Evaluation of a clinically managed weight loss program at the Wellness Institute at Seven Oaks General Hospital

By

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Abstract

The prevalence of adults who are living with overweight or obesity has been increasing throughout the past three decades, which is contributing to increased healthcare costs. The Wellness Institute (WI) is a medical fitness facility that provides programs for chronic disease management. To combat the rise in overweight and obesity rates, the WI decided to create a personalized program based on a lifestyle approach with a targeted audience of individuals living with overweight or obesity. This program is known as the Weight Loss Clinic (WLC) and represents the first program targeted at individuals living with overweight or obesity with a multidisciplinary team of health professionals, such as physician oversight, Registered Dietitian, exercise specialist, and cognitive behavioural therapist or a psychologist. The thesis objective is to assess the feasibility and efficacy of a clinically-managed weight loss program. The WLC is composed of a multidisciplinary team and is based on the transtheoretical model (TTM) approach. Based on the literature review, it was found that there is insufficient evidence about the effectiveness of TTM and a multidisciplinary approach. An evaluation was conducted to further investigate the effectiveness of the clinically-managed weight loss program, specifically the WI. The program is 17-weeks long with a three-stage progression (assessment, intensive, transformation). Statistical analysis was performed using R Studio. The effects of participation were analyzed by the R generalized linear model using a pre- post-design. Other outcomes were analyzed through a paired t-test. A total of 26 participants were included in the evaluation (13 incomplete and 13 complete). The results from the evaluation indicate that participating in the weight loss program leads to significant weight loss ($p=0.0009$) and significant improvements in waist circumference ($p=0.0002$), systolic blood pressure ($p=0.0052$), diastolic blood pressure ($p=0.0057$), and body fat percentage ($p=0.0001$). The data generated from this evaluation will be used by the WI to improve and support the mission of the program in using an evidence-based methodology. As well, this data may be used for future clinical trials and as a model for other health institutes across the province, within Canada, and globally.

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Dedication

I dedicate this thesis to my family, my close friends, and my dog Pepper.

Thank you for your unconditional love and support.

vi. List of Tables

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viii. Abbreviations

BMI	Body Mass Index
BIA	Body Impedance Analysis
DXA	Dual-Energy Xray Absorptiometry
CBT	Cognitive Behaviour Therapist
CCPG	Canadian Clinical Practice Guidelines
CCPT	CSEP-Certified Personal Trainer
CDIC	Chronic Disease Innovation Centre
CPA	Clinical Psychology Associate
CSEP	Canadian Society for Exercise Physiology
GLM	General Linear Model
HDL	High Density Lipoprotein
LDL	Low Density Lipoprotein
MD	Doctor of Medicine
PSQI	Pittsburgh Sleep Quality Index
RD	Registered Dietitian
RN	Registered Nurse
SOGH	Seven Oaks General Hospital
TC	Total Cholesterol

TTM	Transtheoretical Model
WI	Wellness Institute
WLC	Weight Loss Clinic

Chapter I

Literature Review Part 1

1.1 Introduction

Obesity is a worldwide problem, with more than 650 million adults living with obesity today [1]. With the prevalence of obesity increasing, health care professionals believe that obesity may be a major driver in the burden of chronic diseases. Overweight or obesity is characterized by abnormal or excessive fat accumulation that may impair health [2]. Certain people may have genetic predispositions to gaining weight, but generally, obesity can be attributed to environmental and behavioural circumstances that contribute to consuming more energy than is being burned through physical activity and other biological functions [2]. Modifiable individual risk factors that have been associated with obesity include excess energy intake, unhealthy dietary choices, sedentary lifestyle, insufficient or excess sleep, pre- and perinatal exposures (e.g. gestational diabetes, smoking), certain diseases (e.g. Cushing's disease), psychological conditions (e.g. depression, stress), and specific drugs (e.g. corticosteroids) [3]. Other socioeconomic and environmental risk factors associated with obesity include low education, poverty, lack of access to physical activity resources, food deserts, susceptibility to viruses, microbiota dysbiosis, obesogens (e.g. endocrine-disrupting chemicals), and social ties with people who are living with obesity [3,4]. Obesity can be measured in various ways including Body Mass Index (BMI), waist circumference, and body composition. The most common obesity measurement tool is BMI; a measure of an individual's weight in kilograms divided by their height in meters squared (kg/m^2). Table 1 below indicates the categories for BMI for individuals 20 years or older.

Table 1. BMI Categories for individuals 20 years or older

BMI *(kg/m^2)*	***BMI Classification***
less than 18.5	Underweight
18.5 to 24.9	Normal weight
25 to 29.9	Overweight
30 to 34.9	Obese
35 to 39.9	Obese II
Over 40	Obese III

Note: information adapted from **[5]**

BMI only assesses weight to height ratio but is frequently used as an objective marker of adiposity. BMI is simplistic and is used to assess at a population level, whereas, when assessing an individuals' health, there are many other factors involved such as the location of adiposity and other chronic health conditions that may affect adiposity [6]. However, other measurements such as waist circumference and body composition indicate the distribution of adiposity [5], and therefore, may be more appropriate tools to aid in assessing health risks. Waist circumference is an indirect measure of adipose tissue in the abdomen, an increase in adipose tissue in this area is associated with increased risks of chronic diseases. In Caucasians, a waist circumference of more than 88 centimetres in females and more than 102 centimetres in males may indicate a higher risk of developing metabolic problems associated with obesity [5]. Body composition analysis provides a direct assessment of adiposity. The two most commonly used tools for body composition analysis are the Bioelectrical Impedance Analysis (BIA) and the Dual-energy X-ray Absorptiometry (DXA) [7]. The BIA utilizes a mild electrical current to measure differences in resistance and reactance between tissue types based upon water and electrolyte content [7]. Whereas, the DXA utilizes x-rays to measure the x-ray attenuation by each tissue type [7]. Both BIA and DXA measure total body weight to determine body composition. Health Canada recommends the diagnosis of obesity not be based on BMI alone [8], but to be used with other clinical indicators

such as waist circumference and clinical evaluation of cardiometabolic and other obesity-related complications [6]. The 2020 Canadian Clinical Practice Guidelines (CCPG) for obesity management recommend the following interventions for adults living with obesity, individualized care plans that address the root causes of obesity and to provide support for behavioural change such as, diet and lifestyle intervention, psychological intervention, pharmacotherapy or bariatric surgery [6,9]. Since obesity does not present in the same way in all individuals, it requires individualized treatment and long-term support like any other complex chronic disease [9], thus, the care plans consist of a combination of interventions that are tailored to the individual living with obesity. The first-line treatment option for adults who are living with overweight or obesity is a personalized nutrition plan and 30-60 minutes of moderate to vigorous activity on most days of the week [9]. The personalized nutrition plan consists of key messages from Canada's Food Guide, focusing on the foundation of healthy eating, the importance of food skills and a healthy relationship with food, a supportive environment, and impact on social determinants of health [9] [10]. Exercise includes a combination of resistance training and high-intensity interval training [9]. Pharmacotherapy and bariatric surgery are recommended on a case-by-case basis for individuals when lifestyle interventions alone have not been effective or sustainable [9]. Weight reduction is well documented to provide health benefits; however, many available commercial programs are not personalized to the individual and provide little one-on-one support. Not all programs include exercise, most do not include medical oversight, and may not be customizable to an individuals' goals, needs or desires. Many of the studies reviewed in the literature [14,19,21-23] were aimed at lifestyle counselling, supporting the concept of personalized for the individual. Many available programs that have been researched are focused on surgical therapy, hence, catering more towards individuals who are living with obesity. Most study populations are those

with BMI 25-40 kg/m^2 with a majority having BMI > 30 kg/m^2 [14,15,19]. Since most studies are based on individuals living with obesity, with the increase in prevalence, there is a need for earlier intervention, targeting those with a BMI > 25 kg/m^2 [16]. Several weight loss programs utilize a variety of behavioural models, such as motivational interviewing, the theory of planned behaviour, the social cognitive theory, self-efficacy, and the health belief model, however, not many are based on the transtheoretical model (TTM), although most studies with this model have led to positive and meaningful results [17,18]. In terms of self-efficacy, it's shown that higher self-efficacy is generally associated with greater effort and commitment to adopting healthy behaviours [19]. Common features of a successful multidisciplinary intervention include the involvement of at least three health care professionals, predominantly RDs, exercise specialists, and psychologists with a gap in research regarding physician involvement [13,19].

According to the Government of Canada, the annual cost of obesity has increased from 3.9 billion in 2007 to 4.6 billion in 2008 with no recent data reported for the last 11 years [21]. In Canada, during 1978/79, 49% of adults over the age of 18 were overweight or obese. In 2004, 59% of adults over the age of 18 were overweight or obese, for 2017, 64% of adults over the age of 18 are overweight or obese [22]. The most recent data collected from Statistics Canada for 2018 reported that 63.1% of adults over the age of 18 years are overweight or obese [23]. Specifically, in Manitoba, 30.8 % of adults, aged 18 years or older, are obese, which is higher than the national average of 26.8% [22,23]. Within Manitoba, the northern region had the highest obesity prevalence but over time there has been an increase throughout all regional health authorities [24]. In Manitoba, there are a variety of chronic disease programs tailored for those with cardiovascular disease, type 2 diabetes, and chronic obstructive pulmonary disease. Although obesity is

considered a chronic condition [25], there are not many evidence-based programs in Manitoba tailored for individuals who are living with obesity.

The Wellness Institute (WI) is a self-supporting non-profit organization that operates as a medical fitness facility attached to Seven Oaks General Hospital in Winnipeg, Manitoba. For years, the WI has been providing programs for chronic disease management, such as the Cardiac Rehabilitation and Pulmonary Rehabilitation programs [26]. A 2015 outcome analysis done of the WI facility members indicated that 51% of new members have a moderate to high cardiometabolic risk profile, such as high blood glucose, high blood pressure and/or are overweight or obese. In response to these identified risks, the WI developed multiple programs with weight management components such a: Fitter-Firmer-Faster, Weight Management Lifestyle Program, HealthierU, Waist Management, and Pound-the-Pounds [26]. Since all of the programs were in high demand with over 1,000 participants, the WI decided to create a personalized program based on a lifestyle approach with a targeted audience of individuals living with overweight or obesity. This program, known as the Weight Loss Clinic (WLC), focuses on bodyweight reduction combined with improvement in cardiometabolic risk factors. The individuals joining the WLC are required to have tried to lose weight in the past but have been unsuccessful at maintaining weight loss or lifestyle changes and/or may have other health problems. The WLC represents the first program of its kind offered to adults who are living with overweight and obesity in Manitoba, shifting focus to earlier intervention and prevention of obesity-related morbidities. Weight loss is a billion-dollar industry in North America dominated by non-evidence-based programming and products. While the market is overwhelmed by weight loss products and services, there are gaps in evidence-based, professionally delivered clinical weight loss services in Canada. A logic model for the evaluation

has been created in Table 3, going into further detail about inputs, activities, targeted audience, and outcomes (short, intermediate and long term). The logic model provides a condensed version of the components and core values of the WLC. The elements of the WLC are a three-stage approach, totalling 17-weeks. The WLC is based upon the 2006 CCPG and the TTM of behaviour change, where there is a sequential behaviour change from an unhealthy behaviour to a healthy one [27]. The TTM provides an explanation of the stages of change an individual goes through when modifying a problem behaviour or acquiring a positive behaviour, in this case, changing dietary intake or physical activity, or both to achieve sustainable weight loss [27]. The WLC is managed by a multidisciplinary team using an interdisciplinary approach with physician oversight, Registered Dietitians (RDs), Canadian Society for Exercise Physiology (CSEP)-Certified Personal Trainer (CPT), and a Clinical Psychology Associate (CPA) or a Cognitive Behavioural Therapist (CBT). In Table 3, a logic model was created going into further detail about inputs, activities, targeted audience, and outcomes (short, intermediate, and long term). The research project objective is to assess the feasibility of the WI WLC by collecting preliminary data, examining participant feedback and outcome measures pre- and post- program. Therefore, our specific research questions are:

1. Does a clinically managed weight loss program by a multidisciplinary team of physician oversight, RD, exercise specialist, CBT or CPA lead to program compliance and achievement of more than five percent initial body weight loss in adults who are overweight or obese?

2. Does a clinically managed four-month weight loss program lead to an improvement in post measurements, such as, weight loss, waist circumference, blood pressure, cardiovascular risk and lipid profile, quality of life and sleep in adults who are overweight or obese?

To help meet these research objectives, this thesis will include the following, a review of the literature, a systematic review protocol, and a study design and results manuscript. Each chapter further outlines the evidence regarding clinically managed weight loss programs and their effectiveness to achieve goals and improvements in clinical measurements.

1.2 Methods: Data Search Strategy

Note: The search strategy for this thesis' literature review is comprised of two components: 1) summarized below in this chapter, and 2) the subsequent chapter that will be published separately as a manuscript protocol for a systematic review on the efficacy and safety of clinically managed weight loss programs.

A literature search of the databases PubMed, CINAHL, and MedLine was conducted using the following keywords: weight loss "AND" overweight "AND" stages of change "AND" multidisciplinary "OR" interdisciplinary "AND" lifestyle "AND" obesity. Studies were restricted to those published in the English language, between 1999 to 2019, those focusing on multidisciplinary teams with an interdisciplinary approach and its effects on the behavioural model associated with the study. Studies were excluded if they involved only one type of health care professional and if conducted in children (less than 18 years old). Table 2 below provides details of the studies reviewed:

Table 2. A review of clinical studies on weight-loss focusing on interventions that incorporate a multidisciplinary approach and behavioural change.

Authors	***Objectives***	***Study Design Time Frame Participants***	***Intervention Multidisciplinary Team Behaviour Model***	***Outcomes***	***Findings***	***Conclusion***
Volger et al. (2013) [11]	To examine changes in eating behaviours, physical activity, and predictors of weight loss success.	A two-year longitudinal, multi-site randomized controlled trial. 390 adults with obesity (BMI 30-50 kg/m^2); at least 2/5 metabolic syndrome; > 21 years old. 54 drop-outs (reason for drop-outs not listed in study)	*Interventions:* (1) Usual care (no intervention) (2) Brief lifestyle counselling (food, activity, and behavioural strategies) (3) Enhanced brief lifestyle counselling (food, activity, and behavioural strategies and received meal replacements or weight loss medication) *Multidisciplinary team:* MD, RD, psychologist, primary care physician, lifestyle coach *Behaviour model:* social cognitive and behavioural self-management theory	Collected at 0, 6, 24 months. Weight, BMI, eating inventory questionnaire, fruits and vegetable 19-item questionnaire, fat screener 17-item questionnaire, Paffenbarger questionnaire, changes in appetite control	The primary outcomes were weight loss, improved eating behaviours, and increase energy expenditure from moderate to vigorous physical activity. The brief lifestyle counselling group lost an average of 9.2 kg, whereas the enhanced lifestyle counselling group lost an average of 4.6 kg, and the usual care lost 1.7 kg.	Primary care-based lifestyle intervention delivered by primary care physicians with the assistance of an interdisciplinary team can result in clinically significant weight loss.

Perri et al. (2014) [15]	To evaluate the effects of three doses of behavioural lifestyle treatment in rural communities.	A two-year single-blind, multi-site randomized controlled trial. 612 adults with obesity (BMI 30-45 kg/m^2); 21-75 years old; does not have an active uncontrolled chronic condition such as hypertension, diabetes, cardiovascular, cerebrovascular, renal or hepatic disease). 120 drop-outs (due to declined, not available, diagnosed with other illness, bariatric surgery, death, joined other programs).	*Interventions:* (1) Control (2) Low dose treatment (8 weekly sessions, 8 extended sessions) (3) Moderate dose treatment (16 weekly sessions, 16 extended sessions) (4) High dose treatment (24 weekly sessions, 24 extended sessions) *Multidisciplinary team:* interventionists (apart of the Cooperative Extension Service Family and Consumer Agents) or individuals with bachelors or a master's degree in nutrition, exercise science, or psychology *Behavioural model:* N/A	Collected at 0, 6, 24 months. Attendance, weight changes, cost of treatment	Six-month changes followed a dose-response relationship for control, low, moderate, and high, respectively. High dose treatment achieved more than five percent weight loss at six months at 81 percent, where, at 24 months, 58 percent achieved more than five percent weight loss for the moderate and high treatment groups. The attendance of each group did not differ significantly by the condition. The percentage of individuals achieving > five percent weight loss at six months was 45 percent, 63 percent, 75 percent and 81 percent for the control, low, moderate, and high dose, respectively. The cost per kg of	Low-dose treatment was less effective and less cost-efficient. Moderate dose treatment was clinically meaningful weight loss and cost-effective in comparison to high dose treatment.

					weight loss per participant favoured the moderate dose.	
Forman et al. (2019) [28]	To compare the long-term effects of acceptance-based treatment and standard behavioural treatment for obesity on weight, quality of life, and depression.	A two-year longitudinal study. 190 adults who are overweight or obese (BMI 27-50 kg/m^2); 18 to 70 years old; no severe or medical chronic conditions.	*Interventions*: (1) Acceptance-based treatment (goals that align with personal values) (2) Standard behavioural treatment (based on the cognitive behaviour model) Both interventions included a balance-deficit diet and physical activity prescription. *Multidisciplinary team*: doctoral-level clinicians experienced in delivering behaviour weight loss treatments and interventionists *Behavioural model*: cognitive behaviour model	Collected at 0, 6, 12, 24, 36 months. BMI, weight, food acceptance questionnaire, beck depression inventory-II, quality of life Inventory, power of food scale, three-factor eating questionnaire	At 36 months, acceptance-based behaviour treatment was more likely to maintain at least 10 percent of weight loss than standard behavioural treatment.	Acceptance-based behavioural treatment produced more weight loss (one-year post-treatment) but this effect reduced in the years following the end of treatment.
Logue et al. (2005) [29]	To compare health benefits achieved in a trans-theoretical model-chronic disease care	A two-year randomized control trial in 15 primary care practices.	*Interventions:* (1) Augmented usual care (consisted of behavioural self-monitoring principles	Collected at 0, 6, 12, 18, 24 months.	No significant weight loss and changes in blood pressure and lipids between augmented	Adults who are overweight or obese will not lose more weight if they are exposed to the

	minimal intervention for obesity vs. augmented usual care.	665 participants with increased BMI (BMI > 27 kg/m2) or increased waist-to-hip ratio; 40 to 69 years old.	with diet and exercise prescriptions) (2) Trans-theoretical model-chronic disease care (consisted of behavioural self-monitoring principles, anxiety, depression, and stages of change assessment with diet and exercise prescription) *Multidisciplinary team:* MD, RD, weight loss advisor (monitored by a psychologist) *Behavioural model*: behavioural self-monitoring principles and transtheoretical model-stages of change	Weight, BMI, waist circumference, blood pressure, blood lipids, SF-12 subscales, scales for self-efficacy, social support and decisional balance for healthy eating and exercise	usual care and trans-theoretical model-chronic disease care.	trans-theoretical model-chronic disease care intervention vs. the augmented usual care alone.
Gagnon et al. (2011) [30]	To compare the effectiveness and cost of two lifestyle modification programs in individuals at high risk for developing type 2 diabetes.	A one-year randomized controlled trial. 48 adults with obesity (BMI > 27 kg/m^2); prediabetes	*Interventions:* (1) Individual counselling every 6 weeks with 25 group seminars (25 minutes each with diet, exercise, and behavioural modification) (2) Group seminars only *Multidisciplinary team*: RD, RN, endocrinologist	Collected at 0, 3, 6, 9, 12 months. Weight, BMI, waist circumference, body composition, six-minute walking test, accelerometer, indirect calorimetry, clinical chemistry	Participants in individual counselling lost more weight than those who attended group seminars only.	Low-cost, moderate intensity, individual interdisciplinary approach combined with group seminars lead to clinically significant weight loss and metabolic improvement in individuals with prediabetes.

			Behavioural model: N/A			
Jamar et al. (2016) [12]	To investigate the role of the type of macronutrients on health benefits associated with weight loss in treating obesity.	A 26-week randomized controlled trial. 30 adults with obesity (BMI 30-39 kg/m^2); 30 to 50 years old; women.	*Intervention:* interdisciplinary approach to lifestyle change (consisted of nutritional counselling, exercise, and psychological therapy) *Multidisciplinary team:* N/A *Behavioural model:* N/A	Collected pre- and post-. Weight, BMI, waist circumference, body composition (fat free mass, body fat mass), usual food intake (three-day food records), blood test	After therapy, significant reduction in all anthropometric measurements, body composition, consumption (while still providing adequate nutrient intake). There was a significant improvement in LDL-cholesterol.	Decreasing dietary fat consumption had greater impact on the inflammatory process on individuals with obesity, it was concluded that the type of macronutrient influences health benefits associated with weight loss.
Tapsell et al. (2017) [16]	To determine the effectiveness of a novel interdisciplinary treatment compared with usual care on weight loss in overweight and obese adults.	A one-year single-blinded community specific controlled trial. 439 adults who were overweight or obese (BMI 25-40 kg/m^2); 25 to 54 years old; generally well.	*Interventions:* (1) Usual care (general guidelines based on diet and exercise advice) (2) Intervention (interdisciplinary protocol) (3) Intervention and healthy food supplement (30 grams of walnuts per day provided at clinic visits) *Multidisciplinary team*: MD, RD, exercise physiologist, psychologists	Collected at 0, 3, 6, 9, 12 months. Primary outcome: difference in weight loss between baseline and 12 months with five percent or more lost as a clinically relevant target. Secondary outcomes: changes in blood pressure, fasting blood glucose, hemoglobin A1C,	The second group lost more than the first group at three months and the third group more than the first group at three months and six months. The proportion of achieving five percent weight loss was significantly different at three months, six months, and nine months due to fewer controls on target at six months. There were	An interdisciplinary intervention produced greater and more clinically significant weight loss compared with usual care, the intensive phase was sufficient to reach clinically relevant targets but long-term weight management plans may be required.

			Behavioural Model: acceptance and commitment therapy	blood lipids (cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides), diet, exercise, psychological well-being and body composition; diet history interviews, physical activity (using physical activity questionnaire and pedometer), psychological assessment (mental health, SF-12 depression anxiety stress scale) and acceptance and action questionnaire.	reductions in secondary outcomes followed the pattern of weight loss.	
Nilsen et al. (2011) [13]	To assess the effects of low-intensity individual lifestyle interventions by a physician and compare this to the same physician intervention with an interdisciplinary,	An 18-month multi-site randomized controlled trial. 213 adults with obesity (average BMI 36.8 kg/m^2); average 46.5 years old; no history of	*Interventions*: (1) Individual physician group every six months with individual lifestyle intervention by a physician (2) Same physician combined with interdisciplinary, group-	Collected at 0, 6, 12, 18 months. Primary outcomes: weight reduction of more than five percent initial body weight, reduction in more than five	There were no significant differences in changes in lifestyle behaviours between the two groups. Both groups improved aerobic capacity.	It is possible to achieve important lifestyle changes in those at risk for type 2 diabetes with modest clinical efforts.

	group-based approach in a real-life setting.	diabetes or serious chronic disease/psychiatric illness.	based approach in real life setting *Multidisciplinary team:* MD, RD, physiotherapist, ergonomist, RN *Behavioural Model*: motivational interviewing	centimeters waist circumference, improvement in exercise capacity of one MET, consumption of cod-liver oil more than five days a week, and a four-point increase in smart diet score.		
Livia et al. (2016) [31]	To investigate the effect of an intensive lifestyle program on medical measures and motivational profile for physical activity and healthy nutrition.	A three-month quasi-experimental study. 100 adults with overweight or obesity; average 51.49 years old; without type 2 diabetes; treatment seeking.	*Intervention:* Individualized program of 26 sessions of structured indoor exercise and nutritional counselling and eight sessions of group therapeutic education aimed at sustaining the process of lifestyle change. *Multidisciplinary team*: psychologist, RD, sports medicine specialist *Behaviour model:* transtheoretical model	Collected pre- and post-. Weight, BMI, waist circumference, body composition, systolic and diastolic blood pressure, glycaemia, hemoglobin A1C, blood lipids (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides), EMME-3 physical activity and EMME-R nutrition questionnaire	Significant decrease was found for all measures with a small effect size; only exception was for the LDL-cholesterol and triglycerides.	The assessment of motivation at the end of the three-month intensive phase should be considered important for the long-term sustainability of change.

Mazzeschi et al. (2012) [14]	To establish whether baseline mood status or health-related quality of life affects attendance to educational or exercise sessions and whether attendance to these two components of the intervention affects mood and/or health-related quality of life in obesity.	A one-year experimental study. 282 adults with overweight or obesity (BMI > 25 kg/m^2)	*Intervention:* group nutrition education, three-month supervised and structured exercise program, group psychotherapy, group education for motivation to change, group outdoor activities to reinforce lifestyle change *Multidisciplinary team:* endocrinologist, sports medicine MD or cardiologists, psychologist, RD, educators, RN, exercise physiologists, manager for outdoor leisure time activities *Behaviour model:* social cognitive and group empowerment theories	Collected at 0, 3 months. Weight, BMI, waist circumference, fat mass, blood pressure, depression, health-related quality of life.	The intervention significantly reduced BMI, fat mass, waist circumference, blood pressure, depression symptoms, and improved the scores of numerous domains of health-related quality of life.	The study demonstrates the existence of mutual interactions between depression and health-related quality of life and the exercise and educational components of a structured lifestyle intervention in obesity.

1.3 Facilities offering weight loss programs in Winnipeg

Summary and Conclusion

Based on the literature reviewed in Table 2, clinically-managed weight loss programs based on a behaviour model resulted in significant weight loss [11, 15, 16, 28, 30]. The studies outlined investigated different behavioural models, such as, social cognitive/behaviour model, motivational interviewing, self-monitoring, acceptance and commitment therapy, and behavioural self-management. Based on the 2020 CCPG, it is recommended to address the root drivers of obesity and taking a cognitive approach to behaviour change. Other than addressing psychological factors, modifying unhealthy habits is influenced by a personal motivation for change [32, 33]. As previously mentioned, the TTM is explained as a sequential behaviour change from an unhealthy behaviour to a healthy one [17], if this is what is driving positive lifestyle changes, assessing an individuals' readiness to change prior to participating in a weight loss program is crucial. Though there is evidence that suggests a multidisciplinary team with a behaviour based model results in weight loss, it is important to identify what factors are affecting the attendance of these programs, this may include whether an individual is ready to change [31].

The recommended treatment for obesity is a healthy diet, moderate physical activity, pharmacotherapy, and/or surgery with treatment dependent upon the individual's current state of health and medical history. A healthy diet and moderate physical activity are the first line treatment for individuals living with obesity. A five-percent decrease in weight loss is often sufficient to produce significant health benefits in areas such as blood pressure, blood cholesterol, and blood glucose [34]. As previously mentioned, weight loss programs are primarily focused on low-calorie diets and rarely include physical activity or medical oversight. These programs are often offered to individuals living with obesity who require surgical therapy. In Winnipeg, there are a variety of

programs that promote weight loss. Gyms such as GoodLife, Shapes Fitness Centre, YMCA-YWCA, Rady JCC Fitness Centre, and the Active Living Centre at the University of Manitoba, provide individual personal training sessions with an employee from said facility at a fixed cost. There is also nutrition and diet counselling in private practices owned by RDs as well as food service providers, such as Save-On-Foods and Sobeys, where stores offer cooking classes and grocery store tours from an RD. The Reh-Fit Centre is a fitness facility that provides similar services to the WI, such as RD counselling, personal training, massage therapy, and rehab services. WeightWatchers is based on a points system for different foods and a daily budget of points known as the SmartPoints system. The Winnipeg Regional Health Authority Metabolic and Bariatric Surgery Program offers pre- and post-bariatric surgery support which includes surgeons, nurses, RDs, psychologists, and exercise specialists. Other weight loss services include clinics based on supplements, online services (Facebook, Instagram), and support groups. With the weight loss industry overwhelmed with options, it is difficult to determine which weight loss programs are successful. This program evaluation will aid in providing results to determine whether a multidisciplinary approach which includes an RD, CCPT, CPA or CBT, and physician oversight will improve physiological outcomes and yield positive feedback. The evaluation will address different outcome measures and their association(s) with a clinically managed, personalized weight loss program.

Table 3. Logic Model for the WLC Evaluation at the WI

Logic Model for the WLC Evaluation at the WI					
	Outputs		**Outcomes**		
Inputs	**Activities**	**Audience**	**Short Term Outcomes**	**Intermediate Outcomes**	**Long Term Outcomes**
HR -2 Registered Dietitians -2 Certified Personal Trainers -1 Clinical Psychologist/ Cognitive Behavioural Therapist -1 Physician -1 Communications and Technology Associate -1 Program Manager -1 Graduate Student *Funding* -Mitacs Funding -WI Budget -Stakeholders *Equipment/Space* -WI Rehab Clinic Space -WI Assessment Area -Wellness Facility -InBody 570 -BP Monitor -Measurements (tape, scale) -Office supplies (computer, phone, charts)	-Monthly newsletter. -Monthly group classes (Psychology, Nutrition, Exercise). -Access to smartphone software (EatLove Meal Planning Tool, WellnessFit). -Three phases (start-up, intensive, transformation) designed to counsel and educate participants about healthy eating and exercise. -Evaluation study. -Advertisements on social media and company website. -Provides personalized meal and exercise plans.	-Adults concerned with their weight and may have other health problems such as diabetes and high blood pressure. -Adults with BMI $\geq$ 25 kg/m^2	<u>Participant Outcomes</u> 1. Gain awareness, knowledge and skills related to healthier eating and lifestyle habits. 2. Gain awareness, knowledge and skills related to health benefits of physical activity.	<u>Participant Outcomes</u> 1. Increased self-confidence related to healthier lifestyle choices. 2. Increased amount of time spent in physical activity. 3. Decreased body fat percentage, improve lean body mass and gain muscular strength. 4. Decreased weight and waist circumference, and improved blood pressure and heart rate. <u>Program Outcomes</u> 5. Forming strategic partnerships with companies providing meal preparation and delivery. 6. Product extensions with meal replacements.	<u>Participant Outcomes</u> 1. Decreased risk factors for chronic disease. 2. Live a longer, healthier life. 3. Sustainable weight loss <u>Program Outcomes</u> 4. Work with provincial and federal government for future research regarding nutrition, weight loss and lifestyle approaches to chronic disease. 5. Build a technology platform for the program. 6. Expand across Canada and to China.

Bridge to Chapter II

The previous chapter presents the gap in behaviour-based clinically-managed weight loss programs with a multidisciplinary team. The following chapter is comprised of a manuscript protocol for a systematic review on the efficacy and safety of clinically managed weight loss programs. The systematic review protocol outlines the systematic review. It will be published separately, but not in time to be a part of this thesis document. The authors are Katrina P. Cachero, Matthew Granger, Dylan S. MacKay, Rebecca C. Mollard, Nicole Askin, George N. Okoli, and Ahmed M. Abou-Setta. The principal authors are responsible for selecting, extracting and analyzing the articles and results for the systematic review.

Chapter II

Manuscript 1

Efficacy and safety of clinically managed weight loss programs: A systematic review protocol

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2.1 Abstract

Background: Obesity has become a major driver in the burden of chronic diseases. The Canadian Clinical Practice Guidelines recommend a lifestyle intervention for the management and prevention of obesity. This includes behaviour modification, dietary counselling, and physical activity. With the market overwhelmed with weight loss programs, the majority are focused on low-calorie diets and general recommendations for exercise. Most are not personalized and are not administered by health care professionals. An interdisciplinary team of highly trained health care professionals have the ability to provide medically sound and safe advice in all aspects of an individuals' life, such as, lifestyle, sleep, mental health, and behaviours. A clinically-managed weight loss program is defined as a team including a dietitian, and/or exercise professional, and/or psychologist, and/or physician or nurse practitioner oversight. With limiting results in the literature regarding clinically-managed weight loss programs, it is difficult to conclude whether it may be effective. Therefore, the objective of this systematic review is to assess clinically-managed weight loss programs, with a physician or nurse practitioner oversight in comparison to non-clinically-managed weight loss programs with no physician oversight or nurse practitioner oversight in adults who are overweight or obese. **Methods:** A literature search will be executed by a knowledge synthesis librarian on MEDLINE, Cochrane Central, Embase, PsycINFO, and CINAHL. The data collected will be extracted, stored, and managed in MS Excel 2016. The extraction of the data will include study details, study population details, health team details, intervention details, and outcome details. **Discussion:** The prevalence of obesity has been increasing throughout the decades. Results from this systematic review may aid in recommending a more clinically safe weight loss program for those who struggle with overweight or obesity. **PROSPERO ID:** 170014.

Keywords: obesity, weight loss program, dietitian, exercise, psychology, physician, nurse practitioner

2.2 Background

The prevalence of adults living with overweight or obesity has been increasing throughout the past three decades with almost two-thirds of Canadian adults being classified as overweight or obese according to body mass index [34, 35]. This increasing prevalence is believed to be a major driver in the burden of chronic diseases [37]. The World Health Organization defines overweight and obesity as abnormal or excessive fat accumulation that may impair health [38]. There are different ways to measure overweight or obesity with the most common measurement being Body Mass Index (BMI). Individuals with a BMI over 25 are classified as overweight and those over 30 are classified with obesity. The current Canadian Clinical Practice Guidelines (CCPG) on the management and prevention of obesity in adults recommends a comprehensive lifestyle intervention including behavior modification, dietary counselling and physical activity as the first line treatment option to achieve clinically significant weight loss [39]. Weight reduction is well documented to improve cardiovascular risk factors (such as blood pressure, low-density lipoprotein-cholesterol, and triglycerides) and blood glucose metabolism in individuals who are living with overweight or with obesity [38, 39].

Weight loss programs are primarily focused on low-calorie diets and rarely includes medical oversight. Weight loss programs such as, Weight Watchers, Jenny Craig, or Nutrisystems have a nutrition, physical activity, and behavioural strategies component but are not personalized to the individual or do not have healthcare oversight to ensure better health and safety and long-term support for success [41]. Based on the 2006 CCPG, a weight management program should involve a nutrition health professional, an exercise professional, and a clinical psychologist [39]. With this type of interdisciplinary team, all aspects of an individuals' life are considered (i.e. lifestyle, sleep, mental health, behaviours). A weight loss program which is directed by a dietitian, and/or exercise

professional, and/or psychologist, with physician or nurse practitioner oversight, is considered a clinically managed weight loss program. Clinicians are able to actively monitor a participant's health and potentially adjust medications throughout the weight loss program. A study by Tapsell et al. [20] found that an interdisciplinary intervention with physician oversight produced greater and more clinically significant weight loss. Additionally, interdisciplinary weight loss programs have shown improvement in areas other than weight, such as eating behaviours, lipid profiles, aerobic capacity, and overall quality of life [8,9,10].

The consumer marketplace is overwhelmed with weight loss programs; with the majority being focused on calorie-reduced diets [41]. Not all of these programs include exercise, most do not include physician oversight, and may not be customizable. Clinician-oversight may provide additional benefits because clinicians are highly trained professionals who can prescribe or adjust medications and provide medically sound and safe advice. However, some potential drawbacks of physician oversight to a weight loss program's success may include the added expense, participant stress or feelings of judgement, and with the increased number of health care professional involvement, there may be hierarchy conflict.

With varying results in the literature, it is difficult to conclude whether clinician oversight in weight loss programs is more effective or not. Therefore, the objective of this systematic review is to assess the efficacy of clinically-managed weight loss programs, with a physician or nurse practitioner oversight, in comparison to non-clinically-managed weight loss programs with no physician or nurse practitioner oversight in adults who are overweight or with obesity.

2.3 Research Question

Do weight loss programs in adults who are living with overweight or obesity directed by dietitians, and/or exercise professionals, and/or psychologists, with physician or nurse practitioner oversight, lead to greater program success compared to similar programs without physicians or nurse practitioners?

2.4 Methods

Study selection

A literature search strategy for MEDLINE will be designed by a knowledge synthesis librarian and peer reviewed by a second, independent librarian using the PRESS checklist [43]. The peer-reviewed search strategy will then be adapted for other bibliographic databases (Cochrane Central, Embase, PsycINFO and CINAHL) and executed by a knowledge synthesis librarian. Identified citations from the executed searches will be screened for eligibility by two independent systematic reviewers on Rayyan (Rayyan, Doha, Qatar) [44]. The number of ineligible citations at the title/abstract screening stage will be recorded, and both the number and reason for ineligibility will be recorded at the full-text article screening stage. Any disagreements during these screening stages will be resolved by discussion between the two systematic reviewers with a third reviewer to adjudicate, if necessary.

Eligibility criteria

The following studies will be included:

1. Population: overweight or with obesity (BMI $\geq$ 25 kg/m^2) adults (18 – 65 years of age) from North America, Europe, Australia, and New Zealand ($\geq$80% of trial population)
2. Intervention: clinically-managed weight loss programs with physician or nurse practitioner oversight
3. Comparator: weight loss programs with no physician or nurse practitioner oversight
4. Outcomes:
    - Primary; body weight
    - Secondary: BMI, waist circumference, body fat percentage, lipid profile, blood pressure, adherence to the program, withdrawal from the program, quality of life,
    - Safety: any reported adverse events
5. Study design: randomized controlled trials (parallel or cluster-design). For cross-over trials, we will use the data before the cross-over.
6. Publications from the year 1990 to date of search
7. Full-text manuscript in English language (for feasibility)

Data extraction

We will utilize data extraction forms developed in MS Excel 2016 (Microsoft Corporation, Redmond, WA, USA)[45] and piloted on a small selection of studies for quality assurance. Extracted data will be stored and managed in MS Excel. Two systematic reviewers will independently extract data from included studies. Any disagreements will be resolved by discussion between the two reviewers, and a third reviewer will adjudicate if necessary. The following data will be extracted from included studies:

Study details: name of first author, year study was conducted, year of publication, country, setting, population demography, study size, and funding source

Study population details: type of population (for example, adults), age, sex distribution, health and socioeconomic status

Health team details: profession

Intervention details: name, type, method of intervention, measure (amount/extent), duration, contact hours

Outcome details: (See above) Data will be extracted at the end of the trial and at the longest reported follow-up.

Assessment of risk of bias

We will assess risk of bias using the Cochrane Risk of Bias Tool 2.0 [46]. This tool assigns a judgment of high, some concerns, and low risk of bias for each of the following domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. Any disagreements will be resolved by discussion between the two reviewers or by involving a third reviewer if necessary.

Data analysis

We will conduct a meta-analysis where feasible, using a random effects model implemented in RevMan (Version 5.3.5) [47]. We will express pooled continuous data as mean differences or as standardized mean differences where measures of the same outcome are with different scales, presenting the 95% confidence intervals. Pooled dichotomous data will be presented as a risk ratio, or for rare outcomes using the Peto-Odds Ratio. We will assess and quantify statistical heterogeneity between included studies using the I-squared statistic (I^2). We will assess for publication bias visually using funnel plots of effect size versus sample size for each included study and using Egger's regression test.

Then following a priori subgroup and sensitivity analyses are proposed depending on the number of studies included and the availability of data: differences between low risk of bias and some concerns/high risk of bias studies, intervention types, clinician type, population type, participant sex, comorbidity status, and geographical location (for example, continent).

Study Outcome Dissemination

In addition to a peer-reviewed academic publication, we will present our findings at appropriate academic meetings.

2.5 Declarations

Ethics Approval and Consent to Participate

Not applicable.

Consent for Publication

Not applicable.

Availability of Data and Materials

No datasets have been generated related to this published article.

Competing Interests

KC was funded by a Mitacs Accelerate Fellowship. Mitacs is partnered with the Chronic Disease Innovation Centre (CDIC); which is a not-for-profit Canadian corporation. Both CDIC and Wellness Institute (WI) are located within Seven Oaks General Hospital (SOGH), the WI offers clinically managed weight loss programs with physician oversight.

Funding

This systematic review is funded by the Mitacs Accelerate Fellowship partnered with CDIC, which is the research arm of the WI and SOGH.

Authors' Contributions

Each author made substantial contributions to the creation of this paper. All authors have read and approved the final manuscript.

Acknowledgments

Not applicable.

Bridge to Chapter III

The following chapter comprises a manuscript for the evaluation, including the study and program design, and evaluation results. The authors are Katrina P. Cachero and Dylan S. MacKay with co-authors, Rebecca Mollard and Semone Myrie. The principal author collected and analyzed data for the evaluation.

Chapter III

Study Manuscript

Results of a pilot study evaluating the clinically managed weight loss program at the Wellness Institute at Seven Oaks General Hospital

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3.1 Abstract

Background: Obesity is a worldwide problem, with over 650 million adults living with obesity today. With the prevalence of obesity increasing, many weight-loss programs have been created to aid in the epidemic. Based on the Canadian Clinical Practice Guidelines for obesity management, a weight loss program should involve nutrition, exercise, and psychological components. The Wellness Institute at Seven Oaks General Hospital (WI-SOGH), a non-profit organization that operates as a medical fitness facility, created the Weight Loss Clinic (WLC). The WLC aims to provide personalized support for individuals based on diet, exercise, and behaviour changes with a multidisciplinary team and medical oversight, targeting all the core components required for a weight loss program. The objective of this study was to evaluate the feasibility and collect preliminary data from the clinically-managed weight loss program at WI-SOGH. **Methods:** Participants were recruited from January to December 2019. The WLC is a 17-week program with three evolving stages (assessment, intensive, transformation). Outcome measures were collected pre- and post- program, such as weight, waist circumference, blood pressure, lipid profile, sleep quality, self-efficacy, and quality of life. The data was analyzed from December 2019 to April 2020 through R Studio. **Results:** A total of 26 participants (13 completed, 13 incomplete) were included in the evaluation. They were predominantly female aged 50.53 (10.4) years old. Participants who completed the program lost an average of 7.51 kg ($p=0.0009$), whereas those who did not complete the program lost an average of 1.50 kg ($p=0.1365$). As well, completed participants showed improvements in waist circumference ($p=0.0002$), systolic blood pressure ($p=0.0052$), diastolic blood pressure ($p=0.0057$), and body fat percentage ($p=0.0001$). Self-efficacy, sleep quality, and areas of quality of life remained unchanged. **Conclusion:** Participating in the program resulted in significant weight loss and participants were satisfied with the program with 100% of completed participants willing to recommend the program to a friend or family member and 80% of completed participants gained valuable lifestyle changes.

Keywords: obesity, weight loss program, dietitian, exercise, psychology, physician

3.2 Background

Almost two-thirds of Canadian adults are overweight or obese [35], which stresses the health system via increased risk for chronic diseases [39], including type 2 diabetes and cardiovascular diseases. Weight reduction is well documented to improve cardiovascular disease risk factors such as high blood pressure, low-density-lipoprotein (LDL)-cholesterol, and triglycerides [48] and is associated with reduced all-cause mortality in individuals living with overweight or obesity [49]. The 2020 CCPG for obesity management recommend the following interventions for adults living with obesity, individualized care plans that address the root causes of obesity and provide support for behaviour change such as, diet and lifestyle intervention, psychological intervention, pharmacotherapy, or bariatric surgery [9, 38]. There are many weight loss programs, with the majority focused on calorie-reduced diets and exclude exercise and/or medical oversight [41]. Many available programs focus on bariatric surgery, thus catering more to individuals who are morbidly obese, rather than those who are overweight or obese (body mass index; BMI < 40kg/m^2) [50]. However, given that annual direct health care costs to treat obesity in Canada were seven billion in 2011, and projected to increase to 8.8 billion by 2021 [35], more proactive weight loss programs should be offered. In Canada, a few provinces have clinically-managed weight loss programs that focus on surgical therapy. Obesity is complex and is influenced by physiological, genetic, societal, environmental, and emotional factors, therefore the WI at SOGH created a non-surgical personalized program based on a lifestyle approach targeted at individuals living with overweight or obesity. This program, known as the Weight Loss Clinic (WLC), focuses on body weight reduction in combination with improvement in cardiometabolic risk factors. The WLC represents the first of its kind offered to adults living with overweight or obesity in Manitoba, shifting focus to earlier intervention and prevention of obesity-related morbidities. Weight loss is

a billion-dollar industry in North America dominated by non-evidence-based programming and products. There is a gap in evidence-based, professionally delivered clinical weight loss services in Manitoba. Therefore, the objective of this study was to evaluate the feasibility and collect preliminary data from the clinically-managed weight loss program at WI at SOGH.

3.3 Materials and Methods

3.3.1 Study Population and Design

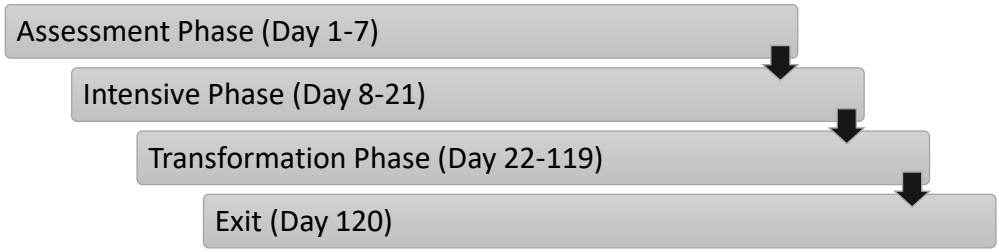
This study evaluated an established weight loss program. The inclusion criteria for the weight loss program were individuals over the age of 18, BMI $\geq$ 25kg/m^2, and have been told by a physician or primary care provider to lose weight, who were concerned with weight and may have other health problems (such as diabetes or high blood pressure), and have had multiple unsuccessful attempts at maintaining weight loss. The exclusion criteria included women who report that they are pregnant or lactating. The participants for the evaluation were recruited from the individuals enrolled in the weight loss program, all potential participants who entered the program were approached to learn about the evaluation. The WLC is located in the WI at SOGH in Winnipeg, Manitoba, Canada. The data was collected at the Chronic Disease Innovation Centre, which is the research arm of WI and SOGH.

Evaluation Study Design

The WLC is comprised of a team of professionals, including a program manager, physician, RD, CCPT, and a psychologist or CBT, who collaborated to prescribe a plan best suited for the

participants' needs. Since the weight loss program is based on sustainable lifestyle changes, all aspects of an individuals' life were considered (i.e., lifestyle, sleep, mental health, behaviours). The program evolved in a 3-stage wise progression, shown in Figure 1 below. The aim of the first week of the program was to get to know the participants, what they are looking to achieve, and assessing their stage of readiness to change. The first stage is the assessment phase where each discipline will have the opportunity to assess the participant based on their area of expertise. The second stage is the intensive phase, this is where the participants receive a nutrition prescription based on the RD's assessment, this may include a meal plan or nutrition goals. The RD uses information gathered from the three-factor questionnaire, mindful eating questionnaire, and three-day food recall filled out at the initial assessment and a one-on-one appointment to further guide the assessment. In terms of exercise, the CCPT used information from the initial assessment questionnaire to guide and provide a personalized exercise prescription. Psychological intervention may be replaced with nutrition intervention at this stage if the participant screens for severe depression, anxiety, disordered eating or present with any psychosocial concerns. The third stage, the transformation phase, which is the remaining 15 weeks in the program included sessions with the RD and CCPT. The nutrition and exercise prescription may be modified depending on lifestyle changes and/or progress that the participant has made.

Figure 1. Weight loss program design



Weight Loss Program Design

The expected duration of participation was four to six months. Since the program was personalized, there was no fixed end date for the participants. The weight loss program is a 17-week program (not including the maintenance phase) during which each participant advances depending upon their personal goals and progress. The assessment phase is from day one to seven, this phase consists of the program intake, a nutrition assessment with the RD, and a psychological assessment with the psychologist or CBT. The next phase is the intensive phase, which is composed of a two-week meal plan along with an exercise prescription given at the end by the CCPT. The team of coaches collaborate to prescribe a care plan best suited for the participants' needs. The transformation phase consists of bimonthly counselling sessions with the RD and CCPT. On day 120, participants attended an exit appointment where outcome measures were collected. After 17-weeks in the program, the participants are given the following options, continuing in the transformation phase, entering the maintenance phase, or exiting the program. During the maintenance phase, the participants have two meetings per month with the RD and CCPT. This phase aids in the progression from previous weeks to the maintenance phase by making the habits participants learned their new normal, learning how to develop their own meal and exercise plans, and supporting them in different ways to sustain these changes. For the purposes of this evaluation and due to the project time frame, the maintenance phase was not included.

Ethics Approval

This evaluation received approval from the University of Manitoba Health Research Ethics Board (Ethics # HS22267 (H2018:401)).

3.3.2 Outcome Measures

Outcomes

The primary outcomes included program compliance and achievement of more than five-percent initial body weight loss. Program compliance was measured by the number of days attended and intervention adherence, if a participant attended more than 96 days of the program, they were considered compliant. The percentage of weight lost was calculated using the difference in weight at baseline and exit, multiplied by 100 and divided by the weight at baseline. The secondary outcomes included changes in weight, BMI, waist circumference, body fat percentage, blood pressure, heart rate, lipid profile, hemoglobin A1C, general self-efficacy, sleep quality, and quality of life. Anthropometric measurements and blood pressure were collected by the CCPT during the program intake. Lipid profile, including total cholesterol (TC), high-density lipoprotein (HDL) cholesterol, LDL cholesterol, triglycerides, and TC/HDL ratio, and hemoglobin A1C were collected and analysed by Diagnostic Services of Manitoba. Self-efficacy was measured using the general self-efficacy scale, which included questions that assessed behaviour-specific self-efficacy, social-cognitive constructs, well-being, health behaviours, and coping strategies [51]. Sleep quality was assessed using the Pittsburgh sleep quality index (PSQI) questionnaire, this questionnaire measured the quality and pattern of sleep in adults and includes seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping meds, and daytime dysfunction [52]. Quality of life was assessed by the SF-36 quality of life questionnaire which measures nine areas: physical functioning, role functioning (emotional), role functioning (physical), energy/fatigue, emotional well-being, social functioning,

pain, general health, and health change [53]. To evaluate the effectiveness, outcome and feasibility measures were collected. Measurements were taken prior to starting the program and at four months after enrollment in the program. For those who did not complete the program, all measures up until the participant exit were collected. Due to the personalized nature of the weight loss goals in this program, the percentage of participants meeting their weight loss goals within the timeline were considered in the evaluation of the program's effectiveness. The outcome measures are listed below.

Anthropometric Measurements and Body Composition. Anthropometric measurements, such as height and weight were measured using a weighing scale stadiometer. Waist circumference was measured three times with the average reported. Body fat percentage was measured using the InBody 570 (InBody USA, 13850 Cerritos Corporate Drive Cerritos, California, USA), a non-invasive 45 second test where the participant stands on a device and holds the hand electrodes [54]. The InBody 570 uses bioelectric impedance analysis (BIA) technology where safe low-level currents are sent through the participant's body through the hand and foot electrodes [7]. Instructions were given to the participant prior to attending the appointment, such as, no eating or drinking three to four hours before (water is permitted), along with no alcohol or caffeine consumption 12 hours prior, and no excessive physical activity 24 hours prior with more information listed on the WI website [55].

Cardiovascular Assessment. An oscillometric blood pressure monitor (Stevens Medical, 425 Railside Drive, Brampton, Ontario, Canada) was used to collect the systolic and diastolic blood pressure and heart rate [56]. The blood pressure was placed on the participant's non-dominant arm and taken three times in three-minute intervals. An average was collected during time of assessment. A cardiovascular risk assessment, such as the Framingham Risk Scale, based

on age, HDL levels, total cholesterol levels, systolic blood pressure, smoking status, and diabetes status was reviewed to determine the participant's 10-year risk of cardiovascular disease [57].

Clinical Chemistry. The following clinical data were collected: total cholesterol, HDL, LDL, triglycerides, total cholesterol/HDL ratio, and hemoglobin A1C. The lipid profile and hemoglobin A1C blood sample were collected and processed by a commercial lab, Diagnostic Services of Manitoba. The results for the clinical data were collected on eChart, which is an electronic database used to access key patient health information [58].

Behaviour Change and Health Screening Questionnaires. The following questionnaires were administered to the participant: stages of change questionnaire, general self-efficacy scale, and the WI health screening questionnaire. The Stages of Change questionnaire (also known as, S-weight) contains five mutually exclusive responses corresponding to the five stages of change: pre-contemplation; contemplation; preparation; action; and maintenance [59]. The general self-efficacy scale is a list of ten questions that assess behaviour-specific self-efficacy, social-cognitive constructs, well-being, health behaviours, and coping strategies [51]. In addition, to identify mild to severe depression and anxiety, respectively, the following are administered: Beck's Depression Inventory and Beck Anxiety Inventory [60]. Information, such as health and medical history, reason for joining, occupation, lifestyle and leisure, sleep patterns, energy levels, goal weight, previous attempts, weight gain triggers, stress levels, and overall wellness goals were obtained from the participant via the initial assessment questionnaire created by the WLC team. The program evaluation included the SF-36 quality of life questionnaire and the Pittsburgh sleep quality index questionnaire. The SF-36 quality of life questionnaire measures nine areas: physical functioning, role functioning (emotional), role functioning (physical), energy/fatigue, emotional well-being, social functioning, pain, general health, and health change [53]. The Pittsburgh sleep

quality index questionnaire measures the quality and pattern of sleep in adults, and includes seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping meds, and daytime dysfunction [52].

3.3.3 Statistical Analysis

Statistical analysis was performed using R Studio (R Studio, Boston, MA, USA) [61]. The effects of participation in the weight loss program on the captured outcomes were analysed by the R generalized linear model (GLM) function using a pre- post- design. The primary outcomes and other binary outcomes, such as personal goal weight (if achieved a loss of over 5% initial body weight) and program compliance were measured by logistic regression. Secondary outcomes, such as changes in body weight, waist circumference, blood pressure, clinical chemistry, quality of life, and sleep were analysed through a paired t-test. Factors such as sex, baseline BMI, and age were included in the model as fixed factors or covariates. Feasibility outcomes were also measured, such as attendance, intervention adherence, and participant feedback.

3.4 Study Results

A total of 26 participants were included in the evaluation; 13 did not complete and 13 completed and were included at the time of analysis in December 2019 to April 2020. The participants were recruited from January 2019 to December 2019. Table 1 provides further detail on the reasons why participants did not complete the program.

Figure 2. Participant flow diagram from recruitment of participants to analysis of data

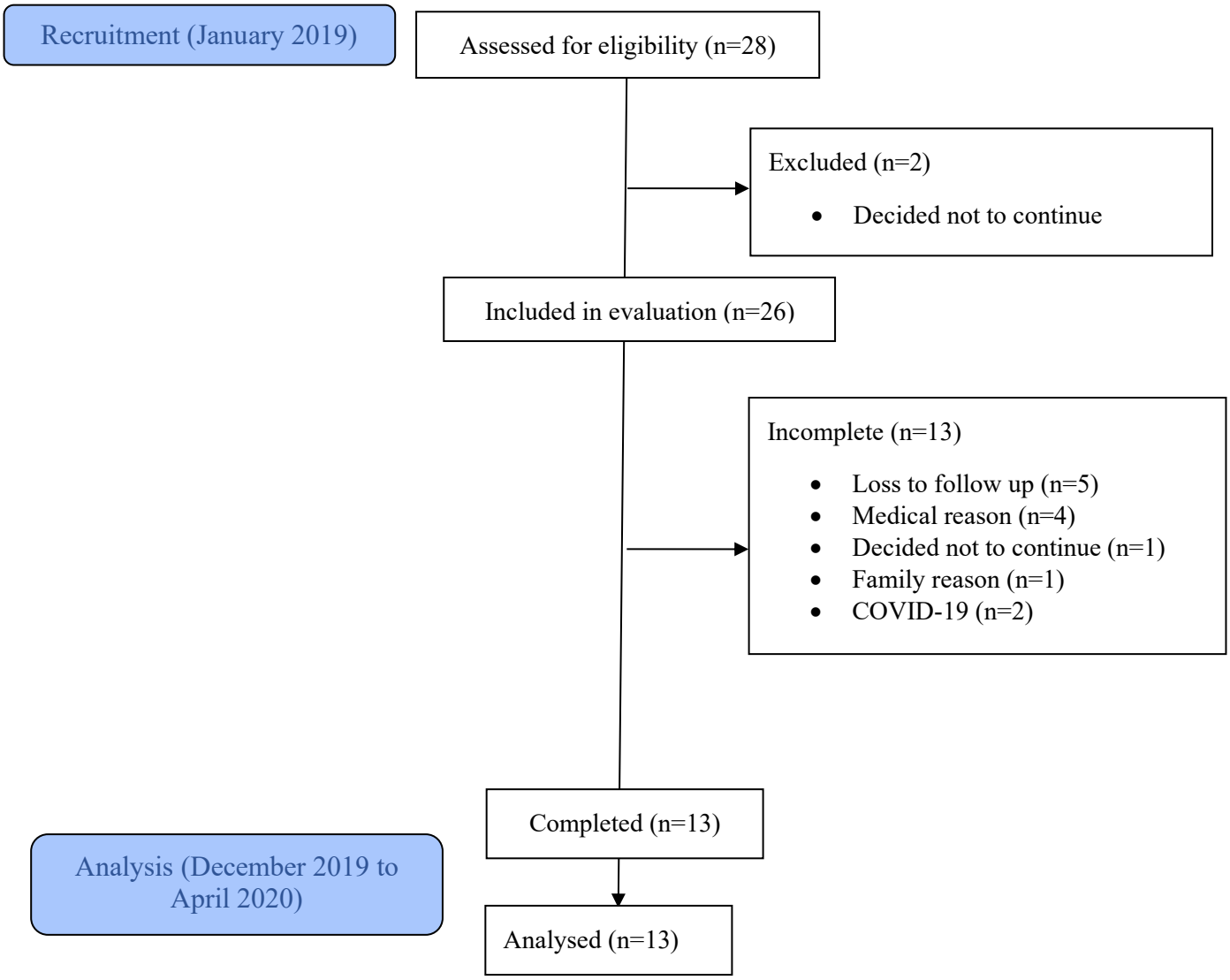


Table 1. Participant reasons for not completing the program and duration of days in the program.

Participant ID	Duration in Program (days)	Reason for incompletion
005	0	Decided not to continue (excluded from sample size)
006	59	Family reason
007	59	Medical reason
008	89	Loss to follow up (no reason given)
009	90	Loss to follow up (no reason given)
013	0	Decided not to continue (excluded from sample size)
014	16	Loss to follow up (no reason given)
015	90	Loss to follow up (no reason given)
016	31	Medical reason
019	45	Decided not to continue (no reason given)
022	164	Medical reason (no reason given)
024	155	COVID-19
026	63	Medical reason (no reason given)
027	119	COVID-19
028	87	Loss to follow up (no reason given)

There were many reasons for the incompletion of the program, such as, medical reasons, family reasons, deciding not to continue, and loss to follow up. Medical reasons included physical injury, a visit to the emergency room, and withdrawal due to eating disorder behaviours. On day zero, two participants decided not to continue with the study, baseline data was not collected and therefore they were not included in the total sample size. Family reason included a bereavement. For those set to complete the program in March 2020, Manitoba's first lockdown due to COVID-19 was implemented which caused immediate closure of all public places, including medical fitness facilities such as the WI, this gave participants the choice to continue with the program virtually

or to go on hold. Due to COVID-19, two participants decided to put their program on hold at this time, thus, are in the non-completed category.

Baseline Data

Table 2. Participant characteristics at baseline.

Parameter	**n**	**Baseline Mean (SD)**	**Ideal Range for Parameters**
Age (Years)	26	50.53 (10.4)	
Sex (% Females)	26	84.6%	
Weight (kg)	25	112.92 (30.76)	
BMI (kg/m^2)	25	39.99 (7.47)	
Waist circumference (cm)	25	123.96 (19.22)	<88 cm (F)[8] <102 cm (M)[8]
Systolic Blood Pressure (mmHg)	26	127.69 (13.12)	<130 mmHg[62]
Diastolic Blood Pressure (mmHg)	26	80.86 (7.34)	<85 mmHg[62]
Heart rate (beats per minute)	26	72.97 (10.08)	60-80 beats per min[63]
Total Blood Cholesterol (TC) (mmol/L)	26	4.86 (1.07)	<5.2mmol/L[64]
HDL Cholesterol (mmol/L)	26	1.25 (0.35)	>1.3 mmol/L (F) [64] >1.0 mmol/L (M) [64]
LDL Cholesterol (mmol/L)	26	2.80 (0.86)	<3.5 mmol/L[64]
TC/HDL cholesterol ratio	25	3.98 (1.35)	<4 (F)[65] <5.2 (M) [65]
Triglycerides (mmol/L)	26	1.81 (0.99)	≤1.7 mmol/L[64]
Hemoglobin A1C (%)	25	5.80 (0.56)	4-6%[66]
Body Fat Percentage (%)	26	48.85 (5.14)	18-28% (F)[67] 10-20% (M)[67]

For baseline data, participants were approximately 50 years old, with the majority of the program intake female. Cardiovascular measures, such as blood pressure, and lipid profile are within range, this could be partly due to most participants being on medication for their reported chronic health condition. As expected, weight, BMI and body fat percentage are higher than the ideal range. Participants filled out an initial assessment questionnaire at the start of the program which provided information on current and past health conditions, current medications/supplements, and goal weights. The most common self-reported health condition(s) were high blood pressure (38.4%), type 2 diabetes (15%) and low thyroid (19%). For participants who reported high blood pressure, 70% of them were on medication. For participants with diabetes, 75% of them were on medication and all participants with low thyroid were on medication. At baseline, participants also filled out questionnaires such as the general self-efficacy scale, Pittsburgh sleep quality index, and SF-36 quality of life with baseline data shown below in Table 6. In Table 3, participant stages of change are collected at baseline. With a total of 24 participants collected, most participants were in the preparation/action stage indicating that they were either getting ready to make a change or they were already implementing the change. There were very few were in the maintenance stage.

Table 3. Participant stages of change at baseline.

Stages of Change	n	Description
Precontemplation	0	Not ready to make a change
Contemplation	0	Just beginning to think about change
Preparation	10	Getting ready to make a change, engaging in planning and commitment
Action	9	Making the change, implementing the plan, taking action
Maintenance	5	Sustaining behaviour change until it is incorporated into lifestyle, maintaining, integrating
Relapse	0	At times slipping back to previous behaviour
Total	24	

Primary Outcomes

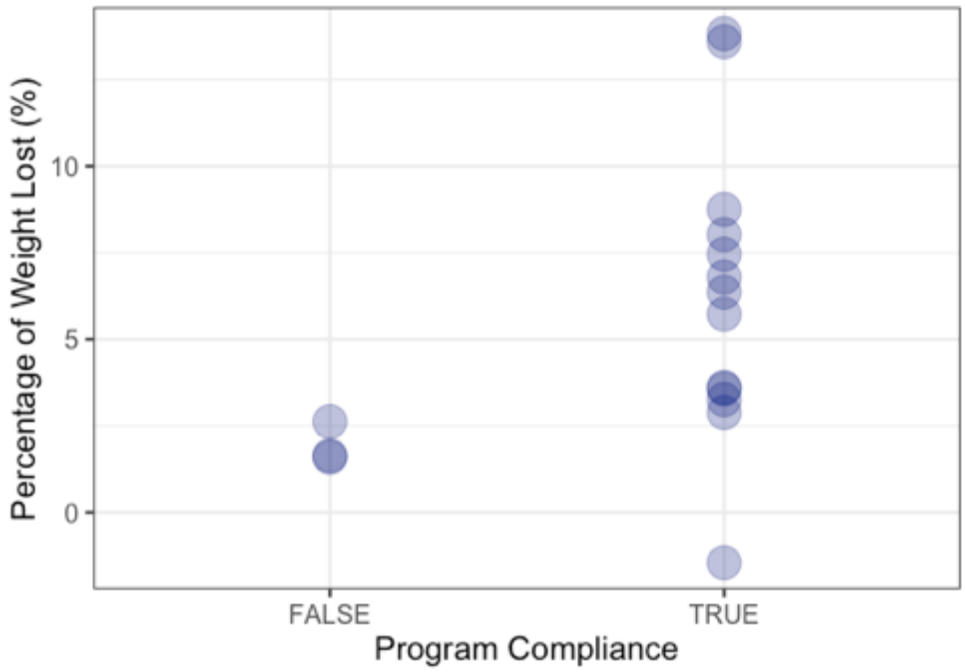


Figure 3. Program compliance versus percentage weight loss for participants who have completed the program (n=13).

Figure 3 outlines the participants' program compliance and percentage of weight lost for those who have completed the program. The primary outcomes were program compliance and achievement of more than five-percent initial body weight loss. Out of 26 participants, 13 were considered compliant. Out of the 13, eight participants lost more than five percent of their initial body weight. For personal weight goals, the target weight loss was 33.14 (16.37) kg for completers and 36.01 (19.17) kg for non-completers. In terms of personal goal weights, the average goal weight was 78.4 (18.56) kg.

Secondary Outcomes

The secondary outcomes include changes in weight, BMI, waist circumference, blood pressure, heart rate, lipid profile, hemoglobin A1C, general self-efficacy, sleep quality, and quality of life. Participants were expected to take part in the program for 17-weeks. The duration of the program varied between each participant as each of them progressed according to their goals and compliance with the program.

Table 4. The mean differences (baseline and exit) and p-values of weight and BMI for all participants.

Parameters	**n**	**Mean Difference (SD)**	*p-value*
Weight (kg)	24	-4.75 (5.81)	0.00055
BMI (kg/m^2)	24	-2.66 (2.01)	0.00076

Table 5. The mean differences (baseline and exit) for the participants who have completed the program. The mean age is 51.5 (0.97) years and includes eleven-females and two-males.

Parameters	**n**	**Exit n=13** **Mean Difference (SD)**	*p-value*
Weight (kg)	13	-7.51 (6.24)	0.0009
BMI (kg/m^2)	13	-2.66 (2.01)	0.0008
Waist circumference (cm)	13	-6.54 (4.49)	0.0002
Systolic Blood Pressure (mmHg)	13	-9.33 (9.87)	0.0052
Diastolic Blood Pressure (mmHg)	13	-5.51 (5.93)	0.0057
Heart rate (beats per minute)	13	3.79 (9.09)	0.1585
TC (mmol/L)	12	-0.04 (0.61)	0.8285
HDL Cholesterol (mmol/L)	12	0.034 (0.09)	0.2261
LDL Cholesterol (mmol/L)	12	-0.098 (0.35)	0.3533
TC/HDL ratio	12	-0.240 (0.69)	0.2485
Triglycerides (mmol/L)	12	0.004 (0.59)	0.9812
Hemoglobin A1C	12	-0.13 (0.20)	0.04262
Body Fat Percentage (%)	13	-2.44 (2.13)	0.0001

For weight data, the last weight taken was collected for each participant, with a total of 24 participants, as per Table 4, this shows that the weight lost within four months was significant at -4.75 kg (p=0.00055), where Table 5 shows us the mean differences for completers. Table 5 shows that there was a mean weight loss of 7.51 kg, along with a significant decrease of 2.66 in BMI and a two-percent decrease in body fat percentage in those that completed the program. Completed participants lost an average of 6.54 cm in waist circumference. Additionally, both systolic and diastolic blood pressure and hemoglobin A1C were reduced, whereas the lipid profile remained unchanged in completers. For those that did not complete the program, the last known weight was collected (n=11), showing a 1.50 (3.07) reduction in weight (p=0.1365).

Table 6. Participant questionnaire data at baseline and exit.

Questionnaire	Baseline				Exit		
	Completers		*Non-completers*		*Completers*		Ideal Range for Questionnaires
	n	Baseline Mean (SD)	n	Baseline Mean (SD)	Mean Differences (SD)	*p-value*	
General self-efficacy scale	12	29.46 (6.58)	11	30.73 (3.10)	-0.57 (4.76)	0.6699	35-40[33]
Pittsburgh sleep quality index score	11	7.836 (5.00)	9	8.33 (4.27)	-1.09 (2.84)	0.2322	<5[68]
SF-36 physical functioning	9	71.11 (14.95)	5	71.00 (14.74)	+8.33 (11.46)	0.0607	85.4-86.2* [69]
SF-36 role limitations due to physical health	9	61.11 (46.95)	5	60.00 (28.5)	+30.55 (41.04)	0.0560	81.5-82.8* [69]
SF-36 role limitations due to emotional problems	9	51.84 (47.47)	5	66.66 (33.35)	+14.82 (44.44)	0.3463	83.3-84.6* [69]
SF-36 energy/fatigue	9	46.11 (17.64)	5	36.00 (2.24)	+10.55 (22.56)	0.1981	65.4-66.1* [69]
SF-36 emotional well-being	9	67.11 (15.07)	5	68.8 (11.80)	+6.67 (11.49)	0.1199	77.2-77.8* [69]
SF-36 social functioning	9	82.00 (17.82)	5	87.5 (15.31)	-5.83 (10.40)	0.1310	85.8-86.6* [69]
SF-36 pain	9	69.00 (14.99)	5	70.00 (9.01)	-0.055 (23.65)	0.9945	75.1-76.0* [69]
SF-36 general health	9	50.00 (24.11)	5	57.00 (19.23)	+18.33 (17.32)	0.0131	76.6-77.3* [69]

*Based on standardized scores for Canadians [15]

As we see above in Table 6, the completers' baseline had a mean self-efficacy rating of 29 whereas, the non-completers baseline was 30. With the ideal range of 35-40, this indicates lower self-efficacy for those entering the program. As for baseline sleep quality, participants scored 7.84 (5.00) and 8.33 (4.27), indicating poor sleep quality for those entering the program. In terms of quality of life, which was measured in eight different categories. At baseline, all participants had lower physical and emotional functioning (e.g., running, lifting heavy objects, moving a table, climbing one flight of stairs, etc.), lower limitations due to physical and emotional health (e.g., cut down the amount of time spent on work or other activities, accomplished less than they would like), low energy/fatigue, low emotional well-being, fair social functioning, moderate pain, and low general health. Since the program is based on a TTM, stages of change were recorded at baseline, where most participants were in the preparation phase. This meant that the participants were getting ready to make a change, this made them the ideal candidate to take part in a weight loss program where nutrition and exercise changes are involved. When comparing pre- and post-, general self-efficacy, sleep quality, physical and emotional functioning, limitations due to physical and emotional health, energy/fatigue were unchanged, with a small increase in general health ($p=0.0131$).

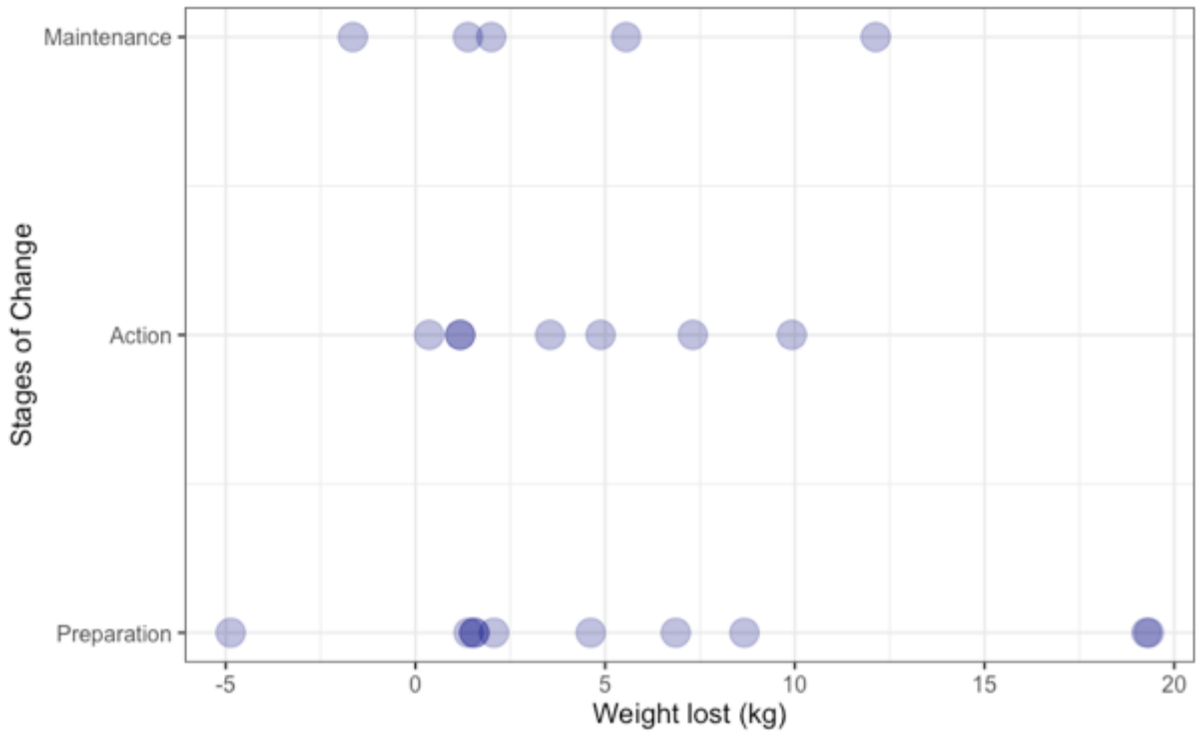


Figure 4. Weight loss versus stages of change for all participants (n=22).

Per Figure 4, where weight loss was compared with baseline stages of change for all participants. For those who completed the program, at baseline, five participants were in the preparation stage with an average weight loss of 10.32 (8.40) kg, four were in the action stage with an average weight loss of 6.41 (2.80) kg, and five were in the maintenance stage with an average weight loss of 3.88 (5.27) kg. With the participants who did not complete the program, five participants were in the preparation stage with an average weight loss of 1.76 (4.79) kg and five in the action stage with an average weight loss of 0.91 (0.47) kg. Participants who completed the program lost more weight than those who did not complete the program. These results indicate that although participants experienced weight loss from attending the program, the data between the amount of weight lost and the participant's stage of change is inconclusive.

3.5 Exit Questionnaire Results

To help in evaluating the feasibility and collecting participant feedback and experience in the program, completed participants were asked to fill out an exit questionnaire about program satisfaction. 73.3% of participants gained knowledge, skills, and confidence as the program went on and 80% of participants gained valuable lifestyle changes. In terms of the satisfaction of the different components of the program, 78.5% were satisfied with the nutrition portion, 100% were satisfied with the exercise portion, and 50% were satisfied with the psychology portion. As well, 100% of participants would recommend the weight loss program to a friend or family member.

3.6 Discussion

Participants who were considered compliant and completed the program lost more than 5 percent of their initial body weight. For a four-month weight loss program, the ideal weight lost is between 7.3 to 14.5 kg (one to two pounds per week) [39]. The average weight lost was 7.51 kg for those who completed the program, which is consistent with the ideal weight lost for a four-month weight loss program for adults living with obesity. The average age of participants who entered the program was 50 years old and the population was predominantly female (22 females, 4 males). The baseline BMI was at 39.9 kg/m^2, which is classified as obese class II. However, all other parameters were within the ideal range, suggesting that the population was not experiencing metabolic complications and/or the participants were being adequately treated for their high blood pressure, cholesterol and/or blood glucose.

A study done by Gagnon et al. [30] looked at individual lifestyle counselling with each member of the multidisciplinary team in comparison to group counselling. It was found that individual

lifestyle counselling showed an improvement in waist circumference, as well as, an improvement in metabolic profile, specifically blood pressure, suggesting a decreased risk of developing type 2 diabetes in high risk individuals [30]. Based on our results, there were improvements in the secondary outcomes, such as waist circumference, systolic blood pressure, diastolic blood pressure, and body fat percentage suggesting a decreased risk of obesity-related morbidities (such as type 2 diabetes) [30], and an improvement in hypertension [70].

At baseline, participants had lower self-efficacy, indicating that participants had low confidence in their ability to execute behaviours. Self-efficacy is a fundamental component in models of behaviour change and has been characterized as a consistent predictor of weight loss [33]. At the exit from the program, self-efficacy remained unchanged, participants still had low self-efficacy. This could be due to the guidance and support of the multidisciplinary team where the participants had confidence to execute positive lifestyle behaviours whereas if they were faced with these challenges alone, their perceived self-efficacy may be otherwise. Some ways to improve self-efficacy include increased self-autonomy during sessions with the dietitian or CCPT, this can include a thorough goal setting session during the assessment stage.

Bonnano et al. (2019) highlighted that the duration and quality of sleep can represent a risk factor of overweight in obesity in participants, therefore, sufficient sleep is required to maintain weight [71]. Participants in this program had poor sleep quality at baseline with no improvements at exit, which could suggest more focus on sleep quality and hygiene, such as, properly screening for sleep disorders during assessment stage and incorporating sleep hygiene into the intervention as needed.

In terms of quality of life, Mazzeschi et al. [14] investigated the impact of lifestyle interventions on an individuals' quality of life, it was found that higher attendance with the program was significantly related with a reduction in fat mass, waist circumference, and an improvement in

quality of life. Our results showed a higher weight loss, decreased waist circumference, and improvements in blood pressure in comparison to those who did not complete the program. Those who completed the program attended every visit with the multidisciplinary team and adhered to given interventions.

More research is needed in terms of maintaining weight, due to the limited time frame of this evaluation, measures were only taken at baseline and exit (around four months). Participants general health improved, which is similar to Payne et al. (2018) which also demonstrated the quality of life improvements, in particular, general health [72]. A five-percent decrease in weight loss is often sufficient to produce significant health benefits in areas such as blood pressure, blood cholesterol, and blood glucose [34]. This is consistent with the evaluation results, in the 62% of participants who lost more than five-percent of their initial body weight, there were significant changes in secondary outcomes, including waist circumference (↓ 6.54 cm), blood pressure (systolic ↓11.91, diastolic ↓ 6.95), and body fat percentage (↓ 2.44%).

Prior to joining the program, 43% of participants had joined one or more of various commercial weight loss programs from the numerous options which the weight loss industry is overwhelmed with. This wide range of options makes it difficult for consumers to determine which weight loss programs are successful. The results showed changes in physiological outcomes and positive feedback from completed participants, indicating that the program is acceptable, making them an ideal competitor in the weight loss industry.

Prior to coming in for the assessment stage, participants are asked to fill out their goal weights. Since this is not reviewed upon entry, more support may be needed during this time to help in

setting realistic goals for a four-month timeline. Setting realistic goals may help gauge whether the participant is ready to make positive lifestyle changes.

The data generated from this evaluation will be used by the WI to improve and support the program's mission in using an evidence-based methodology in their programs. As well, this data may be used for future clinical trials and may be used as a model for other health institutes across the province, within Canada, and globally.

3.7 Other Information

This study is registered on Clinicaltrials.gov ID# NCT04290910. The study protocol can be accessed as a preprint on Research Square DOI:10.21203/rs.3.rs-17487/v1. This evaluation is funded by the Mitacs Accelerate Program and the Chronic Disease Innovation Centre.

3.8 Declarations

Availability of Data and Material

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study. All study data will be entered onto paper forms and then into an excel file. The participants will be identified by a unique study specific code in any database. The name and any other identifying detail will not be included in any study data electronic file. The link between the participant name and participant code will be held on a master list in a locked cabinet at the CDIC.

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Chapter IV

Conclusion

4.1 Summary and Implications

This research aimed to determine whether a clinically-managed weight loss program by a multidisciplinary team would lead to program compliance, achievement of more than five percent initial body weight loss and improvement in clinical measurements (such as, weight, waist circumference, blood pressure, cardiovascular risk and lipid profile, quality of life, and sleep) in adults living with overweight or obesity. Based on the literature review conducted in Chapter 1, there is little evidence to support clinically-managed weight loss programs based on TTM though it is one of the current recommendations for obesity prevention [9]. As well, the systematic review will be further looked into clinically-managed weight loss program with physician or nurse practitioner in comparison to a non-clinically-managed weight loss program in adults who are living with overweight and obesity. This review will be published separately as a manuscript protocol for a systematic review on the efficacy and safety of clinically managed weight loss programs,

After conducting the evaluation and analyzing the results, it was found that participants who completed the four-month weight loss program at the WLC lost an average of 7.51 kg. With 26 participants included in the evaluation, 13 did not complete and the remaining 13 completed and their data was used for analysis. Participants who entered the program were predominantly female with an average age of 50 years old and weight, BMI, and body fat percentage were not within ideal ranges. Since the evaluation is based on the TTM, this was determined at baseline, with the majority of participants in the preparation phase, this suggested they were getting ready to make changes and/or engaging in planning and commitment. The primary outcomes were program

compliance and achievement of more than five percent initial body weight loss. Out of 26 participants, 13 participants were considered compliant with the program and eight of those lost more than five percent of their initial body weight. In terms of secondary outcomes, for all participants, weight and BMI were significantly decreased. For those who completed the program, there was an improvement in BMI, body fat percentage, waist circumference, systolic and diastolic blood pressure. The results from the evaluation were consistent with the previous literature, based on ideal weight loss in a four-month weight loss program. Based on the questionnaire data, there were insignificant improvements in self-efficacy, sleep quality, and areas of quality of life for participants. Although unrealistic goal weights were set, participating in the program resulted in significant weight loss and participants were still nonetheless satisfied with the program with 100% of participants willing to recommend the program to a friend or family member and 80% of participants gained valuable lifestyle changes.

4.2 Strengths and Limitations

Since this was a pilot study, strengths of the evaluation include the collection of data for future trials, being able to assess the feasibility, and record of monitoring the number of people being recruited into the program in a given time frame. Another strength is the personalized nature of the program, the intervention component was personalized per participant depending on their goals, progress, and reason for joining. Since the program was personalized and was not solely based on caloric restrictions and exercise progressions, a limitation of this study was not being able to further assess and analyze the quality of nutrition and exercises interventions on a participant level. Another limitation was not being able to assess the fluctuations in weight, looking at the relationship between current behaviours and their perception on weight may have helped to

assess the reasoning why some participants lost more weight than others. With the questionnaire data, since this was self-reported, some answers may have been dishonest and there may have been some misinterpretation with the questions. In terms of sample size, all participants who entered the program were approached about the evaluation, there was no limit in sample size as the evaluation assessed and aimed to capture the real-life process of the program where both recruitment and the number of participants were considered. With the research project a part of a dissertation, there was a 2-year time frame to complete the project, more participants may have been recruited into the evaluation if there was a longer time frame.

4.3 Future Direction

The literature is amplified with commercial weight loss programs with very little evidence towards clinically-managed weight loss programs based on a TTM model. Though the program was effective in weight loss and helped to examine feasibility, there is a gap in determining the root drivers of the issue. For future direction, interventions involving the comparison between a standardized weight loss program vs. a personalized weight loss program and determining whether the impact poses a difference. Some suggestions for the weight loss program include incorporating various behavioural interventions, such as, comparing TTM with motivational interviewing as it's shown that for the most effective results, counselling approaches work together based on the needs of the individual. As well, with little to no changes in sleep quality and self-efficacy, a focus on sleep quality could include assessing and screening for sleeping disorders and incorporating sleep hygiene, as well as a thorough goal setting to help in self-efficacy and increasing self-autonomy for participants. Both sleep quality and self-efficacy are considered essential components to a weight loss program. In terms of TTM, though participants were in the preparation phase at

baseline, since this is self-reported data, participants may be interpreting their readiness to change differently compared to what phase they are actually in. A better tool in terms of assessing readiness to change at baseline may help in improving the program to ensure that those participating are ready to make lifestyle changes. It is important to identify participants who are ready to participate, this might make for a positive attrition and fill in the gap of attendance in programs. To further enhance the quality of the program, including a meal bar or meal planning component where the WLC is partnered with meal planning companies may help to increase participant interest.

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Appendices

Appendix 1

MEDLINE Preliminary Search Strategy

1. exp overnutrition/dh, dt, pc, th or exp body weight/dh, dt, pc, th

2. exp weight reduction programs/ or weight loss/ or exp diet, carbohydrate-restricted/ or diet, fat-restricted/ or diet, paleolithic/ or diet, reducing/ or caloric restriction/ or exp anti-obesity agents/

3. (exp exercise/ or exp exercise therapy/ or "physical education and training"/ or exp diet/ or exp diet therapy/) and (exp overnutrition/ or exp body weight/)

4. ((weight or obesity) adj3 (loss or reduc* or program* or manag* or interven*)).ti,ab,kf

5. (((diet* or calori*) adj3 (reduc* or restrict* or therap*)) and (weight or overweight or obesity or obese)).ti,ab,kf

6. ((weight or overweight or obese or obesity) adj10 (lifestyle or behavi* therap* or cogniti* therap* or counsel* or exercis* or kinesiotherap* or physical* activ* or fitness)).ti,ab,kf

7. ((low-calorie or low-fat or fat-free or low-carb* or keto* or paleo* or atkins or caveman or stone age or hunter-gatherer) adj3 diet*).ti,ab,kf

8. (antiobesity or anti-obesity or anorectic* or anorexic drug* or anorexigenic* or (appetite adj2 (suppress* or depress* or repress* or control*))).ti,ab,kf

9. or/1-8

10. exp physicians/ or exp professional role/ or exp nurse practitioners/ or nurse clinicians/

11. ((physician* or doctor* or gastroenterologist* or bariatrician* or clinician* or gp or general practitioner* or internist* or hospitalist* or allergist* or cardiologist* or endocrinologist* or geriatrician* or gerontologist* or obstetrician* or gynecologist* or registrar* or dermatologist* or nephrologist* or neurologist* or oncologist* or ophthalmologist* or otolaryngologist* or neonatologist* or pulmonologist* or rheumatologist* or surgeon* or urologist* or hematologist* or haematologist* or hepatologist* or immunologist* or intensivist* or nurse practitioner* or nurse clinician* or np or apn or advance* practice nurse* or nurse specialist* or primary care provider*) adj3 (led or lead or leading or driven or administer* or manag* or guid* or oversight* or oversee* or deliver* or direct* or perform* or aegis or control* or conducted or govern* or supervis* or implement* or involv* or integrat* or role*)).ti,ab,kf

12. or/10-11

13. 9 and 12

14. 13 not ((exp animals/ not humans.sh.) or ((exp child/ or exp infant/ or adolescent/) not exp adult/))

15. Randomized Controlled Trials as Topic/

16. randomized controlled trial/

17. Random Allocation/

18. Double Blind Method/

19. Single Blind Method/

20. clinical trial/

21. clinical trial, phase i.pt

22. clinical trial, phase ii.pt

23. clinical trial, phase iii.pt

24. clinical trial, phase iv.pt

25. controlled clinical trial.pt

26. multicenter study.pt

27. (pragmatic clinical trial or randomized controlled trial).pt

28. Clinical Trials as topic/

29. (clinical adj trial$).ti,ab,kf

30. (RCT or RCTs or quasi-random* or quasi-experimental*).ti,ab,kf

31. ((singl* or doubl* or trebl* or tripl*) adj (blind* or dumm* or mask*)).ti,ab,kf

32. PLACEBOS/

33. (placebo$ or sham).ti,ab,kf

34. (randomized or randomised or randomly).ab

35. trial.ti

36. or/15-35

37. 14 and 36

38. limit 37 to yr="1990 -Current"

Appendix 2

Certificate of Final Approval

UNIVERSITY OF MANITOBA | Research Ethics and Compliance

Research Ethics - Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB
Canada R3E 0W3
Phone +204-789-3255
Fax +204-789-3414

HEALTH RESEARCH ETHICS BOARD (HREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Full Board Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Katrina Cachero	U of M and SOGH/Food and Nutritional Sciences	HS22267 (H2018:401)
HREB MEETING DATE: October 22, 2018	**APPROVAL DATE:** December 3, 2018	**EXPIRY DATE:** October 22, 2019
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. Dylan MacKay		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE:
NA	Evaluation of the clinically managed weight-loss program at Wellness Institute at Seven Oaks Hospital
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: Mitacs Inc.	

Submission Date(s) of Investigator Documents:	REB Receipt Date(s) of Documents:
October 1 and November 26, 2018	October 1 and November 30, 2018

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Protocol including Clarifications as per Letter dated November 26, 2018	V. 2	November 26, 2018
Consent and Assent Form(s):		
Research Participant Information and Consent Form	V. 2	November 26, 2018
Other:		
Program Review Data Form	V. 2	November 26, 2018
Questionnaire Appendix	V. 1	Sept 30, 2018

CERTIFICATION
The University of Manitoba (UM) Health Research Board (HREB) has reviewed the research study/project named on this ***Certificate of Final Approval*** at the ***full board meeting*** date noted above and was found to be acceptable on ethical grounds for research involving human participants. The study/project and documents listed above was granted final approval by the Chair or Acting Chair, UM HREB.

HREB ATTESTATION
The University of Manitoba (UM) Health Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba.

In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

QUALITY ASSURANCE
The University of Manitoba Research Quality Management Office may request to review research documentation from this research study/project to demonstrate compliance with this approved protocol and the University of Manitoba Policy on the Ethics of Research Involving Humans.

CONDITIONS OF APPROVAL:

1. The study is acceptable on scientific and ethical grounds for the ethics of human use only. ***For logistics of performing the study, approval must be sought from the relevant institution(s).***
2. This research study/project is to be conducted by the local principal investigator listed on this certificate of approval.
3. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to the research study/project, and for ensuring that the authorized research is carried out according to governing law.
4. **This approval is valid until the expiry date noted on this certificate of approval. A Bannatyne Campus Annual Study Status Report** must be submitted to the REB within 15-30 days of this expiry date.
5. Any changes of the protocol (including recruitment procedures, etc.), informed consent form(s) or documents must be reported to the HREB for consideration in advance of implementation of such changes on the **Bannatyne Campus Research Amendment Form.**
6. Adverse events and unanticipated problems must be reported to the REB as per Bannatyne Campus Research Boards Standard Operating procedures.
7. The UM HREB must be notified regarding discontinuation or study/project closure on the **Bannatyne Campus Final Study Status Report**.

Sincerely,

[redacted]

John, Arnett, PhD., C. Psych.
Chair, Health Research Ethics Board
Bannatyne Campus

Please quote the above Human Ethics Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone**: (204) 789-3255/ **Fax:** (204) 789-3414

Appendix 3

Research Participant Information and Consent Form

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study:	Evaluation of the Clinically Managed Weight-Loss Program at Wellness Institute at Seven Oaks Hospital
Investigator(s):	Katrina Cachero Dylan MacKay, PhD
Sponsor:	Mitacs Canada A250 Agricultural Engineering Building 96 Dafoe Rd, University of Manitoba Winnipeg, Manitoba R3T 5V6

You are being asked to participate in a study evaluating the clinically managed weight loss program you are participating in. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand.

The institution is receiving professional fees and financial support to conduct this study.

Purpose of study

You are being asked to participate in a study which will be evaluating the clinically managed weight loss program the Wellness Institute. A total of 20 participants will participate in this study.

This research is being done because almost two-thirds of Canadian adults are overweight or obese, which stresses the health system by an increased risk for chronic diseases such as type 2 diabetes and cardiovascular disease. Many weight loss programs are often not customized to an individuals' particular needs. This study will focus on evaluating a program that is customized to the participants particular needs. The team will consist of a study coordinator, as well as the program team including, Program Coordinator, Registered Dietitian (RD), Certified Personal Trainer (CPT) and Clinical Psychology Associate who are responsible for implementing the weight loss program at the Wellness Institute.

Evaluation study components

Participation in the evaluation study will last as long as you participate in the weight loss program. The evaluation study will primarily collect your data from your weight loss program clinical records which are stored at the Wellness Institute. The data collected from your clinical records will include your: anthropometric measurements, blood pressure, heart rate, percentage body fat, lean mass, basal metabolic rate, aerobic fitness, muscular strength, physical activity data, dietary intake data including use of meal replacements, and clinical chemistry data. As a part of the evaluation study, no additional laboratory tests will be conducted. Additionally, you will be asked to fill out 2 additional questionnaires for the evaluation study, one related to your sleep activities and one related to your quality of life at the beginning and every three months during the study. Finally, exit interviews will be conducted as part of the evaluation study. This will give you the opportunity to provide feedback on the weight loss program and identify any barriers you faced while in the program.

If you consent to participate in the evaluation, you will be a part of the clinically managed weight loss program and will be required to fill out additional questionnaires as a part of the evaluation. If you decline consent to participate in the evaluation, you will still be a part of the clinically managed weight loss program but will not be required to fill out additional questionnaires.

In addition to the Weight Loss Program, you will be asked to fill out the Pittsburgh Sleep Quality Index and SF-36 Quality of Life questionnaires. These additional questionnaires will be completed during program check-ins at program start, 4 months and every 3 months thereafter while in the program.

Benefits

There are no specific benefits to you by participating in this evaluation, however your participation provides important information on the program and in turn maybe used to make the program more successful.

Costs

All clinical and professional fees are included in the cost of the Wellness Institute Weight Loss Clinic program. It is not expected that there will be any expenses related to this evaluation. If there are, you will not receive payment or reimbursement for any expenses related to taking part in this evaluation.

Confidentiality

Information gathered in this evaluation study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. All evaluation study documents related to you will bear only your assigned participant code.

Your personal information personal health information is being collected under the authority of The University of Manitoba Act. The information you provide will be used by the University for the purpose of this research project. Your personal information and personal health information will not be used or disclosed for other purposes, unless permitted by *The Personal Health Information Act* (PHIA) or *The Freedom of Information and Protection of Privacy Act* (FIPPA). If you have any questions about the collection of your personal information or personal health information, contact the Access & Privacy Office (tel. 204-474-9462), 233 Elizabeth Dafoe Library, University of Manitoba, Winnipeg, MB, R3T 2N2.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include study staff and staff from groups such as: The Chronic Disease Innovation Center and the Wellness Institute at Seven Oaks Hospital. Representatives from the University of Manitoba Biomedical Health Ethics and/or Mitacs Canada may review research-related records for quality assurance purposes. A final report of aggregated program results will be provided to Mitacs Canada as a part of the Mitacs Accelerate Internship Program. No identifying participant information will be provided to Mitacs Canada.

All clinically managed weight-loss program records are kept at the Wellness Institute. All evaluation study records will be kept in a locked secure area in the Chronic Disease Innovation Center at Seven Oaks Hospital, the research center next to the Wellness Institute, only those persons identified will have access to these records. If any of your research records need to be copied to any of the above, your name and all identifying information will be removed.

Voluntary participation/withdrawal from the evaluation study

Your decision to take part in this evaluation study is voluntary. You may refuse to participate or you may withdraw from the study at any time You can stop participating in the evaluation study at any time by telling a study team member.

Your decision not to participate or to withdraw from the evaluation study will not affect your participation in the clinically managed weight loss program or any other medical care at this site. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Medical Care for Injury Related to the Study

There is no possibility of injury related to the evaluation of the weight loss program.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the study staff:

Dylan MacKay, PhD [redacted]

For questions about your rights as a research participant, you may contact The University of Manitoba Health Research Ethics Board at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

1. I have read this consent form. I have had the opportunity to discuss this research study with the program staff.
2. I have had my questions answered by them in language I understand.
3. The risks and benefits have been explained to me.
4. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements.
5. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate.
6. I understand that I will be given a copy of this consent form after signing it.
7. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time.
8. I freely agree to participate in this research study.
9. I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed.
10. I hereby consent to the release of my medical information and data collected pertaining to my participation as a client of the Weight Loss Program to the evaluation of the program at the Chronic Disease Innovation Centre.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I agree to being contacted in relation to this study.

Yes □ No □

Participant signature: _____ Date: _____

(day/month/year)

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed name: _____ Date: _____

(day/month/year)

Signature: _____ Study Role: _____

ALL SIGNATORIES MUST DATE THEIR OWN SIGNATURE