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

Katrina Cachero (kp_cachero@hotmail.com)
University of Manitoba

Rebecca C. Mollard
University of Manitoba

Semone Myrie
University of Manitoba

Dylan MacKay
University of Manitoba

Study Protocol

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Abstract

**Background:** Obesity is a worldwide problem. 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 (WI) is a non-profit organization that operates as a medical fitness facility and created the Weight Loss Clinic (WLC) to provide personalized support for individuals based on diet, exercise, and lifestyle, targeting all the core components required for a weight loss program. Since the weight loss industry is dominated by non-evidence-based programs with majority focused on calorie-reduced diets, there is a gap in research on weight loss programs with an exercise and psychological component. Thus, the aim of this pilot study is to collect data on the effectiveness of the comprehensive evidence-based clinically managed weight loss program offered at the WI for future research applications.

**Materials and Methods:** The WLC is a 17-week program during which each participant will progress depending on their personal goals.

**Population:** Inclusion criteria are individuals over the age of 18 years old, are overweight or obese (BMI > 25 kg/m²), have been told by a physician or primary care provider to lose weight, who are concerned with weight and may have other health problems, and have tried to lose weight in the past but have been unsuccessful at maintaining weight loss.

**Outcome Measures:** Outcome measures include: anthropometric measurements, body composition, cardiovascular assessment, clinical chemistry, physical activity assessment, nutrition assessment, behaviour change assessment, and health screenings.

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

**Clinicaltrials.gov ID:** NCT04290910

**Background**

Almost two-thirds of Canadian adults are overweight or obese (1), which stresses the health system via increased risk for chronic diseases (2), 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 in overweight and obese individuals (3) and is associated with reduced all-cause mortality in obese individuals (4). The market is overwhelmed with weight loss programs, the majority focused on calorie-reduced diets (5). Not all programs include exercise, most do not include medical oversight, and may not be customizable to a participants’ particular needs. The current Canadian clinical practice guidelines (CCPG) on the management and prevention of obesity in adults recommend a comprehensive lifestyle intervention including behaviour modification,
dietary counselling and physical activity as the first treatment option for overweight and obese adults to achieve clinically significant weight loss (2). Many available programs focus on surgical therapy, thus catering more to individuals who are morbidly obese, rather than those who are overweight or obese (body mass index; BMI<40kg/m$^2$) (6). 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 (1), more proactive weight loss programs should be offered. In Canada, a few provinces have clinically managed weight loss programs that are offered to clients and/or patients. For example, the Ottawa Hospital offers a medical program (CORE), which is medically advised by a physician or nurse practitioner and uses a 900-calorie meal replacement on a six- or twelve-week basis (7). The program also offers long-term lifestyle modifications focused on behaviour changes and includes group sessions and support-group sessions. It requires a commitment of three hours per week for 26 weeks facilitated by a Registered Dietitian (RD), Social Worker/Behaviourist and Exercise Specialist.

This report describes a pilot comprehensive weight loss program, which represents the first offered to overweight and obese, not just morbidly obese, adults in Manitoba, thereby shifting the focus to earlier prevention of obesity-related morbidities. The Wellness Institute (WI) is a self-supporting non-profit organization that operates a medical fitness facility attached to the Seven Oaks General Hospital in Winnipeg, Manitoba. A 2015 outcome analysis done of the WI members indicated that 51 percent of new members have a moderate to high cardiometabolic risk profile including high blood glucose, high blood pressure and/or are overweight or obese. The cardiometabolic risk profile was assessed based on the cardiovascular risk assessment (8). In response to these identified risks, the WI developed a clinically managed weight loss program focused not only on body weight reduction but also improvement in cardiometabolic risk factors. This new program, known as the Weight Loss Clinic (WLC) at WI will provide personalized support for individuals to ensure the program is customized to their needs. The program will be managed by a clinical team including a Program Manager, RDs, Canadian Society of Exercise Physiology (CSEP)-Certified Personal Trainers (CCPTs), Clinical Psychology Associate (CPA) or a Cognitive Behavioural Therapist (CBT), and a Physician. Each member of the clinical team has a specific role dedicated to the implementation of the weight loss program. 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 is a gap in evidence-based, professionally delivered clinical weight loss services in Canada. The aim of this pilot study is to collect data on the effectiveness of the comprehensive evidence-based clinically managed weight loss program offered at the WI for future research applications.

**Materials And Methods**

**Study Design**

The expected duration of participation is four to six months. Since the program is personalized, there is no set end date for the participants. The WLC is a 17-week program during which each participant
advances depending on their personal goals and progress. This pilot study has a pre- and post-design focusing on feasibility parameters, participant feedback and improvement in outcomes.

Participants and Setting

The inclusion criteria of the program are individuals over the age of 18 years old, are overweight or obese (BMI>25kg/m²), have been told by a physician or primary care provider to lose weight, who are concerned with weight and may have other health problems (such as diabetes or high blood pressure), and have tried to lose weight in the past but have been unsuccessful at maintaining weight loss. The exclusion criteria include women who are pregnant or lactating. The participants for the program evaluation will be recruited from the individuals enrolled in the program; it will not be advertised to the general public. All potential participants entering the program will be approached to learn about the program evaluation.

Ethics Approval

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

Study Procedures

The weight loss program is 17-weeks in duration and is comprised of specialists such as a Program Manager, Physician, RD, CCPT, and CPA/CBT. The team of specialists will collaborate together 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 are considered (i.e. lifestyle, sleep, mental health, behaviours).

The aims in the first week of the program are to get to know the participants, what they are looking to achieve, assessing their stage of readiness to change, and being assessed individually by each discipline on the team. The Program Manager will complete an initial assessment on the participant, this includes completing questionnaires relevant to the program (Stages of Change questionnaire(9), the WI Health Screening questionnaire, Beck’s Depression Inventory and Beck Anxiety Inventory(10) and an Initial Assessment questionnaire created by the WLC team). The CCPT will then collect anthropometric measurements, body composition (assessed by the InBody 570), blood pressure, and provide a lab requisition for the participant to collect a lipid profile (such as total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein cholesterol, triglycerides, total cholesterol/HDL, hemoglobin A1C). As well, an aerobic and strength assessment will be conducted. Afterwards, the participant will meet with the CPA/CBT and RD for an initial assessment.

The second week of the program focuses on nutrition. A dietary prescription, which involves a meal plan focused on whole foods with an emphasis on a plant-based diet will be given to the participant. Although the dietary prescription is based on a combination of DASH and the Mediterranean dietary patterns (11) (12), diets are individualized to the participants’ food beliefs and preferences. A DASH diet consists of a
diet high in fruits and vegetables, lean meat and dairy products, and minimally processed foods (11). Psychological intervention may be replaced with diet intervention at this stage if the participant screens for severe depression, anxiety, disordered eating or present with any psychosocial concerns.

The remaining 12 weeks in the program include sessions with the RD and CCPT. The diet prescription may be modified depending on lifestyle changes the participant has made. A new or revised meal plan and exercise plan will be provided. The nutritional goals are to build meal planning, portion control skills, and integrating the diet prescription into the participants' current dietary preferences. During this period of the program, the exercise program will be introduced, which is designed to fit the participant's lifestyle and meal plan. Through regular interactions through e-mail or phone and monthly in-person appointments between participants and RD and CCPT, meal and exercise plans will be adjusted based on progress, barriers, and feedback. During the monthly check-ins with the participant and RD, the following will be addressed: meal balance, nutrient balance promoting weight management and satiety, transitioning to self-planned diet, healthy eating strategies, meal planning, pre- and post-workout nutrition, balancing eating and hunger with activity, how to account for extras (snacks, desserts), weight maintenance planning, reviewing program action plan, managing plateaus, incorporating eating out, and relapse management. Each topic will be addressed according to the participants’ progress, barriers, and feedback. During the monthly check-ins with the participant and CCPT, the exercise will include cardio, resistance training, flexibility prescription (FITT (frequency, intensity, time and type of exercise) principle), weight monitoring and exercise goals.

After 17-weeks in the program, the participants have the option of entering a maintenance phase. During this phase, the participant will have two meetings per month with the RD and CCPT. This phase will aid 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 to sustain their weight. For the purposes of the evaluation, the maintenance phase will not be included.

**Outcome Measures**

To evaluate the effectiveness, outcome and feasibility measures will be collected. Outcome measures will be taken prior to starting the program and at four months. For those who do not complete the program, all measures up until participant exit will be 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 will be 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 will be measured using a weighing scale stadiometer. Waist circumference will be measured three times with the average reported. Body composition will be measured using the InBody 570 (InBody USA, 13850 Cerritos Corporate Drive Cerritos, California, USA), a non-invasive 45 second test where the participant will stand on a device and hold the hand electrodes (13). 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. The impedance is then used to determine body composition, such as percentage of body fat, lean body mass, body fat mass, and basal metabolic rate (14). These measurements will be used to indicate the participant's body composition, BMI and risks for other chronic diseases.

**Cardiovascular Assessment.** An oscillometric blood pressure monitor will be used to collect the systolic and diastolic blood pressure and heart rate. A cardiovascular risk assessment based on age, HDL-C levels, total cholesterol levels, systolic blood pressure, smoking status, and diabetes status will be reviewed to determine the participants 10-year risk of cardiovascular disease and identification of metabolic syndrome (8).

**Clinical Chemistry.** The following clinical data will be collected: total cholesterol, HDL-C, LDL-C, triglycerides, total cholesterol/HDL ratio and hemoglobin A1C. The lipid profile blood sample will be collected and processed by the Diagnostic Services of Manitoba. The results for the clinical data will be collected on eChart, which is an electronic database used to access key patient health information (15).

**Physical Activity.** The Ebbeling single stage treadmill walk test or the six-minute walking test will be used to assess aerobic capacity and endurance as estimated by measuring the participant's maximal oxygen uptake (VO$_2$ max). During the Ebbeling single stage treadmill walk test, the participant will be required to walk at a steady pace on a treadmill (16). The six-minute walking test requires a 100-feet hallway and no exercise equipment, the distance the participant can quickly walk on a flat, hard surface in a period of six-minutes will be measured (17). For those unable to complete the Ebbeling single stage treadmill walk test, a six-minute walking test will be administered. Both tests are validated by the CSEP guidelines (18). Following the aerobic assessment, a strength assessment will be administered, such as a grip strength and push up test. During the push up test, the participant will be asked to perform as many push ups as they can with no time limit (18). To measure grip strength, the participant will be asked to hold a dynamometer and both dominant and non-dominant hands will be tested and recorded (18).

**Nutrition.** Questionnaires that will be provided for the participants include mindful eating questionnaire, three-factor eating questionnaire, and three-day food recall. The three-factor eating questionnaire measures three components: cognitive restraint, uncontrolled eating, and emotional eating (19). Where the mindful eating questionnaire measures five components: disinhibition, awareness, external cues, emotional, and distraction (20). A three-day food recall will be filled out by the participant; this tool may be used to measure adherence to the meal plan. The three-factor eating questionnaire and the mindful eating questionnaire will be scored and interpreted, along with the three-day food recall, to guide the nutrition assessment done by the RD.

**Behaviour Change and Health Screening Questionnaires.** The following questionnaires will be 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;
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 (21). The WI Health Screening questionnaire will also be administered to the participant, which is based upon the Physical Activity Readiness Questionnaire by CSEP (18) and was reviewed by the Medical Director of the WI. It is used to determine any health risks associated with physical activity and if the participant will require a GXT test. In addition, to identify mild to severe depression and anxiety, respectively, the following are administered: Beck’s Depression Inventory and Beck Anxiety Inventory (10). 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 will be obtained from the participant via the initial assessment questionnaire created by the WLC team. The program evaluation will include 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 (22). 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 (23).

**Statistical Analysis**

Statistical analysis will be performed using R Studio (R Studio, Boston, MA, USA) (24). The effects of participation in the weight loss program on the captured outcomes will be analysed by 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 will be measured by logistic regression. Secondary outcomes, such as changes in body weight, waist circumference, blood pressure, clinical chemistry, quality of life, and sleep will be analysed through a paired t-test and McNemar’s chi-squared test with continuity correction. Factors such as sex, baseline BMI, and age may be included in the model as fixed factors or covariates. Feasibility outcomes will also be measured, such as attendance, intervention adherence, and participant feedback. This study is an evaluation of a clinically managed weight loss program that is currently offered, it has only one group and does not include randomization.

**Anticipated Results**

The program evaluation will aid in providing results to determine whether a multidisciplinary approach (which includes an RD, CCPT, CPA/CBT, and physician oversight) will improve physiological outcomes and yield positive feedback. The evaluation will also address different outcome measures and their association(s) with a clinically managed, personalized weight loss program. It is expected that the program will have a high drop-out rate, this may be due to the length of the program. Individuals may also have unrealistic expectations and will not achieve their goals, though it is expected that most will lose up
to five percent of their initial body weight. The data collected may be used for future clinic trials and may be used as a model for other health institutes across the province, within Canada, and globally.

Discussion

The recommended first-line treatment for adults with obesity is a nutritionally adequate diet with regular physical activity (2). Medication(s) and/or surgery can be used as treatment if weight loss is not achieved with a balanced diet and regular physical activity. As previously mentioned, most weight loss programs are primarily focused on low-calorie diets and rarely includes exercise or medical oversight. Weight loss programs such as Weight Watchers, Jenny Craig, or Nutrisystems have nutrition, physical activity, and behavioural strategies components but are not personalized to the individual or administered by health care professionals (5). It is evident that weight loss programs result in weight loss. 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 (25). Based on the 2006 CCPG, initiating a weight management program should involve a nutrition health professional, an exercise professional, and a clinical psychologist (2). With an interdisciplinary team, all aspects of an individuals’ life are considered (i.e. lifestyle, sleep, mental health, behaviours). Interdisciplinary weight loss programs have shown improvement in other areas other than weight, such as eating behaviours, lipid profiles, aerobic capacity, and overall quality of life (25-28). With so many weight loss programs available, it is difficult for people to determine which is the best to choose, this pilot study will evaluate a customizable weight loss program that was developed using evidence-based principles that support sustain weight management, the findings of this study will help evolve the program and inform future research.

Abbreviations

WI: Wellness Institute

WLC: Weight Loss Clinic

CSEP: Canadian Society for Exercise Physiology

RD: Registered Dietitian

CCPT: CSEP-Certified Personal Trainer

CPA: Clinical Psychology Associate

CBT: Cognitive Behaviour Therapist

CDIC: Chronic Disease Innovation Centre

SOGH: Seven Oaks General Hospital
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.

Data Monitoring and Dissemination

Direct access will be granted to authorized representatives from the Study Sponsor, host institution and regulatory authorities to permit study-related monitoring, audits and inspections. This study is an evaluation offered at the WI at SOGH where the program already has a data and safety monitoring program in place which looks after the safety and health of the participants participating in the program. In addition to a peer-reviewed academic publication, we will present our findings at appropriate academic meetings.

Competing Interests

One of the authors is funded from 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 the WI are located within Seven Oaks General Hospital.

Consent for Publication

Informed consent was obtained from the participants prior to entering the program evaluation.

Funding

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Protocol Amendments

The protocol and any participant facing documents will be submitted to the Research Ethics Board at the University of Manitoba, Canada. The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Authors’ Contributions

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


Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Appendix1.docx