The Impact of a Pre-Operative Exercise Program on Patients Awaiting Bariatric Surgery

By

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A Thesis submitted to the Faculty of Graduate Studies of the University of Manitoba in partial fulfilment of the requirements of the degree of

MASTER OF SCIENCE

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ABSTRACT

Background:

Evidence supports the association between physical activity and weight loss following bariatric surgery but evidence is lacking for preoperative exercise.

Objective:

Evaluate short term benefits of a preoperative exercise program in patients awaiting bariatric surgery. Our primary outcome was six minute walk test (6MWT). Secondary outcomes included anthropometric measurements, strength testing, and quality of life.

Methods:

Fifty four patients were enrolled. Twenty-nine patients were randomized to "Control" (standard preoperative care). Twenty-five patients were randomized to "Intervention" (standard preoperative care plus 12 week exercise program).

Results:

There was a statistically significant difference in 6MWT between intervention and control (Change in Control -4.88 m, $p = 0.63$; Change in Intervention 27.46 m, $p = 0.01$; Absolute difference between intervention and control = 32.34 m; $p = 0.03$). There were no significant differences in secondary outcomes.

Conclusion:

A preoperative exercise intervention was associated with a statistically significant improvement in 6MWT in patients awaiting bariatric surgery.

ACKNOWLEDGEMENT

Dr. Krista Hardy (Thesis Advisor)

Dr. Danielle Bouchard (Co-investigator)

Dr. Todd Duhamel (Advisory Committee Member)

Dr. Andrew McKay (Advisory Committee Member)

Dr. Thomas Turgeon (Advisory Committee Member)

DEDICATION

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

Obesity

Obesity is pandemic and the worldwide prevalence has doubled in the last 35 years[1]. In Canada, there was a threefold increase in the prevalence of obesity between 1985 and 2011[2]. The World Health Organization (WHO) defines overweight as a Body Mass Index (BMI) greater or equal to 25 kg/m^2 and obesity is defined as a BMI greater than 30 kg/m^2 [1]. Approximately 39% of the world population meet the criteria for overweight and 13% are considered obese[1]. Thirty three percent of Canadians are overweight and 15.7% meet the criteria for obese[2].

Obesity is further subdivided into three classes: class I (BMI 30-34.9 kg/m^2), class II (BMI 35-39.9 kg/m^2) and class III (BMI $\geq$ 40 kg/m^2). In Canada, the prevalence of Class I, II and III obesity is 11.5%, 3.0% and 1.3%, respectively[2].

Being obese is a risk factor for hypertension[3], hypercholesterolemia[3], and type II diabetes mellitus[3]. Furthermore, a meta-analysis of 97 studies found that obesity was associated with a higher all-cause mortality[4]. The Framingham study found that those with BMI >30 kg/m^2 at age 40 years lived six to seven years less than those adults who were not obese (BMI <24.9 kg/m^2)[5].

Treatment of Obesity

Most individuals achieve an initial weight loss of 5-7% with lifestyle interventions including diet, exercise and behavioral modification[6]. Only 20% of adults who are trying to lose weight are consuming fewer calories and exercising at least 150 minutes each week[7].

Bariatric surgery is recommended for patients with obesity who are unable to lose weight despite life style modifications. The National Institutes of Health (NIH) criteria for bariatric

surgery include 1) BMI >40 kg/m^2, 2) well informed and motivated, 3) acceptable risk for surgery, and 4) failed previous non-surgical weight loss. The NIH also considers patients with BMI >35 kg/m^2 with comorbidities such as diabetes, obstructive sleep apnea (OSA) or joint disease to be candidates for bariatric surgery[8].

The main mechanisms of weight loss in bariatric surgery are restriction and malabsorption. The restrictive method decreases the gastric reservoir therefore limiting caloric intake; whereas, the malabsorptive method decreases the length of functional small bowel resulting in decreased nutrient absorption.

Roux-en-Y gastric bypass (RYBG) involves the creation of a small gastric pouch which is anastomosed to a limb of small bowel. It is a predominantly restrictive procedure with a malabsorptive component. In 2011, RYGB was the most commonly performed bariatric operation comprising 47% of cases globally[9]. In Manitoba, RYBG is performed more frequently and comprises 85% of all cases. Excess weight loss is defined as the percent of weight lost relative to the patient's ideal BMI[10]. The expected excess weight loss at two years following this procedure is 70%[11].

Sleeve gastrectomy is a restrictive procedure which involves the creation of a tubularized stomach by stapling off the greater curvature. Furthermore, removal of the fundus results in decreased ghrelin levels and less hunger. Worldwide, in 2011, 27.8% of all bariatric operations were sleeve gastrectomies[9]. In Manitoba, sleeve gastrectomy comprises 15% of all cases. The expected weight loss at two years following this procedure is 60%[12].

Several studies have demonstrated improved weight loss, comorbidity resolution and mortality reduction with bariatric surgery. For example, The Swedish Obese Subjects[13] study is a prospective, matched surgical intervention trial. Two thousand and ten obese subjects treated

surgically were matched with 2037 obese patients treated with lifestyle intervention. Patients were seen for follow up at 2 years, 10 years and 15 years. The study found that patients treated with bariatric surgery had a reduction in overall mortality (hazard ratio [HR] 0.71, 95% CI 0.54-0.92) compared to matched controls. Moreover, there was a statistically significant decrease in the incidence of diabetes, myocardial infarction, stroke and cancer in the surgical group[14].

Bariatric Surgery in Manitoba

Patients in Manitoba are eligible for publicly funded bariatric surgery if: 1) their BMI is >35 kg/m^2 and they have medical comorbidities such as diabetes, hypertension or hypercholesterolemia or 2) if their BMI is >40 kg/m^2 and they meet general NIH criteria. Patients are referred to the Centre for Metabolic and Bariatric Surgery (CMBS) at the Victoria General Hospital and are invited to attend a multidisciplinary information seminar. If they are interested in pursuing surgery, they submit a pre-operative questionnaire. They are subsequently evaluated by a nurse, dietician, kinesiologist and psychologist. Once approved by the team, patients receive ongoing multidisciplinary care prior to surgery, consisting of two to four visits over a six month time period. Patients are provided exercise counselling by the kinesiologist where they discuss barriers to exercise and formulate an exercise plan. Patients are educated on the health benefits of 150 minutes per week of moderate intensity exercise as well as strength training two to three times per week. Their target heart rate for cardiovascular exercise is calculated and they are educated on exercise safety as well as proper progression. Craving Change™, a lifestyle and dietary modification program must also be completed. Two weeks prior to their surgery, patients consume a liquid diet consisting of 900 calories per day in order to reduce hepatomegaly and facilitate the operation.

Post-Operative Outcomes

Unfortunately, not all patients have success with bariatric surgery. At 10 years post-RYGB, patients experience a mean weight regain of 12% of total body weight or 35% of maximal weight lost at 1 year[13]. Five proposed causes of weight regain include: endocrine/metabolic alterations, anatomic surgical failure, mental health issues, nutritional indiscretion and physical inactivity[15]. By addressing nutritional indiscretion and physical activity through behavior modification, outcomes such as long term weight loss can be optimized.

Measures of Fitness in Bariatric Surgery Patients

The 6 minute walk test (6MWT) is a non invasive test used to measure aerobic fitness and functional status. It is the distance a patient can walk unassisted on a flat surface in 6 minutes. 6MWT performance is associated with objectively measured fitness outcomes such as maximal oxygen consumption (VO_2 max)[16]. This test has been using primarily in patients with heart failure, chronic obstructive pulmonary disease (COPD) and elderly patients to evaluate functional capacity[16]. However, the 6MWT has shown good reproducibility and group validity in patients with obesity[17].

VO_2 max or maximal oxygen intake is a measure of cardiorespiratory fitness and aerobic capacity. This value represents the body's capacity to deliver and consume oxygen during exercise and increases with work[18]. Direct measurement is considered the gold standard for determination of aerobic capacity[19]. Exercise testing in patients with obesity can be challenging due to gait instability, low functional capacity, orthopedic issue and uneven body weight distribution[20]. VO_2 max can also be estimated using equations incorporating age, body weight,

gender, and power[19]. Correction factors and formula adjustments for obesity and body composition have been evaluated but not fully accepted[21,22].

Strength and functional capacity can be assessed utilizing tests to assess muscular endurance of the upper and lower limbs, flexibility and handgrip strength. Obesity has a negative impact on functional capacity[23]. Patients with obesity have a greater sit to stand time[23], reflecting poorer lower body strength and decreased flexibility[24]. The current literature is mixed as to whether obesity influences balance[25–27] and handgrip strength[28–30]

Post-Operative Exercise

Systematic reviews report improved weight loss (4.2% BMI/3.62 kg) one year after bariatric surgery with exercise[31] compared to those who exercise minimally[32]. Participation in a minimum of 150 minutes per week is associated with greater post operative weight loss at 6 and 12 months[33]. Despite this, few studies have examined the effects of organized exercise programs on post-operative weight loss and fitness. Few studies of post-operative exercise have shown improvement in functional capacity[34,35].

Stegen et al[34] enrolled fifteen morbidly obese patients awaiting bariatric surgery into their pilot study. They tested the patient's BMI, functional capacity and aerobic capacity prior to surgery and 4 months after surgery. Patients were allowed to select whether they participated in the exercise group or the control. Eight patients selected the intervention group and they exercised three times per week for 12 weeks starting one month after surgery. Weight loss through gastric bypass resulted in a decrease in muscle strength and no improvement in aerobic capacity in the control group. Those in the exercise group had an improvement in aerobic

capacity and functional capacity. The study concluded that an exercise program could prevent this decrease in capacity and induce an increase in strength.

A randomized control trial performed by Castello et al reported similar results[35]. They assigned 52 patients to a training group (21 patients) or a control group (31 patients). Patients in the intervention group participated in a treadmill based exercise program three times per week for 12 weeks. The study concluded that 12 weeks of aerobic exercise training improves cardiac autonomic modulation and functional capacity after bariatric surgery.

Pre-Operative Exercise

The pre-operative time period is an opportunity for the patients to undergo lifestyle modification while they are actively engaged in the process of preparing for surgery[36]. During this time period, patients also do not have the challenges of recovering from surgery, post-operative diet adaptation and post-operative loss of muscle strength to contend with.

The transtheoretical model of change has five steps: precontemplation, contemplation, preparation, action and maintenance of change[37]. Motivating patients to exercise can be difficult; however, patients awaiting bariatric surgery should be in the action stage since they have undergone extensive appointments with the multidisciplinary team prior to qualifying for surgery. We believe this is a good time period to establish exercise habits and lifestyle changes. One study demonstrated that preoperative exercise instructions resulted in increased postoperative compliance with exercise[31]. A few small studies of pre-operative exercise have shown a positive trend in aerobic capacity and time spent in moderate-vigorous physical activity[38–43]

This preoperative time period is also optimal for identifying and minimizing barriers to exercise. Solutions include cost reduction, regimen simplification, improving side effects, education regarding the benefits, improving understanding of information and treating any emotional distress[37]. Patients can begin exercising routinely and gain confidence about their abilities prior to their surgery.

Wouters et al. studied the psychological aspects which influenced exercise before and after surgery. They found the pre-surgical score of "exercise benefits" and "confidence" was correlated with higher physical activity levels 2 years after surgery. They concluded that post-operative physical activity could be improved by presurgical interventions targeting exercise beliefs and improving confidence[44].

Current Literature

In the current literature, there are several small studies which examine pre-operative exercise programs in patients awaiting bariatric surgery. A pilot study enrolled 12 participants awaiting bariatric surgery in an exercise program consisting of three endurance and strength training sessions per week for 12 weeks[42]. The results showed improvement in weight, physical fitness and quality of life after participating in the program. They concluded a pre-operative exercise program was a feasible intervention in patients awaiting bariatric surgery; however, participants in their study only attended 57.3% of sessions. The authors conducted a randomized control trial[38] enrolling 30 participants who participated in the same exercise program as the pilot. The intervention group showed improvement in physical fitness, social interaction scores and embarrassment pre-surgery. Patients were re-assessed one year post surgery[43] and patients in the intervention group had a larger change in 6MWT (97.8 m +/- 56.8 m) compared to the

control group (46.9 m +/- 70.3m) but the results were not statistically significant (p=0.22). The intervention group had a greater change in BMI (-16.8 vs -13.5 kg/m^2) and also spent a statistically significant greater time in light and moderate physical activity than the control group.

A second cohort study enrolled 4 participants awaiting bariatric surgery in an exercise program consisting of two exercise training sessions twice per week for 4 weeks[45]. The results showed a positive trend in strength testing as well as 6 minute walk test. However, this study had a small sample size and two patients did not complete all eight training sessions.

An unblinded pilot trial randomized 22 patients to a gym based exercise program, home based exercise program or control for 8 weeks[39]. Patients in the exercise programs were instructed to perform thirty-minute aerobic training sessions and two resistance exercises sessions three times per week. Eight patients were assigned to the home-based group, 7 to the gym-based group, and 7 to the non-intervention group. There was a trend towards improved aerobic capacity/VO_2 max (p=0.15) and pre-operative weight loss (p=0.11) in the gym based group but the results were not statistically significant.

The largest study, the Bari-Active study[40], enrolled 75 participants who were randomized to a 6 week physical activity intervention involving weekly face-to-face session with tailored instruction in behavioral strategies or standard care. Patients enrolled in the intervention had an increase in moderate-to-vigorous physical activity pre-operatively. Studies have concluded that a pre-operative exercise program is feasible and patient enrolled in physical activity interventions have increased physical activity[38–41].

OBJECTIVE

The objective of this study was to evaluate the functional benefits of a 12-week preoperative exercise program at a medically certified fitness facility in patients awaiting publicly-funded bariatric surgery. The primary outcome was improvement in six minute walk test (6MWT). Secondary outcomes included changes in anthropometric outcomes, other functional outcomes (e.g., strength), and quality of life.

HYPOTHESIS

It is hypothesized that a pre-operative exercise intervention will result in improved short-term (post-intervention) exercise capacity in patients awaiting bariatric surgery. It is hypothesized that patients enrolled in the intervention will improve strength, moderate/vigorous physical activity and quality of life.

METHODS

Overview

This was a prospective randomized controlled trial of adult patients undergoing publicly funded bariatric surgery where patients received either standard preoperative care or standard care with the addition of a 12 week preoperative organized exercise intervention. Primary outcome (6MWT) and secondary outcomes (anthropometric, strength and quality of life) were captured at baseline and after 12 weeks following randomization. The study is unique since it

combines a scheduled medically supervised exercise program with the opportunity for patient directed exercise in the latter portion of the study.

Subjects

All adult patients (>18 years old) awaiting publicly funded bariatric surgery in Manitoba were introduced to the study certified trainer from the Canadian Society for Exercise Physiology at a fitness facility between July 2014 and October 2015. Inclusion criteria were: patients undergoing bariatric surgery within six months of tentative approval by the multidisciplinary team and patients able to participate in an exercise program at the Reh-fit Centre in Winnipeg, Manitoba. Exclusion criteria included: patients with orthopedic, neurologic, or cardiopulmonary conditions which precluded exercise, wheelchair bound patients, those unable to tolerate moderate physical activity, or patients who were unable to commit to attending regular exercise sessions.

Design

One hundred and four patients awaiting bariatric surgery were interested in the study and completed the Permission to Contact form. They were subsequently contacted by the study coordinator or designate via telephone. Further information was provided to the patients regarding the study and meetings were arranged with those interested in participating. Fifty patients declined participation in the study for various reasons (Table 1). Written informed consent was obtained from fifty-four patients at the initial appointment. Patients were assigned to the control or intervention groups using simple 1:1 randomization using a sealed envelope system generated by a third party.

Baseline Characteristics

Data regarding patient comorbidities was collected from a self reported intake form completed by patients once they were deemed candidates for surgery. For this study, the patient's comorbidities were not confirmed with physical exam, laboratory testing or radiographic imaging. The CMBS does not collect data regarding race or ethnicity as part of the required pre-operative information.

Intervention

Patients in both the control and intervention groups received standard pre-operative care consisting of two to four visits with the multidisciplinary team over a six-month time period. All patients attended a minimum of two visits and additional visits were required to address vitamin or mineral deficiencies or failure to achieve program goals such as nutrition or exercise tracking. Patients were provided exercise counselling led by the Canadian Society for Exercise Physiology-Certified Exercise Physiologist (CSEP-CEP) where they discussed barriers to exercise and formulated an activity plan, mostly based on increased walking. Patients were required to complete Craving Change™, a program that focuses on dietary behavior modification. Demonstration of behavior modification that included tracking of caloric intake and physical activity was required prior to surgery. This was submitted in either electronic or paper form by patients and reviewed at follow up appointments. Patients failing to comply with program requirements were reviewed by the team before formal discharge from the program. All patients consumed a liquid diet consisting of 900 calories two to three weeks prior to their scheduled operation to reduce hepatomegaly and facilitate the operation.

Patients in the intervention group participated in a twelve-week exercise program at the Reh-Fit Centre, a medically certified fitness center with experience in cardiac rehabilitation, in addition to standard pre-operative care. Patients completed a health screening questionnaire and underwent a Graded Exercise Test (GXT) to ensure there were no cardiac or respiratory conditions which could exclude them from the study. Three patients tested positive on the GXT and were subsequently referred by the Reh-Fit medical team to a cardiologist. Following assessment by cardiology, all patients were cleared and allowed to participate in the study.

Patients in the intervention group met with a trainer for an orientation and tour of the facility. At this initial appointment, one-repetition-maximum (1-RM) testing was performed for the seated row, seat chest press, leg press, and lateral pull down. This was performed to precisely measure the participant's maximum strength for each exercise and target weights for the resistance training exercises. The participant's goal heart rate was also calculated for aerobic exercises.

Each patient was provided with an exercise log book documenting their target heart rate for aerobic exercise and target weights for resistance exercises (Appendix 2). Detailed instructions with images were also provided for each exercise (Appendix 3). For the first two weeks of the intervention, patients were required to attend the Reh-Fit three times a week at specific times when a trainer was available for assistance. In the remaining 10 weeks, they had access to facility staff just as other members of the fitness facility and could attend at their convenience.

An exercise prescription was developed by a kinesiologist involved in the study. For each exercise session, participants were asked to walk on the indoor track for approximately 400 meters, to perform 10-25 minutes of cardiovascular exercises, six resistance training exercises

(seated row, seated chest press, leg press, lat pulldown, overhead shoulder press, and abdominal plank), and then another 10-25 minutes of cardiovascular exercises. For each exercise session, participants were given a HR monitor to have live feed-back on their intensity. The goal was to perform 60-75 minutes of exercise three times per week after the first six weeks. The exercise logbooks were used to record the patient's progress and they were routinely reviewed by the trainers. Comments were provided to patients using the exercise log books.

Adherence was assessed via an electronic swiping card and confirmed with exercise logbooks. When participants missed a full week of training, a call was made by a research assistant.

Patients assigned an operation date prior to completion of the intervention stopped two weeks pre-op secondary to the caloric restriction of the liquid diet.

Primary Outcome

The primary outcome was the 6 minute walk test (6MWT), which is the distance a patient can walk unassisted on a flat surface in 6 minutes.

The 6MWT was performed in an unobstructed corridor where a distance of 20 m was marked using tape. Participants were instructed to walk along the corridor for 6 minutes at a self-selected pace. Patients were not encouraged during this test and were not informed how much time was remaining.

This outcome was selected since it has good correlation with peak oxygen uptake via an exercise test and is well validated in populations with obesity[42,46]. It is also inexpensive, reproducible and can be easily performed[47].

Secondary Outcomes

The secondary outcomes included anthropometric, strength and quality of life measures.

Anthropometric Measurements

Anthropometric measurements of height, weight, body mass index (BMI). Neck circumference was measured midway of the neck, below the laryngeal prominence. Waist circumference was measured at the iliac crest during the end of normal expiration while the patient was standing. Hip circumference was measured below the hips at the maximum circumference of the buttocks while the patient was standing. Each measurement was performed twice and if there was a difference greater than 0.5 cm, a third measurement was performed.

Chair Stand Test

The patient began in a sitting position in a chair without arms and stood up as many times as possible within a thirty second time period. The number of total repetitions involving complete knee extension were recorded. This test is used to test leg strength and endurance[48].

One Leg Stance Test

The patient removed their shoes and stood on one leg with their arms crossed. The duration of time was recorded and stopped if the foot in the air touched the ground, the standing foot moved, the arms moved or forty five seconds was reached. This test was performed twice with the patient's eyes open and twice with their eyes closed. This test is used to measure postural stability and balance[49].

Sit and Reach Test

The patient sat at the edge of their chair with one leg bent at ninety degrees and the other leg fully extended with their feet on the floor. The patient placed one hand on top of the other and reached forward towards their toes by bending at the hip while exhaling. The patient was

required to hold this position for two seconds and the distance from the patient's great toe to fingertips was recorded. A negative score was recorded if the patient's fingers did not reach beyond the toes and a score of zero was recorded if the fingers touched the toes. A positive score was recorded if the patient's fingers extended beyond their toes. This test was repeated twice. This test is used to measure flexibility of the lower back and hamstrings[50].

Hand Grip Test

The patient held a hand grip dynamometer at 45 degrees from their body and squeezed their hand with maximum isometric effort for five seconds. The test was performed twice for both the dominant and non-dominant hand. Averages of both scores were recorded. This test is used to measure maximum isometric strength of the hand and forearm and is a general test of strength[51].

Quality of Life Surveys

The patient's quality of life was assessed using the Laval Questionnaire[52]. This questionnaire consists of 44 questions pertaining to six domains: 1) Activity/mobility, 2) Symptoms, 3) Personal Hygiene/Clothing, 4) Emotions, 5) Social interactions and 6) Sex life. This tool utilizes a seven point Likert scale and a high score corresponds to a good quality of life. Average scores were reported for each domain using the rubric of corresponding questions. This questionnaire specifically examines quality of life in patients with morbid obesity[52].

Accelerometer

Actical™ accelerometers (Phillips—Respironics) were used to quantify the patient's physical activity intensity, frequency, and duration as well as energy expenditure[53]. Patients were provided with the accelerometer at baseline testing and post-intervention/post-12 week appointments. They were asked to wear the accelerometer for seven consecutive days during

waking hours. Only those patients who wore the device for a minimum of 10 hours a day for 4 days were included in the analysis. Standard counts per minute have not been developed for obese patients. Intensity was assessed using energy expenditure (kcal/kg/min): sedentary <0.0147 kcal/kg/min, light 0.0147-0.0284 kcal/kg/min, moderate 0.0285-0.0895 kcal/kg/min, and vigorous > or = 0.0896 kcal/kg/min. The amount and percentage of time each patient spent in sedentary, light, moderate and vigorous physical activity was determined.

Timing of Appointments

Baseline testing of primary and secondary outcomes was performed upon completion of the consent form. Patients in the control group were re-assessed at twelve weeks and patients in the intervention group were re-assessed following completion of the exercise program.

Statistics

A sample size of 33 per arm was estimated in order to observe a 70 meter improvement in the 6MWT with a sigma of 100 meters[54] [two means, two-sided t-test (alpha 0.05, power 80%)]. Seventy meters was determined from the suggested numbers in the literature but this was likely an overestimate as it was not intended for higher BMI bariatric surgery patients. The study proposed enrollment of seventy patients to account for drop-outs.

Baseline comparisons were made using student's t-test. Proportions were compared using the Chi square statistic. Comparison of means from baseline to post 12 weeks/intervention between the control and intervention groups was compared with a mixed model with repeated measures using restricted maximum likelihood. A p value of <0.05 was considered statistically significant. A completers-only analysis of the reported outcomes was performed. Pearson's

correlation was used to assess the relationship between percentage sessions attended and primary/secondary outcomes. The SPSS Statistics program (Version 20, IBM) was used for all statistical analyses.

Ethics & Funding

This study was approved by the Health Research Ethics board at the University of Manitoba in Winnipeg, Manitoba. Our study was funded by the Manitoba Medical Service Foundation (MMSF), the Victoria General Hospital Foundation, and the University of Manitoba Department of Surgery Geographic Full Time (GFT) Grant Fund. Our study is registered with the National Institutes of Health website clinicaltrials.gov as trial H2013:388.

RESULTS

Overview & Drop Outs

Fifty four patients were enrolled in our study between July 2015 and Oct 2015 (Figure 1). We were unable able to accrue the target of 33 patients for each arm of the study due to time limitations. Twenty-nine patients were randomized to the control group and 25 patients were randomized to the intervention group. There were 22 dropouts from the study. Of the 29 patients in the control group, 12 dropped out (41.4%) and of the 25 patients in the intervention group, ten dropped out (40.0%) p=0.92. The most common reason for drop outs in the control group was loss to follow up (failure to respond to telephone contact for study appointments); whereas time commitment was the primary reason for drop outs from the intervention group. We undertook a completers-only analysis of the reported outcomes. There was no statistically significant

difference between the gender of the patients who remained in the study or dropped out. Patients in the intervention group were asked to attend three exercise sessions per week for twelve weeks. The average number of sessions attended by the fifteen patients in the intervention group was 27.21 of 36 sessions (75.6%). Three patients had positive GXT results that required cardiology consultation at initial assessment. All patients were subsequently cleared for exercise. No patients were removed from the program during the study for failure to meet program expectations.

Baseline Characteristics

There were no significant differences between the two groups in average age (Control 46.69 +/- 8.88, Intervention 47.53 +/- 8.28, p=0.79). There were more men in the control group (Table 2) however this difference was not statistically significant (p=0.078).

There were no significant differences between the two groups for the presence of diabetes, hypertension, hyperlipidemia, cardiovascular disease, or obstructive sleep apnea (Table 3). There was a higher prevalence of self-reported osteoarthritis in the control group than the intervention group (p=0.01). The results were not co-varied for osteoarthritis due to the small sample size and inability to make valid conclusions.

6MWT

At baseline, the 6MWT results were 473.03 m (+/- 97.95 m) for the control group and 460.10 m (+/- 50.92 m) for the intervention group with a p value of 0.80. When patients in the control group were re-tested twelve weeks later, there was no change in 6MWT distance (-4.88 m +/- 10.01 m, p = 0.63). In comparison, the intervention group had a statistically significant

increase in 6MWT distance of +27.46 m +/- 10.34 m, p =0.01 post-intervention. When comparing the change in 6MWT between completers in the control and intervention groups, the difference was 32.34 m +/- 14.29 and the p value was statistically significant (p= 0.03).

Secondary Outcomes: Anthropometric Variables

At baseline, there was no differences between the control and intervention groups for BMI, neck circumference, waist circumference, or hip circumference (Table 4).

When patients in the control group were re-tested after twelve weeks, there was no change in BMI (-0.40 kg/m^2 +/- 0.42, p = 0.35) or hip circumference (2.54 cm +/- 4.71, p=0.59). There was a statistically significant decrease in neck circumference (-1.05 cm +/- 0.39, p = 0.01) and waist circumference (-3.04 cm +/- 1.04, p = 0.01) for the control group.

Similarly, following completion of the exercise program, the intervention group had no change in BMI (-0.57 kg/m^2 +/- 0.45, p= 0.21) and hip circumference (-9.13 cm +/- 4.99, p = 0.08). There was a statistically significant decrease in neck circumference (-1.24 cm +/- 0.41, p=0.01) and waist circumference (-5.45 cm +/- 1.11, p= 0.00) for the intervention group.

When comparing the change between completers in control and intervention groups for anthropometric variables, the difference was not statistically significant (Table 5).

Secondary Outcomes: Strength Measures

At baseline, there was no difference between control and intervention groups for chair stand repetitions, flexibility, balance (eyes open and eyes closed) or handgrip strength (strong hand and weak hand) (Table 6).

When patients in the control group were re-tested at twelve weeks, there were no differences in chair stand repetitions (1.19 reps +/- 0.78, p =0.13), balance with eyes closed (0.30 sec +/- 0.86, p = 0.73), handgrip strength in strong hand (0.74 +/- 1.24, p = 0.55), and handgrip strength in weak hand (0.79 +/- 1.32, p = 0.56). There was a statistically significant increase in flexibility 5.65 cm +/- 2.69, p = 0.04 in the control group.

Patients in the intervention group had no change in flexibility (2.38 cm +/- 2.86, p= 0.41), balance with eyes open (2.83 sec +/- 2.24, p = 0.40), handgrip strength in strong hand (1.72 +/- 1.32, p= 0.20) and hand grip strength in weak hand (1.65 +/- 1.41, p= 0.25). There was a statistically significant increase in chair stand repetitions (2.33 reps +/- 0.80, p = 0.01).

When comparing the change in strength measures between completers in the control and intervention groups, there were no statistically significant differences (Table 7).

Secondary Outcome: Accelerometer

At baseline, there were no statistically significant differences between the control or intervention groups for the energy expenditure, total time, or percentage of time spent in sedentary, light, moderate or vigorous activity (Table 8). The intervention group had a trend towards higher total time spent in moderate activity (101.07 min +/- 52.25) compared to the control group (68.56 min +/- 34.67) and higher percentage of time spent in moderate activity (7.38% +/-3.85 vs 5.01% +/- 2.54); however, the p values were not statistically significant (p = 0.09).

When patients in the control group were re-assessed at 12 weeks and those in the intervention group were assessed after the exercise program, there were no statistically

significant differences between the two groups for energy expenditure, total time, or percentage of time spent in sedentary, light, moderate or vigorous activity (Table 9).

In the intervention group, there was a statistically significant decrease in energy expenditure for moderate activity (-176.66 +/- 57.03, p = 0.01), total time spent in moderate activity (-35.90 mins +/- 12.93 mins, p=0.02) and percentage of time spent in moderate activity (-2.60 % +/- 0.94, p = 0.02) from baseline to after the exercise program (Table 10).

However, when comparing the changes in accelerometer measures between baseline and re-assessment, there were no statistically significant differences for energy expenditure, total time, or percentage of time spent in sedentary, light, moderate or vigorous activity between the control and intervention groups (Table 11).

Secondary Outcome: QoL Survey

At baseline, patients in the intervention group had higher scores for activity (5.43 +/-1.03 vs 4.29 +/-1.12, p = 0.01) and symptoms (5.12 +/- 0.66 vs 4.41 +/- 1.15, p = 0.05) compared to the control group. Higher scores correspond to a better quality of life. The results were not co-varied due to the small sample size and inability to make valid conclusions. There were no differences between the two groups for responses regarding hygiene, emotions, social, or sex. (Table 12)

There were no changes in the responses for patients in the control group. Whereas, there were statistically significant improvements in all domains for the intervention group. When comparing the differences between the intervention and control groups, there were statistically significant changes for the categories of symptoms, hygiene, and emotions. (Table 13).

Relationship between Intervention Group Attendance and Outcome Measures

Patients in the intervention group were asked to attend three exercise sessions per week for twelve weeks. The average number of sessions attended by the fifteen patients in the intervention group was 27.21 of 36 sessions (75.6%).

Using Pearson's correlation, the relationship between the percentage of exercise sessions attended by the participants in the intervention group and change in 6MWT, BMI, neck circumference, waist circumference, hip circumference, chair stand, sit and reach, one leg stance or hand grip strength was examined. We found no statistically significant relationship between percentage of sessions attended and change in outcome measures. (Table 14)

DISCUSSION

This study demonstrated that a preoperative exercise intervention was associated with a statistically significant improvement in 6MWT as well as quality of life measures in patients awaiting bariatric surgery. This study is unique in that it utilizes a structured, supervised exercise program developed by a kinesiologist and is based at a medically certified fitness facility.

In the current literature, few studies have examined the effects of structured exercise programs in the postoperative period. These studies report that patients enrolled in a post-operative exercise intervention have an improvement in aerobic capacity, functional capacity, cardiac autonomic modulation and weight loss[33–35,55,56].

There is a paucity of literature examining pre-operative exercise programs in patients awaiting bariatric surgery.[38–41]. The largest study, the Bari-Active study[40], enrolled 75 participants who were randomized to a 6 week physical activity intervention involving weekly sessions with instructions in behavioral strategies vs. standard care. Patients enrolled in the

intervention had increased moderate-to-vigorous physical activity pre-operatively. Studies have concluded that a pre-operative exercise program is feasible and patient enrolled in physical activity interventions have increased physical activity[38–41].

6MWT

Patients in the intervention group showed a statistically significant improvement in 6MWT distance when compared to patients in the control group. In the current literature, there are no established reference values for 6MWT in patients with obesity and particularly for bariatric surgery patients. The distance walked is correlated to age, gender and BMI[57]. Baseline 6MWT results were 473.03 m for the control group and 460.10 m for the intervention group. This is lower than the values found in studies by Capodaglio et al of 563.60m[57] or Hulens et al of 538.9m[58]. This difference could be accounted for by the fact that our patients were older (Control mean age 46.69 years, Intervention mean age 47.53 years vs. Capodaglio et al mean age 35.93 years[57] vs. Hulens et al. mean 38.9 years[58]) and had higher BMIs (Control mean BMI 45.21 kg/m^2, Intervention mean BMI 46.27 vs. Capodaglio et al mean BMI 43.39kg/m^2 [57] or Hulens et al of 40.7 kg/m^2 [58]).

Baillot et al. studied a preoperative exercise program in patients awaiting bariatric surgery and found a statistically significant increase in 6MWT distance of 17.4 m +/- 27.2 m in the intervention group compared to -16.4 m +/- 42.4 m for the control group. The p value was 0.03 and statistically significant.

Minimum clinically important differences (MCIDs) reflect changes which occur from a clinical intervention that are meaningful to the patient[59]. This reflects the concept that there may be statistically significant changes secondary to an intervention but there may not be clinical

significance[60]. A statistically significant increase in an 6MWT is often less than a clinically significant increase in an individual[61]. There is debate as to whether a MCID exists for the 6MWT[62,63] and there is limited literature examining the MCID for the 6MWT in patients with obesity. Larsson found good reproducibility and group validity for the 6MWT in obese patients and concluded that an improvement of at least 80 m or 15% was required to make the difference clinically significant[17]. The patients in the intervention group showed a statistically significant increase in 6MWT distance of +27.46 m +/- 10.34 m, p =0.01 or a 6% improvement. However, patients in Larsson's study were less obese (average BMI 40) and walked further at baseline(534 m) than the patients in our study. Larsson's study was also not in the setting of patients awaiting bariatric surgery.

While the clinical significance of this improvement in 6MWT is still undetermined, it is a positive result. Further research is underway to examine the results of the 6MWT at six months postoperatively and its implications on the patient's physical activity levels long term. The sustainability of this change postoperatively will be of clinical interest.

Secondary Outcomes

There were positive trends for the intervention group but no statistically significant changes in BMI, neck/hip or waist circumference when compared to the control group. We anticipated that both the control and intervention group might undergo modest weight loss prior to surgery given that patients are undergoing active dietary modification as part of routine care. They are also required to consume a liquid diet two weeks prior to their operation. Three intervention group patients and one control group patient underwent retesting during the two week liquid diet. A study by Fris found a reduction in percentage of fat of 5.1%, percentage of

BMI of 4.2% and percentage weight loss of 4.1% in patients who consumed the two week low energy liquid diet[64]. The CMBS program does not focus on weight loss preoperatively and there is no weight loss requirement to be approved for surgery.

There were no statistically significant differences in chair stand test, flexibility, balance and hand grip strength when comparing the control and intervention group. Our exercise prescription follows the ACSM and CDC guidelines[65] and includes resistance training in order in improve muscle strength and endurance. Typical resistance training program include 8 to 12 repetitions for 8 to 10 separate exercises[66]. It is possible that our exercise program was not associated with other lifestyles that lead to weight loss. However, baseline data has shown that our bariatric patients spend less than 6% of time in moderately vigorous physical activity so realistic goals need to be set in a 12 week program[67]. Longitudinal data from our study will assess if there are any statistically significant changes at 6 months postoperatively for secondary outcomes.

Accelerometer Data

There were no statistically significant differences between the control and intervention groups at baseline. However, the intervention group had a trend towards higher total time spent in moderate activity and percent of time spent in moderate activity than the control group. Although the accelerometers were worn at baseline and prior to starting the intervention, patients were aware of which study group they were assigned to. It is possible that those patients in the intervention group participated in more physical activity in anticipation of starting the intervention at the Reh-Fit centre. In order to more accurately capture baseline data, patients could wear the accelerometer prior to randomization occurring.

Some patients (three intervention group patients and one control group patient) were required to wear the accelerometer during the two week liquid diet and it is possible that the results could be skewed by decreased physical activity secondary to this caloric restriction. Ideally, patients would wear their accelerometers prior to this two week period however, it was not possible secondary to scheduling of surgery.

Laval Questionnaire: Quality of Life

Patients in the intervention group had higher scores for activity and symptoms than those in the control group, which corresponds to a better quality of life. Surveys are completed prior to randomization therefore it is unlikely this influenced patient responses.

Patients who undergo RYGB and become active post operatively have improved quality of life compared to those who remained inactive[68]. In this study, the intervention group showed improved quality of life in all categories after completing the intervention. There were statistically significant changes for the symptoms, hygiene and emotion categories compared to the control group. Therrien et al[52] studied the Laval questionnaire and attempted to determine the MCID for each domain. The change in scores for the intervention group exceeded the MCID for activity (=0.69) and for symptoms (=0.64) but did not meet the criteria for hygiene (=1.21), emotions (=1.0), social interactions (=0.97) and sexual life (=1.91)[52]. This improved perception of well-being is important and could be used to motivate the patients to change their lifestyle and sustain these changes following bariatric surgery. Future studies could determine what factors (i.e. participating in an activity outside of home, the social interaction or care of the professionals) improved the patient's quality of life and explore this further using patient feedback.

Relationship between Intervention Group Attendance and Outcome Measures

There is no association between the percentage of exercise sessions attended and change in primary or secondary outcome measures in the intervention group. However, other factors to be considered include whether targets were met at each session, the patient's exercise intensity and whether patients increased their activities appropriately. The exercise logbooks were used to monitor progress and the fitness consultants provided feedback in order to encourage to exercise appropriately.

Limitations

Limitations of the study include the sample size. The initial goal sample size was 33 patient within each arm of the study however due to time limitations, we were not able to accrue our target number of patients. Our sample size was further affected by the high dropout rates; however, this is consistent with the current literature in which studies using exercise interventions commonly report dropout rates from 25-50%[69,70]. Drop outs were often due to patients being lost to follow-up or time commitments of the study. Patients approved for bariatric surgery have several appointments with the multidisciplinary team at the CMBS. We could potentially improve follow up with our patients and decrease time commitments by scheduling study appointments in conjunction with other mandatory appointments. Interactive reminders using text messages or emails could be utilize to remind patients of appointments and facilitate improved participation in fitness interventions.

Patients were required to attend all sessions at the fitness facility and were not provided a home option. It is possible to consider a combined program with facility-based and home

options. However, there are limitations to home exercise programs including the type of exercise conducted, documentation of participation and patient motivation.

Other limitations of the study include the potential for sampling bias in the subjects choosing to participate in the study. The study was introduced to all eligible bariatric patients (based on inclusion and exclusion criteria) however the patients who selected to participate in the study could be more motivated to participate in physical activity and therefore this may affect the generalizability and external validity of our results.

There was a higher prevalence of osteoarthritis in the control group compared to the intervention group. However, this was based on a self reported questionnaire completed on intake to the CMBS. No confirmatory testing was performed to diagnose osteoarthritis. If confirmatory testing was performed and the prevalence in the control group remained nine times greater than the intervention group, this would be considered a failure in randomization. Future studies could perform confirmatory testing of comorbidities at baseline, such as, medication reviews and x-rays of affected joints to document the severity. Statistical analyses could be performed with co-variation for comorbidities

Improvements could be made on the timing of accelerometer measures. By collecting data prior to randomization, this would avoid patient related bias in baseline activity level.

Ongoing & Further Research

Short term improvements in physical activity can lead to long term changes and improvement in overall health. The goal is to demonstrate and translate the sustainability of short term changes. We will be assessing change in primary and secondary outcomes at six months

post-operatively. Body composition will also be performed at 6 months post-operatively to assess the change in compared to baseline.

A larger scale study could examine the long-term changes in physical activity and the sustainability during the post operative time period. Further research could examine factors such as the duration of intervention, timing of intervention (pre- vs post- operatively or both) and location (gym, home or combined). Types of activities performed during the intervention could be studied and a behavioural modification component to facilitate adherence could be incorporated.

CONCLUSIONS

The preoperative exercise intervention was associated with a statistically significant improvement in 6MWT in patients awaiting bariatric surgery. There were also statistically significant changes in the quality of life survey for the intervention group. This perceived improvement in quality of life is important and should be used to motivate patients to change their lifestyle prior to and after bariatric surgery. Future research on this cohort will examine if a preoperative exercise program will impact fitness outcomes after bariatric surgery.

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TABLES

Table 1: Reasons for Declining Participation in the Study

Reason for Declining	# of Participants
Unable to contact	15
Personal/Unspecified Reasons	11
Time Commitment	8
Transportation/Distance to Reh-Fit	6
Medical Reasons	5
Not sure if wants surgery	2
Does not want to be in the intervention group	2
Has a personal trainer	1
Total	50

Table 2: Prevalence of Comorbidities in the Control and Intervention Groups

Variable	Control Group	Intervention Group	p value
Age (yrs)	46.7	47.5	0.44
BMI (kg/m^2)	45.2	46.3	0.79
Females (%)	63.0	88.0	0.08
Diabetes (%)	22.7	45.0	0.23
Hypertension (%)	45.5	55.0	0.76
Hyperlipidemia (%)	18.2	20.0	0.88
Cardiovascular Disease (%)	4.5	0.0	0.33
OSA* (%)	36.4	35.0	0.93
Osteoarthritis (%)	45.5	5.0	0.01

Note: N = 42
*Obstructive Sleep Apnea. Treated with CPAP or documented on sleep study

Table 3: Comparison of Anthropometric Variables between Control and Intervention Groups at Baseline and Following 12 weeks/Intervention

Variable		Baseline	p value	Change from Baseline	p value	% Change	Intervention vs Control Change	p value
BMI (kg/m^2)	**Control**	45.73 (5.34)	0.44	-0.40 (0.42)	0.35	-0.87	-0.17 (0.62)	0.78
	Intervention	46.89 (5.40)		-0.57 (0.45)	0.21	-1.22		
Neck Circumference (cm)	**Control**	43.889 (4.33)	0.30	-1.05 (0.39)	0.01	-2.39	-0.19 (0.57)	0.74
	Intervention	42.54 (4.82)		-1.24 (0.41)	0.01	-2.91		
Waist Circumference (cm)	**Control**	134.14 (13.11)	0.50	-3.04 (1.04)	0.01	-2.27	-2.40 (1.52)	0.13
	Intervention	131.83 (11.42)		-5.45 (1.11)	0.00	-4.13		
Hip Circumference (cm)	**Control**	135.60 (22.34)	0.16	2.54 (4.71)	0.59	+1.87	-11.67 (6.87)	0.10
	Intervention	143.12 (14.20)		-9.13 (4.99)	0.08	-6.38		

Note: Control n=27, Intervention n=25

Note for Change from Baseline and Intervention vs Control Change: Control n = 17, Intervention n =15

Mean (SD), Change (Std error)

BMI = Body Mass Index

Table 4: Comparison of Strength Measures between Control and Intervention Groups at Baseline and Following 12 weeks/Intervention

Variable		Baseline	p value	Change from Baseline	p value	% Change	Intervention vs Control Change	p value
Chair Stand Repetitions	**Control**	11.85 (4.09)	0.19	1.19 (0.78)	0.13	+10.04	1.14 (1.11)	0.31
	Intervention	13.12 (2.47)		2.33 (0.80)	0.01	+17.76		
Flexibility	**Control**	-0.59 (13.73)	0.31	5.65 (2.69)	0.04	+957.63	-3.28 (3.93)	0.41
	Intervention	2.64 (7.80)		2.38 (2.86)	0.41	+90.15		
Balance (Eyes Open)	**Control**	21.27 (16.17)	0.77	-0.18 (3.15)	0.96	-0.84	3.01 (4.59)	0.52
	Intervention	22.51 (14.54)		2.83 (3.34)	0.40	+12.57		
Balance (Eyes Closed)	**Control**	4.75 (4.76)	0.76	0.30 (0.86)	0.73	+6.32	-0.84 (1.26)	0.51
	Intervention	5.22 (6.15)		-0.54 (0.92)	0.56	-10.34		
Handgrip Strength (Dominant Hand)	**Control**	36.82 (15.56)	0.23	0.74 (1.24)	0.55	+2.01	0.98 (1.81)	0.59
	Intervention	32.18 (11.70)		1.72 (1.32)	0.20	+5.34		
Handgrip Strength (Non-Dominant Hand)	**Control**	31.87 (15.09)	0.48	0.79 (1.32)	0.56	+2.48	0.86 (1.93)	0.66
	Intervention	29.24 (11.07)		1.65 (1.41)	0.25	+5.64		

Note for Baseline: Control n=27, Intervention n=25

5 Note for Baseline: Control n=27, Intervention n=25

Note for Change from Baseline and Intervention vs Control Change: Control n = 17, Intervention n =15

Mean (SD), Change (Std error)

Table 5: Comparison of Accelerometer Data between Control and Intervention Groups at Baseline

Variable	Control Group (n=26)	Intervention Group (n=25)	p-value
Valid days Actigraph worn	5.65 (2.00)	5.80 (1.78)	.78
Total Steps	7567.72 (3777.06)	7245.78(4701.48)	.80
Total Energy Expenditure	888.84 (440.67)	944.49 (618.93)	.72
Light Energy Expenditure	529.31 (376.34)	397.61 (234.75)	.15
Moderate Energy Expenditure	380.35 (216.32)	454.01 (221.46)	.25
Vigorous Energy Expenditure	1.89 (4.90)	0.88 (3.04)	.39
Total time spent sedentary	973.90 (196.45)	1015.71 (145.52)	.40
Total time spent light activity	329.43 (212.45)	252.61 (146.95)	.15
Total time spent moderate activity	72.12 (36.40)	91.85 (43.13)	.09
Total time spent vigorous activity	0.15 (0.40)	0.07 (0.24)	.35
Percent time sedentary	70.72 (14.84)	74.51 (10.94)	.32
Percent time light activity	23.92 (15.25)	23.92 (15.25)	.17
Percent time moderate activity	5.35 (2.74)	6.79 (3.08)	.09
Percent time in vigorous activity	0.01 (0.03)	0.00 (0.02)	.35

Note: Mean (SD). Energy Expenditure measured as kcal. Total time measured as minutes.

Table 6: Comparison of Accelerometer Data between Control and Intervention Groups when Reassessed after 12 weeks/exercise program

Variable	Control Group (n=13)	Intervention Group (n=14)	p-value
Valid days Actigraph worn	6.08 (1.12)	6.07 (1.27)	.99
Total Steps	8706.20 (6480.48)	6317.41 (3635.28)	.26
Total Energy Expenditure	840.65 (568.59)	694.63 (339.59)	.42
Light Energy Expenditure	537.30 (397.07)	433.61 (289.31)	.45
Moderate Energy Expenditure	330.76 (270.94)	303.88 (145.97)	.76
Vigorous Energy Expenditure	7.92 (16.74)	0.00 (0.00)	.11
Total time spent sedentary	860.14 (333.43)	1047.34 (146.30)	.08
Total time spent light activity	345.17 (231.98)	274.69 (151.96)	.37
Total time spent moderate activity	64.27 (51.25)	63.17 (27.22)	.95
Total time spent vigorous activity	0.32 (0.71)	0.00 (0.00)	.15
Percent time sedentary	67.56 (16.03)	75.30 (10.44)	.17
Percent time light activity	27.41 (16.00)	20.08 (11.11)	.20
Percent time moderate activity	5.01 (3.53)	4.62 (2.01)	.74
Percent time in vigorous activity	0.02 (0.05)	0.00 (0.00)	.14

Note: Mean (SD). Energy Expenditure in kcal. Total time measured as minutes.

Table 7: Change in Accelerometer for Control and Intervention Groups

Variable	Control Group (n=13)		Intervention Group (n=14)	
	Change	**p-value**	**Change**	**p-value**
Total Steps	190.34 (2080.77)	.93	-1814.56 (1377.61)	.22
Total Energy Expenditure	-30.48 (153.55)	.85	-172.70 (96.27)	.10
Light Energy Expenditure	-25.85 (91.00)	.78	3.96 (80.62)	.96
Mod Energy Expenditure	-18.78 (65.32)	.78	-176.66 (57.03)	.01
Vigorous Energy Expenditure	7.02 (4.84)	.17	-0.81 (2.37)	.74
Total time spent sedentary	-100.38 (70.11)	.18	41.47 (40.04)	.32
Total time spent light activity	-19.37 (60.78)	.76	-9.88 (39.25)	.81
Total time spent mod activity	-2.16 (11.45)	.72	-35.90 (12.93)	.02
Total time spent vig activity	0.20 (0.15)	.21	-0.03 (0.08)	.76
Percent time sedentary	-2.44 (2.88)	.42	3.39 (2.59)	.26
Percent time light activity	2.63 (2.54)	.32	-0.77 (2.83)	.78
Percent time mod activity	-0.21 (0.88)	.82	-2.60 (0.94)	.02
Percent time vig activity	0.01 (0.01)	.20	0.00 (0.00)	.76

Note: Change (Std error). Energy Expenditure in kcal. Total time measured as minutes.

Table 8: Comparison of Change in Accelerometer between Control and Intervention Groups

Variable	Intervention vs Control	
	Change	**p-value**
Total Steps	-2004.90 (2825.62)	.22
Total Energy Expenditure	-142.22 (181.24)	.44
Light Energy Expenditure	29.81 (136.28)	.89
Mod Energy Expenditure	-99.10 (75.73)	.52
Vigorous Energy Expenditure	-7.83 (34.3)	.44
Total time spent sedentary	142.85 (80.73)	.09
Total time spent light activity	-21.35 (62.08)	.90
Total time spent mod activity	9.49 (17.27)	.06
Total time spent vig activity	-0.23 (0.14)	.21
Percent time sedentary	5.83 (4.06)	.17
Percent time light activity	-3.40 (3.82)	.38
Percent time mod activity	-2.39 (1.30)	.08
Percent time vig activity	-0.01 (0.41)	.33

Note: Change (Std error). Energy Expenditure measured as kcal. Total time measured as minutes.

Table 9: Comparison of Laval Questionnaire Scores between Control and Intervention Groups at Baseline and Following 12 weeks/Intervention

Variable		Baseline	p value	Change from Baseline	p value	% Change	Intervention vs Control Change	p value
Activity	**Control**	4.38 (1.29)	0.02	0.43 (0.22)	0.06	+9.82	0.30 (0.32)	0.35
	Intervention	5.20 (1.01)		0.73 (0.23)	0.00	+14.04		
Symptoms	**Control**	4.49 (1.02)	0.05	0.003 (0.15)	0.98	+0.07	0.67 (0.23)	0.01
	Intervention	4.96 (0.63)		0.68 (0.16)	0.00	+13.71		
Hygiene	**Control**	4.90 (1.34)	0.19	-0.28 (0.17)	0.11	-5.71	0.93 (0.25)	0.00
	Intervention	5.32 (0.84)		0.65 (0.18)	0.00	12.22		
Emotions	**Control**	3.93 (1.40)	0.39	0.31 (0.18)	0.10	+7.89	0.55 (0.26)	0.05
	Intervention	4.23 (1.09)		0.85 (0.19)	0.00	+20.09		
Social	**Control**	4.71 (1.47)	0.69	0.40 (0.20)	0.05	+8.49	0.42 (0.29)	0.16
	Intervention	4.87 (1.31)		0.82 (0.21)	0.00	+16.84		
Sex	**Control**	4.10 (1.83)	0.44	0.09 (0.28)	0.75	+2.20	0.54 (0.41)	0.19
	Intervention	4.40 (1.32)		0.63 (0.30)	0.04	+14.32		

Note for Baseline: Control n=26, Intervention n=25

Note for Change from Baseline and Intervention vs Control Change: Control n = 17, Intervention n =15

Mean (SD), Change (Std error)

Table 10: Relationship between Percentage of Exercise Sessions Attended and Outcome Measures

Variable	r^2 (p value)
6MWT	-0.290 (0.315)
BMI	0.501 (0.068)
Neck Circumference	-0.060 (0.837)
Waist Circumference	0.168 (0.565)
Hip Circumference	-0.072 (0.806)
Chair Stand	-0.087 (0.767)
Flexibility	-0.191 (0.513)
One Leg Stance (Eyes Open)	-0.167 (0.569)
One Leg Stance (Eyes Closed)	-0.289 (0.316)
Hand Grip Strength (Strong Hand)	-0.102 (0.727)
Hand Grip Strength (Weak Hand)	-0.213 (0.466)

Data presented with correlation value r and p value

5 6MWT = Six minute walk test, BMI = Body Mass Index

Table 11 : Reasons for Drop Out from the Study

Reason for Drop Out	# of Control	# of Intervention
Lost to Follow Up	5	1
Time Commitment	2	5
Incomplete pre-intervention testing	2	0
Medical Issues	1	0
Did not want surgery	1	1
Family Issues	1	1
Did not complete GXT	0	2
Total	12	10

GXT = Graded Exercise Test

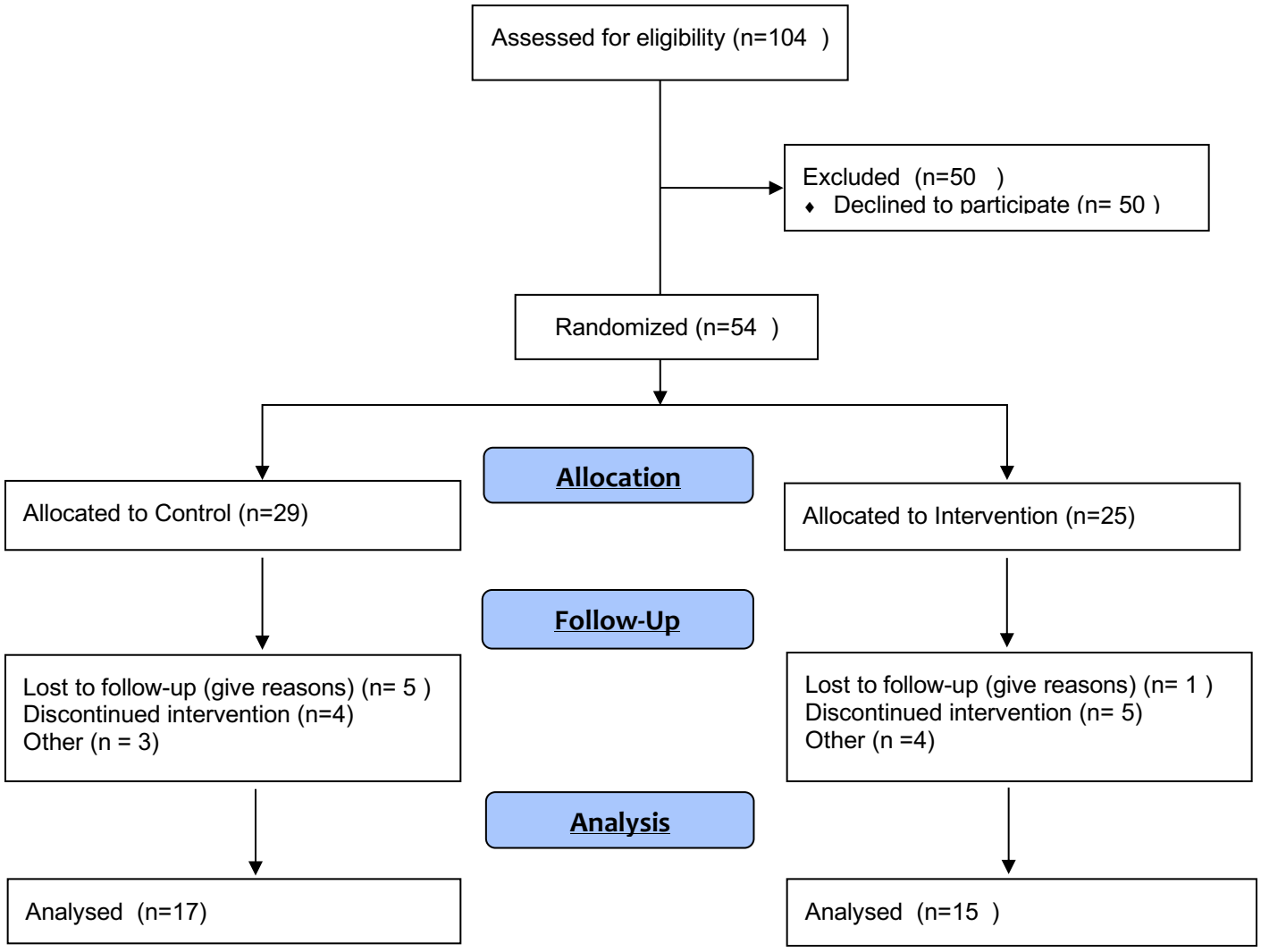
Table 12: Characteristics of Patients who Remained Enrolled in the Study vs Dropouts.

Variable		Non-Dropout (n=31)	Dropout (n=21)	p-value
Age		47.10 (8.46)	47.30 (11.31)	.94
Gender	**Female**	25 (80.6)	15 (65.2)	.20
	Male	6 (19.4)	8 (34.8)	
Study Group	**Control**	17 (53.1)	12 (54.6)	.92
	Intervention	15 (46.9)	10 (45.5)	

Note: N(%)

FIGURES

Figure 1: CONSORT Flow of patient enrollment, allocation, follow up and analysis



APPENDICES

Appendix 1: Consent form

VICTORIA
GENERAL
HOSPITAL

2340 Pembina Highway
Winnipeg, MB
R3T 2E8

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: The Impact of a Pre-Operative Exercise Program on Fitness Outcomes Following Bariatric Surgery
Protocol number: H2013:388

Principal Investigator:
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Assistant Professor
Section of General Surgery
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Ph:(204) 237-2574
Z-3049 St. Boniface General Hospital

Co-Investigators: Dr. Danielle Bouchard, Dr. Karen Kwok, Dr. Ashley Vergis

Sponsor: University of Manitoba

You are being asked to participate in a Clinical Trial (a human research study). 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 clinical trial 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 doctor or study staff to explain any words or information that you do not clearly understand.

The study doctor is not receiving professional fees or financial support to conduct this study.

Purpose of Study

This Clinical Trial is being conducted to study the effects of an exercise program on patients undergoing bariatric surgery. You are being asked to take part in this study because you meet criteria for publicly funded bariatric surgery and are currently awaiting surgery in Manitoba. A total of 70 participants will be included in this study.

The study will examine the effects of an exercise program before bariatric surgery, including changes in general fitness, body composition, strength, and post-surgical weight loss.

This research is being conducted because there is currently little knowledge on the effects of an exercise program on patients awaiting bariatric surgery. Most bariatric surgery programs include some exercise counseling but there are no specific guidelines on what should be included in pre-surgical exercise intervention.

Study Procedures

In this study, you will be "randomized" into one of 2 study groups described below. "Randomized" means that you are put into a group by chance, like flipping a coin. You will have an equal chance of being placed in any group.

The "control" group will participate in the standard care for patients awaiting bariatric surgery in Manitoba. This includes information seminars and evaluations by a nurse, dietician, kinesiologist, and psychologist. Participants will receive ongoing care before surgery consisting of two to four visits over a six-month period of time as well as exercise counseling by a kinesiologist. As part of usual care, all bariatric surgery patients are expected to participate in regular self-directed physical activity as part of their preoperative preparation.

The "treatment group" will receive the standard care and will also be enrolled in a 12-week exercise program at the Reh-Fit Centre in Winnipeg. This will involve regular supervised exercise sessions three times per week at the Reh-fit Centre. There will be an initial visit (60 minutes) with a tour of the Reh-Fit and an interview to determine your exercise history and physical limitations. At a second visit, you will be asked to participate in a treadmill exercise test and general strength test to determine your medical safety to participate in the exercise program. You will be asked to complete three weekly exercise sessions of approximately one hour. The program will be overseen by a Canadian Society for Exercise Physiology certified kinesiologist. Your progress will be monitored and recommendations will be made to adjust your program as required.

If you take part in this study, you will undergo several fitness tests at the beginning of the study and at three other intervals over the course of follow-up. It is estimated that each assessment will take 30 minutes (total 2 hours over four assessments). These measures will include:

1. **The six minute walk test – the distance you can walk on a flat surface in six minutes will be measured**
2. **Chair stand test – how many times you can go from sitting to standing in 30 seconds**
3. **Hand Grip Strength test – measures the strength of your hand and forearm muscles**
4. **Half squat test – how long you can stand against a wall in a squat position**
5. **Measurement of your height, weight, body mass index (BMI), neck circumference, waist and hip circumference.**
6. **Dual- Energy X-ray Absorptiometer—used to measure your body composition and see the change in fat vs. lean muscle**
7. **You will wear an accelerometer for one week at a time in order to measure your physical activity.**
8. **Blood work for the hormone Irisin**
9. **Abdominal wall muscle biopsy during bariatric surgery (optional)**

Both the control and treatment group will be tested once accepted to the study. In addition, the treatment group will be tested after participating in the exercise program and the control group will be tested at two to four weeks before surgery. Both groups will also be tested at three and six months. In total, this will require approximately 2 hours of your time (30 minutes each session X 4 sessions) at a minimum. Testing will be scheduled at your convenience through the Victoria General Hospital. You may be contacted in the future to have this testing repeated as part of a study of longer-term results.

Participants will have their body composition measured with a special device called a Dual X-Ray absorptiometer (DEXA) at the Richardson Centre for Functional Foods and Nutraceuticals, located at the University of Manitoba campus. This will be performed at the beginning of the study and six months post-surgery. Patients will be required to lie in the DEXA scanner for a short time period while their body is being scanned. Information from this test is used to measure regional as well as today body fat percentage, fat mass, bone mass, and lean mass. The purpose of this measurement is to see the change in fat versus lean (muscle) mass composition of your body.

As part of this study, in addition to the above outcomes, we will also be examining patient's quality of life, exercise beliefs and satisfaction. Patients will complete an exercise belief questionnaire before and after the intervention. You will also complete a quality of life questionnaire and a satisfaction survey six months after surgery. You may also be contacted in the future to have this testing repeated as part of a study of longer-term results.

Blood (6 ml or approximately 1.5 tsp) will be drawn to measure a hormone called Irisin. There is evidence to suggest that this hormone changes with exercise and weight loss. We are trying to understand its role in bariatric patients. The

bloodwork will be done during usual bariatric bloodwork with no extra needle insertion required except for the draw immediately before surgery at the hospital.

For the control group, blood will be drawn upon study entry (6 mL), immediately before surgery at the hospital (6 mL), after surgery at the hospital (6 mL), as well as at three and six months post-surgery (6 mL each time).

For the intervention group, blood will be drawn before the exercise intervention (6mL), immediately after the exercise intervention (6mL), immediately after surgery in hospital (6 mL) as well as at three and six months post-surgery (6 mL each time).

Blood will be taken at the Victoria General Hospital by a registered technician. Bloodwork before surgery will be performed fasting whenever possible, while bloodwork after surgery will not require fasting.

All blood samples obtained during the study will be stored in a freezer with a code (e.g. P14XXAB, with XX representing your participant enrollment order and AB representing your initials) instead of your name. Only your flie, which is kept in a locked cabinet located at the Manitoba Institute of Child Health, will have information, which relates your name to the code.

The blood specimens will be kept at the Manitoba Institute of Child Health on the fifth floor. The freezer is locked in a room with limited access for research staff only. All blood samples will be kept in a freezer to perform analysis thereafter. The length of this storage could go up to 5 years. Blood specimens will only be used for analyses outlined in the consent form.

Weight loss will be determined at your usual follow-up visits and will not involve any extra visits to the Centre for Metabolic and Bariatric Surgery.

Participation in the study will involve 12 weeks prior to scheduled bariatric surgery and follow-up to 6 months post-surgery (the intervals described above).

The researcher may decide to take you off this study if it is medically in your best interest. Most patients that are initially approved for bariatric surgery will go on to meet goals during the pre-surgical period. However, you may also be asked to discontinue the study if you not meeting team goals and your surgery has been delayed by the team for other reasons (per usual program protocol).

You can stop participating at any time. This will not influence your approval for bariatric surgery or the timing of your operation. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first.

Anonymous results of the study will be made available to participants through the Centre for Metabolic and Bariatric Surgery after the data has been collected and analyzed. This might be several months after you have completed your

participation in the study. The results will not identify you individually but will summarize of the results of all participants.

Optional Muscle Biopsy

An optional muscle biopsy will be performed at the time of bariatric surgery while under general anesthetic. A small biopsy needle will be used to sample the oblique abdominal wall muscle through a port site incision on the left abdominal wall. This will not involve an extra incisions or lengthening of the existing port incision. It will involve removing approximately 16 grams of muscle tissue (i.e. the size of your fingernail) for analysis of the genes producing the hormone Irisin.

Genes determine the traits that we inherit, such as eye and hair color. The genes associated with the hormone Irisin is not known to be associated with any medical conditions. However, we believe the hormone irisin may be associated with exercise outcomes and obesity.

All muscle biopsy specimens obtained during the study will be stored in a freezer with a code (e.g. P14XXAB, with XX representing your participant enrollment order and AB representing your initials) instead of your name. Only your flie, which is kept in a locked cabinet located at the Manitoba Institute of Child Health, will have information, which relates your name to the code.

The muscle biopsy specimens will be kept at the Manitoba Institute of Child Health on the fifth floor. The freezer is locked in a room with limited access for research staff only. All muscle samples will be kept in a freezer to perform analysis thereafter. The length of this storage could go up to 5 years. Muscle biopsy specimens will only be used for analysis outlined in this consent form.

You have the option to participate in this part of the study or to opt out of it. You are free to change your mind about participation up until the time of surgery. This will not influence your participation in the rest of the study or your surgical care.

Risks and Discomforts

While on the study, you are at risk for certain side effects. Participating in exercise may cause some discomfort, such as muscle aches and stiffness. Studies have demonstrated that the benefits of exercise outweigh risks. The risk of death is minimal and is reported to be one death for every 334, 000 hours of exercise, usually from unexpected cardiac events. In our study, participants will be exercising at the Reh-Fit Centre where there are medically trained personnel on site. You will also be asked to complete an exercise treadmill test before being approved for the exercise program.

If you are concerned that you have sustained an injury related to exercise in the study, you are asked to contact the study coordinator through the Centre for Metabolic and Bariatric Surgery. It will be determined whether your participation in the study should be discontinued at that point. Your eligibility for surgery will not

be influenced by any injury related to participating in the study. You may be asked to see your regular family physician or other health care providers for further evaluation.

Patients will undergo a dual x-ray absorptiometry (DEXA) scan in order to assess body composition. This test involves exposing the patient to ionizing radiation in order to produce images of the body. The dose used in this procedure is very low and is approximately one tenth of a chest x-ray or less than the radiation received during a 10-hour flight.
However, effects of radiation can add up over a lifetime and excessive exposure to radiation can lead to injury or disease. Therefore, when deciding to enter this study, consider your previous and future contact with radiation.

Women should inform their physician or x-ray technologist if there is any possibility that they are pregnant.

Blood draws will be done with routine bloodwork four out of five times. There will be one additional blood draw for the study. This is associated with small potential discomforts such as bruises, slight pain from the needle, and infection. The technicians are well-trained to minimize any discomfort.

The biopsy will be performed during the surgery while you are completely asleep under general anesthesia. Therefore, no discomfort or pain should be associated to the procedure itself. There will be no additional scars or lengthening of the scars. There is a small increased chance of bruising or bleeding from the biopsy site and a rare chance of having to explore or extend the incision if there is bleeding at the time of biopsy.

Benefits

By participating in this study, you will be providing information to the study doctors that will show the effects of exercise on patients awaiting bariatric surgery. There may or may not be direct medical benefit to you from participating in this study. We hope the information learned from this study will benefit other participants who are awaiting bariatric surgery in the future.

Costs

All clinic and professional fees, diagnostic tests and fitness tests performed as part of this study are provided at no cost to you. There will be no cost for the study treatment that you will receive. Parking at the Reh-Fit Centre is free. Parking at the Richardson Centre for Functional Foods and Nutraceuticals and Victoria General Hospital will be provided at no cost to you. Any cost in addition to your usual visits will be reimbursed at the end of the study.

Payment for participation

You will receive reimbursement for all parking expenses related to participating in this study.

Alternatives

Instead of participating in this study, you may request the standard multi-disciplinary care for patients awaiting bariatric surgery in Manitoba.

You do not have to participate in this study to receive treatment for your condition. Please talk to your family doctor or referring doctor about all your treatment options.

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. All study documents related to you will bear only your assigned patient number.

The University of Manitoba Health Research Ethics Board may review research-related records for quality assurance purposes.

All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to study investigators, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the Centre for Metabolic and Bariatric Surgery or the Reh-Fit Fitness Centre.

With your permission your Family Physician (GP) will be notified about your participation in this study.

Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your other medical care at this site. If your study doctor feels that it is in your best interest to withdraw you from the study, your study doctor will remove you without your consent.

You have the option of participating in the muscle biopsy. You are free to change your mind and withdraw your consent to the muscle biopsy at any time leading up to surgery.

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

If you should become physically injured as a result of any research activity, the study doctor will make available the usual insured services through Manitoba Health for those who sustain exercise-related injuries prior to bariatric surgery.

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 doctor and the study staff: Dr. Krista Hardy at the Centre for Metabolic and Bariatric Surgery, Victoria General Hospital at (204)-477-3450

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

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Krista Hardy and/or her study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. 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. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of my medical records by the University of Manitoba and The University of Manitoba Health Research Ethics Board.

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 give consent to the muscle biopsy.
Yes □ No □

I agree to being contacted in the future in relation to this study.
Yes □ No □

I agree to my family physician being notified of my participation in 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: _____

Role in the study: _____

Relationship to study team members:_____

QUESTIONNAIRE DE LAVAL

The Laval Questionnaire contains 44 items divided into 6 domains:
(1) activity /mobility; (2) symptoms; (3) personal hygiene / clothing; (4) emotions; (5) social interactions; (6) sex life (Table 1).

The questionnaire is constructed so that it can be self-administered by the patient. This allows distribution by mail.

A Likert scale of 7 points accompanies each item. A high score corresponds to a good quality of life.

The results should be reported as average scores for each domain on a scale of 7 points. For the questions that do not apply to the respondent, the respondent simply omits these questions on questionnaire. In this case, the average score for each domain is calculated based on the number of items which the respondent answered.

Table 1 – Questionnaire de Laval: Areas and corresponding items

Item domains	
Activity / mobility	6, 7, 26, 27, 28, 29, 30, 31, 32
Symptoms	1, 2, 3, 4, 20, 21, 22, 23, 24, 25
Personal hygiene / clothing	14, 41, 42, 43, 44
Emotions	5, 13, 15, 16, 17, 18, 19, 35, 36, 38, 39
Social interactions	8, 9, 10, 11, 33, 34, 40
Sex life	12, 37

The Laval Questionnaire
The questionnaire was formulated to let us know how your obesity has affected your life in the past 4 weeks.
You will be asked about the impact that excess weight has had on your daily activities, your emotions, your social life, your sex life, your personal hygiene, and about symptoms that are caused by your obesity.

Over the last 4 weeks:	All the time	Most of the time	A good part of the time	Some of the time	A small part of the time	Almost never	Never
1. Did you get short of breath with little effort?	1	2	3	4	5	6	7
2. Did you feel tired or exhausted?	1	2	3	4	5	6	7
3. Did you wake up repeatedly during the night?	1	2	3	4	5	6	7
4. Did you feel there were times where you were perspiring and sweating excessively?	1	2	3	4	5	6	7
5. Did you feel anxious and / or stressed?	1	2	3	4	5	6	7
6. Did you feel unable to do things that you would have liked to undertake?	1	2	3	4	5	6	7
7. Did you have to take regular breaks to rest during the day?	1	2	3	4	5	6	7
8. Did you avoid public places and social activities (cinema, restaurant, shopping centre, bus, shows, meeting friends)?	1	2	3	4	5	6	7
9. Did you feel unaccepted by others?	1	2	3	4	5	6	7
10. Did you feel you prevented people in your family (spouse, children, friends) living fully?	1	2	3	4	5	6	7

11. Did you feel different from others?	1	2	3	4	5	6	7
12. Did you feel physically unattractive?	1	2	3	4	5	6	7
13. Did you avoid looking at yourself in a mirror?	1	2	3	4	5	6	7
14. Did you wear clothes to hide your appearance?	1	2	3	4	5	6	7
15. Were you concerned about your health?	1	2	3	4	5	6	7
16. Did you feel there were times that you did not have control over what was happening to you?	1	2	3	4	5	6	7
17. Did you feel discouraged and / or depressed?	1	2	3	4	5	6	7
18. Did you feel like you were just surviving rather than living life to the full?	1	2	3	4	5	6	7
19. Did you have times where you felt like doing nothing?	1	2	3	4	5	6	7

Over the last 4 weeks:	Extremely	A great deal	A lot	Moderately	A little	Occasionally	Not at all
20. Did you feel pain in your lower back?	1	2	3	4	5	6	7
21. Did you have to fight against sleep during the day?	1	2	3	4	5	6	7
22. Did you feel pain in your knees, ankles, and / or feet?	1	2	3	4	5	6	7
23. Have you had any sores and / or chafing (between the thighs, the belly, at the groin, under the breasts)?	1	2	3	4	5	6	7
24. Did you have swelling of your legs?	1	2	3	4	5	6	7
25. Did your snoring disturb someone else?	1	2	3	4	5	6	7
26. Did you have trouble squatting (tying shoes, sitting, bending to pick up objects)?	1	2	3	4	5	6	7
27. Did you have difficulty going up and / or down the stairs?	1	2	3	4	5	6	7
28. Did you have difficulty getting up from a chair?	1	2	3	4	5	6	7
29. Did you have trouble getting dressed or undressed (socks, bra)?	1	2	3	4	5	6	7
30. Did you struggle to move around or walk?	1	2	3	4	5	6	7
31. Did you have trouble participating in activities with your partner, your children or your friends?	1	2	3	4	5	6	7
32. Did you have trouble crossing your legs?	1	2	3	4	5	6	7

33. Were you afraid of not finding a seat to fit your waist in public places?	1	2	3	4	5	6	7
34. Were you afraid of what others may think of you?	1	2	3	4	5	6	7
35. Did you have many disappointments?	1	2	3	4	5	6	7
36. Did you feel unhappy in your life?	1	2	3	4	5	6	7
37. Did you have trouble with sexual activity?	1	2	3	4	5	6	7
38. Did you lose self confidence?	1	2	3	4	5	6	7
39. Were you dissatisfied with your physical appearance?	1	2	3	4	5	6	7
40. Would you have been afraid to attend an interview for a job?	1	2	3	4	5	6	7
41. Did you struggle to wash?	1	2	3	4	5	6	7
42. Did you have trouble wiping after using the toilet?	1	2	3	4	5	6	7
43. Did you have trouble cutting your toenails?	1	2	3	4	5	6	7
44. Did you have trouble finding clothes to fit your size?	1	2	3	4	5	6	7