qualified personnel should be implemented for people with type 2 diabetes to improve glycemic control, cardiovascular risk factors and physical fitness.

Chapter Three: **Facilitating Exercise in Type 2 Diabetes Management**

3.1 Introduction

Despite the strong body of evidence demonstrating the protective effects of exercise in the management of type 2 diabetes, much of this population remains inactive. Facilitating and supporting sustained behaviour change is a key challenge in diabetes management. This chapter will provide a brief overview of the literature on exercise behaviour change and long-term maintenance.

3.2 Scope of the problem

Only around 50% of North American adults are meeting physical activity guidelines of 150 minutes per week for aerobic activity.[27,28] In older adults with diabetes (over age 65), the proportion is much lower; that is, 25% report meeting the American Diabetes Association guidelines for aerobic activity, and older adults (defined as > 65 years of age) with diabetes are 32% less likely to participate in physical activity when compared to their non-diabetic counterparts.[29] Participation rates for resistance training are even lower with only 12% of Canadian adults with diabetes reporting any resistance training[30] in one survey. In addition to this lack of adoption, many of those who begin a regular exercise program do not continue long-term.[31]

There has been limited research examining post-program adherence rates in the type 2 diabetes population.[9] In other chronic disease populations, it has been shown that fewer than 50% of participants exercised regularly at 1-year follow-up among those with chronic pulmonary disease[32] and maintenance rates have been shown to be 30-50% in adults with known cardiovascular disease upon the completion of a cardiac rehabilitation program.[33,34] Specifically within the diabetes population, we have previously reported[35] that cardiac patients with diabetes, especially females, were less likely than cardiac patients without diabetes to complete a cardiac

rehabilitation program and attend follow-up.[35] Patients with diabetes were also less likely to maintain changes in cardiorespiratory fitness at a 1-year follow up when compared to patients without diabetes, however details of exercise behaviour were not available. In order to achieve long-term health benefits of physical activity, maintenance of physical activity behaviour is essential.

3.3 Physical activity behaviour change: a theoretical overview

In examining strategies to improve the adoption and maintenance to exercise program, it is important to consider the theoretical basis for physical activity behaviour change. Although there are numerous theories of behavioural change, there are four that have been applied to physical activity more predominantly than others[36]; these include Social Cognitive Theory,[37] the Theory of Planned Behaviour,[38] Self-Determination Theory[39], and the Transtheoretical model.[40] All of these theories have been applied towards understanding the determinants of physical activity in a variety of populations.

Social Cognitive Theory[37] suggests that behaviour change is affected by several factors such as environmental influences, personal factors, and characteristics of the behaviour itself. This theory posits that self-efficacy is a central tenet of behaviour change. Self-efficacy is defined as "the belief in one's capabilities to organize and execute the courses of action required to manage prospective situations".[37] More specifically, self-efficacy is thought to influence the goals people set, their ability to persist in the face adverse circumstance, and their ability to cope with setbacks.[36] Within the domain of physical activity, self-efficacy has been found to have the most predictive value on physical activity behaviour in a variety of contexts.[36,41] However, one of the challenges of Social Cognitive Theory is the concern of how to measure the construct of

self-efficacy, especially within different modes of physical activity, with more research being needed

The Theory of Planned Behaviour[38] states that individual behaviour is shaped primarily by a person's intention to perform the behaviour, and that attitudes towards the behaviour, subjective norms and perceived behavioural control together shape an individual's behaviour. Perceived behavioural control is similar to the concept of self-efficacy, in that perceived behavioural control over skills, resources, and opportunities are believed to be a crucial aspect of the behavioural change process. Meta-analyses have shown that the theory of planned behaviour performs well in explaining physical activity behaviour[42], however this has not been without critiques. Mainly, there have been concerns regarding the measurement of the time interval between intention and behaviour, with more recent evidence suggesting that intention-behaviour relationships weaken over time.[43] Additionally, it has been found that studies using the Theory of Planned Behaviour in older individuals tend to find stronger effects than studies in younger participants.[42] Future research is needed to distill whether these characteristics moderate the effects of this theory.

Self-Determination Theory[39] makes the distinction between three types of motivation; 1) *amotivation*, where there is a lack of any intention to take part in a behaviour, 2) *extrinsic motivation*, where motivation comes from external sources and the behaviour is performed in order to achieve outcomes separate from the behaviour itself, and 3) *intrinsic motivation*, where the drive to perform the behaviour comes from within the individual and the behaviour is performed for the enjoyment and satisfaction inherent in performing the behaviour. Furthermore, the theory proposes that individuals have three basic psychological needs: autonomy, competence and relatedness (feeling connected to others), and that these needs are

essential so that individuals can act intrinsically towards the behaviour. A recent systematic review[44] reported beneficial effects for the use of Self-Determination Theory in exercise behaviours. However, to date most of the evidence on Self-Determination Theory has been observational in design, which limits the generalizability of the findings.[36]

The Transtheoretical model[40] has also been employed as a framework for describing and predicting physical activity behaviour change.[45] The Transtheoretical model explains behavioural change as a process involving progress through a series of five stages: (a) *precontemplation,* not considering behaviour change in the next 6 months; (b) *contemplation,* considering behaviour change within the next 6 months; (c) *preparation,* preparing for behaviour change within the next 1 month; (d) *action,* overt behaviour change has been made within the last 6 months; and (e) *maintenance,* maintaining the desired behaviour change for longer than 6 months. Each stage is characterized by a particular pattern of psychological and behavioural changes, and interventions are designed and targeted to the individual's stage of change. Additionally, the model includes the construct of decisional balance incorporating the concept of pros (benefits) and cons (barriers), and proposes that changes in perceived benefits, barriers and movement across stages are necessary for behavioural change. Although applied in practice, the body of evidence on the Transtheoretical model is mixed.[46] A systematic review[47] identified 29 randomized controlled trials using the Transtheoretical model on lifestyle behaviours, 13 of which included a physical activity intervention. This review found that some interventions based on the Transtheoretical model reduced smoking and improved diet, but none of those tested increased physical activity levels when compared to usual care. A small number of studies not included in the above-mentioned systematic review have explored the use of the Transtheoretical model specifically in physical activity behaviour and diabetes management[48-51] also with varying

results. To date the effectiveness of interventions based on the Transtheoretical model in increasing physical activity is unclear.

Although all of the aforementioned behavioural theories for physical activity have several strengths and weaknesses, they can provide useful frameworks for explaining physical activity behaviour. In exploring the various theories, the construct of "perceived barriers" and "perceived facilitators" can be applied to each of these theories within their associated concepts.

3.4 Barriers and facilitators to supervised exercise programs

A range of factors can interfere with a patients' willingness to seek and receive healthcare services such as a supervised exercise program. In exploring strategies to improve the uptake of physical activity behaviours, it can be valuable to consider barriers and facilitators to health behaviour change. The concept of barriers was originally introduced in the Health Belief Model[52] a conceptual framework for understanding why individuals did or did not engage in a variety of health related actions. Barriers were construed as costs inherent in health actions, and the greater the perceived barriers to adhering to a protocol, the lower the probability a patient would adhere to it. Within the Health Belief Model the "likelihood of action" is directly influenced by the "perceived benefits" minus the "perceived barriers" to preventative health behaviours. A critical review of investigations using this model determined that perceived barriers were the most powerful of the Health Belief Model determinants across various study designs and behaviours.[53] Overall, barriers, and how barriers are perceived, interpreted, and addressed have a large influence on health behaviour change, goal setting and goal attainment.

In attempting to promote lifestyle behaviour change it becomes important to address identified barriers, as well as potential facilitators. In the general population, identified barriers to physical activity include lack of time, lack of motivation, medical problems, cost, and lack of

energy.[54,55] A review of barriers and facilitators to physical activity in patients attending cardiac rehabilitation programs[56] reported similar results, with major barriers reported as lack of time (competing priorities), lack of motivation, pain or other discomfort, new illness and bad weather. In a qualitative study by Casey and colleagues[31] on barriers and facilitators to a supervised exercise program in people with type 2 diabetes, "motivation" emerged as the most critical factor in exercising both during and following a supervised exercise program. Additionally, participants voiced a need for better transition to post-program realities of less support and supervision. Other perceived barriers to supervised exercise programs can extend beyond the personal level to the systems level where issues of access, cost, and pre-program requirements such as pre-exercise stress testing can decrease the likelihood of people engaging in physical activity. Enhancing participation, by minimizing barriers, and applying strategies to support long-term adherence are imperative in order to promote the sustained health benefits of an exercise program. In this thesis, the focus will be on the barrier of "lack of motivation" and the exploration of a counselling approach thought to help patients to overcome this barrier in order to make and sustain changes in lifestyle related behaviours.

3.5 Motivational interviewing to facilitate behaviour change and adherence

Given the foundation of lifestyle behaviours within the clinical management of type 2 diabetes, employing psychological strategies to assist individual behaviour change is a central tenet of care. Motivational interviewing has emerged as an approach designed to enhance patients' motivation for change and adherence to therapy.[57] It is a directive, patient-centered counselling style that aims to help patients explore and resolve ambivalence surrounding complex behaviour change. Traditionally, recommendations for behaviour change are delivered through brief education and advice-giving, in which overt recommendations are provided.

Motivational interviewing is fundamentally different from educational approaches in that motivation for change is elicited from individuals, rather than imparted by a health care provider.[57] Initially developed for application within the substance abuse field,[58] it is a skillful clinical style for eliciting from patients their own motivations for making behaviour changes in the interest of health. The overall "spirit" of motivational interviewing has been described as collaborative, evocative and honoring patient autonomy.[59] Relatedly, the practice has four guiding principles; 1) express empathy, 2) develop discrepancy, 3) support self-efficacy and 4) roll with resistance. The popularity of motivational interviewing within the diet and exercise field is quickly growing, as are the recommendations for use in clinical practice.[60] For example, the American Heart Association [61] now recommends motivational interviewing as an approach for enhancing adherence to health behaviour interventions. Despite these recommendations and the increase in popularity, sound empirical evidence is currently lacking within obesity-related and diabetes-related lifestyle behaviours. The ensuing chapters (Chapter Four and Five) outline two studies that were performed in order to explore the use of motivational interviewing, as a potential facilitating factor in health behaviour change, within the obese and type 2 diabetes patient populations.

Chapter Four: **The Effectiveness of Motivational Interviewing for Weight Loss**

This chapter provides an overview of the current literature on the effectiveness of motivational interviewing for reducing body mass in obese populations through the completion of Study A. Although the target population of this thesis is patients with type 2 diabetes, this systematic review addresses the use of motivational interviewing in overweight and obese populations which also included patients with type 2 diabetes. The reason for this was that there were not sufficient studies including only type 2 diabetic participants upon our initial literature scan. As obesity is a potent risk factor for the development of type 2 diabetes, and weight management is an important component of the management of this condition, we decided to include interventions that addressed weight loss in any overweight or obese adult population. The goal of this study was to perform a comprehensive systematic review and meta-analysis on this topic. This study has been published as a manuscript in Obesity Reviews under the title "Motivational interviewing to improve weight loss in overweight and/or obese patients: a systematic review and meta-analysis of randomized controlled trials".[62]

Motivational interviewing to improve weight loss in overweight and/or obese patients: a systematic review and meta-analysis of randomized controlled trials

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4.1 Abstract

Background: Motivational interviewing, a directive, patient-centered counselling approach focused on exploring and resolving ambivalence, has emerged as an effective therapeutic approach within the addictions field. However, the effectiveness of motivational interviewing in weight loss interventions is unclear.

Methods: Electronic databases were systematically searched for randomized controlled trials evaluating behaviour change interventions using motivational interviewing in overweight or obese adults. Standardized mean difference (SMD) for change in body mass, reported as either BMI (kg/m^2) or body weight (kg), was the primary outcome, with weighted mean difference (WMD) for change in body weight and BMI as secondary outcomes.

Results: The search strategy yielded 3,540 citations and of the 101 potentially relevant studies, 12 met the inclusion criteria and 11 were included for meta-analysis. Motivational interviewing was associated with a greater reduction in body mass compared to controls (SMD = -0.51 [95% CI, -1.04, 0.01]). There was a significant reduction in body weight (kg) for those in the intervention group compared with those in the control group (WMD = -1.47 kg [95% CI, -2.05, -0.88]). For the BMI outcome, the WMD was -0.25 kg/m^2 (95% CI, -0.50, 0.01).

Conclusions: Motivational interviewing appears to enhance weight loss in overweight and obese patients.

4.2 Background

Obesity has reached epidemic proportions. In the United States, more than 33% of adults are obese and 68% of adults are overweight with a body mass index (BMI) of 25.0 kg/m^2 or higher.[63] The health consequences of excess weight include an increased risk of type 2 diabetes, cardiovascular disease, high blood pressure, osteoarthritis, some cancers, and a decrease in quality of life.[64] In addition, individuals may experience psychosocial problems, functional limitations, and physical disability as a result of excess adiposity. Given the increasing prevalence and health-related consequences of obesity, developing effective treatment approaches has been identified as a research and population health priority.[65]

The etiology of obesity is largely multi-factorial; however, given the influence of individual and personal choice in its development, psychological strategies to assist individual behaviour change are crucial to the clinical management of obesity. Motivational interviewing is a strategy designed to enhance patients' motivation for change and adherence to treatment.[57] It is a directive, patient-centered counselling style that aims to help patients explore and resolve ambivalence surrounding complex behaviour change. Traditionally, recommendations for behaviour change are delivered through brief education and advice-giving, in which overt recommendations are provided. Motivational interviewing is fundamentally different from educational approaches in that motivation for change is elicited from individuals, rather than imparted by a health care provider.[57]

Motivational interviewing was initially developed for application within the substance abuse field[58], and its effectiveness in this setting has been demonstrated in several systematic reviews and meta-analyses.[66-68] To date, several reviews[67,69-73] have focused in part, on the effectiveness of motivational interviewing for weight-loss and modifying diet and physical activity behaviours, with effect sizes ranging from 0.23 to 0.77 standard deviations. However,

many of these meta-analyses combined studies of weight management behaviours with studies of substance-abuse behaviours. In weight management, in contrast to substance abuse, the behaviour change process involves modification or addition rather than elimination of a behaviour (reshaping rather than abstaining).[74] The concepts of abstinence and relapse as seen in the addictions field are less applicable for weight management behaviours; however despite this, there has been increased recommendation for the use of motivational interviewing in clinical practice to address weight loss.[60,74,75] As such, there is a need to evaluate the effectiveness of motivational interviewing within weight management independent of other addictive behaviours.

The aim of this paper was to systematically review randomized controlled trials (RCTs) that investigate the effectiveness of motivational interviewing for reducing body mass, measured by change in body weight or BMI in adults who are overweight or obese. To our knowledge this is the first meta-analysis on this topic based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[76] Furthermore, it incorporates eight randomized RCTs[77-84] evaluating motivational interviewing for weight loss published since 2007, which have not previously been incorporated into a systematic review or meta-analysis.

4.3 Methods

Data Sources and Search Strategy

We performed this systematic review using a predetermined protocol and in accordance with standardized reporting guidelines.[76] Two reviewers (M.J.A. and T.A.M.) performed independent searches of the following electronic databases regardless of publication language: MEDLINE (1950-through November 2009), EMBASE (1980-November 2009), PsycINFO (1967-November 2009), CINAHL (Cumulative Index to Nursing and Allied Health), and CENTRAL (Cochrane Central Registry of Controlled Trials). Two comprehensive search themes were developed. To

identify the relevant population of interest, the first search was undertaken using the Boolean operator "or" to explode and map the Medical Subject Heading (MeSH) such terms included; obesity, obese, overweight, body mass index, adult, aged, middle aged, young adult, diabetes mellitus, hypertension, and hyperlipidemias. To identify relevant interventions, a second search was performed using the following search terms: counselling, psychological intervention, directive counselling, interview, motivation*, motivation* interview and motivational interviewing. We combined these themes by using the Boolean "and" operator. We then used the randomized controlled trial filter described by the Cochrane collaboration[85] for MEDLINE and EMBASE to limit our search to RCTs. The reference lists of prior reviews and all identified research articles were hand searched to find other potentially eligible studies. Experts in the field were contacted for information about other ongoing or unpublished studies.

Study selection

Articles were independently evaluated for eligibility in a 2-stage procedure by each of the 2 reviewers (M.J.A. and T.A.M.). In the first stage, all identified titles and abstracts were reviewed. In the second stage, we performed a full-text review of articles that met the inclusion criteria and for articles for which there was uncertainty as to eligibility. If an article was selected by either reviewer, it was included in full-text review and evaluated by both reviewers. Inclusion criteria consisted of 1) study population (overweight or obese adults defined by having a BMI $\geq$ 25.0 kg/m^2); 2) intervention (behaviour change using motivational interviewing) differing between groups only in the use of motivational interviewing in one group but not the other; 3) comparison (standard care, education, attention control, or no treatment); 4) outcome (body mass measured as body weight in kg or BMI in kg/m^2); and 5) study design (RCT).

We included RCTs where authors defined the intervention as "motivational interviewing" or if within the description of the intervention the authors indicated the use of methods developed by Miller and Rollnick.[57] Studies were included if outcomes reported change in body mass, reported either as weight (kg) and/or BMI (kg/m^2). Studies were excluded if they involved children or adolescents due to differences in weight outcome indices. Studies involving more than one intervention, (for example a behavioural weight loss program) were included if the intervention and comparator groups differed only in the use of motivational interviewing in one group but not the other. Studies were excluded if the motivational interviewing intervention was used in combination with other strategies or compared to a no treatment control. This was in order to examine the unique effect of motivational interviewing and not a variety of weight loss approaches.

Data Extraction and Quality Assessment

Both reviewers independently extracted data from all identified studies that fulfilled the inclusion criteria (Appendix A). Agreement between reviewers on the relevance of records was assessed using Cohen's kappa statistic (κ), which adjusts the proportion of records for which there was agreement by the amount of agreement expected by chance alone.[86] Any disagreements in data extraction and/or specific study inclusion were resolved through consensus by discussion with other authors (B.R.H. and R.J.S.). The primary outcome was change in body mass reported as either body weight in kg, or BMI reported in kg/m^2. For our purposes, we refer to the term "body mass" to encompass both BMI and body weight. Baseline and post-intervention means and standard deviations (SD) for body mass change were extracted from intervention and control groups. The authors of potentially eligible studies were contacted when necessary to resolve

ambiguities in reported results and to seek missing or incomplete data. In four of the studies, SDs for mean change were not directly reported and we were unable to obtain this information from the authors. In three of these instances,[77,87,88] SDs for mean changes were calculated using the 95% confidence intervals[89] for within group means. In the other two cases,[81,83] SDs were computed based on the standard error of the mean (SEM). One study[88] investigated the effect of high and low dose motivational interviewing on behaviour change in hypertensive patients using a single control group. In this instance we divided the control sample in half as recommended in the Cochrane Handbook.[90] In another study,[84] outcomes were reported at several time points including 6, 12, and 18 months. We chose to include the 12-month reported data because this study was much longer in duration than the other included studies and there was not a motivational interviewing intervention applied for the last 6 months of the intervention. Other data extracted included sample size, mean age, percent female, baseline demographics, ethnicity, study period, and length of follow-up. Characteristics of the motivational interviewing intervention were also extracted, including professional background of individuals delivering the intervention, mode (i.e., face to face, telephone, computer or group), and dose of delivery (frequency and duration). The use of treatment fidelity, a measurement tool used to assess the quality of motivational interviewing was extracted; more specifically we assessed if a validated motivational interviewing treatment coding scale was employed. Measures of study quality were also extracted including allocation concealment, randomization, intention-to-treat analysis, blinding, and loss to follow up. These measures were scored by each reviewer and assessed using the validated 5-point scale described by Jadad et al.[91]

Data Analysis

Statistical analysis was performed using Stata, version 11.0 (Stata Corp., College Station, TX). In each study the effect size for the intervention was calculated by the change in mean body mass (in kg or kg/m^2) from baseline to end of follow-up and compared between groups. This allowed for a comparison of weight lost over and above what was lost in the control group, and not simply a comparison of weight lost in each study. As a result of the outcome being measured on different scales (i.e. either kg and/or kg/m^2), the outcomes were combined and the mean difference was standardized by dividing it by the within group SD to account for the different units. If both outcomes were presented, BMI was used in the analysis. The results were then weighted by sample size and the average taken (standardized mean difference [SMD]). We initially pooled the SMD in each study using a fixed-effects model. To assess heterogeneity across studies we visually inspected forest plots and calculated both the Q (significance level of $P \leq 0.10$) and I^2 statistics. The I^2 statistic quantifies the percentage of variability that can be attributed to between-study differences.[92] When significant heterogeneity was evident, the DerSimonian and Laird[93] random-effects model to account for the heterogeneity of studies was used to estimate pooled effects.

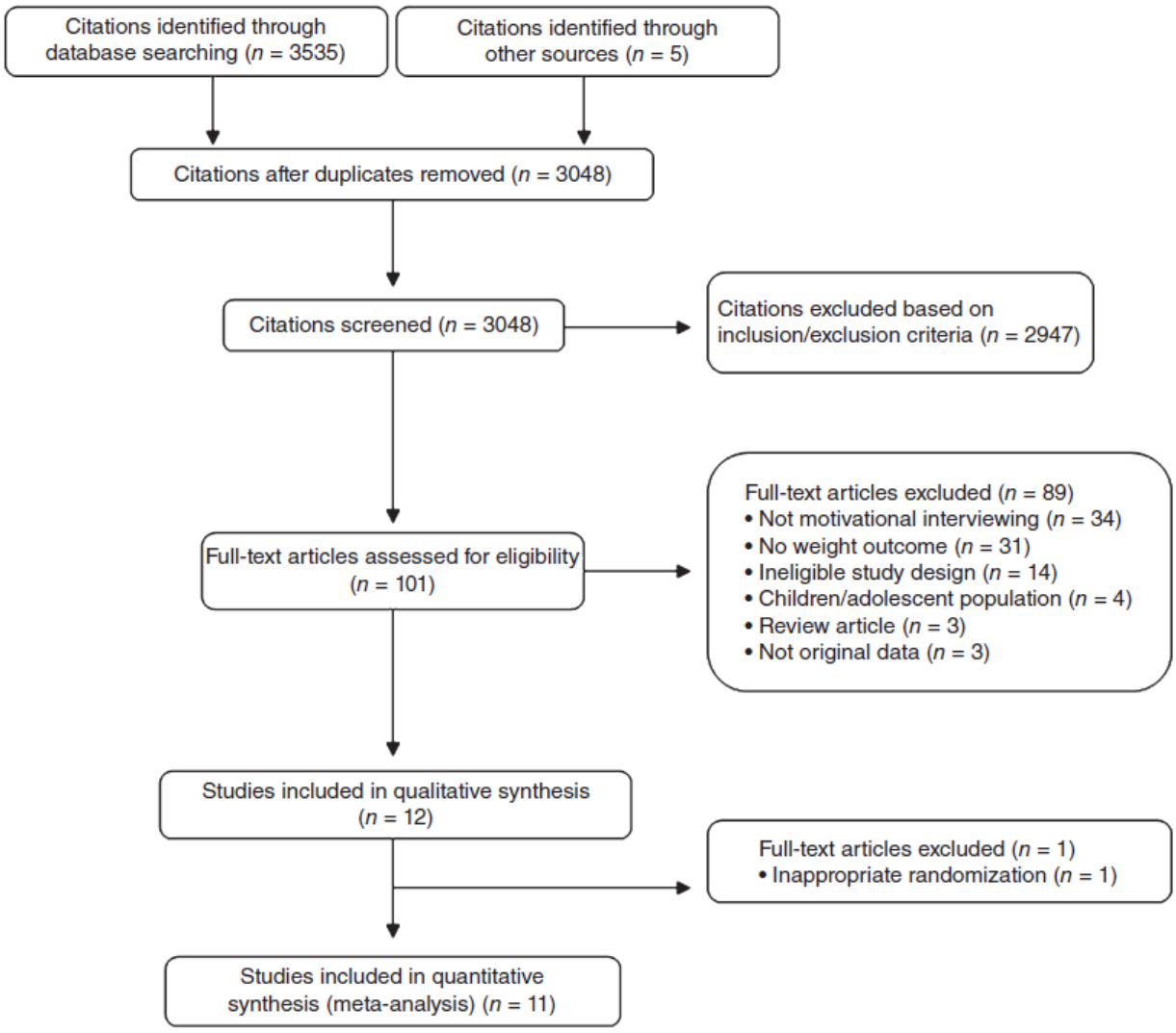
We also stratified the results by each of the two outcome measures, weight (kg) and BMI (kg/m^2), using the weighted mean difference (WMD). If a study reported both outcomes we included the study in both analyses. We further stratified studies by variables that may affect heterogeneity of study results including whether body weight was the primary outcome of the study, the duration of treatment, if an attention control was used, if there was a motivational interviewing fidelity measure employed, and if motivational interviewing was used as an adjunct to a behavioural weight loss program. Univariate meta-regression was also performed to explore

whether the methodological factors mentioned above mediated the effects of motivational interviewing on weight loss. Finally, publication bias was assessed through visual inspection of funnel plots, the Begg's[94] (rank correlation) test for asymmetry, and Egger's[93] (weighted regression) test. A significant statistical test ($p<0.05$) or funnel plot asymmetry suggests potential publication bias.

4.4 Results

The progress through the stages of the systematic review is summarized in Figure 4.1 Study flow. The initial database search yielded 3,048 citations, with duplicates removed. Through title and abstract review, we excluded 2,947 articles ($\kappa = 0.71$). The most common reasons for exclusion were inappropriate population, intervention or outcomes, as well as not being a RCT. For the remaining 101 citations, full-text articles were obtained for more detailed evaluation. We excluded 88 articles during this screening phase due primarily to use of multiple simultaneous interventions (making it impossible to isolate the effects of motivational interviewing), the lack of a motivational interviewing intervention, or lack of a weight outcome (BMI or kg). Overall, 12 studies ($\kappa = 0.86$) were deemed appropriate for inclusion for the review.[77-84,87,88,95,96] For the purpose of meta-analysis, 11 studies were deemed eligible for the SMD analysis. One study[96] was excluded due to the interventionists being randomized rather than the participants.

Figure 4.1 Study flow



Study Characteristics

The characteristics and weight outcomes of the 12 trials that met our inclusion criteria are shown in Table 4.1 and a summary of the methodological details of the trials is presented in Table 4.2. Publication dates ranged from 1995-2009 with the number of participants per study varying from 22 to 599 and proportion of females from 3% to 100%. Mean baseline BMI ranged from 27.1 to 37.9 while mean age ranged from 41 to 62 years. One of the 13 trials[88] presented data for 2 comparisons (high dose, low dose) hence both interventions are presented.

Table 4.1 Characteristics of included studies by outcome measure

Study (first author and year)	Sample size, *n*	*n* analysed (loss to follow-up, %)	Mean age	% female	Outcome	Intervention group			Control group		
						Pre	Post	Change	Pre	Post	Change
Smith, 1997 (36)	22	16 (27)	62	100	BMI	34.7 (4.9)	NR	NR	34.9 (4.9)	NR	NR
Mhurchu, 1998 (28)	97	84 (14)	NR	49	BMI	26.7 (3.9)*	NR	−0.45 (0.7)*	27.3 (4.2)*	NR	−0.44 (0.6)*
Brug†, 2007 (37)	209	142 (32)	59	NR	BMI	30.7 (5.7)	29.6 (5.5)	NR	29.8 (4.3)	28.7 (4.0)	NR
Elliot, 2007 (22)	599	480 (20)	41	3	BMI	27.1 (3.9)‡	27.3 (3.9)‡	+0.2 (3.9)‡	27.9 (3.5)‡	28.4 (4.6)‡	+0.5 (4.2)‡
Carels, 2007 (20)	55	46 (16)	48	87	BMI	37.0 (7.4)	34.7 (8.3)	−2.3 (1.9)	36.0 (7.6)	34.5 (8.0)	−1.48 (2.0)
West, 2007 (25)	217	195 (8)	53	100	BMI	36.5 (5.5)	NR	NR	36.5 (5.4)	NR	NR
Hardcastle, 2008 (24)	334	218 (35)	51	67	BMI	33.7 (5.4)‡	33.5 (5.8)‡	−0.2 (1.0)‡	34.3 (7.0)‡	33.4 (4.4)‡	+0.15 (1.1)‡
Greaves, 2008 (23)	141	141 (18)	55	64	BMI	>28.0§	NR	NR	NR	NR	NR
Befort, 2009 (19)	44	33 (23)	44	100	BMI	37.92 (6.7)	36.9 (7.4)	−1.0 (1.5)	40.7 (5.9)	39.6 (6.2)	−1.1 (2.0)
Armit, 2009 (18)	136	136 (15)	NR	60	BMI	28.3 (4.6)	28.2 (4.6)	−0.1 (4.6)*	27.9 (5.1)	29.7 (5.1)	+1.8 (5.1)*
DiMarco, 2009 (21)	39	26 (33)	NR	82	BMI	33.1 (3.2)	31.6 (3.1)	−1.48 (3.1)	31.62 (2.8)	30.9 (3.1)	−0.7 (2.9)
Woollard, 1995 (29) (low dose)	166	146 (12)	58	47	Weight (kg)	78.5 (16.2)*	NR	−1.0 (3.8)*	78.4 (9.5)*	NR	+0.05 (2.0)*
Woollard, 1995 (29) (high dose)	166	146 (12)	58	47	Weight (kg)	78.6 (16.8)*	NR	−1.7 (3.6)*	78.4 (9.5)*	NR	+0.05 (2.0)*
Smith, 1997 (36)	22	16 (27)	62	100	Weight (kg)	NR	NR	−5.5 (3.9)	NR	NR	−4.5 (2.2)
Elliot, 2007 (22)	599	480 (20)	41	3	weight (kg)	87.4 (12.3)	87.9 (12.3)	+0.54 (12.3)	89.1 (13.7)	90.7 (14.8)	+1.6 (14.3)
Carels, 2007 (20)	55	46 (16)	48	87	weight (kg)	100.6 (23.2)	96.1 (23.7)	−4.5 (3.0)	99.8 (25.8)	97.7 (26.3)	−2.1 (2.8)
West, 2007 (25)	217	195 (8)	53	100	Weight (kg)	97.0 (17)	NR	−4.8 (0.6)	97.0 (15)	NR	−2.7 (0.6)
Hardcastle, 2008 (24)	334	218 (35)	51	67	Weight (kg)	93.7 (17.1)‡	91.9 (21.9)‡	−0.7 (3.6)‡	91.73 (17.2)‡	93.0 (13.1)‡	+0.12 (3.3)‡
Greaves, 2008 (23)	141	141 (18)	55	64	Weight (kg)	91.6 (13.3)	89.7 (13.7)	−1.86 (3.7)	94.4 (14.2)	93.9 (14.8)	−0.54 (3.0)
Befort, 2009 (19)	43	33 (23)	44	100	Weight (kg)	101.3 (22.8)	98.6 (24.8)	−2.62 (4.2)	109.9 (18.5)	106.7 (18.1)	−3.2 (5.7)

*Standard deviation calculated from 95% confidence interval.
†Not included in meta-analysis.
‡Standard deviation from standard error of the mean.
§BMI > 28.0 was study inclusion criteria.
BMI, body mass index; NR, not reported.

Table 4.2 Methodological characteristics of included studies

Reference (first author and year)	Study duration (months)	Population	Primary outcome(s)	Base intervention	Additional motivational interviewing intervention used	Motivational interviewing delivery	Attention control	Motivational interviewing fidelity	Results
Woollard, 1995 (29) (low dose)	4.2	Adults with hypertension	Blood pressure	GP usual care	One single face-to-face counselling session, followed by 5 × 15 min telephone sessions every 4 weeks. Goal was to change diet, alcohol, smoking and physical activity behaviours	Nurse	No	No	No change in weight or blood pressure, decrease in alcohol (164 g week^{-1}, $P < 0.05$), decrease in sodium (33 mmol per 24 h, $P < 0.05$). Physical activity and smoking behaviours not described
Woollard, 1995 (29) (high dose)	4.2	Adults with hypertension	Blood pressure	GP usual care	Six 45-min individual face-to-face counselling sessions. Motivational interviewing to change diet, smoking and activity behaviours	Nurse	No	No	Decrease in body weight (1.7 kg, $P < 0.05$), decrease in systolic pressure (6 mmHg, $P < 0.05$), decrease in diastolic pressure (5 mmHg, $P < 0.05$), no change alcohol or sodium intake. Physical activity or smoking behaviours not described
Smith, 1997 (36)	4	Older obese women with type 2 diabetes	Adherence, HbA1c, weight loss	16-session behavioural weight-loss programme	Three individual motivational interview sessions (in addition to behavioural weight-loss programme)	Psychologist	No	No	Decrease in weight (no significant difference between groups). Intervention group had greater attendance ($P = 0.01$), completed more diaries and better glucose control ($P = 0.05$)
Mhurchu, 1998 (28)	3	Patients with hyperlipidaemia	Diet knowledge, intake and lipid levels	Standard dietary care	Adapted MI for use by non-specialists applied over three sessions. Dietary counselling also provided at each visit	Dietitian	No	Yes (audiotaped and coded using adapted coding tool)	Decrease in fat and energy intake in both groups. No significant differences between groups for weight, daily nutrient intakes, total and HDL cholesterol, and triglycerides
West, 2007 (25)	18	Overweight women with type 2 diabetes	Weight loss, HbA1c	42-session behavioural weight-loss programme and attention control	Five 45-min MI sessions every 3 months (all participants received 42-session weight-control programme)	Psychologist	Yes (health education sessions)	Yes (weekly review of audiotaped sessions using 'standardized' coding)	Intervention group lost more weight at 6 ($P = 0.01$), 12 ($P = 0.02$) and 18 ($P = 0.04$) months. Glycaemic control was better in the intervention group at 6 months ($P = 0.02$). African–American women lost less weight compared with Caucasian women
Elliot, 2007 (22)	12	Firefighters	Physical activity, diet behaviours	Test results only	Four face-to-face sessions of a mean of 42 min, with the possibility of 5 h of additional contacts	Counsellor	No	Yes (10% of tapes were evaluated using Motivational Interviewing Skill Code)	MI intervention group had less weight gain ($P < 0.05$), increased fruit and vegetables consumption ($P < 0.05$), increased number of sit-ups per minute ($P < 0.05$)
Carels, 2007 (20)	6	Obese sedentary adults	Weight loss	Behavioural weight-loss programme with stepped care	Upon completion of a 20-session behavioural weight-loss programme, those who failed to meet weight-loss goals (weight reduction by 10%) were randomized to MI or no-MI groups. 45- to 60-min individual face-to-face sessions were undertaken until weight-loss goals were achieved	Psychology Students	No	Yes (25% of sessions randomly coded using Motivational Interviewing Treatment Integrity Code)	MI intervention group lost more weight ($P < 0.05$), increased planned physical activity (58 min week^{-1}, $P < 0.05$). No between-group differences in change of physical fitness or macronutrient intake

Table 4.3 continued

Reference (first author and year)	Study duration (months)	Population	Primary outcome(s)	Base intervention	Additional motivational interviewing intervention used	Motivational interviewing delivery	Attention control	Motivational interviewing fidelity	Results
Brug, 2007 (37)*	NR	Adults with type 2 diabetes	Diet	Dietitians with no MI training	Trained dietitians randomized to receive MI training and recruited up to 10 patients each. Patients had an initial 30- to 45-min face-to-face counselling session followed by 3–4 15-min follow-up sessions	Dietitians	No	Yes (first 15 min of two sessions audiotaped and scored using Motivational Interviewing Treatment Integrity Code)	MI patients showed increase in fruit intake ($P = 0.03$). Both groups reported significant decrease in BMI, waist circumference, HbA1c and saturated fat intake
Greaves, 2008 (23)	6	Adults with BMI >28.0 kg m^{-2}	Weight loss, physical activity	Print education materials	Up to 11 individual MI sessions over 6 months. Both face-to-face and phone contacts were used with a mean duration of 34 min per contact	Health Promotion Counsellors	No	Yes (interview transcripts coded using Behaviour Change Counselling Index)	A significantly higher proportion of those in the intervention group achieved 5% weight loss (24% in intervention vs. 7% in control). No significant increase was found in physical activity
Hardcastle, 2008 (24)	6	Obese adults	Coronary heart disease risk	Usual care (health promotion leaflet)	Up to five individual sessions for 20–30 min over 6 months	Physical Activity Specialist/ Registered Dietitian	No	Yes (analysis of consulting transcripts)	Significant decrease in BMI and increase in physical activity in intervention group. Intervention group also had reduced blood pressure and cholesterol
Befort, 2009 (19)	4	Obese African–American women	Weight loss	16-session behavioural weight-loss programme	Four 30-min sessions (two face-to-face, two phone)	Student Psychologist	Yes (health education sessions)	Yes (all sessions taped, 25% selected for review and assessed by fidelity checklist)	No significant differences between groups for body weight, BMI, programme adherence or dietary behaviours. Both groups lost significant weight, decreased energy intake and increased fruit and vegetable. Both groups experienced significant reductions in motivation
Armit, 2009 (18)	3	Inactive adults	Physical activity	GP 'usual care'	One 30-min individual counselling session followed by three 10- to 15-min phone calls over 12 weeks	Exercise Scientists	No	No	Small decrease in BMI at 12 weeks in MI group compared with an increase in the control group. MI group also showed non-significant increase in proportion reaching physical activity guidelines at 12 weeks (42% vs. 26%)
DiMarco, 2009 (21)	3	Overweight adults	Weight loss	Eight session-guided self-help behavioural weight-loss programme	Two 60-min MI sessions at first and fifth treatment sessions	Student Psychologist	Yes	Yes (audiotapes reviewed)	Intervention group had a decrease in BMI ($P < 0.001$), as well as an improvement in eating concern and control over-eating

*Not included in meta-analysis.
BMI, body mass index; GP, general practitioner; HDL, high-density lipoprotein; MI, motivational interviewing.

For the meta-analysis of weight outcomes, 4 studies[82,84,88,95] reported change in body weight (kg) only and 3 studies[77,80,87] reported change in BMI (kg/m^2) only. An additional 4 studies[78,79,81,83] reported changes in both BMI and body weight and were included in both analyses. Weight loss was the primary outcome in 6 of the studies.[78,79,82-84,95] The delivery of the motivational interviewing intervention varied across studies, as did follow-up duration (range from 3 to 18 months). Professional background of the interventionists was variable and included nurses, psychologists, graduate students in psychology, dietitians, health counselors, and exercise scientists. The delivery mode of motivational interviewing varied from individual face-to-face, to telephone, and group sessions. Three studies[77,78,88] used face-to-face motivational interviewing at an initial consultation and provided follow-up via telephone. In 7 of the 11 studies[78,79,81-84,87] a motivational interviewing fidelity measure was used in order to ensure treatment integrity. This was most commonly done by evaluating tapes of the intervention session using the motivational interviewing treatment integrity (MITI) code,[97] or the motivational interviewing skill code (MISC).[98] The dose of motivational interviewing, calculated as a product of the number of motivational interviewing sessions multiplied by mean session duration, ranged from 50 to 323 minutes. The comparison conditions varied from usual care, to print materials, to attention control. Three studies[78,80,84] employed an attention control condition, where persons in this placebo condition receive a treatment that mimics the amount of time and attention received by the treatment group. This is to control for any impact that individual attention from a health care professional might produce. Motivational interviewing was used in four studies[78-80,84,95] used as an adjunct to a behavioural weight loss program, which traditionally involves 16-24 treatment sessions over 6 months with a team of health care professionals.

Quality Assessment

The quality of trials according to the Jadad score[91] was moderate to low (Table 4.3). Nine trials[77-79,81-84,87] reported allocation concealment and blinding was reported in eight[77,78,81-84,95,96] of the 13 studies. Common sources of potential bias included research staff not blinded to the treatment groups, non-reporting of intention-to-treat analysis, and unclear description of randomization. All trials adequately described drop outs, except one.[88]

Effect of motivational interviewing on body mass

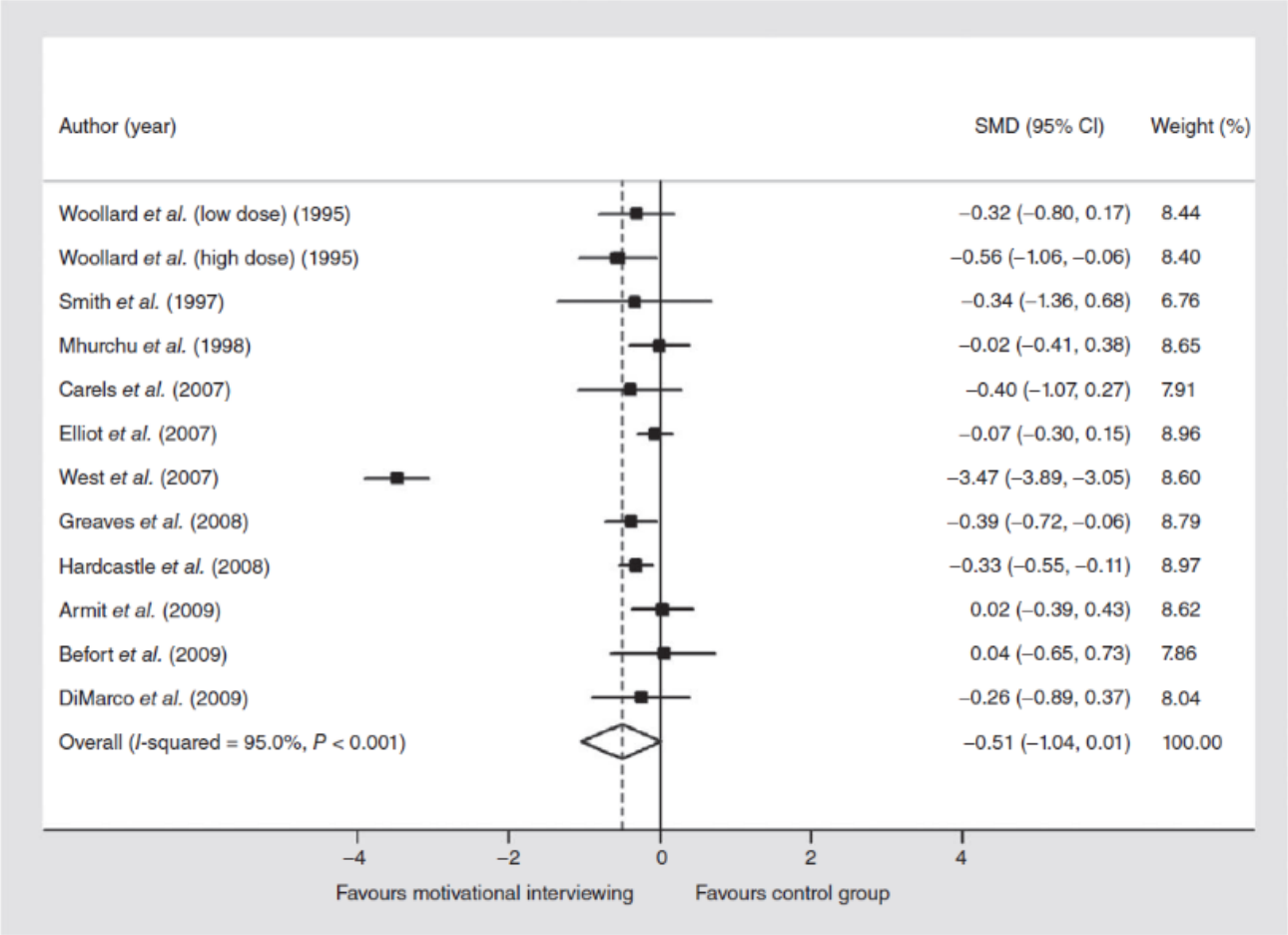
A total of 1448 participants were included in the 11 studies reporting a mean change in body mass. There were 801 participants who underwent the motivational interview intervention and 651 control comparator participants. Studies were grouped based on reported weight outcome (BMI in kg/m^2 or body weight in kg) and pooled to assess effect estimates. Using a random-effects model, the SMD for the effect of motivational interviewing on reduction in body mass was -0.51 (95% CI, -1.04, 0.01, $p = 0.053$; Figure 4.2). Significant heterogeneity was observed in this pooled estimate ($I^2 = 95.0\%$, $p < 0.001$). There was no evidence of publication bias with Begg's test ($p = 0.30$), Egger's test ($p = 0.62$), or with visual inspection of the funnel plots. Using stratified analysis limited to studies with weight loss as the primary outcome, a larger reduction in weight was observed compared to studies where weight loss was not the primary outcome of interest (SMD = -0.83 [95% CI -1.91, 0.25] versus -0.13 [95% CI -0.29, 0.21] respectively; Table 4.4).

Table 4.3 Study quality characteristics

Reference (first author and year)	Inclusion/ exclusion criteria	Randomization described	Allocation concealment	Blinding	Intention to treat analysis	Loss to follow-up described	Loss to follow-up, %	Jadad scoring
Woollard, 1995 (29)	NR	Unclear	Unclear	NR	Unclear	Yes	12	1
Smith, 1997 (36)	Yes	Unclear	Unclear	Outcome technicians	Unclear	Yes	27	2
Mhurchu, 1998 (28)	Yes	Yes	Yes	NR	Unclear	Yes	14	3
Brug, 2007 (37)	Unclear	Unclear	Unclear	Participants, MI fidelity scorer	Unclear	Yes	32	1
Carels, 2007 (20)	Yes	Yes	Yes	NR	Yes	Yes	16	3
Elliot, 2007 (22)	Yes	Yes	Yes	Researchers	Unclear	Yes	20	3
West, 2007 (25)	Yes	Yes	Yes	BWLP team, researchers	Unclear	Yes	8	3
Greaves, 2008 (23)	Yes	Yes	Yes	Researchers/statisticians	Yes	Yes	18	3
Hardcastle, 2008 (24)	Yes	Yes	Yes	Statistician, practice nurse	Yes	Yes	35	3
Armit, 2009 (18)	Yes	Yes	Yes	Participants	Yes	Yes	15	3
Befort, 2009 (19)	Yes	Yes	Yes	Participants	Yes	Yes	23	3
DiMarco, 2009 (21)	Yes	Unclear	Unclear	NR	Unclear	Yes	33	2

BWLP, behavioural weight-loss programme; MI, motivational interviewing; NR, not reported.

Figure 4.2 Meta-analysis of standardized change scores in body mass in motivational interviewing intervention group compared with control



Degree of shading corresponds with study weighting in random-effects model. SMD; standardized mean difference.

Table 4.4 Stratified analysis

	Standardized mean differences (95% CI)	Weight (kg) Weighted mean difference (95% CI)	BMI (kg m^{-2}) Weighted mean difference (95% CI)
Overall pooled estimate	−0.51 (−1.04, 0.01), $n = 12$	−1.47 (−2.05, −0.88), $n = 9$	−0.25 (−0.50, 0.01), $n = 7$
Primary outcome	−0.83 (−1.91, 0.25), $n = 6$	−1.47 (−2.25, −0.70), $n = 6$	−0.36 (−0.59, −0.13), $n = 3$
Secondary outcome	−0.13 (−0.29, 0.02), $n = 6$	−1.37 (−2.25, −0.49), $n = 3$	−0.26 (−0.79, 0.28), $n = 4$
≥6 months	−0.93 (−1.94, 0.08), $n = 5$	−1.57 (−2.33, −0.81), $n = 5$	−0.37 (−0.60, −0.14), $n = 3$
<6 months	−0.17 (−0.37, 0.03), $n = 7$	−1.25 (−2.11, −0.39), $n = 4$	−0.20 (−0.78, 0.38), $n = 4$
Attention control	−1.24 (−3.69, 1.21), $n = 3$	−1.33 (−3.69, 1.04), $n = 2$	−0.16 (−1.17, 0.85), $n = 2$
No attention control	−0.23 (−0.35, −0.11), $n = 9$	−1.19 (−1.68, −0.70), $n = 7$	−0.27 (−0.59, 0.04), $n = 5$
Fidelity measure	−0.70 (−1.52, 0.11), $n = 7$	−1.47 (−2.24, −0.70), $n = 6$	−0.39 (−1.22, 0.44), $n = 2$
Fidelity measure not employed	−0.18 (−0.41, 0.04), $n = 5$	−1.37 (−2.26, −0.48), $n = 3$	−0.25 (−0.58, 0.08), $n = 5$
MI and BWLP (vs. BWLP alone)	−0.90 (−2.55, 0.75), $n = 5$	−2.09 (−2.25, −1.93), $n = 4$	−0.40 (−1.19, 0.40), $n = 3$
MI without BWLP (vs. minimal intervention alone)	−0.22 (−0.37, −0.08), $n = 7$	−1.11 (−1.62, −0.60), $n = 5$	−0.25 (−0.58, 0.09), $n = 4$

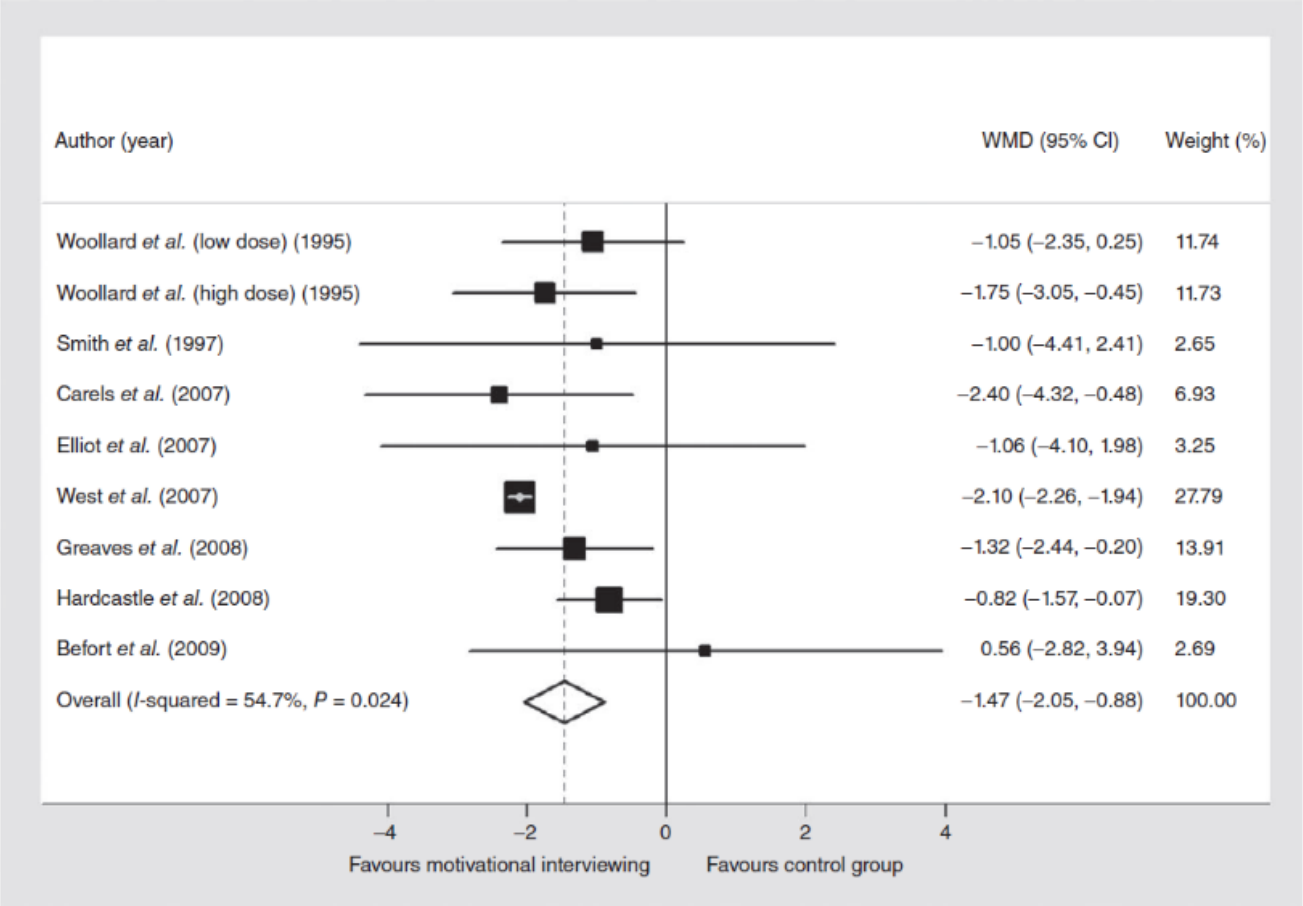
BMI, body mass index; BWLP, behavioural weight-loss programme; CI, confidence interval; MI, motivational interviewing.

Effect of motivational interviewing on body weight and body mass index

We further analyzed the body weight and BMI data separately using the weighted mean difference (WMD) and a random effects model, allowing for mean differences to be analyzed in separate units (kg and kg/m^2). The WMD for the decrease of body weight between those in the intervention group and those in the control group was statistically significant at -1.47 kg (95% CI, -2.05, -0.88, p <0.01, I^2 = 54.7 %; Figure 4.3). In the analysis of BMI, the WMD was -0.25 kg/m^2 (95% CI, -0.50, 0.01, p =0.058, I^2 = 24.5%; Figure 4.4). There was significant heterogeneity in studies reporting change in body weight, however heterogeneity was not significant in studies reporting BMI.

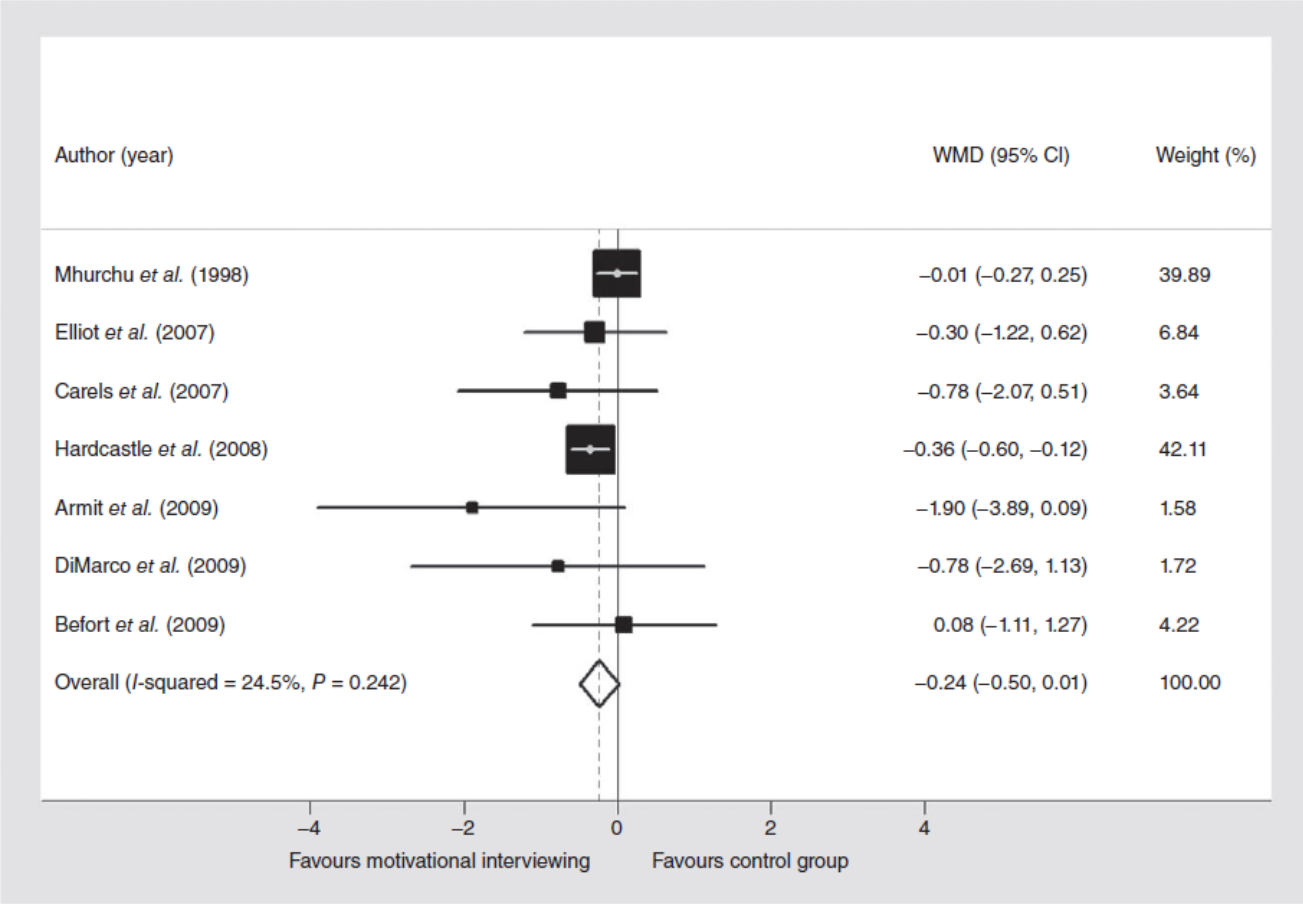
We further stratified studies based on whether or not weight was the primary outcome, the duration of treatment intervention (less than or greater than 6 months), whether an attention control was used, whether there was a treatment fidelity measure used, and whether motivational interviewing was used as an adjunct to a behavioural weight loss program. These results are summarized in Table 4.4. Having weight as the primary outcome, duration of treatment longer than 6 months, the use of an attention control, a treatment fidelity measure, and the use of a behavioural weight loss program, each were associated with an increased effect of the motivational interviewing treatment on body mass. Given the heterogeneity observed in the pooled body mass studies above, further analyses were conducted in an attempt to identify potential sources. Upon meta-regression of these variables, none were found to be significant sources of heterogeneity, although results are limited by the small number of available studies.

Figure 4.3 Meta-analysis of weighted change scores in body weight (kg) in motivational interviewing group compared to control



Degree of shading corresponds with study weighting in random-effects model. WMD; weighted mean difference.

Figure 4.4 Meta-analysis of weighted change scores in body mass index (kg/m^2) in motivational interviewing group compared to control



Degree of shading corresponds with study weighting in random-effects model. WMD; weighted mean difference.

4.5 Discussion

We identified 12 randomized controlled trials examining the effect of motivational interviewing on weight loss in overweight and/or obese people. One study was excluded due to the interventionists, not the participants, being randomized and the available weight data were incomplete. Using the SMD to meta-analyze 11 of these trials, motivational interviewing demonstrated an effect size of 0.51 standard deviations (SD) for reducing body mass over and above the control interventions. This is similar to the effect size of 0.56 SD found in a prior

motivational interviewing review and meta-analyses [69] of four studies in the area of diet and exercise, and would be considered a "medium" effect size by Cohen's criteria.[99] Some reviews have published effect sizes as large at 0.72,[73] however their inclusion criteria were not as strict and there was an assumption of homogeneity between study estimates. More specifically, in studies reporting body weight as an outcome, the WMD showed motivational interviewing significantly enhanced weight loss (1.47 kg greater than control treatments). This signifies that those in the intervention groups lost 1.47 kg over and above those in the control groups, it should be noted that in several cases both the intervention and control groups lost significant amounts of weight. In studies reporting change in BMI, motivational interviewing interventions showed an enhanced, but non-significant reduction of 0.25 kg/m^2 over controls.

It is important to note that several prominent large-scale studies have included motivational interviewing as a component of their lifestyle weight-loss interventions, most notably the Diabetes Prevention Program[100] and the Look AHEAD trial.[101] However, these studies did not meet our inclusion criteria and thus were not included in this meta-analysis. These trials used a range of methods in their lifestyle modification interventions. It was not the goal of these trials to examine the unique effects of motivational interviewing, but rather a combination of interventions and strategies within a "lifestyle intervention". Studies included in this meta-analysis only differed on the use of motivational interviewing. However, this speaks to the importance of evaluating motivational interviewing alone for weight loss and to evaluate its unique effects independent of other behavioural strategies.

Achieving long-term, sustainable weight loss is difficult. The "medium" effect on weight loss demonstrated by motivational interviewing interventions in our analysis is promising. A previous meta-analysis of weight loss interventions comparing diet only with diet and physical

activity showed average changes of 1.64 kg or 1.24 kg/m^2 after a combination of improved dietary and increased physical activity interventions.[102] Similarly, in a recent systematic review[103] of long-term non-pharmacological weight loss intervention for adults with type 2 diabetes, Norris and colleagues found a pooled weight loss of 1.7 kg which translated to a reduction of 3.1% of baseline body weight among 517 subjects. Weight loss as low as 1 to 9 pounds (0.45-4.08 kg) has been shown to be associated with decreased mortality in overweight individuals with diabetes,[104] whereas 3% decreases in weight have been shown to improve metabolic control significantly.[105] Recently, it has been asserted that clinical evidence does not provide support for the existence of a clinically significant minimum level of weight loss that must be achieved to impart benefit.[106] Additionally, many practitioners assert that at a minimum, the goal of obesity treatment is to prevent further weight gain.[107] This 'minimum clinical standard' further supports the effectiveness of motivational interviewing as only 2 of the 11 studies[77,78] found no additional benefit of the intervention on weight loss.

In our stratified analysis, targeting weight loss as the primary outcome resulted in significantly more weight loss compared to studies not identifying weight loss as the primary outcome; (instead, behaviour changes were the outcomes of interest; Table 4.4). When weight loss is not the primary outcome, targeting multiple behaviours such as physical activity, diet, and hypertension or diabetes treatment, may saturate patients so that applying these behavioural principles to weight management becomes less of a priority, however the small sample size and a degree of heterogeneity in this meta-analysis does not allow specific conclusions to be drawn. The notion of targeting the behaviour (e.g. diet and exercise) or targeting the outcome (e.g. weight lost) is vexing in clinical practice. It may be preferable to focus on prioritizing the

greatest patient need, whether it is achieving successful behaviour change or enhancing weight loss outcome.

Additional stratified analysis found duration of treatment longer than 6 months, the use of an attention control, and ensuring motivational interviewing fidelity all increased the amount of weight loss in the intervention group. The one study[84] that demonstrated the greatest effect on weight loss (4.8 kg at 12 months), applied all of these factors and defined weight loss as the primary outcome. Such methodological rigor and focused effort may have enhanced the effectiveness of motivational interviewing on weight loss. If so, this protocol could be replicated by other studies to confirm this observation. Of importance however, is that this study was also the longest in duration. Therefore, increasing the time taken to overcome the inertia of behaviour change using motivational interviewing may have contributed to the observed improvements in weight loss.

Of the studies reviewed, those demonstrating the greatest amount of weight lost employed motivational interviewing as an adjunct to group-based behavioural weight loss programs,[78-80,84,95] which is considered by some to be the most effective non-surgical treatment available for obesity.[108] This is further supported by the stratified analysis (Table 4.4), where the standardized mean difference was -0.90 in the studies using a behavioural weight loss program versus -0.22 in those studies using a minimal intervention. In other words, the difference between motivational interviewing plus behavioural intervention and behavioural intervention alone tended to be greater than the difference between motivational interviewing alone and minimal-intervention control. In these studies, motivational interviewing appeared to improve adherence to the behavioural weight loss program. The degree of adherence to weight loss interventions can be a strong predictor of weight loss. Smith et al.[95] observed significantly

increased attendance by motivational interviewing participants at behavioural weight loss program sessions than controls ($p<0.01$). In a study investigating the effect of weight management program adherence on weight loss, Finley et al.[109] demonstrated that improved program adherence enhanced absolute weight loss over one year. Given these improvements in retention, it seems possible that motivational interviewing may work to increase attendance to a behavioural weight loss program resulting in greater weight loss. However, in this systematic review there was a limited number of available studies on this topic thereby limiting the generalizability of this conclusion. It may be important to consider the base intervention to which motivational interviewing is applied.

In contrast, it is possible that standard motivational interviewing is not as effective among some ethnic minority groups. Befort[78] failed to improve outcomes of a behavioural weight loss program, with motivational interviewing, for obese African American women. Women in the motivational interviewing intervention group lost a mean of 2.6 kg, whereas women in the control group actually lost more weight, a mean of 3.2 kg. Similarly, West[84] reported that African American women lost 3.0 kg (compared with White women, who lost 4.5 kg) and appeared to have a diminished benefit from the addition of motivational interviewing. This highlights a potential need to make adaptations to the motivational interviewing approach for ethnic minority groups. It should also be noted that the participants in the included studies were predominantly female, so it is uncertain whether or not motivational interviewing would be as effective in males. The low statistical power of the small number of studies, and study participants, in this analysis does not permit firm conclusions on these issues, however it does warrant further research.

Sources of heterogeneity

A number of confounders may have influenced the moderate effect (-0.51; p=0.05; Figure 4.2) of motivational interviewing on weight loss, including methodological and statistical heterogeneity. The I^2 test for statistical heterogeneity was significant in both the SMD in body mass and the WMD in body weight; therefore cautionary considerations are required in interpreting this meta-analysis. Variations on the dose and duration of motivational interviewing, the use of motivational interviewing fidelity measures and whether or not weight loss was the primary outcome of the study were identified as potential sources of heterogeneity.

Previous reviews[69,73] have suggested that length and number of motivational interviewing sessions are positively associated with behaviour change. In one review[73] of studies with at least two motivational interviewing sessions and at least 60 minutes of contact per encounter, 81% of the studies showed significant positive effects. However this review included studies predominantly from the addictions field, with few studies representing other health behaviours. In the present meta-analysis, the dose of motivational interviewing ranged from 50 to 323 minutes.

Ensuring the fidelity of motivational interviewing is a salient characteristic of studies examining this behavioural intervention. In this systematic review, three of the motivational interviewing studies failed to assess treatment integrity over the course of the intervention while 7 of the 10 studies included a measure of motivational interviewing fidelity. There is a growing body of literature surrounding the use of coding systems. The motivational interviewing skills code (MISC)[98] and the motivational interviewing treatment integrity code (MITI)[97] are both validated tools that have been developed and are widely used in other fields using motivational interviewing.

A number of limitations of the present analysis should be acknowledged. As discussed, one must consider the heterogeneity of dose, delivery, and duration of motivational interviewing interventions. Half of the included studies lacked allocation concealment and/or blinding, which may introduce bias in the estimation of the effect of motivational interviewing. Six studies recruited less than 50 participants to each treatment group, and there were a relatively small number of studies included in the analysis. Further, the use of varying outcome measures, such as body weight and BMI, limited the number of studies able to be stratified and reduced the ability to make inferences about potential sources of heterogeneity.

Despite these limitations, this meta-analysis includes the most recently published studies using motivational interviewing and is the first to use the PRISMA guidelines for systematic reviews.[76] Although only a medium effect was observed, this review supports the effectiveness of motivational interviewing in weight loss treatments. In order to draw firm conclusions regarding the effectiveness of motivational interviewing, there is a need to operationalize its implementation in order to reduce methodological heterogeneity. To understand the benefit of motivational interviewing more completely, it would be important to standardize the treatment. Results from this meta-analysis should be considered in future trial design; evaluating motivational interviewing as an adjuvant treatment in behavioural weight loss programs appears to warrant further exploration. Ensuring the use of a fidelity measure, an attention control and a follow-up of more than 6 months may also lead to improved trial design in this area. The optimal dose and delivery of motivational interviewing for successful weight loss have yet to be determined and is an area for more investigation. Ensuring the fidelity of the intervention is essential for quality assurance and can improve the transparency of the implementation of motivational interviewing in interventions. It is also unclear which patients would benefit most

from motivational interviewing. Recruiting ethnic minority and male participants in future studies will enable further examination of its effectiveness in these populations. Doing so may also confirm whether or not modifications to this counselling approach need to be made.

In conclusion, motivational interviewing appears to be a promising value-add for weight loss interventions in obesity management. It is consistent with recommendations from patients, health care providers, and researchers for more "patient-centered" approaches in health care, where the provider-patient relationship is seen as a partnership, rather than an expert-recipient one. It provides practitioners with a means of working with patients who are ambivalent about change. This meta-analysis suggests that motivational interviewing is a useful intervention in weight management and its effectiveness may be enhanced when applied alongside behavioural weight management programs.

Chapter Five: **Motivational Interviewing to Promote Exercise Maintenance in People with Type 2 Diabetes**

Building upon Chapter Four which revealed motivational interviewing as a promising approach to facilitate behaviour change within lifestyle interventions, Chapter Five explores the application of a motivational interviewing-based counselling approach in promoting sustained behaviour change following a supervised exercise program. This paper has been submitted for publication and is currently under review at Diabetes Care under the title "Motivational interviewing-based counselling promotes the maintenance of physical activity in people with type 2 diabetes: a pilot randomized controlled trial".

Motivational Interviewing-Based Counselling Promotes the Maintenance of Physical Activity in People with Type 2 Diabetes: a Pilot Randomized Controlled Trial

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Registry number at www.clinicaltrials.gov: NCT01067924

5.1 Abstract

Objective: Promoting maintenance of physical activity (PA) in people with type 2 diabetes (T2D) is a challenge. Motivational interviewing is a directive, patient-centered counselling approach focused on exploring and resolving ambivalence in behaviour change. This pilot study examined the effectiveness of motivational interviewing-based exercise counselling in improving PA maintenance in individuals with T2D after completion of a supervised exercise program.

Research design and methods: Upon completion of an 8-week supervised exercise program, participants with T2D (n=55, 55% female, mean age 60.3) were randomly assigned to standard care plus motivational interviewing (Intervention) or standard care alone (Control). Minutes of weekly moderate to vigorous physical activity (MVPA), resistance training, HbA_{1c}, health-related quality of life, and self-efficacy over 6 months were compared between groups.

Results: Intervention group participants were significantly more likely to achieve the recommended guideline of $\geq$150 minutes of MVPA per week (Odds Ratio [OR]= 3.85, p=0.04), and to report higher scores of quality of life on the physical composite summary (PCS) score (+4.8, p=0.04). Control participants had a significant decrease in self-efficacy scores (-1.0 for aerobic training, p=002; -0.9 for resistance training, p=0.01). Intervention group participants were less likely to report completing zero minutes of MVPA at 6 months (OR= 0.23, p=0.051), and were more likely to report completing resistance training but this was not significant (OR= 2.1, p=0.23). There was no significant effect on HbA_{1c}, but low baseline HbA_{1c} limited room for improvement.

Conclusions: The addition of motivational interviewing-based sessions following an 8-week exercise program improved PA maintenance in people with T2D.

5.2 Background

Regular exercise (planned, structured physical activity) provides substantial health benefits to individuals with type 2 diabetes, and practice guidelines consistently call for exercise training to be part of standard therapy for diabetes.[9,12,110,111] Despite this, 50-79% of this population remains insufficiently active[27,28,112,113] and many of those who begin a regular exercise program do not continue long-term. Long-term maintenance of physical activity is paramount to sustain health improvements, and has been identified as a key challenge in clinical and community-based practice.[114,115]

One approach proposed to aid in the promotion of health behaviour change is motivational interviewing. Motivational interviewing[57] is a communication style designed to enhance patients' motivation for change and adherence to treatment. It is a directive, patient-centered counselling style that aims to help patients explore and resolve ambivalence surrounding complex behaviour change.[57] To date, numerous reviews[62,70-73,116,117] have evaluated the effectiveness of motivational interviewing for modifying health behaviours including diet and physical activity, with effect sizes ranging from 0.19 (small) to 0.77 (moderately large).[99]

The popularity of motivational interviewing for promoting lifestyle modification within medical care settings is growing,[118] as are the recommendations for its use in practice. The American Heart Association[61] recommends motivational interviewing as an approach for enhancing adherence to health behaviour interventions, including diet and physical activity. A systematic review evaluating motivational interviewing for weight loss suggests that it is associated with a medium effect (standardized mean difference [SMD] -0.51) in overweight and obese individuals,[62] however this review did not isolate the effects on physical activity. Another recent systematic review[116] evaluated motivational interviewing interventions to increase physical activity in people with chronic health conditions. It identified 10 studies and found that

motivational interviewing led to modest increases (SMD = 0.19) in physical activity. Among the included studies, none involved people with type 2 diabetes, only three had durations of 6 months or greater, and none evaluated motivational interviewing as an adjunct to a supervised exercise program. Within the type 2 diabetes population, two recent systematic reviews [119,120] concluded that studies (n=8) describing motivational interviewing as a counselling intervention yielded mixed results and there was insufficient evidence to recommend motivational interviewing.

Given the evidence and recommendations for aerobic and resistance training for people with diabetes, effective methods to help people with type 2 diabetes maintain physical activity are required. "Maintenance" has been defined as continuation of the behaviour beyond 6 months from initial adoption.[115] To date, we are unaware of any study that has evaluated motivational interviewing in promoting maintenance of exercise training. The purpose of this study was to examine whether or not the addition of motivational interviewing-based exercise counselling after the completion of a supervised exercise program improves maintenance of aerobic and resistance training in people with type 2 diabetes six months after the supervised program ends.

5.3 Methods

We conducted a 6-month, randomized controlled trial with a parallel-group design. Upon completion of an existing 8-week supervised exercise program, participants with type 2 diabetes were randomized to receive either standard care plus individual sessions of motivational interviewing-based counselling (MInt + SC) or standard care alone (SC). The interventionist who delivered the motivational interviewing could not feasibly be blinded to group assignment after randomization, but the main study outcomes were measured by blinded research assistants and

technologists. The study was approved by the Conjoint Health Research Ethics Board of the University of Calgary.

Participants

Participants were recruited from a supervised exercise program offered through Alberta Health Services in Calgary, Alberta, Canada. To be eligible for this program participant must have a chronic condition and be able to function in a group setting. Recruited participants were from the "Keep Going" class; they reported few functional limitations to exercise and they were able to walk at least 10 minutes before starting the exercise program. Inclusion criteria consisted of self-reported physician-diagnosed type 2 diabetes, age at least 18 years, clearance for exercise by program clinical staff, ability to read and write in English, and a level of cognitive function sufficient to benefit from a counselling intervention. Exclusion criteria included insulin therapy beginning less than 2 years after diabetes diagnosis, changes during the previous 2 months in oral hypoglycemic agents, and other illness judged by the patient or researchers to make participation inadvisable. At the intake session, clinical staff from the program identified patients with type 2 diabetes and asked their permission to be introduced to the study recruiter. Participants were eligible for randomization if they attended at least 16 out of 24 sessions throughout the 8-week program.

Supervised Exercise Program

The "Living Well with a Chronic Condition" supervised exercise program is a community-based, 8-week, 24 session program occurring at 5 different community centres (Appendix B). Participation in the exercise program is by way of physician, health care

provider, or self- referral. At the initial orientation/intake session, participants are screened by clinical staff using a pre-exercise stress test triage algorithm to determine if a graded exercise stress test is necessary before beginning an exercise program. They are also triaged to the appropriate level of class. After screening, each participant is scheduled for an individual pre-exercise assessment including anthropometrics (height, weight and waist circumference), blood pressure (BP) measurements, a six-minute walk test, and a sit-to-stand in 30 seconds test. Group-based exercise classes are offered three times per week for 60-75 minutes and are led by Clinical Exercise Specialists® certified through the American College of Sports Medicine or equivalent. Classes consist of 30-45 minutes of aerobic training and 20-30 minutes of resistance training, followed by light stretching. Participants are asked to complete initial and post-program assessments, and return for a recall assessment at 6 months. This current pilot study was nested within this existing program; only participants who completed this 8-week program were eligible for randomization.

Randomization

Participants were randomly allocated in equal numbers to either the motivational interviewing intervention + standard care (MInt + SC) or standard care alone (SC). At recruitment, participants were informed that one group would be randomized to partake in two 30-45 minute interviews about their physical activity habits. In order to minimize bias, participants were not informed that these would be "motivational interviewing" sessions. Randomization occurred at the end of the 8-week program, before the final program assessment, and was performed in blocks randomly varying in size of 4 or 6, and stratified by sex and age group (<60 or ≥ 60 years old). Treatment allocations were prepared by a statistician independent

of the study investigators. Investigators and research staff were not aware of the treatment allocation prior to randomization.

Intervention

The intervention consisted of two in-person motivational interviewing-based counselling sessions added to standard care, the first immediately following program completion and the second at 3 months post-program completion. The sessions followed a semi-structured interview format of motivational interviewing-based counselling, adapted for physical activity. Although there was structure to the interview (Appendix C), the use of an explicit script was avoided in order to maintain the "spirit" of motivational interviewing. The sessions lasted 30-45 minutes and were delivered by a Clinical Exercise Specialist® (MJA) who received training in motivational interviewing. This training included reviewing training recordings and materials, three 3-day intensive training sessions coached by trainers from the Motivational Interviewing Network of Trainers [121] that included role-playing, lecture, and discussion, as well as 6 hours of direct supervision. In the current study, the counselling sessions were audio-recorded, and in order to establish motivational interviewing technique fidelity, 25% were randomly selected and reviewed by a doctoral level Clinical Psychologist and Director of Clinical Training (TSC) at a nationally accredited (Canadian Psychological Association) program using the Motivational Interviewing Treatment Integrity (MITI) coding system.[122] In comparison, the control arm of the study received standard care after the end of the supervised exercise program, which consisted of outcome measure collection at the end of the 8-week exercise program and the provision of information on available community exercise programs. Although there was no formal attention control, the control group members did receive a telephone call in addition to standard care from

our research assistant at 3 and 6 months post-program, where they were asked about their levels of physical activity as part of the questionnaire completion.

Outcome Measurement

Data were collected at exercise program initiation, at the end of the 8-week program (randomization), and at 3 and 6 months post-program completion. This study was embedded within an existing supervised exercise program and certain study outcome measures (BMI, waist circumference, BP, six-minute walk test, and sit-to-stand in 30 seconds) were collected as part of usual care by clinical staff from supervised exercise program rather than by research staff. These outcomes were accessed through an electronic database and were collected only at the beginning of the program, end of the program, and at 6 months. The primary outcome was self-reported moderate to vigorous physical activity (MVPA) as measured by a modified version[30] of the validated Godin Leisure Time Exercise Questionnaire (GLTEQ).[123] Participants were asked to report the average number of times per week over the past month they had engaged in strenuous, moderate, and mild physical activity. The GLTEQ was slightly modified to have respondents also specify the average time per session (minimum of 10 minutes per session) for each of the three levels of intensity. The modified GLTEQ was used to estimate average exercise minutes per week by multiplying the average frequency by the average duration for "moderate" and "strenuous" intensity physical activities. We also administered a questionnaire created for this study regarding frequency of resistance training in a typical week.

Secondary outcomes were HbA_{1c}, quality of life, self-efficacy for physical activity, BMI, waist circumference, BP, six-minute walk test, and sit-to-stand in 30 seconds. All questionnaire outcomes (Appendix D) were collected by research staff, HbA_{1c} was collected via lab requisition

at Calgary Lab Services®, and all other outcomes (BMI, waist circumference, BP, six minute walk test and sit-to-stand in 30 seconds) were collected by exercise specialists employed by the supervised exercise program. HbA_{1c} was measured on the Integra 800 CTS (Roche Diagnostics, Laval, QC, Canada) using a colorimetric method and was DCCT/NGSP standardized. All personnel collecting outcome measures were blinded to group allocation.

Health-related quality of life was measured using the Medical Outcomes Study 12-item Short Form (SF-12),[124] which provides summary scores for physical and mental health status referred to as the Physical Composite Summary and the Mental Composite Summary scores. Self-efficacy was assessed using a validated Exercise Self-Efficacy Scale.[125] Participants were asked to rate their confidence (1=not at all confident; 5=extremely confident) that they would participate in regular exercise in a variety of adverse circumstances; for example, "when you are a little tired" or "when you have other demands on your time". Participants were asked to rate their confidence for aerobic and resistance training separately for each of the ten adverse circumstances. All questionnaire outcomes were administered by telephone and recorded by a research assistant.

Weight was measured on a calibrated scale and height was measured using a standard stadiometer. Waist circumference was measured midway between the lowest rib and the top of the iliac crest, at the mid-axillary line. BP was measured using a BP-Tru automated monitor (BP-Tru, Coquitlam, Canada). Cardiovascular fitness was assessed by a six-minute walk test [126] and muscular fitness by the sit-to-stand in 30 seconds test.[127] All outcome measures were collected by assessors blind to experimental condition.

Statistical Analysis

Primary analyses were modified intention-to-treat, which included all participants as randomized, provided they had at least one post-randomization measurement. To test for differences between groups on baseline characteristics we performed χ^2 analyses for categorical variables, and independent t-tests for continuous variables. As pre-specified, all outcome variables were first examined using a linear mixed-effects model for repeated measures over time. However, the values of the primary outcome (minutes of MVPA per week) were not normally distributed. The distribution was closer to being bimodal, with participants either continuing to exercise regularly or doing very little exercise. Given that the purpose of this study was to assess the maintenance of physical activity, and upon advice from expert statisticians, we choose to report the results of minutes of MVPA per week as dichotomous outcomes: the proportion who were meeting the recommended guidelines of $\geq$150 minutes of MVPA per week,[9,12] the proportion reporting resistance training at least weekly, and the proportion who reported zero minutes of MVPA. For these outcomes, odds ratios and 95% confidence intervals were calculated using logistic regression. For the measurements reported from the supervised exercise program that were not part of the main study analysis, Student t-tests were used as well as Wilcoxon signed-rank and rank-sum tests for outcomes that were non-normally distributed. Statistical analysis was performed using STATA Version 11 (Stata Corp, College Station, TX) and SAS Version 9.3 (SAS Institute, Cary, North Carolina).

Sample Size Calculation

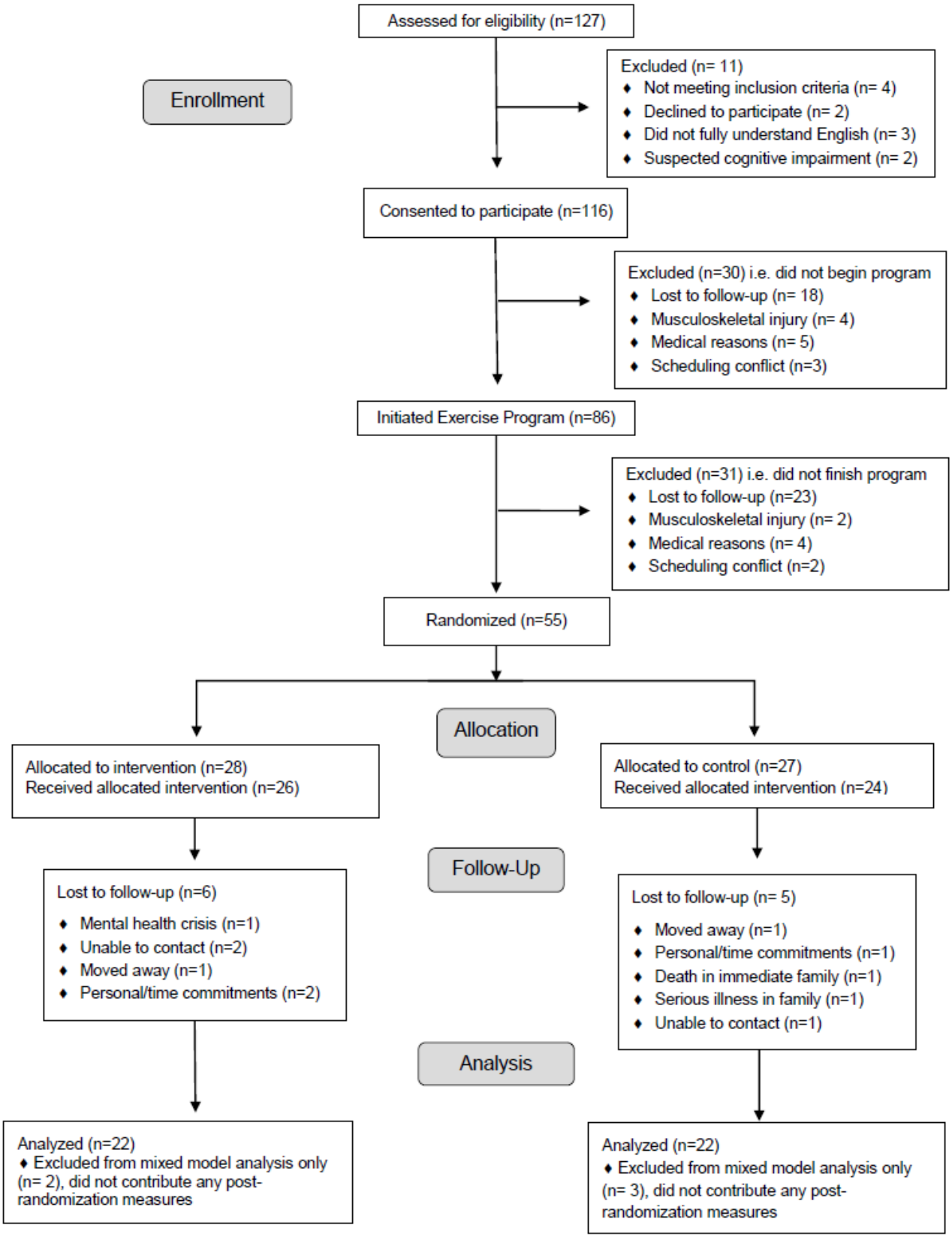
We calculated that a sample size of 44 persons (22 per group) would provide 80% power to detect a large 0.87 SD difference in physical activity levels[128] between study groups, with an α

value of 0.05. This sample size was deemed to be sufficient for a pilot study to inform sample size for a larger more definitive study. Based on our previous exercise trial experience, we estimated that about 20% of those randomized would drop out between randomization and 6 months. We therefore randomized 55 participants in order to have approximately 44 complete the protocol and outcome measures.

5.4 Results

Between September 2009 and June 2011, 127 participants were screened and 116 consented to participate in the study. Figure 5.1 shows the flow of participants from recruitment to follow-up. The most common reasons for exclusion were inability to read or comprehend English, not having type 2 diabetes, and suspected cognitive impairment. Of the 116 consenting to be part of the study, 55 attended at least 16 of 24 exercise sessions and were therefore eligible to be randomized. The most common reason for not being randomized was not attending or completing the 8-week supervised exercise program. Of the 55 participants randomized, 44 (80%) completed the main 6-month outcome measures. At randomization, there were 5 participants who were lost to follow-up immediately after randomization (2 allocated to intervention, 3 allocated to control) and did not have any outcomes measures completed; they were excluded from the analysis. The reasons for these 5 drop outs were mental health crisis (n=1), a death in the immediate family (n=1), a serious illness in the family (n=1), and our inability to contact them despite numerous attempts (n=2). Among the remaining 50 participants randomized, 6 were lost to follow-up throughout the intervention phase; reasons included moving away from Calgary (n=2), inability to complete the study due to personal/time commitments (n=3), and our inability to contact the participant (n=1).

Figure 5.1 Study flow diagram



Baseline characteristics are presented in Table 5.1. Participants' mean age was 60.3 years, 54.6% were female and 87% were white. There were no significant differences between groups at baseline on most measures, with the exception of the control group who reported higher health-related quality of life for the mental composite score. The intervention group reported a slightly higher mean minutes of weekly MVPA at baseline, but this value was driven by one participant and the difference between the groups was not statistically different. Upon review of the audiotapes by a Clinical Psychologist, all interviews were rated as "competent" according to the MITI coding system for motivational interviewing treatment fidelity.

Table 5.1 Baseline characteristics at randomization

	All participants (n=50)	Control (n= 24)	Intervention (n=26)
Age, years	60.7 ± 7.7	61.1± 7.8	60.3 ± 7.8
Women, *n* (%)	26 (52%)	13 (54%)	13 (50%)
Non-white race, *n* (%)	6 (12%)	3 (13%)	3 (12%)
MVPA per week, minutes	167.0 ± 66.2	156.3 ± 46.4	176.9 ± 79.9
Reporting weekly resistance training, *n* (%)	50 (100%)	24 (100%)	26 (100%)
HbA_{1c}, % [*n*=48]	6.88 ± 1.1	6.85 ± 1.3	6.90 ± 1.0
BMI, kg/m^2	32.3 ± 7.1	32.8 ± 7.1	31.8 ± 7.1
Waist circumference, cm [*n*=48]	105.8 ± 15.3	104.8 ± 15.1	106.5 ± 15.7
BP, mmHg [*n*=42]			
Systolic	121 ± 14	117 ± 12	124 ± 15
Diastolic	72 ± 11	70 ± 10	74 ± 11
Six minute walk test, m	556 ± 103	535 ± 111	573 ± 95
Sit-to-stand in 30 seconds, # of stands	14.7 ± 3.7	14.1 ± 4.3	15.2 ± 2.9
Self-efficacy, score out of 5			
Aerobic	4.2 ± 0.7	4.3 ± 0.6	4.1 ± 0.7
Resistance	4.1 ± 0.7	4.2 ± 0.8	4.0 ± 0.7
SF-12			
Physical Composite Score	48.2 ± 7.5	47.5 ± 7.8	48.8 ± 7.3
Mental Composite Score	56.9 ± 7.8	59.8 ± 3.8	54.2 ± 9.5

Randomization is at the end of the supervised exercise program. Data are means ± SD or *n* (%) unless otherwise indicated. MVPA, moderate to vigorous physical activity; BP, blood pressure; SF-12, Medical Outcomes Study 12-item short-form questionnaire.

Figure 5.2 displays the results of the dichotomous outcomes for the maintenance of physical activity. At 6 months after completion of the exercise program, participants in the motivational interviewing-based counselling group were significantly more likely to be meeting the guideline of 150 minutes of MVPA per week (Odds Ratio [OR]= 3.85, 95% CI: 1.09, 13.67, p=0.04). Intervention group participants were non-significantly more likely to maintain resistance training (OR= 2.1, 95% CI: 0.63, 7.03, p=0.23). Participants in the intervention group were also less likely to report doing no physical activity at all (i.e. 0 minutes of MVPA per week) 6 months after the completion of the exercise program and this approached significance (OR= 0.23, 95% CI: 0.05, 1.01, p=0.051).

Overall changes in HbA_{1c}, quality of life and self-efficacy are shown in Table 5.2. There was not a significant effect on HbA_{1c}, but mean HbA_{1c} at randomization was relatively low at 6.9% in both groups. There was an overall increase in health-related quality of life in the intervention group and decrease within the control group over the 6 months after program completion. Specifically, the control group had a statistically significant decrease compared to the intervention group in the physical composite summary (PCS) score (-3.0 [95% CI: -6.3, 0.3] versus 1.7 [95% CI: -0.2, 1.5], p = 0.04). Reported self-efficacy for aerobic and resistance training was high in both groups at the end of the exercise program. At 6 months, the control group reported a significant decrease (aerobic exercise self-efficacy: -1.0 [95% CI: -1.6, -0.4], p=0.002; resistance training self-efficacy: -0.9 [95% CI: -1.6, -0.3], p=0.01), however there was not a significant difference between the groups.

Figure 5.2 Results of dichotomous outcomes for the maintenance of physical activity
(A) Percent of participants meeting guideline of ≥150 minutes of MVPA per week. (B) Percent of participants reporting zero minutes of MVPA per week. (C) Percent of participants reporting resistance training. MVPA, moderate to vigorous physical activity; CPG, clinical practice guidelines; OR, odds ratio; CI, confidence intervals.

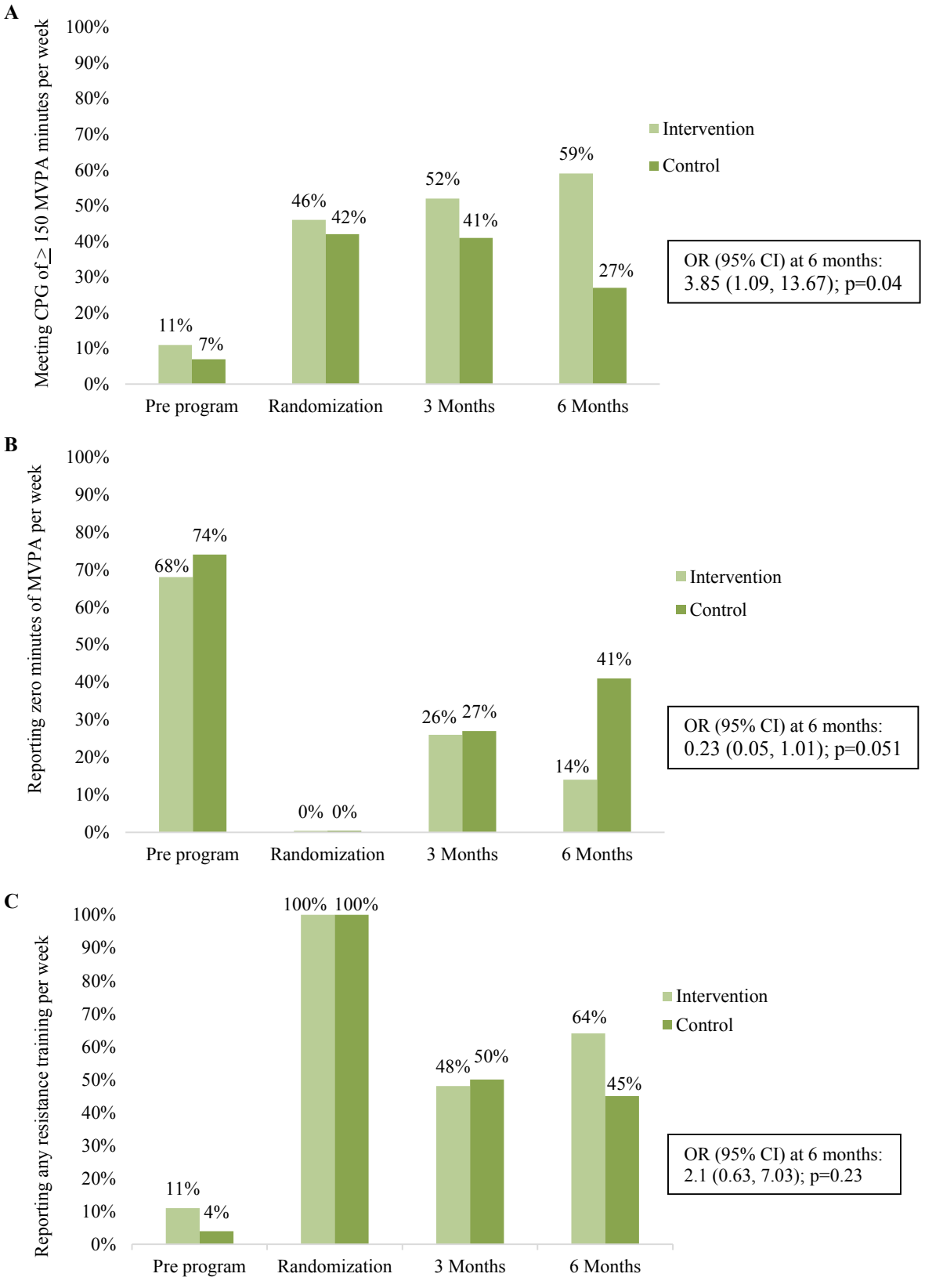


Table 5.2 Changes in HbA_{1c}, SF-12, and self-efficacy scores

Variable	N	End of exercise program (randomization)	3 months	6 months	Within group change randomization to 6 months (95% CI)	Between group difference in change randomization to 6 months (95% CI)	p-value
HbA_{1c}, %							
Control	24	6.9 (0.2)	6.9 (0.2)	6.7 (0.2)	-0.2 (-0.5, 0.1)		0.31
Intervention	24	6.9 (0.2)	6.9 (0.2)	7.0 (0.2)	0.04 (-0.3, 0.3)		0.81
Intervention vs. Control						0.2 (-0.2, 0.6)	0.37
SF-12 Mental Composite Summary score							
Control	24	59.8 (1.5)	59.5 (1.2)	58 (1.3)	-1.8 (-4.7, 1.2)		0.23
Intervention	26	54.2 (1.4)	56.9 (1.1)	56.4 (1.3)	2.3 (-0.6, 5.2)		0.12
Intervention vs. Control						4 (-0.1, 8.2)	0.06
SF-12 Physical Composite Summary score							
Control	24	47.5 (1.5)	46 (1.8)	44.5 (1.8)	-3.0 (-6.3, 0.3)		0.07
Intervention	26	48.8 (1.5)	47 (1.7)	50.5 (1.7)	1.7 (-1.5, 5)		0.28
Intervention vs. Control						4.8 (0.2, 9.4)	0.04
Self-Efficacy -aerobic exercise							
Control	24	4.3 (0.1)	3.7 (0.2)	3.3 (0.3)	-1.0 (-1.6, -0.4)		0.002
Intervention	26	4.1 (0.1)	3.5 (0.2)	3.7 (0.3)	-0.4 (-1, 0.2)		0.18
Intervention vs. Control						0.6 (-0.2, 1.5)	0.15
Self-Efficacy -resistance exercise							
Control	24	4.2 (0.1)	3.7 (0.2)	3.3 (0.3)	-0.9 (-1.6, -0.3)		0.01
Intervention	26	4 (0.1)	3.3 (0.2)	3.5 (0.3)	-0.5 (-1.1, 0.2)		0.14
Intervention vs. Control						0.4 (-0.5, 1.3)	0.34

*****Results are estimated means (SE) from linear mixed-effects models for repeated measures using intention-to-treat analyses. Abbreviations: SF-12, Medical Outcomes Study 12-item short-form questionnaire.

Outcomes during the Supervised Exercise program

As previously explained, this study was nested within an existing program. We report the change in outcomes over the course of the initial 8-week supervised exercise program (prior to randomization) in Table 5.3. There were significant favorable changes in BMI, waist circumference, diastolic BP, six-minute walk test, sit-to-stand in 30 seconds, minutes of MVPA per week, quality of life and self-efficacy. However, HbA_{1c} and systolic BP did not change significantly. These outcomes are not truly part of this study since randomization only occurred after participants completed the 8-week supervised exercise program.

The outcomes measured by the clinical program staff for the 6 month recall visit include BMI, waist circumference, BP, six minute walk test, and sit-to-stand in 30 seconds. For these outcomes, only 21 of the 55 (38%) participants completed the outcome measures. Some participants reported scheduling conflicts and were unable to attend the visit, and others were unable to be contacted by exercise program staff to schedule this visit. Due to the reality that many of the participants did not complete these 6 month outcomes measures, we have reported the results only for those who have complete data. These results are demonstrated in Table 5.4. None of the outcomes were significantly different between the groups in those participants who attended the 6-month recall assessment at the supervised exercise program. The lack of data for the majority of the participants limits our ability to determine whether or not changes attained over the 8-week exercise program were sustained over the 6 month maintenance period.

Table 5.3 Exercise program outcomes for pre-program to end of 8–week program

Variable	N	Pre Exercise Program	Randomization (end of program)	Change	t-test (p-value)
HbA_{1c} %	48	6.97 ± 0.98	6.88 ± 1.12	- 0.10 ± 0.33	0.41
BMI	50	33.1 ± 7.2	32.3 ± 7.1	- 0.86 ± 1.6	<0.001
Waist Circumference (cm)	48	108.7 ± 16.7	105.8 ± 15.3	- 2.9 ± 4.5	<0.001
Systolic BP (mmHg)	41	124.2 ± 17.8	120.6 ± 14.1	- 3.6 ± 15.0	0.13
Diastolic BP (mmHg)	41	75.0 ± 9.2	72.1 ± 10.7	- 2.9 ± 8.2	0.03
Six minute walk test (m)	50	514.6 ± 96.0	555.5 ± 103.3	+ 40.95 ± 43.5	<0.001
Sit-to-stand in 30 seconds (# of stands)	49	12.7 ± 4.1	14.7 ± 3.7	+ 2.0 ± 2.2	<0.001
Minutes of MVPA per week	50	31.2 ± 60.2	167.0 ± 66.2	+ 135.8 ± 61.0	<0.001
SF-12					
Physical Composite Score	50	43.5 ± 10.4	48.2 ± 7.5	+ 4.7 ± 9.0	<0.001
Mental Composite Score	50	53.4 ± 9.3	56.9 ± 7.8	+ 3.5 ± 6.9	<0.001
Self-efficacy score					
Aerobic exercise	50	2.9 ± 1.2	4.2 ± 0.7	+ 1.3 ± 1.1	<0.001
Resistance exercise	50	2.8 ± 1.2	4.1 ± 0.7	+ 1.2 ± 1.1	<0.001

Participants included are only those with complete data. Data are means ± SD. MVPA, moderate to vigorous physical activity; BP, blood pressure; BMI, body mass index; SF-12, Medical Outcomes Study 12-item short-form questionnaire.

Table 5.4 Exercise program outcomes for participants with complete data at both time points

Variable	N	Randomization (end of exercise program)	6 months	Change	Wilcoxon signed rank test (*p*-value) - within group change	Wilcoxon rank sum test (*p*-value) -between group difference in change
BMI (kg/m^2)						
Control	10	32.4 (8.2)	32.1 (7.3)	-0.37 (2.3)	0.96	
Intervention	10	31.6 (10.2)	31.6 (10.1)	+0.03 (1.2)	0.80	
						0.97
Waist Circumference (cm)						
Control	9	106.1 (17.1)	106.5 (14.3)	+0.4 (5.8)	0.44	
Intervention	10	101.8 (20.7)	102.1 (20.7)	+0.3 (1.5)	0.38	0.27
Systolic BP (mmHg)						
Control	9	117.8 (8.0)	119.3 (8.8)	+1.6 (7.4)	0.55	
Intervention	8	127.6 (22.8)	119.6 (21.2)	-8.0 (16.4)	0.18	0.16
Diastolic BP (mmHg)						
Control	9	71.7 (5.6)	72.3 (7.4)	+0.7 (9.3)	0.81	
Intervention	8	73.0 (13.8)	69.8 (11.3)	-3.3 (9.7)	0.32	0.56
Six minute walk test (m)						
Control	10	541.8 (136.2)	557.0 (121.0)	+15.2 (30.7)	0.14	
Intervention	10	564.3 (122.6)	579.8 (102.3)	+15.5 (36.7)	0.18	0.97
Sit-to-stand in 30 seconds (# of stands)						
Control	10	13.4 (4.4)	14.1 (4.7)	+0.7 (1.1)	0.08	
Intervention	9	14.7 (2.2)	15.7 (2.2)	+1.0 (1.8)	0.17	0.74

Data are means $\pm$ SD. BP, blood pressure; BMI, body mass index.

5.5 Discussion

Our primary finding from this pilot randomized controlled trial is that the addition of motivational interviewing-based counselling sessions following an 8-week exercise program improved the maintenance of MVPA in people with type 2 diabetes who were participating in a supervised exercise program. Participants in the intervention group were significantly more likely to maintain the recommended guideline of $\geq$150 minutes of MVPA per week and were less likely to report completing zero minutes of MVPA at 6 months following an 8-week supervised exercise program. Intervention participants were also more likely to report performing resistance training in a typical week, although this was not significantly different from the control group. The addition of motivational interviewing-based counselling also significantly improved quality of life scores within the physical composite summary score. There were no significant differences between the groups on quality of life mental composite summary score, self-efficacy, or HbA_{1c}, but most participants had good glycemic control upon entry into the study, leaving limited room for improvement. For other clinical outcomes, such as BMI, waist circumference, BP, six minute walk test, and sit-to-stand in 30 seconds, we are unable to draw firm conclusions because a high percentage of participants did not return for the 6 month recall assessment for the exercise program.

To our knowledge, this study is the first to evaluate the use of motivational interviewing-based counselling in promoting maintenance of exercise behaviours in people with type 2 diabetes. The results of this study suggest that when providing supervised exercise program for people with type 2 diabetes, clinicians may want to consider implementing motivational

interviewing-based counselling sessions as an adjunct in order to help support the maintenance of individuals meeting MVPA guidelines after the completion of a supervised exercise program.

Several previous studies evaluated the use of motivational interviewing to promote the initiation of an exercise program in clinical populations. The aforementioned systematic review by O'Halloran and colleagues[116] reported a small effect (SMD =0.19) in trials that used motivational interviewing to increase physical activity in people with chronic health conditions. In evaluating the effect size from the present study,[129,130] we found a stronger effect (SMD=0.75). One reason for this difference may be the use of a treatment fidelity measure allowing for reassurance that the principles of motivational interviewing were applied. In many of the reported studies applying motivational interviewing, the fidelity of the intervention is uncertain. Systematic reviews[62,71,116] have suggested that studies that used a fidelity measure have a greater effect. Moreover, the fact that the current motivational interviewing intervention was an adjunct to an established supervised exercise program may limit the generalizability to other settings where motivational interviewing might be the sole intervention. A systematic review[62] of trials evaluating motivational interviewing for weight loss reported that, upon sensitivity analyses, studies that incorporated motivational interviewing as an adjunct to a behavioural weight loss program had more of an effect on weight loss compared to studies that used motivational interviewing alone versus usual-care controls.

Within the type 2 diabetes population, the evidence for motivational interviewing on self-management behaviours has been mixed. West and colleagues[84] demonstrated that, in 217 overweight women with type 2 diabetes, the addition of motivational interviewing to an 18-month behavioural weight control program resulted in significantly more weight loss and

enhanced adherence to the program. This study also reported significantly greater HbA_{1c} reductions at 6 months but not at 18 months. In contrast, Rosenbek et al.[131] did not find any benefit on glycemic control or weight in 349 people with diabetes (78% with type 2) randomized to receive or not receive counselling sessions based on motivational interviewing in addition to a 4-day group education program. Reasons for this discrepancy are not clear, however in the former study the adjunct program was a 42-session behavioural weight loss program delivered over 18 months, with the intervention delivered by a clinical psychologist, and participants had higher baseline HbA_{1c} values. Whereas in the latter study, motivational interviewing was used as an adjunct to a 4-day diabetes education program, covering a variety of diabetes management themes and delivered mostly by nurses and dieticians.

The strengths of the present study include that it was a randomized controlled trial, embedded within an existing health care program, with 80% adherence to the intervention (i.e. 80% attended the counselling intervention sessions) and to the main study outcome measures. This intervention involved just two brief 30-45 minute counselling sessions over a 6 month period. Given that long-term maintenance of physical activity is a challenge in practice, this type of intervention could add value to already-existing supervised exercise programs.

There are several potential limitations to this study. Participants in this study self-selected to participate in the established supervised exercise program, and may have been more motivated and less burdened by comorbidity relative to many patients with type 2 diabetes. At randomization, the mean distance on the six minute walk test was 556 metres, indicating a relatively high level of physical functioning compared to other reports within the type 2 diabetes population.[132,133] Our primary outcome (minutes of MVPA) was confined to a self-report

measure of physical activity. Studies comparing self-report data with objective measures, such as accelerometers, suggest that levels of activity are often misrepresented by self-report measures.[134,135] Because our primary outcome was physical activity rather than HbA_{1c}, we did not take measures to control medication or dietary co-intervention. Additionally, this study did not employ an "attention control", making it impossible to be certain whether the motivational interviewing-based counselling or simply the extra contact was responsible for the differences seen between the groups. Finally, the sample size used in this pilot study was relatively small, making the results sensitive to outliers. Further research is needed using objective measures of physical activity, larger samples, and possibly an attention control.

In the present trial, motivational interviewing-based exercise counselling showed promise as an adjunct to a supervised exercise program. Future larger randomized controlled trials and real-world pragmatic trials might provide more support for its use in evidence-based practice. Given the proven benefits of aerobic and resistance training in people with type 2 diabetes, finding effective methods to promote the long-term maintenance of exercise behaviours is an important endeavor within diabetes management.

Chapter Six: **Examining pre-exercise stress testing in people with diabetes**

Chapter Five reported the results of a randomized controlled trial evaluating motivational interviewing-based counselling applied to promoting the maintenance of exercise in people with type 2 diabetes. During recruitment for this trial, we discovered that over 50% of patients referred to the exercise program were required to complete a pre-exercise stress test before initiating the exercise program. We also found that many of those who registered for the exercise program failed to initiate the exercise program (approximately 26%, see Figure 5.1). More than half of those who registered but did not begin the program reported that frustration with having to complete a stress test as well as the delay (often >3 months) associated with waiting for the stress test was a significant barrier to initiating the exercise program. Moreover, Living Well with a Chronic Condition program staff also voiced their concern that a requirement for pre-exercise stress testing was a significant barrier to patients initiating the exercise program within staff meetings and informal conversations. Many felt that the need for a stress test created an additional barrier for patients who may already be hesitant about joining an exercise program, and that this extra requirement would tip the decisional balance scale in favor of not participating. Exercise staff also reported that they were unsure of the usefulness of stress testing. Beyond the Living Well Program in Calgary, the need for a pre-exercise stress has been identified as a significant barrier to providing structured exercise programming for people with type 2 diabetes in rural areas who may not have access to stress testing facilities. Currently in the province of Alberta there are discrepancies in the requirements for stress testing among structured exercise programs provided by Alberta Health Services (*Briefing Note, Alberta Health Services, unpublished*). Some programs have adopted the policy of stress testing every

participant with diabetes and other cardiovascular risk factors prior to program participation, whereas other sites are not performing any stress testing at all. These findings and observations speak to the importance of evaluating the clinical usefulness of stress testing for pre-exercise screening in people with type 2 diabetes.

The purpose of the following study is to examine the utility of pre-exercise stress testing for people with diabetes within the context of the current Living Well with a Chronic Condition program. This chapter has been prepared as a manuscript under the title: “Examining pre-exercise screening using exercise stress testing in people with diabetes: a data linkage study”.

Examining pre-exercise screening using exercise stress testing in people with diabetes: a data linkage study

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6.1 Abstract

Introduction: The clinical utility of pre-exercise screening with stress testing in people with diabetes remains unclear. The aim of this study was to determine, in patients with diabetes referred for stress testing prior to initiating an exercise program, the proportion that subsequently experienced a cardiovascular outcome and/or a change in care as a result of the stress test referral.

Methods: We completed a retrospective cohort study evaluating patients with diabetes who attended an intake session for a supervised exercise program between March 2007 and February 2012. Data from clinical and administrative databases were extracted and linked. Outcomes of interest included results of stress testing, cardiac catheterization, revascularization procedures, cardiovascular-related hospital admissions, and mortality.

Results: Among 1,705 people with diabetes, 40% (n=676) were referred to undergo pre-exercise stress testing according to the program's algorithm (previously sedentary and at least one cardiovascular risk factor other than diabetes and age). Within one year of intake, more revascularization procedures were performed in patients who were referred for stress testing compared to those who were not referred (2.1% vs. 0.8%, p=0.027). However, over the entire 5 year period the proportion of patients who underwent a revascularization procedure was not different between the groups (3.7% of those initially referred for stress testing vs. 2.8% among those who were not; p=0.325). There was no difference between the groups on any other cardiovascular outcomes. The one-year rate for combined cardiovascular death and non-fatal MI for the entire cohort was 0.7%, with a cumulative rate of 2.9% over a mean (SD) follow-up of 3.3 (1.4) years for an average of 0.88% per year. Among patients who completed a pre-exercise

stress test, a change in care was documented in 4.6% of cases. Among those patients who experienced a cardiovascular outcome, all but one had at least one of the following at baseline: previous cardiovascular event, previous arrhythmia, age over 80 years, angina symptoms, nephropathy or neuropathy.

Conclusion: Referral for pre-exercise stress test was associated with higher rates of cardiac revascularization within the first year, but not during longer-term follow-up. The rate of cardiovascular outcomes was low in both groups, and referral for pre-exercise stress testing did not result in a change of care for the majority of patients.

6.2 Background

People with diabetes are at a significantly increased risk of cardiovascular disease.[136-139] Cardiovascular disease is an important cause of morbidity and mortality in people with diabetes; individuals with diabetes are over three times more likely to be hospitalized with cardiovascular disease than individuals without diabetes.[5] Although there is extensive evidence demonstrating the cardio-protective benefits of exercise in people with diabetes, it is important to consider the possible risks associated with exercise in the diabetes population and place them in context. Some of the potential exercise-induced adverse events include increased risk of cardiac events such as sudden cardiac death, acute myocardial infarction (MI), angina, and arrhythmias, although this increased risk has mostly been shown with highly vigorous exercise.[140] In general, it is accepted that the benefits of exercise substantially exceed its risks, however, the major concern relates to whether exercise may be hazardous because of occult coronary artery disease (CAD).

In patients with diabetes, the issue of screening for CAD in asymptomatic patients has been the subject of much debate.[141-143] The recent American Diabetes Association Standards of Medical Care[11] state that the need for routine CAD screening in people with diabetes is not recommended, however, this guideline cannot necessarily be extrapolated to the use of screening prior to initiating an exercise program.

A major part of the rationale for pre-exercise screening is the increased risk of silent (asymptomatic) coronary ischemia in patients with diabetes. The prevalence of silent ischemia in adults with diabetes varies widely among studies (4-75%)[144], likely due to variations in baseline cardiac risk in the cohort studied and in the definitions of silent ischemia itself. Most studies

have found that in middle-aged to older people with diabetes the prevalence is approximately 15-25%. A large-scale prospective study (n=1123) reported the prevalence in asymptomatic people aged 50-75 years with type 2 diabetes as 22%[145] and in another study the prevalence of silent myocardial ischemia in new-onset middle-aged type 2 diabetes patients (n=111) without other cardiovascular risk factors was found to be 17%.[146] Several screening methods for silent ischemia are available, of which the most widely utilized is the non-invasive treadmill electrocardiogram (ECG) exercise stress test (referred to as 'stress test' for our purposes).

Because of the higher risk of silent ischemia associated with diabetes, several professional organizations[9,12,147-150] have issued recommendations on pre-exercise stress testing in asymptomatic individuals with diabetes (see Appendix E for a summary). Although there appears to be some inconsistency, in general, these guidelines suggest that stress testing should be considered for individuals with diabetes who want to perform vigorous exercise or are considered high risk. One of the more conservative recommendations from the American College of Sports Medicine and American Diabetes Association recommend that people with diabetes over the age of 40, with or without cardiovascular disease risk factors, be considered for graded exercise stress test prior to the initiation of "exercise more vigorous than brisk walking" or "for activities exceeding the demands of everyday living". Although suggested by several organizations, the value and utility of stress testing for screening of asymptomatic patients with diabetes is uncertain.[151] This is demonstrated by the weak level of evidence grading accompanying these recommendations, such as Grade D, Level C and Class IIb (See Appendix E). Specifically, the frequency with which stress testing finds previously-unsuspected clinically

important abnormalities, for which treatment could prevent cardiac events in asymptomatic patients with diabetes is not clear.

A good screening test should have high sensitivity and high specificity, it should also have high positive and negative predictive values. Lee et al.[152] studied 191 diabetes patients (and 1092 patients without diabetes) with a mean age of 59 years presenting with chest pain who underwent a ECG stress test and coronary angiography within a 4-month period. The sensitivity of the exercise test among diabetic patients was 47%, and the specificity was 81%, with a positive predictive value of 85% and negative predictive value of 41%. This study also suggested that stress testing offered similar diagnostic value for patients with and without diabetes who present with chest pain. It should be noted, however, that since these patients *presented with chest pain*, the prevalence of coronary disease would be higher than in asymptomatic patients. In a review of 4 studies using stress testing in the diagnosis of CAD in *asymptomatic* patients with diabetes,[144] 14-20% had abnormal stress tests, and positive predictive values ranged from 60-94%. Sensitivity and specificity could not be calculated as not all subjects underwent an angiogram. In general, there appears to be wide variability in the diagnostic accuracy of the ECG stress tests. An older meta-analysis of 147 studies[153] who underwent both coronary angiography and ECG exercise testing revealed the mean sensitivity was 68% with a range of 23% to 100% and mean specificity was 77% with a range of 17% to 100%. The values appear to be worse in women with a meta-analysis reporting mean sensitivity of 61% and sensitivity of 70%.[154] A more contemporary meta-analyses[155] has reported mean sensitivity of 67% and a specificity of 46%.

The question of whether or not stress testing yields useful information that will influence clinical management is central when considering the usefulness of referring people with diabetes for pre-exercise screening. More recently, noteworthy studies have been published that have added to the evidence in this area. The Detection of Ischemia in Asymptomatic Diabetics (DIAD) trial[156] included 1123 patients aged 50-75 with type 2 diabetes randomized to either screening with adenosine-stress myocardial perfusion imaging (MPI) or usual care (no screening). Patients were followed for 5 years, and the primary outcome was non-fatal MI and cardiac death with secondary outcomes including unstable angina, heart failure, stroke and coronary revascularization. At the 5 year follow-up, cardiac event rates were not reduced significantly by MPI screening (2.7% in screened group vs. 3.0% no-screening group). The positive predictive value of the screening was 12%, meaning that of those identified with moderate or large perfusion defects, only 12% went on to experience the primary outcome of cardiac death or myocardial infarction. Overall, cardiac event rates in the study population were lower than anticipated and were not significantly reduced by screening for myocardial ischemia. An important and surprising finding from the DIAD study was that 79% of patients who had abnormal perfusion abnormalities at the time of enrollment, had *complete resolution* of the perfusion defects at 3-year follow-up, presumably as a result of intensive medical treatment of their risk factors with aspirin, statins and ACE inhibitors.[145] Another recent study[157] found similar results to the DIAD trial. In this trial, 631 participants aged 55-57 years old, with T2D and at least 2 additional cardiovascular risk factors but no known CAD were randomized to either be screened with exercise stress testing or to a no-screening observation-only control group. Participants were followed for a mean 3.5 years. In the screening group, 21.5% were

found to have asymptomatic ischemia at baseline. However, there was no significant difference between the groups in subsequent cardiovascular events. Of note however, is that participants in these studies were not planning to start an exercise program, so the conclusions of these studies cannot necessarily be inferred to the use of stress testing prior to exercise.

The clinical utility of pre-exercise screening with stress testing in people with diabetes who have no symptoms suggesting cardiovascular disease remains unclear. Participation in an exercise program might, in theory, involve cardiac stress and result in an increased risk of ischemic events that would not have occurred in the absence of the exercise program. It is likely, however, that most people with diabetes are at much greater risk from sedentary behaviour than from participation in exercise. To date, we are unaware of any studies that have addressed whether or not pre-exercise stress testing was necessary or useful before participation in a supervised exercise program.

The aim of this study was to evaluate the usefulness of pre-exercise stress testing in people with diabetes who were referred to an established supervised exercise program by determining: 1) the proportion of participants who required a pre-exercise stress testing referral, 2) the proportion of participants who completed stress testing and required further follow-up prior to clearance for the exercise program, 3) the differences in cardiovascular-related outcomes in those who completed, or did not complete, a pre-exercise stress test. To elucidate this issue further, we also examined the proportion of pre-exercise stress tests referrals that resulted in a change in clinical care prior to clearance for the supervised exercise program. Our hypothesis was that referral for pre-exercise stress testing would result in little to no differences in the proportion of patients who experience an adverse cardiovascular outcome within one year of the

exercise intake session, and that referral to stress testing would result in very few cases of changes in care.

6.3 Methods

Study population

We conducted a retrospective cohort study of patients who were referred to the *Living Well with a Chronic Condition* ("Living Well") supervised exercise program between March 1, 2007 and February 29, 2012 in the city of Calgary, Alberta. Patients were included if they were 18 years of age or older, attended an exercise intake session, and were identified as having "diabetes mellitus" or "type 2 diabetes" under current medical history within the Living Well clinical database. Approval for this study was granted by the University of Calgary Conjoint Health Research Ethics Board.

Supervised Exercise Program

The "Living Well" program is a community-based, eight-week, supervised exercise program occurring at seven different community centers. Participation in the exercise program can be arranged through physician or health care provider referral, or by self- referral (see Appendix B for details). Since March 2007, all participants were required to attend an initial orientation/intake session where participants were given information regarding the exercise program, triaged to the appropriate level of class, and screened by clinical staff using a pre-exercise ECG stress test triage algorithm to determine if a graded exercise stress test was necessary before beginning the exercise program. Appendix F outlines the pre-exercise stress

testing algorithm used. In short, this algorithm requires patients with diabetes who are previously sedentary and have more than one other cardiac risk factor to be screened by ECG stress testing prior to entry into the supervised exercise program. The aerobic training component of the supervised exercise class is mostly done on aerobic machines including recumbent bikes, elliptical machines and recumbent cross-trainers (e.g. NuStep), which can all be used at levels more intense than brisk walking, or be considered to exceed the demands of everyday living. The Living Well program does offer an "Easy Going" class for patients with significant mobility and balance issues; it is primarily a balance, mobility and strengthening class. Participants in this class are typically limited in their functional status and could not perform a treadmill ECG stress test so a pre-exercise stress test is not required in those triaged to this level of class provided they do not report symptoms of angina. Upon clearance for exercise training, participants attend group-based classes that are offered three times per week for 60-75 minutes and supervised by clinical staff including Kinesiologists, Physiotherapists and Respiratory Therapists.

Data Sources

In Alberta, residents who are eligible for Alberta Health coverage are assigned a Provincial Health Number (PHN), a lifetime number that uniquely identifies the individual. The PHN is included in all claims for health services and therefore allows for tracking health service utilization across various datasets and over time. Data from the following routinely-gathered administrative and clinical databases were linked on unique PHN identifier: 1) The Alberta Health Services' *Chronic Disease Management* clinical database, which captures data for chronic disease management programs within the city of Calgary, the *Living Well Program*

pathway contains information on patient sex, age, reason for referral to exercise program, current medical conditions, and details of chronic disease management program participation. 2) The Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease (APPROACH) database[158], a prospective clinical database collection initiative that captures detailed clinical information on all adults patients undergoing cardiac catheterization and revascularization in the province of Alberta since 1995, was used to obtain data on any patients undergoing catheterization and/or revascularization procedures subsequent to the exercise intake session. 3) The hospital administrative *Inpatient Discharge Abstract Database*, was used to obtain data on all cases experiencing a cardiovascular hospital admission in Alberta. The administrative data contain up to 25 diagnosis codes, diagnoses are identified using the International Classification of Diseases, Tenth revision, Canada (ICD-10-CA) code taxonomy.[159] 4) *Vital Statistics* obtained from Alberta Health was used to determine death date and cause of death also using the ICD-10-CA code taxonomy. 5) *Chart Review of stress test screening visits* were performed at three CV screening clinics in the city of Calgary where patients requiring a pre-exercise stress test were referred to by a health care provider from the Living Well program.

Derivation of Study Cohort and Study Variables

The Chronic Disease Management clinical database was used to identify patients with diabetes who attended the exercise intake session and were triaged to a referral for a pre-exercise stress test prior to initiating the exercise program. Patients who were identified by the screening clinics as having a referral from Living Well for pre-exercise risk assessment were also included. In order to determine if a participant attended the pre-exercise screening appointment, data were

obtained from the screening clinics on all individuals referred by the Living Well program who attended a screening visit. In order to obtain the testing details and clinical information of those who attended the screening visit, chart reviews were performed on each identified individual at each of the various clinics. Chart review data were collected by one individual (MJA) using a Data Abstraction Form (Appendix G) to determine presence or absence of pre-specified clinical characteristics and co-morbidities. These included: a history of a previous major adverse cardiovascular event (e.g. MI or stroke), a history of previous cardiac arrhythmia, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), smoking status, hypertension or taking anti-hypertensive medications, dyslipidemia or taking cholesterol lowering medications, BMI $\geq$ 30 kg/m^2, Type 1 diabetes diagnosis, and diabetic complications including diabetic neuropathy, retinopathy, and chronic kidney disease. Other variables extracted were the type of testing performed, the outcome of the testing, and the clinical decision with respect to clearance for the exercise program of each screening visit. In examining each case, it was determined whether or not the referral to pre-exercise screening resulted in a change in care. A "change in care" was defined as any change that happened as a direct result of the screening visits and would otherwise not have been identified through routine clinical care. For any patients where the change of care was not clear it was coded as unclear and details were collected.

Outcomes

Cardiac catheterization, revascularization procedures [e.g. percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG)], cardiovascular-related hospital admissions, all-

cause mortality, and cardiovascular mortality were the outcomes of interest. Outcomes were only considered after the date on which subjects attended the exercise intake session. Follow-up was complete to Dec 31, 2012 for all patients. Cardiac-specific hospitalizations in Alberta for acute coronary syndrome and stroke were determined by the use of ICD-10-CA codes.[159,160] The diagnostic codes for myocardial infarction (I21.X, I22.X), unstable angina (I20.X, I24.X), stroke (I63.X, I64.X), transient ischemic attack (G45.X), bleeding (I60.X, I61.X) and venous sinus thrombosis (I63.6, I67.7, G08.X) were employed. All admissions were categorized in terms of their relationship to the main discharge diagnosis and coded as "cardiovascular-related" or "not primarily cardiovascular-related". In Canada, the main discharge diagnosis is defined as the diagnosis requiring the most resources during a hospital stay. The diagnoses were entered at the time of discharge, and represented the physician's interpretation of all the clinical data, which may have included electrocardiography, biomarker elevation and results of cardiac testing when appropriate. Cardiovascular-related admissions were characterized as those whose main diagnoses were related to coronary artery disease, chest pain, congestive heart failure, arrhythmias, valvular heart disease, or stroke. Only those that were coded as cardiovascular-related were included in the analysis. Diagnoses that were excluded in the cohort (n=4) were respiratory infections and failure, duodenal ulcers, and complications from diabetic foot amputation. All-cause mortality was considered as well as cardiovascular-related deaths. All deaths coded within the "diseases of the circulatory system" subcategory were considered cardiovascular-related death, with the exception of "chronic rheumatic heart diseases" (n=1) as it is not related to coronary disease or ischemic heart disease. We examined outcomes within one year of the exercise intake session, and also within the entire follow-up period (2007-2012). We

considered cardiovascular death and acute myocardial admission as major cardiovascular events, as well as a composite of the cardiovascular outcomes defined as one or any of: revascularization procedures (PCI or CABG) or cardiovascular-related admission or cardiovascular-related death.

Statistical Analysis

Differences in baseline age and sex were compared between patients who were identified as requiring referral for pre-exercise screening versus those who did not require a referral. Differences in categorical data were assessed using χ^2 tests, and differences in continuous data were assessed using student t tests. Because clinical characteristics were only available through data abstraction in chart review, these details were only available in patients who were referred for pre-exercise screening. Differences in outcomes within one year of the exercise intake session and over the entire study period were examined according to the requirement of a pre-exercise stress test referral to the screening clinics. Categorical variables are presented as frequencies and percentages, and continuous variables as mean (SD) values. Differences in continuous data were assessed using student t tests. Because the numbers of cases were small for several outcomes, differences in categorical data were assessed using Fisher's exact test. All statistical tests with a two-sided p value ≤ 0.05 were considered significant.

6.4 Results

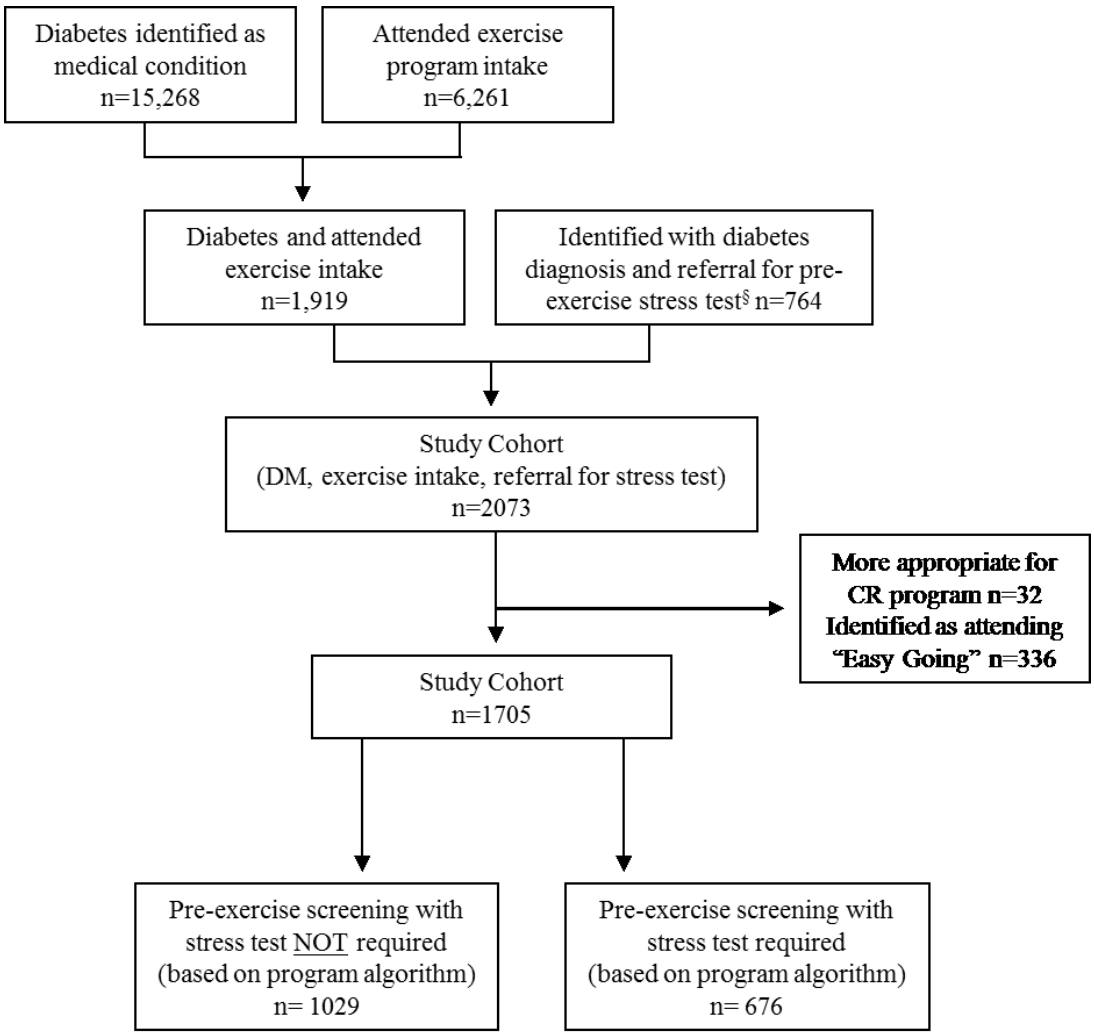
A total of 1,705 patients with diabetes were identified as participants who attended an exercise intake session over the study period. Among these patients, 40% (n=676) were identified as requiring a referral for a pre-exercise stress test at the screening clinics. Figure 6.1 demonstrates

the flow and derivation of the study cohort. At the exercise intake session, those patients who were determined to be more appropriate for a cardiac rehabilitation program (e.g. had a recent MI and did not complete cardiac rehabilitation, see Appendix F) were referred directly to the local cardiac rehabilitation program and not included in the cohort. Patients who were triaged to the "Easy Going" class were also excluded. Baseline characteristics are displayed in Table 6.1. The cohort was 41% male with a mean age of 60 years, there were no significant differences at baseline. Among the 676 patients identified as requiring a stress test through the Chronic Disease Management database, data abstraction was performed on 524 of the patients, as these were the patients identified by the screening clinics with chart data available.

The flow of these patients upon referral to stress testing clinics is demonstrated in Figure 6.2. Patients were stratified according to whether or not the pre-exercise screening referral indicated the patient reported angina or ischemia-related symptoms (such as severe shortness of breath upon exertion or syncope) at the exercise intake session; 14% reported angina/symptoms within the interview with the Living Well program staff at the exercise intake session. Among the 524 patients referred for stress testing, approximately 9% of patients did not attend the scheduled screening visits. Among all the patients who completed an exercise treadmill test (n=441), mean (SD) exercise capacity was 6.8 (2.3) metabolic equivalents. Among those not reporting chest pain or symptoms who completed an ECG exercise treadmill test, 69% were cleared for the exercise program. In those patients reporting chest pain who attended the appointment, 50% were cleared upon the ECG exercise treadmill. The remainder were identified as requiring further testing before clearance for the exercise program. Further testing included

mostly nuclear stress testing (i.e. myocardial perfusion imaging), and/or echocardiogram or Holter monitoring.

Figure 6.1 Derivation of study cohort



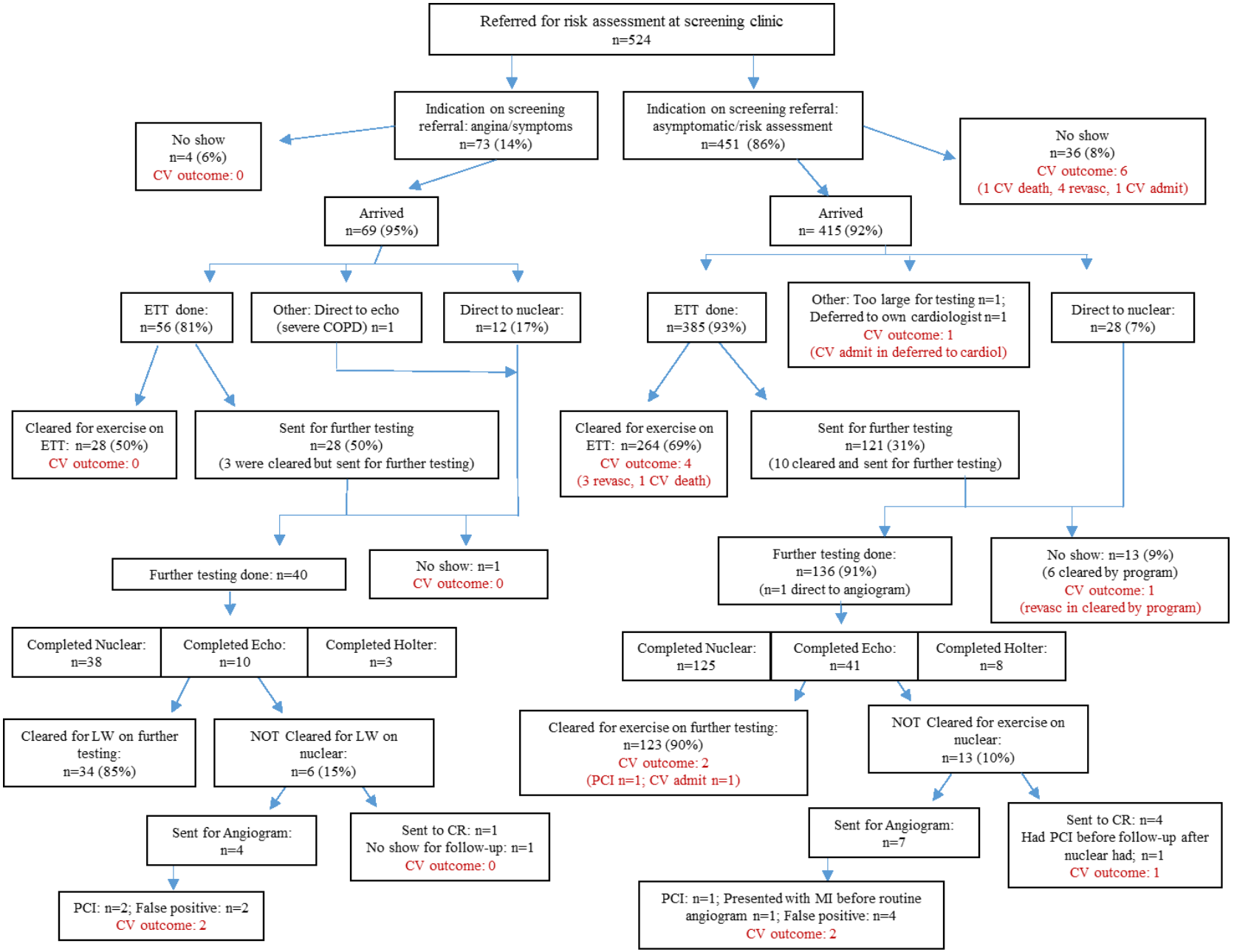
§Data obtained from screening clinics, CR; cardiac rehabilitation

Table 6.1 Baseline characteristics of patients with diabetes attending exercise intake session

	Whole cohort	Referral for stress test NOT required*	Referral for stress test required*	P value (no stress test vs. stress test)
Sample size (n)	1705	1029	676	
Mean Age, years (SD)	60.2 (11.3)	60.1 (11.3)	60.4 (11.3)	0.511
Percent male, n (%)	705 (41.4%)	415 (40.3%)	290 (42.9%)	0.292

*Referral for stress test required according to the referral algorithm use in the Living Well program.

Figure 6.2 Flow of patient cohort referred for pre-exercise stress testing



Among those completing this additional testing (n=176), 89% were cleared for the exercise program. In those who were not cleared for the exercise program, most were deemed more appropriate for the local cardiac rehabilitation program which included more cardiac monitoring and aggressive risk factor modification. Overall, among the 524 patients referred for pre-exercise stress testing, 2.1% (n=11) were considered candidates for referral to cardiac catheterization. In examining the results of the 11 catheterization procedures, six were identified as false positive tests, four resulted in PCI, and one had no intervention as good collateral circulation was identified. It should be noted that one participant presented with a MI prior to the appointment for routine catheterization and underwent PCI. Patients who reported chest pain at intake did not have higher rates of the composite cardiovascular outcome at one year when compared to those who did not report chest pain (2.7% vs 3.8%, p=1.00). However, when examining the rate of revascularization that was identified as a direct result of the pre-exercise referral, those with angina symptoms on referral had a non-significantly higher rate (2.7% vs. 0.4%, p=0.09).

Cardiovascular related outcomes

The data linkage allowed for comparison on cardiovascular outcomes between those who were identified as requiring a pre-exercise stress test and those who were deemed not to require a stress test according to the algorithm (Appendix F). Table 6.2 demonstrates the results within one year of the intake session, and over the entire follow-up period. Within one year of the exercise intake session, there were no significant differences between the groups for all-cause, cardiovascular mortality, hospitalizations for cardiovascular disease, or the composite of cardiovascular outcomes. There was a significant difference between the groups for catheterization and revascularization procedures. In the 12 months after the exercise intake

session, the proportion of patients who underwent a revascularization procedure was lower in patients not referred for pre-exercise stress testing compared to those who were referred (0.8% vs 2.1%, p=0.027). However, in considering outcomes over the entire follow-up period [mean (SD) 3.3 (1.4) years], there were no significant differences between the groups. For the composite of cardiovascular outcomes (including revascularization, hospitalization and cardiovascular mortality), the proportion of patients who experienced any outcome within one year of the exercise intake was similar in both groups, 1.9% in those not referred for a stress test versus 2.8% in those patients who were referred (p=0.250), and this was also true over the entire study period (6.5% vs. 5.9%, p=0.683), respectively. In examining cardiovascular death and non-fatal MI alone (major CV events), the event rate for the whole cohort over the first year was 0.7%, and the cumulative event rate over the 5 years of follow-up was 2.9% over the mean 3.3 years follow-up for an average of 0.88% per year.

Table 6.2 Outcomes by pre-exercise stress testing status within one year of intake and over entire follow-up period

	Within one year of exercise intake session			*Entire follow-up period (2007 to 2012)*		
	Referral for stress test NOT required n=1029	Referral for stress test required n=676	P value	Referral for stress test NOT required n= 1029	Referral for stress test required n=676	P value
Major CV events	7 (0.7%)	5 (0.7%)	1.0	31 (3.0%)	19 (2.8%)	0.883
CV death	4 (0.4%)	2 (0.3%)	1.0	21 (2.0%)	9 (1.3%)	0.348
Myocardial infarction admission	3 (0.3%)	3 (0.4%)	0.687	10 (1.0%)	10 (1.5%)	0.364
CV Admission	14 (1.4%)	11 (1.6%)	0.684	35 (3.4%)	25 (3.7%)	0.789
Death						
All-cause	16 (1.6%)	7 (1.0%)	0.400	57 (5.5%)	28 (4.1%)	0.212
Non-cardiovascular	12 (1.2%)	5 (0.7%)	0.462	36 (3.5%)	19 (2.8%)	0.485
Catheterization procedure	23 (2.2%)	29 (4.3%)	0.021*	66 (6.4%)	56 (8.3%)	0.115
Revascularization	8 (0.8%)	14 (2.1%)	0.027*	29 (2.8%)	25 (3.7%)	0.325
PCI	4 (0.4%)	9 (1.3%)	0.043*	16 (1.6%)	17 (2.5%)	0.208
CABG	4 (0.4%)	5 (0.7%)	0.332	14 (1.4%)	8 (1.2%)	0.829
Any CV outcome*	20 (1.9%)	19 (2.8%)	0.250	67 (6.5%)	40 (5.9%)	0.683

Note: *Any CV outcome is defined as one or any of: CV death, revascularization procedure (PCI or CABG) or CV admission. P values are determined by Fisher's exact test. PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; MI, myocardial infarction; CV, cardiovascular

In the overall cohort, non-cardiovascular death was more common than cardiovascular death. Table 6.3 outlines the age and sex characteristics of patients experiencing a cardiovascular related outcome within one year of the exercise intake. Details of causes of death are outlined in Table 6.4. Patients who were male and older were significantly more likely to experience an outcome. Details of other clinical characteristics were not available on the entire cohort because clinical variables were only available on patients who were referred to the screening clinics through chart review.

Table 6.3 Age and sex characteristics of patients experiencing a CV outcome within one year of intake

	No stress test referral			*Stress test referral*		
	No CV outcome	CV outcome	P value	No CV outcome	CV outcome	P value
Sample size (n)	1009	20		657	19	
Mean Age, years (SD)	59.9 (11.3)	68.6 (9.4)	0.0006*	60.2 (11.2)	68.4 (8.5)	0.0017*
Percent male, n (%)	403 (40.0%)	12 (60%)	0.070	275 (41.9%)	15 (79.0%)	0.001*

CV outcome is defined as one of: CV death, revascularization (PCI or CABG), CV admission, within one year of exercise intake session. CV, cardiovascular; SD, standard deviation, PCI, percutaneous coronary intervention, CABG coronary artery bypass graft. P value is for comparison between No CV outcome vs CV outcome.

Table 6.4 Cause of death details by stress testing referral status

	Referral for stress test NOT required (n=1029)	Referral for stress test required (n=676)
Within one year of exercise intake		
Total deaths	16 (1.6%)	7 (1.0%)
Cardiovascular related deaths		
Acute myocardial infarction	0	0
Chronic ischemic heart disease	4	2
Other deaths		
Disease of respiratory system (COPD, pulmonary disease)	2	0
Cancer (Neoplasms)	2	1
Disease of Digestive System	1	2
Endocrine diseases (ketoacidosis, peripheral circulatory complications)	3	0
Viral infections (hepatitis)	2	0
Accidental Fall	1	0
Suicide	1	0
Alcoholic liver disease	0	1
Rheumatoid arthritis	0	1
Over the entire study period (2007-2009)		
Total deaths	57 (5.5%)	28 (4.1%)
Cardiovascular related deaths		
Acute myocardial infarction	2	1
Diseases of the circulatory system	19	8
Other deaths		
Cancer (Neoplasms)	11	9
Diseases of the respiratory system	9	1
Diseases of the digestive system	4	3
Accidental Injury Unspecified fall	0	2
Diseases of the genitourinary system	1	0
Diseases of the musculoskeletal system	1	1
Endocrine diseases	4	1
Viral infections	2	0
Suicide	2	0
Mental and behavioural disorders	2	0
Disease of skin and subcutaneous tissue	0	1
Intestinal infectious disease	0	1

COPD; chronic obstructive pulmonary disease

Change in care due to pre-exercise stress testing referral

Table 6.5 demonstrates the proportion of patients in whom the referral for pre-exercise stress testing resulted in a change in clinical care. Among patients referred for stress testing, 4.6% were identified as undergoing a change in their clinical care, but in 8.6% of patients change in care was coded as unclear. Due to the nature of the data it was not possible to capture whether medications were significantly adjusted, although if a medication was added by the clinician performing the stress test visit this change was recorded. Table 6.6 provides details on cases where the screening did result in a change in care. The most common change in care was that the patient was deemed more appropriate for the local cardiac rehabilitation program, followed by the discovery of a previously unidentified cardiac arrhythmia which resulted in the addition of a new medication or a referral to an appropriate specialist.

Table 6.5 Referral to pre-exercise stress testing resulting in a change in care

	Patients with stress test referral n=524	Stress test referral indication angina/symptoms n=73	Stress test referral indication: risk assessment/ no symptoms n=451
Screening referral resulted in change in care?			
Yes (see Table 6.6 below for details)	24 (4.6%)	7 (9.6%)	17 (3.8%)
No	444 (84.7%)	59 (80.8%)	385 (85.4%)
Unclear			
No show	45 (8.6%)	6 (8.2%)	39 (8.7%)
Event prior to screening appointment	2 (0.4%)	n/a	2 (0.4%)
Underwent catheterization and no significant CAD identified	6 (1.2%)	1 (1.4%)	5 (1.1%)
Upon thallium results sent to cardiologist but no catheterization	2 (0.4%)	n/a	2 (0.4%)
Presented with MI before routine catheterization appointment	1 (0.2%)	n/a	1 (0.2%)

CAD, coronary artery disease; MI, myocardial infarction

Table 6.6 Details of change care in patients referred for pre-exercise stress testing

	Patients with stress test referral n=24	Stress test referral indication: angina/symptoms n=7	Stress test referral indication: risk assessment/ no symptoms n=17
BP meds prescribed due to exaggerated BP response to exercise	2 (8.3%)	n/a	2 (11.8%)
New medication added (e.g. nitro, beta-blocker)	3 (12.5%)	1 (14.3%)	2 (11.8%)
More appropriate for CR, ischemia already known	7 (29.2%)	n/a	7 (41.2%)
Identified previously unknown ischemia will monitor	1 (4.2%)	n/a	1 (5.9%)
Ischemia identified, more appropriate for CR	1 (4.2%)	1 (14.3%)	n/a
New arrhythmia identified (new medication added or referral to appropriate specialty)	6 (25.0%)	2 (28.6%)	4 (23.5%)
Percutaneous coronary intervention	3 (12.5%)	2 (28.6%)	1 (5.9%)
Referral to vascular surgeon for PAD	1 (4.2%)	1 (14.3%)	n/a

BP, blood pressure; CR, cardiac rehabilitation; PAD, peripheral artery disease

Characteristics of patients experiencing cardiovascular outcomes

Details of clinical characteristics were available from chart review on patients who were referred for pre-exercise stress testing. Table 6.7 outlines the proportion of patients with diabetes who were identified with other co-morbidities and risk factors stratified by those who experienced a cardiovascular-related outcome. Patients who experienced an outcome were significantly more likely to have had a previous MI or stroke, more likely to have a previously identified cardiac arrhythmia, and more likely to have a diagnosis of congestive heart failure when compared to those who did not experience an outcome. Patients with cardiovascular outcomes also had higher rates of diabetic neuropathy, nephropathy and retinopathy than those who did not experience cardiovascular outcomes, although the difference was not statistically significant. Moreover, those patients who experienced an outcome were more likely to have experienced chest pain upon testing at the screening clinics.

Specific details of each individual who experienced a cardiovascular outcome within the first year of intake are outlined in Appendix H for those who were referred for stress testing (n=19), and Appendix I those who were not referred for stress testing (n=20). Among those patients who experienced a cardiovascular outcome, all but one had at least one of the following at baseline: previous cardiovascular event, previous arrhythmia, age over 80 years, chest pain or angina symptoms, nephropathy or neuropathy. Four of these individuals were identified through the screening referral process and ultimately underwent a revascularization procedure. It should be noted that three of these individuals reported chest pain either upon stress testing or at the exercise intake session prior to referral. Several patients (n=6) were cleared upon the pre-exercise stress testing and went on to experience an outcome within 12 months.

Table 6.7 Risk factors of patients referred for pre-exercise stress testing

	Patients with stress test referral (n=524)	No CV outcome (n=505)	CV outcome (n=19)	P value
Male sex, n, %	223 (42.6%)	208 (41.2%)	15 (80.0%)	0.001*
Mean age (SD)	60.5 (11.1)	60.2 (11.1)	68.4 (8.5)	0.0017*
>55 years old, n (%)	380 (72.5%)	362 (71.7%)	18 (94.7%)	0.033*
Mean duration of DM*, years (SD)	9.5 (9.5)	9.4 (9.3)	11.9 (12.9)	0.407
Type 1 DM, n (%)	21 (4.0%)	2 (4.2%)	0 (0.0)	1.00
Previous MI/stroke, n (%)	112 (21.4%)	1103 (20.4%)	9 (47.4%)	0.009*
Previous known arrhythmia, n (%)	34 (6.5%)	29 (5.8%)	5 (26.3%)	0.005*
Neuropathy and/or retinopathy, n (%)	66 (12.6%)	61 (12.1%)	5 (26.3%)	0.078
COPD, n (%)	26 (5.0%)	24 (4.8%)	2 (10.5%)	0.089
CHF, n (%)	17 (3.2%)	14 (2.8%)	3 (15.8%)	0.004*
BMI >30, n (%)	493 (94.1%)	474 (93.9%)	19 (100%)	0.616
Current smoker? n (%)	78 (14.9%)	75 (14.9%)	3 (15.8%)	0.999
Quit smoking? n (%)	164 (31.3%)	155 (30.7%)	9 (47.4%)	0.135
Hypertensive**, n (%)	444 (84.7%)	426 (84.4%)	18 (94.7%)	0.334
Dyslipidemia**, n (%)	445 (84.9%)	428 (84.8%)	17 (89.5%)	0.752
Chest pain recorded on testing	22 (4.2%)	19 (3.8%)	3 (15.8%)	0.040*

CV, cardiovascular; SD, standard deviation; DM, diabetes mellitus, COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; BMI, body mass index; P value is for comparison between no CV outcome and CV outcome

* Duration of diabetes was only available on 37% (n=194) of patients.

** Patients were identified as either having hypertension or taking anti-antihypertensive medications.

*** Patients were identified as either having dyslipidemia or taking lipid lowering medications.

6.5 Discussion

Our primary findings were that cardiovascular outcomes rates were low in this cohort of people with diabetes who attended an exercise intake session in order to participate in a supervised exercise program. Referral for pre-exercise stress test was associated with higher rates of cardiac catheterization and revascularization within the first year, but not during longer-term follow-up. Referral for pre-exercise stress testing did result in an identified change of care in a small number (5%) of patients. Interestingly, the frequency of death from cardiovascular events was lower than for deaths from non-cardiovascular events.

The decision for referral for a pre-exercise stress test was based on whether or not patients were inactive and identified as having more than one CVD risk factor, as suggested by several professional bodies. Patients who reported angina symptoms at the intake were also referred for pre-exercise evaluation. Although patients who were referred for stress testing were theoretically at higher risk for CVD events, there was not a difference in cardiovascular outcomes within one year of the intake or over the entire 5-years of follow up. Surprisingly, patients who reported chest pain at intake did not have higher rates of the composite cardiovascular outcome at one year when compared to those who did not report chest pain (2.7% vs 3.8%); but when examining the rate of revascularization that was identified as a direct result of the pre-exercise referral, those with angina symptoms on referral had a higher rate (2.7% vs. 0.4%), giving support to the recommendation that people with diabetes who report angina symptoms should be referred for investigation. It should also be noted that there were several revascularization procedures (n=4) in those reporting no symptoms at intake that occurred in patients who were cleared for exercise through stress testing within one year of the exercise intake. In fact, only 4 of the 14 (28%) revascularization procedures in those referred for stress

testing were identified as a direct result of the pre-exercise stress test referral; and three of these patients had angina symptoms on stress testing at the screening clinics. It is not clear whether or not these patients would have experienced angina symptoms within the supervised exercise program and could have been referred for investigation at this point. The one individual who did not experience angina symptoms but went on to undergo a revascularization procedure, was at very high cardiovascular risk because he had chronic kidney disease, duration of diabetes of 35 years and a strong family history of premature cardiovascular disease. However, given the very small number of cases who experienced a cardiovascular outcome, it is not possible to draw conclusions on predictors of such events.

In our study, the one year rate for combined cardiovascular death and non-fatal MI (the primary end point used in many studies) for both groups was 0.7%, with a cumulative rate of 2.9% over a mean follow-up of 3.3 (1.4) years for an average of 0.88% per year. Although previous older studies have reported much higher cardiac event rates,[137] the event rate found in our study is consistent with more recent large randomized controlled trials in patients with type 2 diabetes.[156,161] The aforementioned DIAD trial[23] of 1123 asymptomatic people with type 2 diabetes randomized to screening or no screening with nuclear MPI reported a cardiac event rate of 2.9% averaged to 0.6% per year, with no difference between the groups. The Look AHEAD trial[161] of 5145 patients with diabetes randomized to an intensive lifestyle intervention aimed at reducing body weight reported an annual cardiac event rate of 0.7% in the control group at the 3-year time point.[162] In both of these trials the low cardiac event rates were surprising findings; power calculations for both studies assumed cardiac event rates of approximately 2% per year.

The low cardiac event rate is this study compared to older studies might be attributable to differences in the patient populations included in those studies. It is possible that the patients in

our study, those with diabetes who attend an exercise intake session with the intention of beginning an exercise program, did not represent the general diabetes population. In applying the screening algorithm, only 40% of patients with diabetes were identified as being physically inactive and having >1 cardiovascular disease risk factor; this may indicate a much healthier diabetic population than other reported studies. Additionally, patients who were low functioning and deemed more appropriate for the "Easy Going" class, or deemed more appropriate for cardiac rehabilitation at intake, were excluded; these exclusions probably reduced cardiovascular event rates in our study population. An alternative explanation could be that rates of cardiovascular events in people with diabetes have declined markedly over time.[163] Over the last decade, aggressive application of optimal medical treatment, including risk factor modification such as lipid-lowering therapy with statins, blood pressure control, and antiplatelet therapy, has been the recommended approach for patients with increased cardiovascular risk scores. This is evident in the present study, with 85% of the patients referred for stress testing reporting anti-hypertensive and lipid lowering medication use. A recent study[164] of over 12 million patients with diabetes in Ontario and the UK reported that the excess risk of mortality for patients with diabetes was significantly lower during later years versus earlier years over a study period from 1996 to 2009. It is possible that earlier detection and higher prevalence of early diabetes may have also contributed to lower overall risks. Although guideline-based risk factor management has improved markedly over time,[11] patients with diabetes still carry a significantly increased risk of coronary heart disease compared with patients without diabetes[136,138,139] and traditional signs and potent risk factors should not be overlooked in the context of pre-exercise screening.

The number of events and cardiovascular outcomes was small in this cohort which limits the conclusions that can be drawn. However, patients who experienced cardiovascular outcomes

in our study were more likely to be older and have higher frequencies of previous MI or stroke, known arrhythmias, congestive heart failure, and signs of end-organ damage such as retinopathy, nephropathy, and neuropathy compared to those with no cardiovascular event. These results support heightened vigilance in screening for cardiovascular disease in these patients, and provide some support of guidelines suggesting screening with stress testing in those with previous known CAD and diabetic complications who plan to perform exercise more vigorous than brisk walking. Furthermore, among those who were referred for catheterization as a result of the stress test referral, most reported chest pain during testing. This finding reinforces increased attentiveness to signs and symptoms of angina in patients with diabetes who are participating in exercise programs; and perhaps should serve as a reminder to exercise staff to be sure to educate patients on these signs and symptoms within the context of exercise programming and progression of exercise programs.

Strengths of this study include that it is the first that we are aware of that has examined the use of pre-exercise screening in people with diabetes. Since this study sample was drawn from a real-world sample of patients with diabetes initiating a supervised exercise program within a health care system perhaps means that it is not subject to the potential selection bias of recruited participants in other research studies. However, many patients had self-selected to participate in the supervised exercise program intake session, so our sample is not necessarily representative of the overall population with type 2 diabetes. In addition, the chart review of over 500 screening clinic charts allows for a rich data set on presence of co-morbidities and insights into the clinical decisions and end outcomes of the referral to screening clinics. However, there are several limitations to this study that must be noted. This study is a retrospective analysis of a cohort study rather than a randomized trial, which limits our ability to draw causal inferences.

The data were originally collected for clinical and administrative purposes, and therefore subject to imperfect or incomplete data entry. Data on persons who moved away from Alberta are not available. The lack of clinical details beyond age and sex for the patients not referred for pre-exercise screening does not allow for comparison against those referred or adjustment of clinical covariates. Unfortunately, data on attendance at the exercise program were not available and hence do not allow for further assessment of stress testing as a barrier to participation in the exercise program.

Although exercise testing can be useful in exercise prescription and long term prognosis,[165] concerns with costs, high rate of false positives, follow-up with expensive noninvasive/invasive tests and potential low yield suggest that it may be impractical to use exercise testing to screen for cardiovascular events in all people with diabetes (with or without cardiovascular disease risk factors) who are asymptomatic and wanting to begin an exercise program. Future research should include larger prospectively gathered observational studies with better data capture on clinical covariates, which would allow for investigation of possible risk stratification approaches to identify which patients with diabetes would benefit the most from pre-exercise screening with stress testing. Currently there does not exist a useful, evidence-based pre-exercise screening algorithm. Findings from the present study, such as the very low rate of cardiovascular events, may help shed light on this issue; however in the absence of an evidence-based clinical prediction rule, there is not a clear answer to this issue. What is clear is that people with diabetes are at much higher risk from being physically inactive than from being physical active. Minimizing the need for pre-exercise stress testing may help manage costs and improve access to supervised exercise programs, potentially increasing participation and subsequently helping to improve outcomes and the burden of this disease.

Chapter Seven: **Synthesis and Overriding conclusions**

The burden associated with type 2 diabetes is undeniably growing. Exercise has long been recognized as an important component of the treatment regimen of type 2 diabetes patients as it results in a variety of favorable physiological and metabolic adaptations. With clear evidence on the efficacy and effectiveness of exercise in the type 2 diabetes population, the major challenge now is how to support and facilitate exercise adoption and long-term adherence successfully. The studies completed through this program of research have synthesized new knowledge contributing to the evidence base on this matter.

Study A, the systematic review and meta-analysis on motivational interviewing for weight loss in overweight and obese individuals, revealed that this approach appears to have promise as an adjunct to behavioural weight loss programs. The study provided a meta-analysis of the evidence to date and found that motivational interviewing interventions were associated with a greater reduction in body mass when compared to control.

In Study B, we performed a randomized controlled pilot trial to evaluate the effectiveness of motivational interviewing-based exercise counselling in promoting maintenance of exercise after the completion of a supervised exercise program. The results suggested that the addition of motivational interviewing-based sessions following an 8-week exercise program improved exercise maintenance in people with type 2 diabetes.

Through completion of Study B, we discovered that pre-exercise stress testing was identified as a barrier to participation in the supervised exercise program. Subsequently, we performed Study C, an examination of the use of ECG stress testing in pre-exercise screening within a supervised exercise program. Findings from this study suggest that the rate of cardiovascular events and related outcomes was low in a real-world population of people with

diabetes wanting to initiate an exercise program. People who experienced cardiovascular events tended to have more cardiac risk factors and comorbidities at baseline than those who did not experience such an event. These findings suggest that better risk stratification might more appropriately identify those who would benefit from a pre-exercise stress test rather than the recommendation[9,148] that all people with diabetes over the age of 40 should complete a pre-exercise stress test.

Implications for clinical practice

Research conducted as part of this thesis was intended to be practical and with the potential to directly influence clinical practice. To this end, all three of these studies have implications for front-line clinical practice. The results of this thesis may influence future decisions in clinical exercise programming as well as provide key points for consideration in the planning stage of future programs. Given the results of the meta-analysis in Study A and the effects of the motivational interviewing based intervention in Study B, it may be worthwhile for established exercise programs to consider implementation of motivational interviewing-based counselling within their programs. This could be accomplished initially through training staff in motivational interviewing-based techniques, yet it would also be important to ensure that staff have appropriate follow-up and support to ensure fidelity of this type of approach. Working to integrate more client-centered, collaborative methods such as motivational interviewing-based communications, as opposed to traditional advice-giving and educational interactions, may help foster more effective clinical interactions. Within supervised exercise programs, applying motivational interviewing-based counselling at all stages of clinical interactions (i.e. from the initial adoption phase, to supporting long-term maintenance, to addressing relapse if the

behaviour has been stopped) may help better support people with type 2 diabetes become more physically active. Broader than motivational interviewing, the results of Study B give support for increased contact following the completion of a supervised exercise program. Within disease-management programs focused on improving diabetes care, meta-analysis[166] have shown that increased frequency of contact had more effect on the reduction of HbA_{1C}. These findings should be considered in exercise program implementation, perhaps restructuring programs to better help support the transition to post-program realities of less support and supervision would help improve the long-term sustainability of behaviour change.

Building on our findings in Study C, although more research is needed in this area, an initial suggestion is to consider building a reporting system both at the local level in Calgary, and ideally at the provincial level, that would allow for better data capture on referral for pre-exercise stress test, subsequent health services utilization and outcomes of such screening. Such a reporting tool could also serve other measurement and quality improvement purposes. Building a data infrastructure that would allow for large observational studies would help better inform the issue of pre-exercise screening and allow for future evidence-based decisions. In the absence of this information, implementing a decision algorithm that more appropriately risk stratifies people with diabetes who want to begin an exercise program may prove to help reduce the number of patients who are sent for unnecessary pre-exercise stress tests.

Future directions

The results from this program of research have laid a foundation on which future work could build. The results of the meta-analysis and pilot trial could be used in the design of an adequately powered randomized controlled trial that could better assess the effectiveness of

motivational interviewing. Employing the use of more objective measures of physical activity may allow for more accurate measurement, and perhaps new technologies would allow for data capture on other forms of exercise beyond walking and running. In addition, studies that allow for much longer-term follow up would give better insight in to the sustainability of motivational interviewing-based counselling and its effects on other clinical outcomes. Further to this, real-world pragmatic trials addressing knowledge translation and employing methods identified through the knowledge-to-action framework[167] may help ensure that future research into improving long-term adherence of exercise behaviour is more likely to be translated into practice. Methods such as pre-study stakeholder consultations and engagement, along with end-of-study knowledge translation strategies may help ensure that these lines of research are more likely to effect change in clinical practice.

Future work into the utility of pre-exercise stress testing in people with diabetes would involve moving beyond description and could include prospective data collection through cohort studies. Collecting data on variables such as previous health history, previous cardiac investigations, co-morbidities, and attendance would allow for a richer dataset that would help give more insight into possible variables for risk stratification. Given the relatively low cardiovascular event rates we observed, a multicenter cohort would likely be necessary for adequate power. Further work could then involve the derivation of a clinical prediction rule followed by validation cohort studies, impact analysis, and implementation; all with the end goal of identifying those people with diabetes who would benefit the most from screening prior to an exercise program. If, in the immediate future, the Living Well with a Chronic Condition program decides to make changes to the current pre-exercise stress testing algorithm, consideration should be given to data capture to allow for evaluation of any decisions that are implemented.

Consideration should also be given to capture data on the patients who were screened out of this study cohort such as those who are referred to the "Easy Going" program.

Conclusion

In endeavoring to increase the adoption of physical activity among people with type 2 diabetes as well as supporting long-term maintenance, strategies that work to minimize barriers and find effective facilitators are necessary. The findings from this program of research have contributed to the knowledge base in this area as was outlined in the conceptual model of this thesis (Figure 7.1) through the examination of motivational interviewing, a probable facilitator, and the utility of pre-exercise stress testing, an identified barrier. Reducing system-based barriers and finding effective facilitators for exercise behaviours will contribute to the evolution of interventions that are more effective, more efficient, and less expensive for the provider; and less onerous, frustrating and costly for the consumer. Given the current epidemic of type 2 diabetes, and strong evidence of the cardioprotective effects of exercise, applying exercise training as a modality for vascular risk reduction could substantially reduce the burden of diabetes on society. In the long term, these lines of research will contribute to increased participation and increased long-term adherence to exercise, and ultimately better health outcomes in people with diabetes.

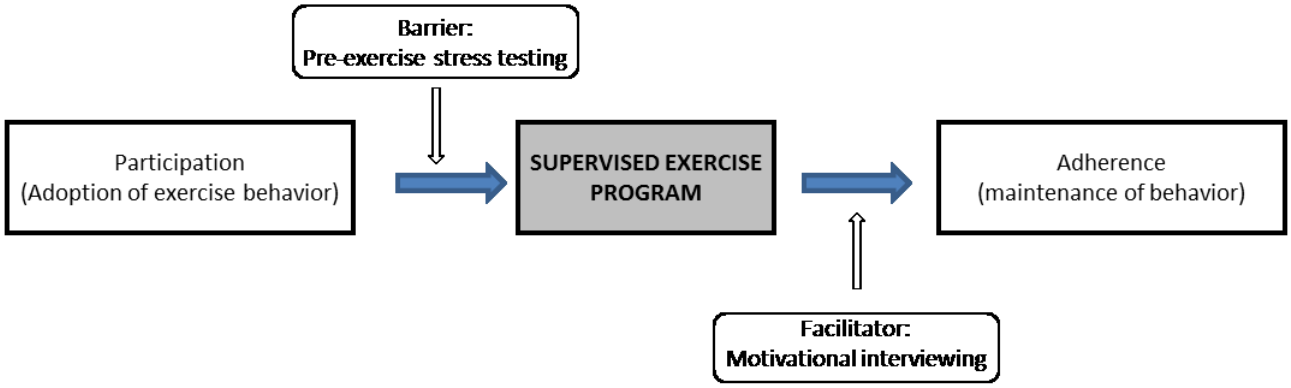


Figure 7.1 Conceptual model of thesis (revisited)

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Appendices

Appendix A: Systematic review data abstraction form

INCLUDE ☐ EXCLUDE ☐ CONTACT AUTHOR ☐

DATA EXTRACTION FORM

Systematic review and meta-analysis of randomized controlled trials using motivational interviewing to improve weight loss in overweight and obese patients

---

Reviewer: _____

Reference:
Lead Author: _____
Title: _____
Journal: _____
Year: _____
Vol. /Issue: _____
Pages: _____

Eligibility Criteria:

Reports on Original Data:	Yes	No	Unclear
Randomized Controlled Trial:	Yes	No	Unclear
MI used as component of intervention	Yes	No	Unclear

Baseline Data:

	MI	no MI
Mean age (SD)		
Female n (%)		
Ethnicity n (%)		
Caucasian		
African American		
Hispanic		
Asian		
Other		
Height (m)		
Weight (kg)		

BMI (kg/m^2)		
HbA1c (%)		
BP (mmHg)		
Co-morbidities (%)		
Cardiovascular Disease	Y N	Y N
Type 2 Diabetes	Y N	Y N
Fibromyalgia	Y N	Y N
Hyperlipidemia	Y N	Y N
Hypertension	Y N	Y N
Other		
Nutrition behaviour		
Fruits and Vegetables (/day)		
Saturated Fat Intake (g/d)		
Exercise behaviour		
Time per week (min)		

Motivational Interviewing Protocol:

Setting: _____

Delivered by: Psychologist Nurse Researcher Other _____

Focused Lifestyle Behaviour: Diet Exercise None Both

Additional to: No treatment Standard Care Education
Other psychological Intervention _____)
Lifestyle Intervention _____)

MI frequency (no. of encounters): _____ per month week

MI duration per encounter: _____ minutes

Type of Intervention: Telephone Face-to-face Group
Unclear

Fidelity (MI Quality) Scored: Yes No Unclear

Data Outcomes:

	MI	no MI
Change Body Weight (kg)		
Change BMI (kg/m^2)		
Change HbA1c (%)		
Change Nutrition behaviour		
Fruits and Vegetables (/day)		
Saturated Fat Intake (/day)		
Change Exercise behaviour		
Time per week (min)		

Study Quality:

Recruitment procedure described: Yes No
Inclusion / Exclusion criteria specified: Yes No
Randomization described: Yes No
Study Blinding described: Yes (Single ☐ Double ☐) No
Use of Comparator: Yes No
Comparator: _____
Reported Attrition: Yes (_____%) No
Loss of follow up reported: Yes No
Reasons: _____
Intention to Treat Analysis: Yes No
Any Important Baseline Differences?: Yes No

Comments:

Methodology

Results/Outcome Measures:

Appendix B: Living Well with a Chronic Condition program information

FREQUENTLY ASKED QUESTIONS

Do I need to go to my doctor before I can participate in the program?

You can self refer by calling 943-2584. If you choose to participate in the exercise portion of the program, we will consult with your doctor.

Can I bring someone with me?

You are very welcome to bring a support person, such as a spouse or family member, to all components of the program. A screening questionnaire will be administered prior to a support person participating in the exercise program and your guest must be registered at the time of booking.

Does this program replace existing programs and treatments for chronic conditions?

This program does not conflict with existing programs or treatments. It is designed to enhance such programs or treatments.

I have been told I have a heart problem. Can I still participate in the exercise classes?

All participants are given an assessment before they start the exercise program. If Living Well is not appropriate for you, alternative programs will be discussed and recommended.

What will I learn from the Row Your Own Boat workshop?

You will learn a variety of skills needed to cope with the physical and emotional problems caused by your disease.

Can I take all the exercise, education and self-management classes at one location?

Yes, this program offers one stop shopping. Most classes are offered at each location.

What happens when the program is over?

Most community facilities offer ongoing exercise classes that you can join.

LIVING WELL WITH A Chronic Condition

Would you like to learn more about your particular chronic health condition and its symptoms?

Have you considered starting an exercise program but want it to be supervised and tailored to your specific health needs?

Do you want to learn how to better manage your long-term illness?

calgary health region

LIVING WELL WITH A Chronic Condition

A supportive program for people with diabetes, high blood pressure, arthritis, chronic lung disease, asthma or other long-term conditions

CHRONIC DISEASE MANAGEMENT

For more information about the program, fees, or to register call:

(403) 9-HEALTH
(943-2584)

Monday/Tuesday: 8 a.m. to 8 p.m
Wednesday: 8 a.m. to 6 p.m.
Thursday/Friday: 8 a.m. to 4 p.m.

Calgary Health Region
Chronic Disease Management
Macleod Place I
300, 5920 Macleod Trail SW
Calgary, Alberta T2H 0K2

www.calgaryhealthregion.ca/cdm

November 2006
(information in this brochure may change without notice)
To reorder brochure call 943-2584

calgary health region

LIVING WELL WITH A Chronic Condition

The aim of this program is to help you learn a healthy way to live with your chronic illness. Our goal is for you to live the best possible life with a long-term condition.

TAKE CHARGE OF YOUR OWN HEALTH!

Join Calgary Health Region's Living Well with a Chronic Condition program. If you have a long-term health condition such as diabetes, heart disease, high blood pressure, chronic lung disease, asthma, osteoporosis, arthritis or others, this program is for you.

There are three parts to this program – supervised exercise classes, disease-specific education classes, and a self-management workshop (Row Your Own Boat). You can take any one part or all parts of the program in any order. We recommend that you take the whole program to best manage your chronic condition.

The Living Well with a Chronic Condition program is offered throughout the city and in rural areas. Programs are offered in locations such as fitness facilities, community centres and churches in early mornings, during the day, and in early evenings.

SUPERVISED EXERCISE CLASSES

- Classes are offered two to three times a week for eight weeks and include a one-on-one assessment by a health-care professional.
- Classes are taught and monitored by health-care professionals and fitness leaders.
- Three types of exercise classes are offered:

Easy Going

For individuals with significant limitations to exercise who require close supervision. Exercise focuses primarily on improving mobility and balance.

Get Going

For individuals with some limitations to exercise who require a moderate level of monitoring. Exercise focuses primarily on improving aerobic endurance, muscular strength/endurance, flexibility and balance.

Keep Going

For individuals with few limitations to exercise that require minimal supervision. Exercise focuses primarily on improving aerobic endurance, muscular strength/endurance, flexibility and balance.

All classes are held in a fun, social environment.

DISEASE-SPECIFIC EDUCATION CLASSES

- Classes are offered in a variety of formats for varying lengths of time depending on the topic. Please contact 9-HEALTH to discuss the topics you're most interested in.
- Topics available include: Diabetes, Preventing Diabetes, High Blood Pressure, High Cholesterol, Lung Disease, Chronic Pain, Falls Prevention, Weight Loss (Energy Balance series).
- Aside from disease-specific education, we also offer 'Lifestyles' education, which concentrates on exercise and nutrition information for anyone with a chronic condition.
- Classes are taught by health professionals including nurses, dietitians, kinesiologists, physical therapists, respiratory therapists and occupational therapists.
- Education classes are offered at no cost to the participant.

SELF-MANAGEMENT WORKSHOP (ROW YOUR OWN BOAT)

- Classes are offered once a week for six weeks, for 2 ½ hours per session
- People with a variety of chronic illnesses participate together to share ideas and learn the skills needed to live successfully with their chronic conditions
- Subjects covered include:
  - Goal setting and problem solving
  - Coping with pain and fatigue
  - Managing difficult emotions such as frustration and fear
  - Relaxation techniques and self-talk
  - Communication and creating positive relationships with the health care team
- Classes are led by trained leaders who also have long-term illnesses

FEES
- *Exercise $80*
- *Self-Management $48*
- *Both of the above $100*

Program assistance is available.

www.calgaryhealthregion.ca/cdm

(403) 9-HEALTH (943-2584)

Appendix C: Motivational interviewing session guides

Date: _____ **Participant ID #:**_____

Time 1: End of 8-week Living Well exercise program

Start time: _____

Open conversation
(My name is Marni Armstrong, and I am a grad student with the University of Calgary. I am interested in physical activity and people with Type 2 Diabetes. We have about 30 minutes for this meeting today. I was hoping to be able to chat about your opinions and ideas about your exercise program, would that be ok with you?)

Okay, I want to start by finding out a little more about your thoughts around exercise. What made you decide to participate in the Living Well exercise program?

Before you started the program, what made you think you needed to change something about your exercise plan? (What if any, health concerns (related to lack of activity) have you had?)

What will you take away from the Living Well program?

Explore benefits and costs of physical activity

I am curious, now that you are finishing the program, what do you think will be some of the hard things about trying to maintain a regular exercise program? What would make it difficult to keep up with an exercise plan? What else? (e.g., takes time to incorporate physical activity into schedule, motivation, making it a priority.).

And what would concern you about not continuing on with the changes you've made? What else?

In the past, how has your fitness level stopped you from doing what you want to do? (Elicit impact on physical health, mental health (e.g., guilt, shame, self-esteem, and depression), romantic relationships, family relationships, social life, etc.)

What makes you think you still need to keep working on your goals from the Living Well Program? (what is it that makes you want to continue with your exercise program now?)

Summarize Benefits and Costs of Exercise

From what you've said so far, some of the hard things about getting enough exercise and maintaining a program will be…(list barriers stated)

But you're worried about (or wondering about)… (list bad consequences stated)
Does that sound about right? Am I missing anything?

Importance and Confidence for Maintaining Change

We've been talking about your exercise plan—about the good and not so good things about continuing on with what you've accomplished in Living Well. So, at this moment, how important is it to you to continue with your exercise plan? If 0 was "not important" and 10 was "very important" what number would you give yourself?
Rating (0-10): _____

Discuss choice—*why X?*

If high:

(A) How did you decide on that number?

(B) What would need to happen for your importance score to move up from x to y?

If low:

(A) what would have to happen for it to become much more important for you to change?

(B) Why x and not y (lower number)?

Okay, now we're going to do the same for confidence. How confident are you that you could continue with the changes you've made in Living Well? If 0 means that you are "not at all confident" and 10 means that you are "extremely confident if you set your mind to it"—where would you put yourself right now?
Rating (0-10): _____

If high:

(A) Why have you given yourself such a high score on confidence?

(B) How could you move up higher, so that your score goes from x to y?

If low:

(A) What would make you more confident about making these changes?

(B) Why x and not y (lower score?)

Self-Efficacy

So far we've been talking quite a bit about the idea of making changes. What kinds of changes have you made in the past two months as a result of participating in Living Well program? (what are you already doing to be healthy?)

(Although you know that you've got a long road ahead of you) So, you've already been_____(e.g., exercising regularly, writing down your foods, and changing your diet). How is this different from when you first started the Living Well program?

What makes this time different from other times when you've attempted to exercise (and/or lose weight); what have you learned from the way things went wrong last time you tried?)

What is there about you, what strong points do you have that could help you succeed in making this change?

Looking to the Future

Looking forward, what do you imagine as the best possible outcome from participating in Living Well?

What do you think it would take to get there?

What might need to be different in your life for you to make this change?

On the flip side, what's at stake if you don't stick with the changes you've made in Living Well?

Making a Change

At this point, what is your plan to keep up with your exercise goal (keep up with the exercise changes you've made)?

How will you know if your plan is working?

How might others in your life (family/friends/co-workers) support you in successfully reaching this goal?

What barriers and difficult times might you run up against?

How will you prevent and manage these barriers?
How will you monitor (keep track) of your progress?

Summarize decision: *Is this what you want/intend to do?*

On a scale of 0-10, how confident are you that you'll successfully accomplish this plan? (what are your chances of success).

Terminate Interview

If participant is considering change: *I hear that you really want to do something about your exercise plan, and that you'd like to get going right away/keep working at it. We talked about things you could do differently and you think that it would be best to … Is that correct?*

I'm confident that when you make a firm decision and commitment to _____ you'll find a way to do it!

If participant is still ambivalent about change: *This interview gives people a chance to think about their exercise habits. You have thought of some things you might want to change about your exercise regime* (review possible changes). *Does that sound about right?*

For all participants: *The interview is over now and I just want to thank you for being willingness to talk with me about your exercise plant. Do you have any last thoughts about what we've talked about today?*

I just want to remind you that you will be getting a brief phone call from me in 6-8 weeks to see how you are doing and to set up another follow-up assessment in three months time. Would that be alright?

Stop time of interview: _____

Date: _____ **Participant ID #:**_____

Time 2: Three months post-program

Start time: _____

Open conversation
(So today we have about 30 min to check in and discuss your exercise plan. Would that be alright with you?)

Exploration of Exercise Behaviour

Tell me how you've been doing since the last time we talked.

How are you feeling about your exercise habits at this point in time?

[if frustrated]

(A) *So, in spite of your best efforts, you really haven't been able to maintain a regular exercise program. What do you make of that?*

(B) *"You're really frustrated that you haven't been exercising as much as you would have liked. I can imagine lots of people in your situation would say, "I'm not able to keep up with my program. This program isn't for me." But you haven't done that. What keeps you going in spite of your frustration?"*

[if feeling good about exercise plan]

(A) *"From what you're telling me about the efforts you've made, it is clear that you're committed to sticking with this, and that commitment is paying off in the changes you see. How do these changes make you feel about yourself?"*

(B) *Since you're satisfied with the changes you've made so far, what keeps you interested in continuing to exercise?*

For you, what are some of the hard things about continuing on with your exercise plan? What else? (e.g., takes time to incorporate physical activity into schedule, have to learn new ways to cook, changing whole family's way of eating, enjoy food, food is used to escape problems, help cope with depression, anxiety, conflict, boredom, loneliness, etc.).

And what would concern you about not continuing on with the changes you've made. What else?

What makes you think you still need to keep working on your exercise goals? (what is it that makes you want to continue with your exercise plan now?)

Summarize Benefits and Costs of Exercise

From what you've said so far, some of the hard things about continuing to exercise are….
But you're worried about (or wondering about)….
Does that sound about right? Am I missing anything?

Readiness and Confidence for Change

We've been talking about your exercise plan—about the good and not so good things about continuing on with your exercise program. So, at this moment, how important is it to you to continue working on exercise plan? If 0 was "not important" and 10 was "very important" what number would you give yourself?
Rating (0-10): _____

Discuss choice—*why X?*

If high:

(C) How did you decide on that number?

(D) What would need to happen for your importance score to move up from x to y?

If low:

(C) what would have to happen for it to become much more important for you to change?

(D) Why x and not y (lower number)?

Okay, now we're going to do the same for confidence. How confident are you that you could continue with the changes you've made in your exercise habits? If 0 means that you are "not at all confident" and 10 means that you are "extremely confident if you set your mind to it"—where would you put yourself right now?
Rating (0-10): _____

If high:

(C) Why have you given yourself such a high score on confidence?

(D) How could you move up higher, so that your score goes from x to y?

If low:

(C) What would make you more confident about making these changes?

(D) Why x and not y (lower score?)

Self-Efficacy

So far we've been talking quite a bit about the idea of making and maintaining changes. What kinds of changes have you made in the past five months as a result of participating in Living Well program? (what are you already doing to be healthy?)

(Although you know that you've got a long road ahead of you) So, you've already been_____(e.g., exercising regularly, keeping track scheduling activity, and changing your diet). How is this different from when you first started the Living Well program?

What makes this time different from other times when you've attempted to exercise (and/or lose weight); what have you learned from the way things went wrong last time you tried?)

What is there about you, what strong points do you have that could help you succeed in making this change?

Looking to the Future

Looking forward, what do you imagine as the best possible outcome from participating in Living Well?

What do you think it would take to get there?

What might need to be different in your life for you to make this change?

On the flip side, what's at stake if you don't stick with the changes you've made in Living Well?

Making a Change

At this point, what is your plan to keep up with your exercise/weight-loss goal (keep up with the dietary/exercise changes you've made)?

How will you know if your plan is working?

How might others in your life (family/friends/co-workers) support you in successfully reaching this goal?

What barriers and difficult times might you run up against?

How will you prevent and manage these barriers?

How will you monitor (keep track) of your progress?

Summarize decision: *Is this what you want/intend to do?*

On a scale of 0-10, how confident are you that you'll successfully accomplish this plan? (what are your chances of success).

Terminate Interview

If participant is considering change: *I hear that you really want to do something about your exercise plan, and that you'd like to get going right away/keep working at it. We talked about things you could do differently and you think that it would be best to … Is that correct? I'm confident that when you make a firm decision and commitment to _____ you'll find a way to do it!*

If participant is still ambivalent about change: *This interview gives people a chance to think about their exercise habits. You have thought of some things you might want to change about your exercise regime* (review possible changes). *Does that sound about right?*

For all participants: *The interview is over now and I just want to thank you for being willingness to talk with me about your exercise plant. Do you have any last thoughts about what we've talked about today?*

I just want to remind you that you will be getting a brief phone call from me in 6-8 weeks to touch base and in order to set up a brief follow-up assessment in three months' time.

Stop time of interview: _____

Appendix D: Questionnaires for randomized controlled trial (study B)

Modified Godin Leisure Time Exercise Questionnaire

For this question, we would like you to recall your average weekly participation in aerobic physical activity over the past month. How many times per week on average did you do the following kinds of physical activity during your free time over the past month?

When answering these questions please:

- Consider your average **per week** over the past month.
- Only count physical activity sessions that lasted 10 minutes or longer in duration.
- Do not include weight lifting or other strength training; we'll ask about that later
- Do not count physical activity that was done as part of your employment or household chores.
- Note that the main difference between the three categories below is the intensity of the physical activity.
- Please write the average amount of times per week on the first line and the average time on the second line.

	Times Per Week	Average Time Per Session (minutes)
A. Strenuous physical activity (heart beats rapidly, sweating) (e.g., running, jogging, hockey, soccer, squash, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes, elliptical machine)		
B. Moderate physical activity (not exhausting, light perspiration) (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)		
C. Mild physical activity (minimal effort, no perspiration) (e.g., easy walking, yoga, archery, fishing, bowling, lawn bowling, shuffleboard, horseshoes, golf, snowmobiling)		

Resistance Training Questionnaire

Resistance training *refers to exercises completed to improve strength.* ***Resistance training*** *refers to activities using free weights, weight machines, bands, body weight and tubing*.

1. In a typical week, do you complete resistance training?

   Yes □ No □

2. In a typical week, how many days do you complete resistance training?

   1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □

3. How many **sets** of each exercise are you performing?

4. How many **repetitions** of in each set of exercises are you performing?

5. What **intensity** would you rate your resistance training?

   Easy □ Moderate □ Hard □

6. What **kind** of resistance training are you performing (ie; free weights, weight machines, body weight, resistance bands, tubing)

7. **Where** are you performing resistance training exercises? (ie; fitness facility, in class, at home, outside)

8. Do you own resistance training equipment?

   Yes □ No □

Additional comments:

***The next section asks you about how confident you are to meet the Guidelines for Physical Activity*:**

Please rate how much the following circumstances affect your confidence to meet the guidelines for the Living Well program of:

<u>150 minutes/week</u>

Some examples:

- **30 minutes, 5 times per week**
- **~ 40 minutes, 4 times per week**
- **50 minutes, 3 times per week**

**Note: Please do not leave the question blank.*

		Not at all confident	***Not very confident***	***Moderately confident***	***Very confident***	***Extremely confident***
1.	**When I am a little tired:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
2.	**When I am in a bad mood or feeling depressed:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
3.	**When I have to do it by myself:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5

		Not at all confident	*Not very confident*	*Moderately confident*	*Very confident*	*Extremely confident*
4.	**When it becomes boring:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
5.	**When I can't notice any improvements in my fitness:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
6.	**When I have many other demands on my time:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
7.	**When I feel a little stiff or sore:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
8.	**When the weather is bad:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
9.	**When I have to get up early, even on weekends:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5
10.	**When I feel a little ill:**					
	I could do Aerobic Activity	1	2	3	4	5
	I could Strength Train	1	2	3	4	5

Quality of Life Assessment: SF-12

In general you would say your health is:

Excellent	_____	Fair	_____
Very Good	_____	Poor	_____
Good	_____		

The next items are about your **HEALTH** and activities you might do during a *typical day.*

Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	**Yes, Limited A Little**	**No, Not Limited At All**
Moderate activites, such as moving a table, pushing a vacuum cleaner, golf.			
Climbing **several** stairs.			

The next items are in regards to your **PHYSICAL HEALTH** in the *past 4 weeks*.

During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activites *as a result of your physical health*?

	Yes	**No**
Accomplished less than you would like.		
Were limited in the **kind** of work or other activities.		

The next items are in regards to your **EMOTIONAL HEALTH** in the *past 4 weeks*.

During the *past 4 weeks,* have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	Yes	**No**
Accomplished less than you would like.		
Did work or activities **less carefully than usual.**		

The next items are in regards to **PAIN** in the *past 4 weeks*.

During the *past 4 weeks,* how much did *pain* interfere with your normal work (including both work outside the home and housework)?

1	2	3	4	5
Not at all	A little bit	Moderately	Quite a bit	Extremely

These next questions ask about how you **FEEL** and how **THINGS HAVE BEEN** with you during the *past 4 weeks*.

For each question, please check off the one answer that comes *closest* to the way you have been feeling much of the time during the past 4 weeks.

Have you felt calm and peaceful?

All of the time	Most of the time	A Good bit of the time	Some of the time	A little of the time	None of the time

Did you have a lot of energy?

All of the time	Most of the time	A Good bit of the time	Some of the time	A little of the time	None of the time

Have you felt down-hearted and blue?

All of the time	Most of the time	A Good bit of the time	Some of the time	A little of the time	None of the time

These next question ask about **PHYSICAL HEALTH** or **EMOTIONAL PROBLEMS** in the *past 4 weeks***.**

During the past 4 weeks, how much of the time has your *physical or emotional problems* interfered with your social activiites (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little bit of the time	None of the time

Appendix E: Professional organization pre-exercise stress testing recommendations

American Diabetes Association and the American College of Sports Medicine, Position Stand on Exercise and Diabetes (2010)[9], p. 2289

In general, ECG stress testing may be indicated for individuals matching one or more of these criteria:

Age >40 years, with or without cardiovascular disease risk factors other than diabetes
Age >30 years and • Type 1 diabetes or Type 2 diabetes of >10 years' duration • Hypertension • Cigarette smoking • Dyslipidemia • Proliferative or preproliferative retinopathy • Nephropathy, including microalbuminuria
Any of the following, regardless of age • Known or suspected coronary artery disease, cerebrovascular disease, or peripheral vascular disease • Autonomic neuropathy • Advanced nephropathy with renal failure

Evidence statement. Before undertaking exercise more intense than brisk walking, sedentary persons with T2DM will likely benefit from an evaluation by a physician. ECG exercise stress testing for asymptomatic individuals at low risk of CAD is not recommended but may be indicated for higher risk. ACSM evidence category C. ADA C level recommendation.

Canadian Diabetes Association Clinical Practice Guidelines (2013),[12] Physical Activity and Diabetes Chapter, p S43

> 5. People with diabetes with possible CVD or microvascular complications of diabetes who wish to undertake exercise that is substantially more vigorous than brisk walking should have medical evaluation for conditions that might increase exercise-associated risk. The evaluation would include history, physical examination (including funduscopic exam, foot exam, and neuropathy screening), resting ECG and, possibly, exercise ECG stress testing [Grade D, Consensus].

Canadian Diabetes Association Clinical Practice Guidelines (2008), Physical Activity and Diabetes Chapter, p S38.

> 3. An exercise ECG stress test should be considered for previously sedentary individuals with diabetes at high risk for CVD who wish to undertake exercise more vigorous than brisk walking *[Grade D, Consensus]*.

American Heart Association Scientific Statement 2009[147], p. 3251

Table 7. Guidelines for Stress Testing Before Exercise Training in Asymptomatic Individuals With T2DM [IIb (C)]

Stress Testing Not Necessary (All Criteria Should Be Present)	Stress Testing Recommended (if ≥1 Criteria Present)
No clinical history of CAD	History of CAD; no stress test within past 2 years
Asymptomatic	Symptoms of chest discomfort or dyspnea
No evidence of PAD or CVD	Clinical or laboratory evidence of PAD or cerebrovascular disease
ECG normal	ECG evidence of infarction or ischemia
Light to moderate exercise program	Vigorous exercise program

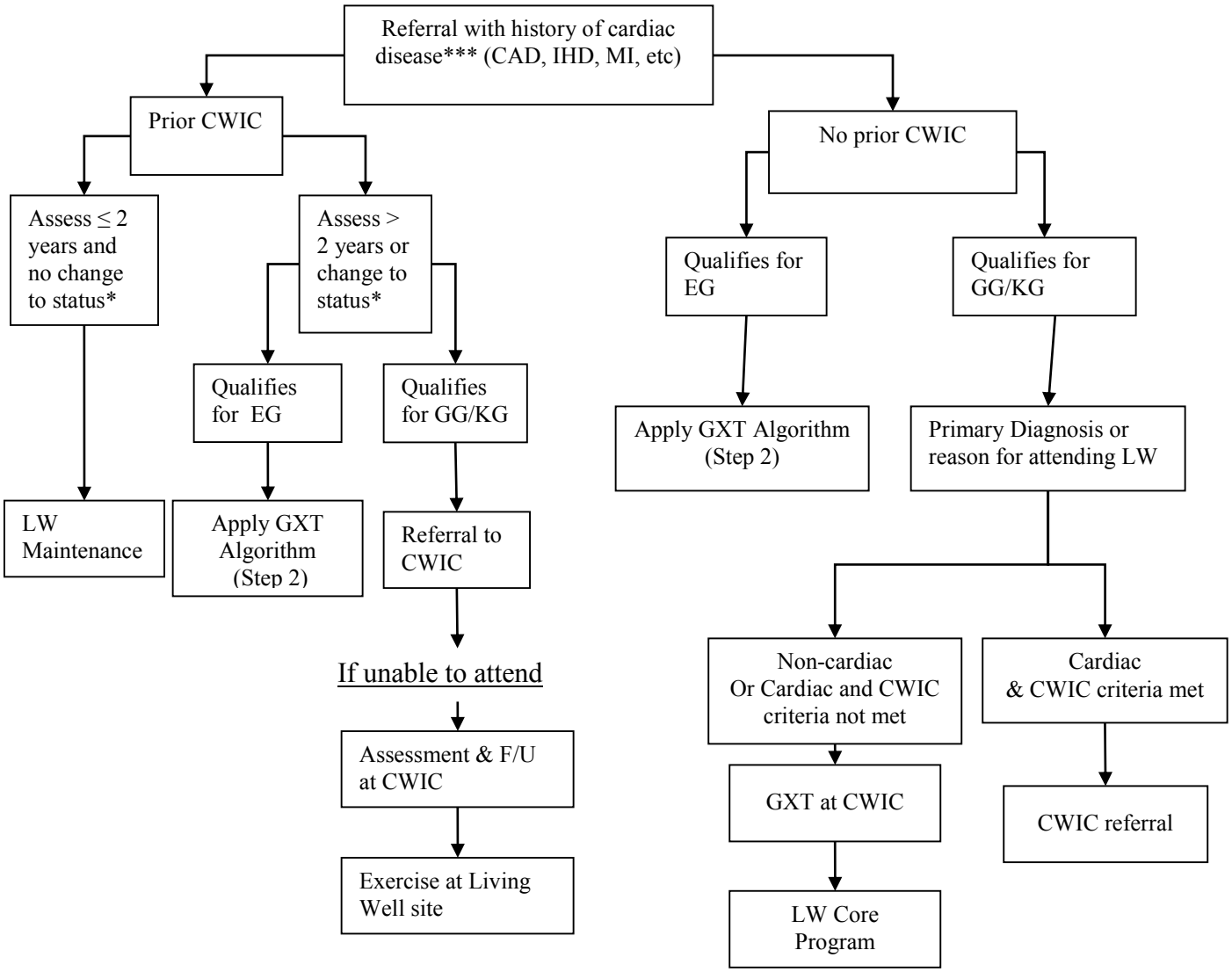
PAD indicates peripheral arterial disease.

Appendix F: Living Well with a Chronic Condition program pre-exercise screening Algorithm

LIVING WELL WITH A Chronic Condition

Stress Test/CPET triage algorithm

Step 1: Cardiac Referrals to Living Well vs. Cardiac Wellness Institute of Calgary



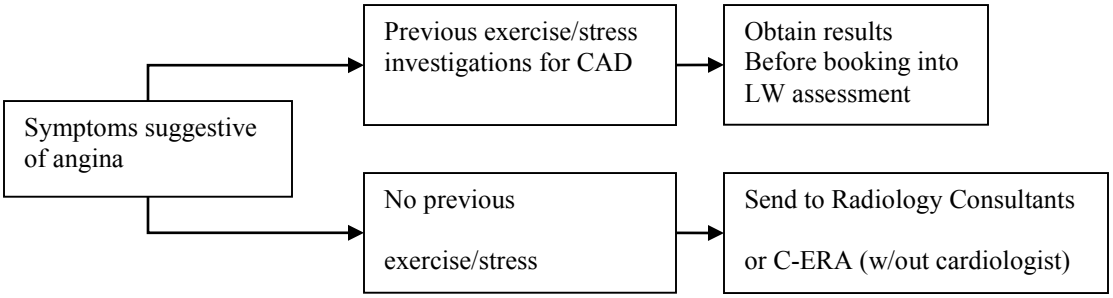
Acceptance criteria for CWIC:

- Myocardial Infarction (**STEMI**: ST elevation MI or **NSTEMI**: Non ST elevation MI)
- PCI: Percutaneous Coronary Interventions
- Open heart procedures (CABG: Coronary Artery Bypass Grafting, revascularization, heart valve repair or replacement)
- CAD with at least one lesion/blockage of >70% in a coronary artery

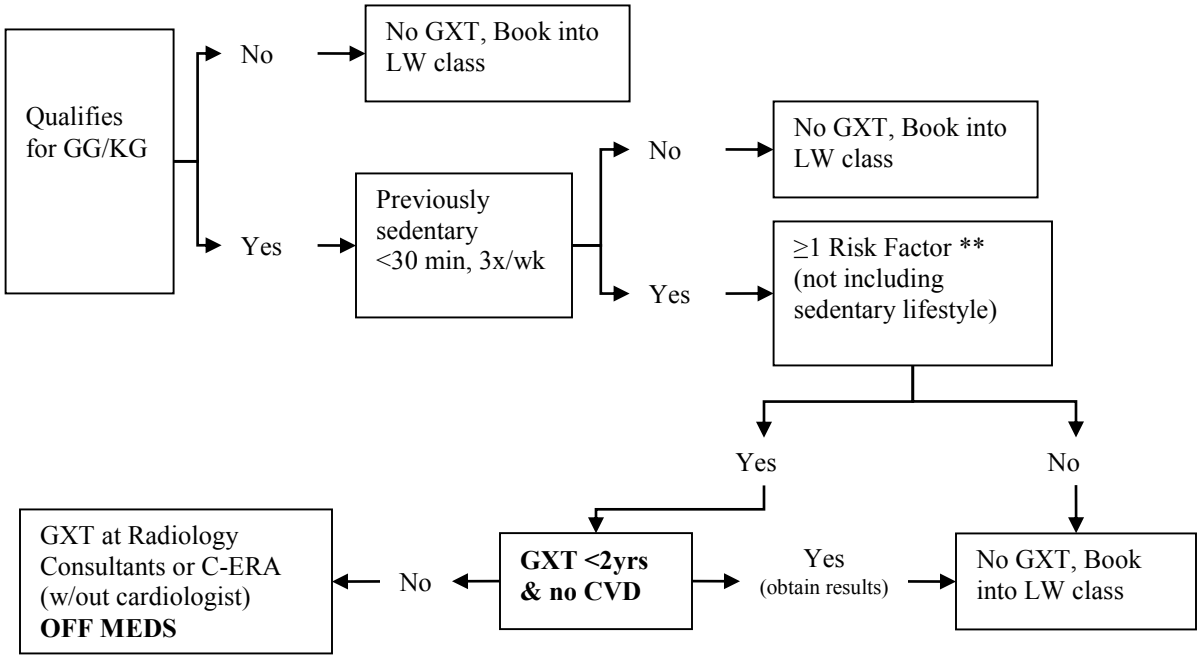
- Positive Thallium stress test
- Cardiomyopathy with admission for CHF; or LVEF less than 40%
- Congenital heart disease (referred by Adult congenital heart clinic)
- CHF (referred by Heart Function Clinic – CC, Cardiac Function Clinic – FMC, PLC, RGH)
- Heart transplant

STEP 2: Living Well Exercise Test Triage

1. Symptoms suggestive of angina – no known CAD (if no, go to #2)



2. Known Diabetic (if no, go to #3)



Definitions:

GXT – Graded exercise test
CPET- Cardio pulmonary exercise test

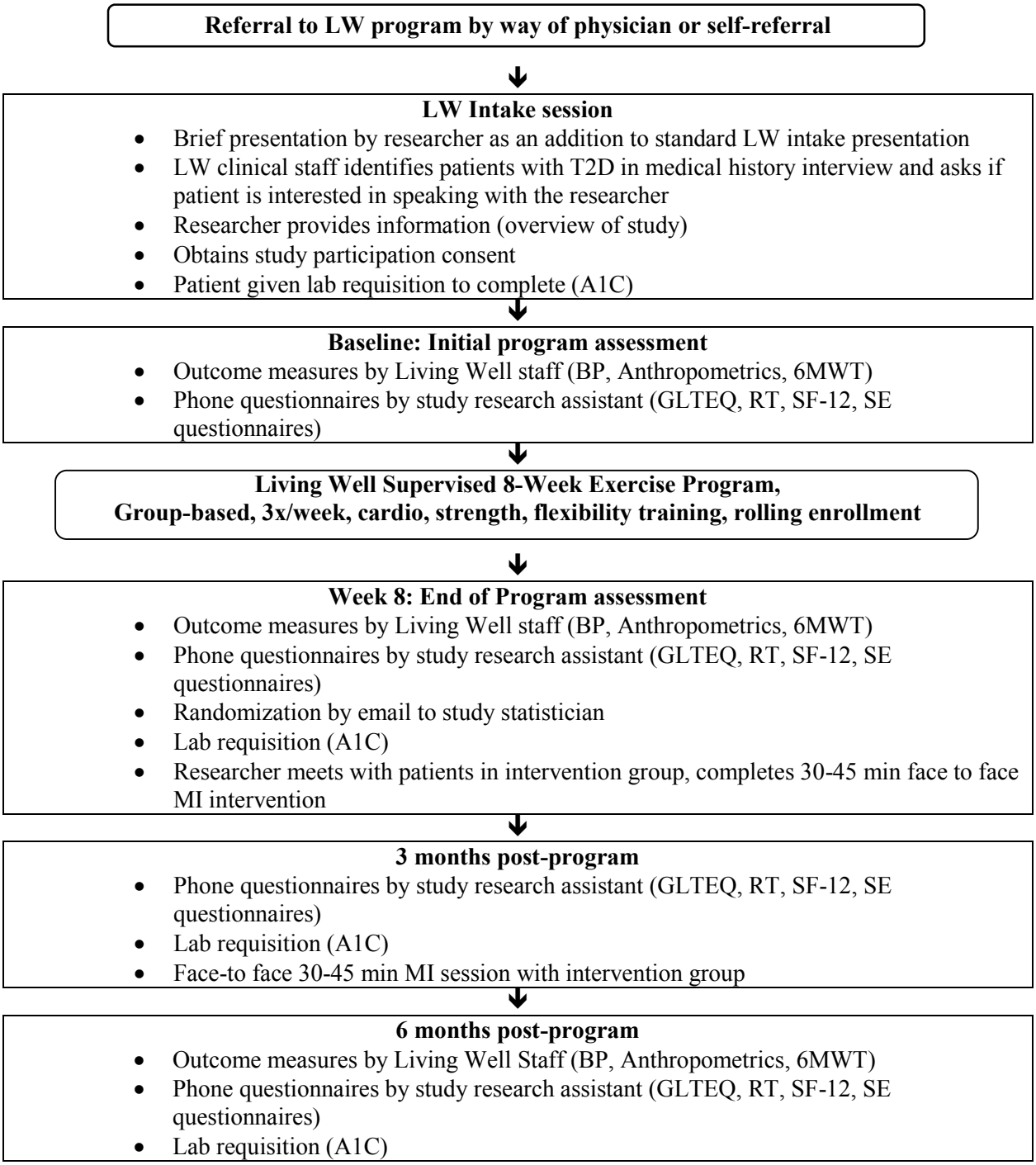
***Change in Status** (since participation in CWIC or since last CV assessment)

- New event – Myocardial Infarction
- New Intervention – CABG, revascularization, PCI, Valve repair/replacement, other cardiac surgery
- Change or Increase in symptoms – Angina or other symptoms suggestive of CVD

****Risk Factors (ACSM):**
Family History: MI, coronary revascularization, or sudden death before 55 yrs in father or other male first degree relative (brother or son) or before 65 yrs in mother or other first degree relative (sister or daughter)
Obesity: BMI >30, or Waist Girth >102cm Male and >88cm Female
Hypertension
Dyslipidemia
Cigarette smoking: Current smoker or those who quit within the previous 6 months
Impaired Fasting Glucose

*****Note:** Valve disease/surgery, pacemakers and electrical disturbances are not considered cardiac disease (ischemic heart disease) and therefore, testing is not necessary. If you have questions, please speak to an exercise consultant.

Appendix H: Study flow and timeline



GLTEQ= Godin Leisure Time Exercise Questionnaire; RT= Resistance Training; SF-12= Medical Outcomes Study 12-item Short Form; SE= Self-Efficacy; 6MWT= Six Minute Walk Test. MI: Motivational Interviewing, A1C: Hemoglobin A1C

Appendix I: Data abstraction form for chart review at screening clinics

Variable	**RESULTS**				
PHN:					
Date of test:					
Site:	C-era ☐	RC ☐	CWIC ☐		
CV Risk factors:	Previous MI ☐	Previous Arrhythmia ☐	Hypertension ☐	Dyslipidemia ☐	
	Diabetic complications (e.g. DN, DR, PAD) ☐	Smoking status: Yes☐ Never☐ Quit☐	Family Hx ☐	BMI >30 ☐	
Results of Test:	Low risk ☐	Intermediate risk ☐	High Risk ☐	Non diagnostic ☐	Direct to Nuclear ☐
Reason for test termination:					
Test interpretation:					
Maximum METS achieved:					
Cleared for exercise?	YES ☐	NO ☐			
Reason for non-clearance:	ST-depression ☐	Arrhythmia ☐	Incomplete test ☐		
	Abnormal BP response ☐		Angina ☐		
	Severe Dypsnea ☐		ECG changes ☐		
	Blocks ☐		Unable to complete test ☐		
	Other ☐				
Further testing required? (see next page)	YES ☐	Details:	NO ☐		

Nuclear myocardial perfusion imaging			
Type of test completed:	Exercise thallium/sestamibi ☐	Adenosine thallium/sestamibi ☐	
	Other ☐		
Results of test:	Low Risk ☐	Intermediate Risk ☐	High Risk ☐
Cleared for exercise program?	YES ☐	NO ☐	
Further testing required?	YES ☐	NO ☐	
Further testing?	Cath ☐	Echo ☐	Holter ☐
Details:			

Appendix J: Characteristics of patients experiencing a cardiovascular outcome who were referred for a pre-exercise stress test

Pt no	Event	Timing (months after intake)	Cleared for LW?	Age	DM duration	Previous arrhythmia	Previous CV event	Smoker	COPD	CHF	Chest pain	Neuro-pathy /CKD	Notes
5	PCI*	2.0	Direct to cath on ETT	63	8	no	no	yes	no	no	yes	no	ST changes and chest pain on ETT, Cera sent direct to cath,
14	PCI*	2	Sent for cath by Cera	77	NR	no	no	yes	no	no	yes	no	Chest pain at intake
8	PCI*	3.0	Referred for cath by c-era	51	0.5	no	no	no	no	no	yes	no	Referral said chest pain, non-exertional A1C=10.4, proteinuria
7	CV admit STEMI, PCI*	4.0	MI before routine cath appt	74	35	no	no	no	no	no	no	yes	CKD, thallium id ischemia, referred for routine cath and presented to ER before appointment, family hx of premature CVD
4	CV admit, PCI	2.7	No	75	4	yes	no	quit	no	no	no	no	Ischemia id on nuclear, but presented to ER before follow up, Low func capacity, A fib
6	Unstable angina admit, PCI	3	Cleared on ETT	69	NR	yes	no	quit	no	no	no	no	Cleared on ETT 2.5 months before PCI, started program, had event during time at program, not at exercise class
3	Dead Chronic IHD	3.2	No show for RCA	57	9	yes	yes	quit	no	no	no	no	Quad cabg in 1999 at age 48, referral says fluid in lung and partial bowel removal
16	CV admit UA and CABG	3.4	Had CABG prior to CWIC	80	3	no	no	no	no	no	no	no	Known angina, had previous CVA, prostate cancer,
13	CABG	4	Sent for cath after intake	68	NR	no	yes	quit	no	no	no	yes	Previous silent MI 5 years prior, neuropathy and PAD
18	CV admit UA and CABG	4.8	Had event prior to CWIC	62	NR	no	yes	quit	yes	yes	no	no	Known CHF, on insulin, previous MI 16 years ago, COPD

Pt no	Event	Timing (months after intake)	Cleared for LW?	Age	DM duration	Previous arrhythmia	Previous CV event	Smoker	COPD	CHF	Chest pain	Neuro-pathy /CKD	Notes
12	CABG	5	Cleared by CWIC	71	8	yes	yes	quit	no	no	no	no	Valve disease, MI in 1971 and 2006, previous stroke
2	CV admit unstable angina	5.1	By own cardiologist	85	30	yes	yes	quit	no	yes	no	no	CHF, deferred to own cardiol, previous cath 4 months before referral
10	PCI	6	Yes by program	67	2	no	no	no	yes	no	yes	no	Cleared by program staff as chest pain had been hospitalized for chest pain in past and cleared, severe COPD, current smoker
1	CV admit, then CABG	8.1	Yes on ETT by CWIC	64	NR	no	yes	quit	no	no	no	no	MI 12 years ago and CABG 10 months, known angina on nitro
15	CV admit Coronary Thrombosis	8.2	Cleared, normal MPI	74	3	no	no	quit	no	no	no	no	Long-time smoker, test id pleural calcinosis, query COPD
17	CV admit UA and PCI	11.2	Did not show to CWIC	59	NR	no	yes	no	no	no	no	yes	Said not interested in CWIC, on insulin, previous PCI, kidney problems
11	Admit: stroke	11.3	No showed to CWIC	75	NR	no	yes	no	no	no	no	no	Quad CABG 7 years previous, no showed and said was not interested in program
19	Dead Chronic IHD	11.5	Cleared on ETT	67	29	no	no	no	no	yes	no	yes	DM for 29 years, on insulin, CHF, chronic kidney failure (got to 80% max HR , 6.5 Mets no symptoms)
9	CV admit UA and PCI	11.8	Yes	64	2	no	no	yes	no	no	no	yes	Cleared by cera, but thallium id small area of ischemia , so told to watch for symptoms and was medically managed

*Indicates screening referral initiated PCI referral.

Abbreviations: PCI, percutaneous coronary intervention; cath, catheterization; IHD, ischemic heart disease; CWIC Cardiac Wellness Institute of Calgary; HR, heart rate; CV, cardiovascular; ETT, exercise treadmill test; UA, unstable angina; CHF, congestive heart failure; CKD, chronic kidney disease

Appendix K: Characteristics of patients experiencing a cardiovascular outcome who were not referred for a pre-exercise stress test

Pt no	Event	Timing	Cleared for LW?	Age	DM duration	Previous arrhythmia	Previous CV event	Smoker	COPD	CHF	Chest pain known?	Neuro-pathy /CKD	Notes
1	AMI admit, CABG	2 days after intake	Yes at intake (EG?)	63	10	no	yes	quit	yes	yes	yes		Previous MI and PCI in 2003, angina on nitro, COPD, CHF. Probably EG
2	CV admit, stroke	3 days after intake	Yes with stress test results	56	35	no	yes	no	no	no	no	yes	Requested stress test results and cleared; CKD, Charcot foot, Type 1, CVA 3 years prior
3	AMI admit, PCI	2 months	Yes	61	0	no	no	yes	no	no	yes	no	Fibromyalgia and OA, current heavy smoker, BMI >50
4	CV admit, stroke	3 months	Cleared on CPET	77	NR	no	yes	quit	yes	no	no	no	Severe COPD (V02=13), had CPET 3 days before stroke admit, HTN
5	CV admit, CAD, CABG	3 months	Yes with stress test results	67	16	no	yes	quit	no	no	no	yes	Previous MI in 1987, on nitro, CKD, Completed program had CABG one month later.
6	CV admit, stroke	3 months	Yes (EG?)	75	20	no	yes	quit	no	no	no	no	EG, previous CVA in 1991with speech impairment
7	CV admit, TIA	5 months	Yes	75	yes	yes	yes	quit	no	no	no	no	Previous stroke 1 yr previous, completed program, BMI 40
8	CV admit stroke	7 month	Yes, with stress test results	74	29	no	yes	yes	no	no	no	yes	Previous MI and CABG and stroke, 5 years prior, GXT from 2008 results were requested, recent heavy smoker

Pt no	Event	Timing	Cleared for LW?	Age	DM duration	Previous arrhythmia	Previous CV event	Smoker	COPD	CHF	Chest pain known?	Neuro-pathy /CKD	Notes
9	CV admit stroke	9 months	Yes	57	NR	no	yes	yes	no	no	no	yes	Previous stroke 2005, severe PVD, current smoker, refuses tx, cancelled out of program, A1C =10.2
10	CV admit: stroke	10 months	Yes, stress test request	63	NR	no	yes	yes	no	no	no	no	Previous PCI 16 years previous, on nitro, PVD, recent quit smoking after 49 years, never attended program
11	CV admit, unstable angina; PCI	11 months,	Yes, previous active	64	16	no	yes	quit	no	no	no	no	Previous MI 12 years ago,
12	AMI no cath	11 month	Yes, previous active	64	NR	no	yes	yes	no	no	no	no	Previous CABG, current smoker, no showed to LW; PCI one year later
13	Death, ischemic heart disease	7 months	Yes	81	13	no	no	no	no	no	no	no	80 years old, had several falls, EG
14	Death, Ischemic heart disease	10 months	Yes	84	13	no	yes	no	no	no	no	no	Chinese program, cleared by LW staff prior to exercise, prior MI 18 years ago
15	Death, Ischemic heart disease	10 months	No, needed stress test but never followed up	83	18	yes	no	quit	no	no	no	yes	Low renal function, A fib, on warfarin

Pt no	Event	Timing	Cleared for LW?	Age	DM duration	Previous arrhythmia	Previous CV event	Smoker	COPD	CHF	Chest pain known?	Neuro-pathy /CKD	Notes
16	Death, Ischemic heart disease	11.5 months	Yes, results requested	61	36	yes	yes	no	no	no	no	yes	On nitro, CKD and neuropathy, a fib,
17	CABG	8 months	Yes	50	NR	no	yes	no	no	no	no	yes	DM neuropathy, had stress test at RCA, pericarditis, cleared 6 months before cath, previous heart disease
18	PCI	11 month	Yes, requested results	74	NR	no	yes	yes	yes	yes	no	no	CHF, previous MI
19	Cath and CABG 2 months after EOI	2 months	Scheduled for valve repair	80									No details, on hold
20	PCI	10 months	Did not complete program	66	NR	no	yes	quit	no	no	yes	no	Previous MI 2 years ago, on nitro

Abbreviations: PCI, percutaneous coronary intervention; cath, catheterization; IHD, ischemic heart disease; CWIC Cardiac Wellness Institute of Calgary; HR, heart rate; CV, cardiovascular; ETT, exercise treadmill test; UA, unstable angina; CHF, congestive heart failure; CKD, chronic kidney disease; A Fib, atrial fibrillation