ADOLESCENTS WITH SEVERE OBESITY: OUTCOMES OF PARTICIPATION IN AN INTENSIVE OBESITY MANAGEMENT PROGRAM

by

Paola D. Luca

A thesis submitted in conformity with the requirements for the degree of Master of Science
Institute of Medical Science
University of Toronto

© Copyright by Paola D. Luca 2013
Adolescents with Severe Obesity: Outcomes of Participation in an Intensive Obesity Management Program

Paola D. Luca
Master of Science
Institute of Medical Science
University of Toronto

2103

Abstract

Objective: To evaluate the SickKids Team Obesity Management Program (STOMP), an obesity management program for severely obese adolescents.

Methods: Non-randomized study of 6 and 12 month outcomes in STOMP patients vs. a comparison group of obese adolescents.

Results: At 6 months, STOMP patients stabilized their BMI (0.08±0.3 kg/m²; p=0.79) and reported improved psychological and health behaviour measures, whereas comparison participants increased their BMI (0.7±0.2 kg/m²; p=0.004) and had worsening of cardiometabolic outcomes. Between-group differences included improved cardiometabolic, psychological and health behaviour measures in STOMP patients. At 12 months, STOMP patients stabilized their BMI (0.8±0.5 kg/m²; p=0.07), had improvements in anthropometric and cardiometabolic outcomes and reported an increase in health behaviours, whereas comparison participants increased their BMI (1.2±0.4 kg/m²; p=0.001) and had worsening of cardiometabolic outcomes. Between-group differences included improved anthropometric, cardiometabolic and health behaviour outcomes in STOMP patients.

Conclusions: Participation in STOMP improved anthropometric, cardiometabolic, psychological and health behaviour outcomes among severely obese adolescents.
Acknowledgments

I would like to sincerely thank my supervisor, Dr. Jill Hamilton, for her incredible support over the past two years. I cannot express my gratitude for her guidance and mentorship, directly related to the thesis and extending far beyond. It has been inspiring to see the dedication and commitment she provides to her patients, students and colleagues.

I would like to thank the members of my Primary Advisory Committee, Dr. Catherine Birken, Dr. Brian McCrindle, Dr. Elizabeth Dettmer and Dr. Kathryn Parker, for their invaluable feedback throughout the project.

I am so grateful to have worked with an incredible research team. I want to thank Munaza Jamil, Rachel Steger and Sholeh Ghayoori for the hours they put into this project and for their positive spirits.

I feel fortunate to have had the chance to work with the incredible members of the STOMP team. I want to thank them for the opportunity to participate in and learn about the STOMP program firsthand. Their commitment to this program and to the families it serves is amazing.

I would like to thank the staff and fellows in the Endocrine division at The Hospital for Sick Children, for their support and for the opportunity to present our work on several occasions.

I would like to finish by thanking my parents and my sisters, Nadia, Mary Clare and Stephanie. I am so fortunate to have such a loving and supportive family and I want to thank them for their unconditional love and unwavering support.
Table of Contents

Contents
Abstract ................................................................................................................................. ii
Acknowledgments ................................................................................................................... iii
Table of Contents .................................................................................................................. iv
List of Tables and Figures ....................................................................................................... ix
Abbreviations ......................................................................................................................... xi
Chapter 1 Introduction and Background .............................................................................. 1

1 INTRODUCTION ............................................................................................................... 1

1.2. MEASURES, DEFINITIONS AND ETIOLOGY OF CHILDHOOD OBESITY .......... 2
1.2.1 Measures and Definitions of Childhood Overweight and Obesity ....................... 2
1.2.2 Definition of Severe Complex Obesity ................................................................... 4
1.2.3 Etiology of Childhood Obesity ................................................................................ 5

1.3 CO-MORBIDITIES ASSOCIATED WITH CHILDHOOD OBESITY ...................... 6
1.3.1 Medical Co-morbidities Associated with Childhood Obesity ............................... 6
1.3.2 Psychological Co-morbidities Associated with Childhood Obesity ..................... 8
1.3.3 Long-Term Effects of Childhood and Adolescent Obesity ................................. 10

1.4 ASSESSMENT OF THE OVERWEIGHT AND OBESE CHILD AND ADOLESCENT ...... 11

1.5 MANAGEMENT OF CHILDHOOD AND ADOLESCENT OBESITY ...................... 15

1.6 EVALUATION OF PEDIATRIC WEIGHT MANAGEMENT INTERVENTIONS ........ 16
1.6.1 Effectiveness of Pediatric Lifestyle Interventions ................................................. 16
1.6.2 Effectiveness of ‘Real-World’ Pediatric Weight Management Programs ................ 23
1.6.3 Current Status of Pediatric Weight Management Programs in Canada ............... 26

1.7 ADOLESCENT BARIATRIC SURGERY .................................................................... 29
1.7.1 Overview of Adolescent Bariatric Surgery ............................................................ 29
9.2.4 Letter of Consent for Comparison Parents ................................................................. 108

9.3 PSYCHOLOGY QUESTIONNAIRES ........................................................................ 108

9.3.1 PedsQL 4.0 Questionnaire .................................................................................. 108

9.3.2 IWQOL-Kids Questionnaire ................................................................................ 108

9.3.3 CDI Questionnaire ............................................................................................. 108

9.4 HEALTH BEHAVIOUR CHANGE QUESTIONNAIRES ....................................... 108

9.4.1 Teen Readiness to Change .................................................................................. 108

9.4.2 Parent Readiness to Change ............................................................................... 108

9.4.3 HAES Questionnaire .......................................................................................... 108

9.4.4 STOMP Participants’ Dietary Readiness to Change Assessment by STOMP Dietitian 108

9.4.5 Comparison Participants’ Dietary Readiness to Change Questionnaire ................. 108

9.6 DATA COLLECTION FORMS ................................................................................ 108

9.6.1 Intake Form ........................................................................................................ 108

9.6.2 Co-Morbidity and Medication Checklists .............................................................. 108

9.6.3 Comparison Participants’ Data Collection Form ..................................................... 109
List of Tables and Figures

Figure 1: Definition of Complex Severe Obesity (11) 4
Table 1: Adolescent Psychology Questionnaires 45
Table 2: Parent Psychology Questionnaires 46
Table 3: Definitions of Obesity-Related Co-morbidities 47
Figure 2: Recruitment, Enrollment and Follow-up of STOMP and Comparison Participants 56
Table 4: Baseline Demographic and Anthropometric Characteristics of STOMP and Comparison Participants 57
Figure 3: Parental Education Levels 57
Figure 4: Annual Household Income 58
Table 5: Baseline Co-Morbidities of STOMP and Comparison Participants 58
Figure 5: Baseline Co-Morbidities of STOMP and Comparison Participants 59
Table 6: Baseline Cardiometabolic Characteristics of STOMP and Comparison Participants 59
Figure 6: Baseline Cardiometabolic Measures of STOMP and Comparison Participants 60
Table 7: Baseline Psychological Measures of STOMP and Comparison Participants 60
Figure 7: Baseline PedsQL 4.0 Scores of STOMP and Comparison Participants Vs. Healthy Youth (73) 61
Figure 8: Baseline IWQOL-Kids Scores of STOMP and Comparison Participants Vs. Healthy Youth (74) 61
Table 8: Baseline Measures of Health Behaviour in STOMP and Comparison Participants 62
Figure 9: Baseline Teen Readiness to Change Scores 62
Figure 10: Baseline Parent Readiness to Change Scores 62
Figure 11: Baseline Dietary Readiness to Changes Scores 63
Table 9: Within Group and Between Group Change in Anthropometric Measures from Baseline to 6 and 12 Months 64
Table 10: Within Group and Between Group Change in Cardiometabolic Measures from Baseline to 6 and 12 Months 65
Table 11: Within Group and Between Group Change in Psychological Measures from Baseline to 6 and 12 Months 66
Table 12: Within Group and Between Group Change in Health Behaviours from Baseline to 6 and 12 Months

Figure 12: Between and Within Group Changes From Baseline to 6 Months

Figure 13: Between and Within Group Changes From Baseline to 12 Months

Figure 14: Within Group and Between Group Change in HOMA-IR

Table 13: Regression Model of Factors Associated with a Greater Reduction in BMI Between Baseline and 6 Months

Figure 15: Factors Associated with Greater Reduction in BMI at 6 Months*

Table 14: Regression Model of Factors Associated with a Greater Reduction in BMI Between Baseline and 12 Months

Figure 16: Factors Associated with Greater Reduction in BMI at 12 Months*

Table 15: Anthropometric Measures At Baseline, 6 Months and 6 Months Post-Operative

Table 16: Cardiometabolic Measures At Baseline, 6 Months and 6 Months Post-Operative

Table 17: Psychological Measures At Baseline, 6 Months and 6 Months Post-Operative

Figure 17: Overview of STOMP Program: Components, Delivery, Short-Term Impact and Long-Term Goals
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>Attention deficit hyperactivity disorder</td>
</tr>
<tr>
<td>ALT</td>
<td>Alanine aminotransferase</td>
</tr>
<tr>
<td>AST</td>
<td>Aspirate aminotransferase</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>BP</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive behaviour therapy</td>
</tr>
<tr>
<td>CCT</td>
<td>Controlled clinical trial</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CDI</td>
<td>Children’s Depression Inventory</td>
</tr>
<tr>
<td>CHD</td>
<td>Coronary heart disease</td>
</tr>
<tr>
<td>CHW-SB</td>
<td>Centre for Healthy Weights-Shapedown BC</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CNS</td>
<td>Central nervous system</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>GERD</td>
<td>Gastroesophageal reflux disease</td>
</tr>
<tr>
<td>HAES</td>
<td>Habitual Activity Estimation Scale</td>
</tr>
<tr>
<td>HDL</td>
<td>High-density lipoprotein</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>Homeostatic measurement assessment-insulin resistance</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health-related quality of life</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEP</td>
<td>Individualized education plan</td>
</tr>
<tr>
<td>IFG</td>
<td>Impaired fasting glucose</td>
</tr>
<tr>
<td>IGT</td>
<td>Impaired glucose tolerance</td>
</tr>
<tr>
<td>ILI</td>
<td>Intensive-instructor-led intervention</td>
</tr>
<tr>
<td>IWQOL-Kids</td>
<td>Impact of Weight on Quality of Life-Kids</td>
</tr>
<tr>
<td>LAGB</td>
<td>Laparoscopic adjustable gastric band</td>
</tr>
<tr>
<td>LD</td>
<td>Learning disorder</td>
</tr>
<tr>
<td>LDL</td>
<td>Low-density lipoprotein</td>
</tr>
<tr>
<td>MC4R</td>
<td>Melanocortin-4 receptor</td>
</tr>
<tr>
<td>MCID</td>
<td>Minimal clinically important difference</td>
</tr>
<tr>
<td>MLE</td>
<td>Maximum likelihood for parameter estimation</td>
</tr>
<tr>
<td>MPOWER</td>
<td>Michigan Pediatric Outpatient Weight Evaluation and Reduction</td>
</tr>
<tr>
<td>MSK</td>
<td>Musculoskeletal</td>
</tr>
<tr>
<td>NAFLD</td>
<td>Non-alcoholic fatty liver disease</td>
</tr>
<tr>
<td>NCHC</td>
<td>National Center for Health Statistics</td>
</tr>
<tr>
<td>OGGT</td>
<td>Oral glucose tolerance test</td>
</tr>
<tr>
<td>OSA</td>
<td>Obstructive sleep apnea</td>
</tr>
<tr>
<td>PCOS</td>
<td>Polycystic ovarian syndrome</td>
</tr>
<tr>
<td>PedsQL 4.0</td>
<td>Pediatric Quality of Life Inventory 4.0</td>
</tr>
<tr>
<td>POMC</td>
<td>Pro-opiomelanocortin</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>PSMF</td>
<td>Protein Sparing Modified Fast</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>SCFE</td>
<td>Slipped capital femoral epiphysis</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>SDS</td>
<td>Standard deviation score</td>
</tr>
<tr>
<td>SH</td>
<td>Self-help</td>
</tr>
<tr>
<td>SickKids</td>
<td>The Hospital for Sick Children</td>
</tr>
<tr>
<td>STOMP</td>
<td>SickKids Team Obesity Management Program</td>
</tr>
<tr>
<td>TC</td>
<td>Total cholesterol</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 diabetes</td>
</tr>
<tr>
<td>TG</td>
<td>Triglyceride</td>
</tr>
<tr>
<td>UCSF</td>
<td>University of California, San Francisco</td>
</tr>
<tr>
<td>USPSTF</td>
<td>US Preventive Services Task Force</td>
</tr>
<tr>
<td>Vs.</td>
<td>Versus</td>
</tr>
<tr>
<td>WATCH</td>
<td>Weight Assessment for Teen and Child Health</td>
</tr>
<tr>
<td>WBV</td>
<td>Weight-based victimization</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Chapter 1 Introduction and Background

1 INTRODUCTION

Childhood and adolescent obesity is an important public health concern in Canada. Previous national health surveys have demonstrated a rise in the prevalence of overweight and obese youth in the last three decades, especially among adolescents ages 12 to 17 years where the rate of overweight/obesity more than doubled and the rate of obesity tripled (1). The most recent Canadian survey shows stabilization of obesity rates, however, 31.5% of 5 to 17 year olds remain overweight (19.8%) or obese (11.7%) in 2009 to 2011 (2). There were significant differences between males and females as 15.1% of boys were obese versus (vs.) 8% of girls (2).

Childhood obesity is a complex condition, influenced by genetics, nutritional intake, level of physical activity, and social and physical environment factors (3, 4). As a result, the treatment of obese children and adolescents is equally challenging. Effective treatments are important because childhood obesity is associated with a number of co-morbid conditions, including hypertension, type 2 diabetes (T2DM), dyslipidemia, obstructive sleep apnea (OSA), polycystic ovarian syndrome (PCOS), non-alcoholic fatty liver disease (NAFLD), depression and anxiety (3). In addition, obese children are at an increased risk of becoming obese adults (5). This risk increases for children with greater degrees of obesity and those who are obese at older ages (5).

Studies have shown that lifestyle interventions are modestly effective in treating childhood obesity (6-8). However, the majority of these studies are randomized controlled trials (RCTs), and the effectiveness of clinical programs is not clear. While RCTs are considered the gold standard to study an intervention, evaluating the clinical effectiveness of programs
operating in the ‘real world’ is important as it can enable the assessment of patient outcomes in less ideal conditions and may increase the generalizability of results.

1.2. MEASURES, DEFINITIONS AND ETIOLOGY OF CHILDHOOD OBESITY

1.2.1 Measures and Definitions of Childhood Overweight and Obesity

In children, the most commonly used measure of obesity is body mass index (BMI), which is weight in kilograms (kg) divided by the square of height in meters (9). While BMI provides clinicians and researchers with a practical tool, it has its limitations, in general, and specifically when used in children (9). Firstly, BMI is not a direct measure of body fatness (9). Body weight and fat mass are correlated, and therefore, BMI is generally correlated with percent body fat (9). But, body weight and muscle and lean mass are also correlated, and BMI can be correlated with muscle and lean mass (9). However, until practical measures of excess fat in children are developed in addition to accepted standards, BMI remains a valuable surrogate measure (9).

Secondly, as linear growth proceeds in children, BMI values vary with weight and age, and need to be compared to a reference that is age and sex specific (9). The reference used in children is usually a z-score or a percentile. To create these reference charts, an extensive set of transformations of the weight and height data must be performed; for example, a smoothing process needs to be applied to a BMI distribution to generate smooth percentiles and a normalizing transformation is required to calculate z-scores (9). This can complicate the interpretation of results. For example, because standard deviations (SDs) differ across ages, the difference between the same two z-scores can represent different changes in BMI units at
different ages (9). Secondly, by statistical smoothing and removal of the extreme ends of BMI, children and adolescents with extremely high BMI are not adequately represented, making these charts less informative when managing this population.

In addition, the pediatric definitions of overweight and obese are generally defined statistically and are not risk-based, and evidence is lacking on which definition is best to apply (9). In contrast, in adults, BMI values of 25 kg/m² and 30 kg/m² are linked approximately to health risk, such as mortality from heart disease, and are used to define overweight and obesity (9). The difficulty in relating BMI cut-offs to health risks in children is due primarily to the long time span before adverse events take place as well as the small number of youth with cardiovascular risks (9).

One pediatric definition of overweight and obesity comes from the U.S. Centers for Disease Control and Prevention (CDC) 2000 growth chart, developed from five national data sets in the United States (9). This chart defines overweight in youth 2-19 years old as a BMI from the 85th to the 95th percentile, and obesity as a BMI greater than or equal to the 95th percentile (10).

Recently, however, the World Health Organization (WHO) developed a new growth reference for youth 5-19 years old (the WHO Reference 2007) using the 1977 National Center for Health Statistics (NCHS)/WHO growth reference (10). While the reference is still based on cross-sectional American data, several changes were made. The WHO chose to use data collected between 1963-1974 to limit the influence of the obesity epidemic, and measurements for children and adolescents with high adiposity were removed (10). Here, overweight is defined as a BMI greater than the 85th percentile, obesity is defined as a BMI greater than the 97th percentile and severe obesity is defined as a BMI greater than the 99.9th percentile. These cut-off points correspond, at age 19 years, to the adult cut-offs for overweight, obesity and severe
obesity (BMI $\geq 25$ kg/m$^2$, BMI $\geq 30$ kg/m$^2$ and BMI $\geq 35$ kg/m$^2$ respectively) (10). The percentile cut-offs also correspond to z-scores of +1, +2 and +3 SDs respectively (10).

1.2.2 Definition of Severe Complex Obesity

In 2008 in Ontario, a Pediatric Complex Care Coordination Expert Panel was tasked to define a group of children with obesity who may require more intensive intervention. Pediatric complex severe obesity was defined as individuals less than 18 years of age with a BMI $>95^{th}$ percentile for their age and gender, in addition to one of: a significant obesity-related co-morbidity that requires subspecialty care; another co-existing chronic illness; or a BMI greater than the 99$^{th}$ percentile for age and gender (Figure 1) (11). The committee estimated that approximately 1 to 2% or 30,000-60,000 children and adolescents in Ontario would meet the definition of severe complex obesity (11).

Figure 1: Definition of Complex Severe Obesity (11)
1.2.3 Etiology of Childhood Obesity

The causes leading to childhood obesity are multifaceted, arising from interactions between the individual, intrauterine exposures, genetics and the environment (12). Some risk factors for childhood obesity include exposure to gestational diabetes or high maternal adiposity and being born small- or large-for-gestational age (4). An early adiposity rebound is also associated with an increased risk of obesity in adulthood (13). Adiposity rebound is defined as the point when a child’s body fatness declines to its lowest point, usually at ages 5-6 years, before gradually increasing again in adolescence and most of adulthood (13). Family characteristics associated with childhood obesity include ethnicity (e.g. Hispanic and South Asian) and low socioeconomic status in high-income countries and urban residence (4). Low levels of physical activity, a high number of hours spent watching television, short sleep duration, intake of a high energy diet in infancy and a high intake of sweetened drinks in childhood have all been associated with increased risk of obesity (4). Medical treatments including radiation or surgery resulting in hypothalamic damage and certain medications (e.g. pharmacologic doses of glucocorticoids, atypical antipsychotics such as risperidone and olanzapine) are also associated with increased weight gain in children and adolescents (4, 12).

Rare monogenic disorders that cause obesity include leptin deficiency, leptin receptor deficiency, prohormone convertase-1 deficiency and pro-opiomelanocortin (POMC) splicing mutation, the latter characterized by red hair and adrenal insufficiency (12). Mutations in the melanocortin-4 receptor (MC4R) account for up to 5% of cases of severe obesity, and presents with early-onset hyperphagia, obesity and rapid growth (12). Obesity can also be part of the presentation of several genetic syndromes. These include Prader-Willi syndrome (characterized by small hands and feet, almond-shaped eyes and hypogonadism), Bardet-Biedl syndrome
(characterized by short stature, developmental delay, retinitis pigmentosum and polydactylyl), and rare conditions such as Carpenter syndrome, Cohen syndrome and Alstrom syndrome (4, 12, 14). Endocrine conditions that are classically thought to present with obesity and short stature include hypothyroidism, Cushing syndrome, growth hormone deficiency and pseudohypoparathyroidism 1a (characterized by short fourth and fifth metacarpals, developmental delay and round facies) (12, 14), however, of these, only Cushing syndrome presents with severe obesity.

1.3 CO-MORBIDITIES ASSOCIATED WITH CHILDHOOD OBESITY

1.3.1 Medical Co-morbidities Associated with Childhood Obesity

Childhood and adolescent obesity are associated with a number of co-morbid conditions, including features of the metabolic syndrome (i.e. clustering of risk factors of insulin resistance/dysglycemia, hypertension and dyslipidemia), sleep disorders, PCOS and NAFLD (3). The risk of obesity-related complications has been shown to increase in a linear or curvilinear fashion as BMI z-scores increase (15). For example, results from the Bogalusa Heart Study found that as children’s BMI percentile increased from the ≥95th to the ≥99th percentile, the prevalence of ≥2 risk factors (including adverse levels of lipids, insulin and blood pressures (BPs)) increased from 39% to 59% (16).

The association between obesity and the metabolic syndrome, and its increased risk of atherosclerotic cardiovascular disease (CVD), is well established in adults (17). Weiss et al. assessed the prevalence of the metabolic syndrome among 439 obese American children and adolescents ages 4-20 years using a modified version of adult criteria of the metabolic syndrome
(17). They found that the overall prevalence of the metabolic syndrome was 38.7% in moderately obese subjects (BMI z-score 2-2.5) and 49.7% in severely obese subjects (BMI z-score >2.5) (17). Among subjects who were seen in follow-up after approximately two years (n=77), 71% of youth who initially met criteria for the metabolic syndrome still met the criteria, and 37% of youth who did not meet criteria at baseline developed the metabolic syndrome during this time period (17). T2DM developed in 8 subjects who had impaired glucose tolerance (IGT) at baseline (17). This highlights the prevalence of the metabolic syndrome among obese children and youth and its ability to evolve fairly quickly over time (17).

Obesity is also associated with NAFLD, characterized by elevations in hepatic transaminases, alkaline phosphatase and gamma glutamyl transpeptidase, and/or a bright echo pattern of the liver on ultrasound related to intrahepatic fat accumulation (3, 18). One study involving 75 obese children found that 53% had an ultrasound appearance consistent with fatty liver and 25% had elevated transaminase levels (18). Both abnormalities improved with weight loss (18). OSA is also strongly associated with obesity (3). For example, in a clinical sample of 91 overweight and obese patients, 41% of overweight children and 19% of obese children had OSA (19). Neurologic co-morbidities that can be seen in obese youth include pseudotumor cerebri, presenting with papilledema and headache (12). In female adolescents, obesity is commonly associated with PCOS, which manifests with hyperandrogenism and oligomenorrhea or amenorrhea (12).

Orthopedic conditions such as slipped capital femoral epiphysis (SCFE) and Blount disease may also occur (20). More recently, studies have documented musculoskeletal (MSK) pain, an increase in fracture risk and the development of structural deformities such as genu
valgum with obesity in childhood (20). Skin problems associated with childhood obesity include acanthosis nigricans, skin tags, boils and intertrigo (3, 14).

1.3.2 Psychological Co-morbidities Associated with Childhood Obesity

Most literature focuses on medical co-morbidities, however, several psychological co-morbidities including depression, anxiety, as well as poor quality of life (QOL) can occur and can be very debilitating to children and adolescents with severe obesity (3). For example, among 33 severely obese adolescents seeking bariatric surgery, 52% reported using a psychological service at least once and 21% were currently being treated with an antidepressant (21). Approximately one third of patients had depressive symptoms within clinical range (21). Further, parent and patient-reported health-related quality of life (HRQoL) scores on physical functioning, emotional well-being, social relations and school functioning were significantly lower compared to healthy youth and their parents (21).

Similarly, Schwimmer et al. found that children and adolescents referred for an evaluation of obesity reported significantly lower HRQoL scores compared to healthy youth, with a likelihood of having impaired HRQoL 5.5 times greater than a healthy child or adolescent (22). Sjoberg et al. also found that obesity was significantly associated with depression in a large group of adolescents ages 15 to 17 years of age, and that this relationship could be explained by experiences of shame, parental separation and parental unemployment (23).

Teasing and bullying about weight, termed weight-based victimization (WBV), is an extremely problematic issue for this population. Adolescents attending a weight loss camp were asked to fill out an on-line survey addressing the different forms of WBV (24). WBV was extremely common with 64% of the study participants reporting at least one experience of WBV at school (24). WBV was also long-standing, with 36% of participants reporting experiencing
teasing/bullying for 5 years (24). The most frequent form of WBV was verbal teasing (75-88%) followed by relational victimization (74-82%), cyberbullying (59-61%) and physical aggression (33-61%) (24). The perpetrators of WBV were most commonly peers (92%) and friends (70%), however, the teens also identified adults including physical education teachers/sport coaches (42%), parents (37%) and teachers (27%) as individuals conducting WBV (24). School locations for the occurrence of WBV were widespread, including the classroom (80%), the stairs/hallway (77%) and the cafeteria (70%) (24).

Given that WBV is common in school surroundings, the association between obesity and school attendance and academic development has also been explored. Using data from the 2009 National Health Interview Survey where parents reported their child’s number of sick days in the past 12 months, overweight and obese adolescents were found to have 36% and 37% more sick days, respectively, than teens of normal weight (25). The authors proposed that this increase in number of sick days could be due to obesity-related co-morbidities, such as diabetes and hypertension, as well as increased rates of depression and low self-esteem among overweight and obese youth (25). It is also possibly due to school avoidance due to social anxiety related to WBV.

Krukowski et al. examined the effect of overweight and weight-based teasing on academic performance (26). They found that overweight children were more likely to have poorer school performance (reported by their parents) than children of normal weight (26). However, this association was no longer significant when they also looked at weight-based teasing, and they found that children who experienced weight-based teasing were more than 50% less likely to have good school performance vs. children who reportedly did not experience weight-based teasing (26).
1.3.3 Long-Term Effects of Childhood and Adolescent Obesity

A systematic review of the long-term impact of overweight and obesity in childhood and adolescence found that the majority of studies reported an increased risk of premature mortality with child and adolescent overweight and obesity, where the outcome of interest was all-cause mortality in most studies (27). In addition, overweight and obesity in childhood was significantly associated with non-fatal cardiometabolic morbidity, such as diabetes, hypertension, ischemic heart disease and stroke, in adulthood (27).

Baker et al. examined the association between BMI in children ages 7 to 13 years and coronary heart disease (CHD) in adulthood (i.e. after age 25 years) in a cohort of 276,835 Danish schoolchildren born between 1930 through 1976 (28). There was a positive association between the risk of nonfatal or fatal CHD events and BMI for boys and girls (28). At every age from 7 to 13 years for boys and from 10 to 13 years for girls, every one unit increase in BMI z-score significantly increased the risk of a CHD event; the risk also increased as the age of the child increased (28). The authors proposed that the presence of cardiovascular risk factors in overweight children could be the mechanism linking a higher BMI in childhood with an increased risk of CHD in adulthood (28). Another possible explanation is that the obese children remained obese as adults and developed CHD (28), however, the authors of this study did not have information on adult BMI values (28).

In contrast, Juonala et al. reviewed both childhood and adult BMI in four large prospective cohort studies (29). They found that children who were overweight or obese and remained obese as adults had increased risks of T2DM, hypertension, dyslipidemia and carotid-artery atherosclerosis (29). However, children who were initially overweight or obese and then became nonobese by adulthood had similar risk of these outcomes to individuals who were never
obese (29). An exception to these findings was the association between childhood obesity and
the risk of hypertension, however, this association was attenuated after taking into account adult
obesity (29). Overall, these observational findings suggest that the treatment of childhood obesity
may decrease cardiovascular risk in adulthood (29).

The social and economic consequences of overweight in adolescence have also been
examined. Using national survey data, Gortmaker et al. looked at obese (BMI >95th percentile)
youth ages 16 to 24 years of age in 1981 and then 7 years later (30). They found that women who
had been overweight had completed 0.3 years less of school, were 20% less likely to be married,
had lower household incomes ($6710 less per year) and had a 10% higher rate of household
poverty compared to the women who had not been obese; this was independent of their
socioeconomic status and scores on aptitude testing at baseline (30). They also found that men
who had been obese were 11% less likely to be married (30). In contrast, when they examined
the impact of having other chronic physical conditions on subsequent socioeconomic
characteristics and marital status, they did not find a significant effect (30). The authors
concluded that being obese during adolescence has social and economic consequences in
adulthood, and that discrimination and stigma against obese individuals may be contributing
factors (30).

1.4 ASSESSMENT OF THE OVERWEIGHT AND OBESE CHILD AND
ADOLESCENT

A comprehensive assessment of overweight and obese children and adolescents is an
important component of their medical care. The medical history should include the child’s
history of weight gain including age of onset and identified triggers. It should explore the impact
of the child’s weight on activities of daily living such as school, social and family function, and overall psychological well being. The history should assess for the presence of risk factors of obesity and for secondary causes of obesity (31). This includes asking about birth weight, exposure to diabetes while in utero, family history of obesity, T2DM and CVD including hyperlipidemia and hypertension in both first- and second-degree relatives, and the use of medications that promote weight gain (e.g. conventional and atypical antipsychotics, anticonvulsants and prednisone) (14).

The medical history should assess for the presence of weight-related co-morbidities. These include snoring as a sign of OSA; shortness of breath and cough due to asthma; abdominal pain related to gastroesophageal reflux disease (GERD), constipation or gallbladder disease; polyuria and polydipsia to indicate the presence of T2DM; urinary incontinence; menstrual irregularities, acne and hirsutism due to PCOS; orthopedic symptoms caused by SCFE, Blount disease or increased weight-bearing; and skin rashes or irritation due to intertrigo (14, 32). The medical history should also explore symptoms of depression, anxiety and disordered eating, and for the presence of body dissatisfaction, low self-esteem and school avoidance (14).

An assessment of dietary intake and physical activity are important components of the assessment (14, 32). The dietary assessment should include eating patterns, assessing the child’s readiness to change and identifying areas to change in a family-centered manner (14). Dietary risk factors for obesity include drinking sugar sweetened beverages (33), eating quick-service food (34) and consuming excessive portion sizes for age (35).

The physical activity assessment includes information about the amount and intensity of daily activity (14). Similarly, sedentary activities (and, in particular, screen time) should be quantitated (14). In order to make a plan for change with the family, the safety of the
environment and the availability of parks, gyms and pools should be elicited in addition to an assessment of the family’s readiness to change and motivation to change (14, 32).

The physical exam should include measurement of height (in centimeters (cm)) and weight (in kg) to calculate BMI (14). Waist circumference, a surrogate measure of central adiposity, can be measured and compared to age- and gender-derived normative charts (14). BP should also be interpreted using sex- and height-based pediatric BP tables (32). The head and neck should be assessed for papilledema, a goiter and enlarged tonsils (14). The skin should be examined for acanthosis nigricans, skin tags, intertrigo and furunculosis, xanthelasma, and signs of Cushing syndrome including deep purple striae, a round face and ruddy complexion (14). The lungs should be auscultated for signs of asthma and the abdomen assessed for liver enlargement (14). In young girls, pubertal stage should be assessed as precious puberty is more common in obese girls (36). The knee, leg and foot should be assessed for pain, range of motion and peripheral edema (32). Lastly, the child should be evaluated for dysmorphic features and physical signs of syndromes or genetic conditions associated with obesity such as Prader-Willi syndrome, POMC mutations and pseudohypoparathyroidism (14).

Investigations should be performed based on the child or adolescent’s BMI, medical history, physical exam and risk factors (14). Recommendations on screening for dyslipidemia include universal screening with a fasting or a non-fasting lipid profile between the ages of 9 to 11 years and 17 to 21 years (37). At other time points, fasting lipid profiles should be performed at varying intervals if certain risk factors are present, including obesity or previous abnormal lipid profiles (37).

The Canadian Diabetes Association recommends screening children ≥10 years of age, or younger if puberty has started, for T2DM with a fasting plasma glucose every 2 years if they
have ≥2 of the following risk factors: BMI ≥95th percentile for age and gender; high-risk ethnicity and/or family history of T2DM and/or history of exposure to diabetes in utero; signs or symptoms of insulin resistance such as acanthosis nigricans, high BP, dyslipidemia or NAFLD; IGT; or are taking antipsychotic medications/atypical neuroleptics (38). Children with a BMI ≥99th percentile for age and gender who meet the criteria above should be screened annually with an oral glucose tolerance test (OGTT) (38).

Liver enzymes (aspirate aminotransferase (AST) and alanine aminotransferase (ALT)) should be measured in youth with a BMI 85-94th percentile with risk factors in the history or physical exam or if the BMI is ≥95th percentile (14), with consideration of an ultrasound of the liver to detect NAFLD, as hepatic steatosis may be present with normal liver enzymes (39).

For children with a BMI >95th percentile, a microalbumin/creatinine ratio can be performed to assess for focal segmental glomerulosclerosis which has been reported in obese children (14).

When specific diagnoses are suspected, additional tests may be required. More common ones include: 24-hour ambulatory BP monitoring if BP measurements are high; polysomnography, oxygen saturation measurement and carbon dioxide measurement if OSA is suspected; 24 hour urinary free cortisol measurement or midnight salivary cortisol if Cushing syndrome is suspected; thyroid function tests if hypothyroidism is suspected; and plasma androgens and/or pelvic ultrasound if symptoms of PCOS are present (14). In the rare event that a syndrome is suspected, genetic testing should be performed (14).
1.5 MANAGEMENT OF-childhood and adolescent obesity

Several consensus statements have been published outlining approaches to obesity treatment. A US expert panel recommended a four-stage approach, based on available evidence (40). This begins in the primary care office (Prevention Plus), adding additional expertise within the primary care setting such as a registered dietitian (structured weight management) and proceeding, if needed, to a comprehensive multidisciplinary weight management program or tertiary care intervention (40).

Movement within the four stages will depend on various factors such as response to treatment, risk factors and readiness for healthy lifestyle changes (40). The general goal in most cases is for the BMI to decrease until it is less than the 85th percentile (40).

The Prevention Plus stage can be implemented by a primary care provider or a registered nurse in a primary care office and targets risk behaviours known to be associated with obesity including advising on the intake of fruits and vegetables, minimizing or removing sugar-sweetened beverages from the diet, limiting screen time and increasing physical activity, advising on eating behaviours, and involving the entire family (40). The frequency of visits should be patient-based and dependent on the family’s readiness to change and the severity of obesity (40).

The second stage, structured weight management, can be provided monthly by a primary care provider/nurse practitioner with training or a registered dietitian (40). The focus continues to be on healthy lifestyle changes with closer follow-up and a more structured approach that uses monitoring activities; medical screening is recommended at this stage (40). Provider skills helpful to implement this stage include motivational interviewing and behavioural counseling,
parenting skills, family conflict management, food planning and physical activity counseling (40).

The comprehensive multidisciplinary stage is provided by a community weight management program, a weight management centre or a commercial program (40). The program should include nutrition, exercise and behavioural/psychological counseling, and the team should include a physician, a behavioural counselor (e.g. social worker, psychologist or other mental health care provider), a registered dietitian and an exercise specialist (40). This stage is more intensive in that patients have more frequent contact with providers and there is more active use of behavioural strategies and monitoring (40). Moderate to strong parental involvement is recommended for children <12 years of age with a gradual decrease in involvement as adolescents get older (40).

The final stage, tertiary care intervention, is provided by a multidisciplinary team working within a pediatric weight management centre (40). The structure and components are similar to stage 3 but may also include special diets (e.g. meal replacement, very-low-energy diet), medications and bariatric surgery (40).

1.6 EVALUATION OF PEDIATRIC WEIGHT MANAGEMENT INTERVENTIONS

1.6.1 Effectiveness of Pediatric Lifestyle Interventions

Several systematic reviews have been published on the effectiveness of lifestyle interventions in childhood obesity (6-8). Each of these reviews included only RCTs or, in the case of one systematic review, included RCTs and controlled clinical trials (CCTs). A table summary of these reviews is included in Appendix 9.1.1.
The 2009 Cochrane Review included 64 RCTs (5230 participants) and examined lifestyle interventions (dietary, physical activity and/or behavioural therapy) (54 studies) in addition to drug interventions (10 studies) for treating obesity in children and adolescents with a mean age less than 18 years of age (8). Overall, a variety of behavioural approaches were used in the studies included in the review, such as family therapy, cognitive behaviour therapy (CBT) and problem-solving techniques (8). The duration of the interventions ranged from one month to 24 months; 14 had a duration less than 6 months and 40 had a duration greater than 6 months (8). The majority of the studies took place in North America (29 in the United States, one in Canada); 12 studies took place in Europe and 7 studies were conducted in Australia and Asia (8).

The authors identified several limitations in assessing the effectiveness of these studies. Study designs were variable and a variety of approaches or treatment strategies were used, making it difficult to identify which interventions are most effective in treating childhood and adolescent obesity (8). The quality of the studies was also variable. For example, sample sizes were small and ranged from 16 to 218 participants in the lifestyle interventions (8). The majority of the studies were underpowered and most studies did not take into account missing data, with less than 50% of all studies performing intention to treat analyses (8). In addition, several different outcome measures were used, making it difficult to combine results. (8).

Despite these limitations, the authors concluded that interventions that combined dietary, physical activity and behavioural components appear to be effective in treating overweight children and adolescents compared to standard care or self-help in the short- and long-term (8). More specifically, for children 12 years and older, the authors reviewed 12 lifestyle interventions with a behavioural component as the main focus (8). Four of these studies reported similar outcome measures at 6 months and the data were pooled in a meta-analysis. In 362 participants,
pooled data showed a beneficial effect of a behavioural intervention over standard care or control condition of -3.04 kg/m² on absolute BMI (95% confidence interval (CI) -3.14 to -2.94) (8). Pooled data for three studies that reported BMI-standard deviation score (SDS) outcomes in 291 participants showed a beneficial effect of a behavioural intervention over standard care or control condition of -0.14 (95% CI -0.17 to -0.12) (8). Pooled outcomes at 12 months follow-up was analyzed from two studies and demonstrated a beneficial effect of a behavioural intervention over standard care or control condition of -3.27 kg/m² on absolute BMI (95% CI -3.38 to -3.17) and -0.14 on BMI-SDS (95% CI -0.18 to -0.10) (8).

The Cochrane review also included a small number of studies that reported on measures of psychological well-being (8). They found 11 studies that discussed the impact of interventions on a variety of outcomes, including QOL, global self-concept, physical appearance, absence of depressive symptoms and self-esteem (8). Improvements in psychological measures were noted and none of the studies found that interventions had adverse effects on the children’s well-being (8). For example, Jelilian et al. looked at the impact of a 16 week cognitive behavioural group treatment plus either a peer-enhanced adventure therapy or aerobic exercise intervention on participants’ self-concept, physical self-perception, social support and peer rejection (41). These outcomes were measured at baseline, after the intervention and 10 months later (41). Participants (mean age 11.19 years, n=76) in both treatment arms reported a significant improvement in measures of global self-concept, physical appearance and physical self-worth across time (41). They did not, however, report significant improvements in measures of social support, peer rejection or loneliness over time (41). Wadden et al. found that measures of self-esteem and depression improved significantly in 36 obese black female adolescents after participating in a 16 week behavioural weight control program, although pre-treatment scores were within normal
limits on both measures (42). Further, parent-reported QOL scores improved significantly after
attending a best-practice behavioural program or standard care with their children for 6 months
(43). Child self-reported QOL scores improved in both groups and the change was significant in
the control group only (43).

Whitlock et al. conducted a targeted systematic review to provide support for the updated
recommendation from the US Preventive Services Task Force (USPSTF) on screening for
obesity in children and adolescents (7). They included 15 studies on comprehensive behavioural
interventions. For inclusion, the intervention had to incorporate counseling on healthy diets or
weight loss, physical activity counseling or participation, and behavioural management
techniques that enable lifestyle changes and maintenance of these changes (7). In some studies,
mental health treatments were provided beyond behaviour modification techniques for physical
activity and nutrition (7). They classified the intensity of the intervention using hours of contact
as a proxy with high intensity being >75 hours, moderate intensity being 26-75 hours, low
intensity being 10-25 hours, and very low intensity being <10 hours (7).

The authors found 11 behavioural intervention trials (10 RCTs, 1 CCTs) that reported 6
to 12 month outcomes in 1099 youth ages 4 to 18 years (7). The majority of study participants
had a BMI >95th percentile (7). The studies were relatively small and only three trials had >40
participants in the treatment arms; in addition, three trials had a retention rate <70% (7). Each
study demonstrated a reduction in BMI, BMI-SDS or percentage overweight, however, the
results were not all statistically significant (7). At the 6 to 12 month follow-up, the intervention
groups had a change in BMI of -0.3 to -3.3 kg/m² compared to the controls (7). The three
interventions that were more intensive (moderate- to high-intensity) had the largest effects, with
between-group BMI differences of -1.9 to -3.3 kg/m² (7).
The durability of the intervention beyond active participation has been evaluated in a small number of studies. Four studies included in the review examined results at least 12 months after completion of the lifestyle intervention (15-48 months after initiation of treatment) (7). Three of these trials found that the intervention groups had sustained improvements in BMI or percent overweight compared with controls (7). Two studies reported change in BMI and the difference in BMI between the treatment groups and control groups was -1.7 kg/m² at follow-up (7).

Similar to the Cochrane review, the limitations of this systematic review include heterogeneous treatment approaches across studies and a lack of information on blinding for allocation of treatment and assessment of outcomes (7). However, the authors also concluded that behavioural interventions can be effective for children and adolescents (7).

More recently, Ho et al. looked at the effectiveness of lifestyle interventions on both BMI reduction and cardiometabolic outcomes in overweight children (6). They included 38 RCTs with overweight and obese participants ≤18 years published from 1975 to 2010. The lifestyle intervention had to incorporate a nutrition or dietary component compared to no treatment or wait-list control (intervention duration ranged from one month to 2 years), usual care (intervention duration ranged from 3 months to one year), or minimal advice or written diet and physical activity material (intervention duration varied in one study and ranged from 6 months to one year in the remainder) (6). The number of participants in each study ranged from 16 to 258 and the median number was 72 participants (6).

This systematic review also had limitations similar to those already described including retention rates ranging from 38% to 100%, although 29 of the 38 studies had retention rates of ≥70% at 6 months or >60% at one year (6). Nine studies performed intention to treat analyses.
Information about the method of randomization was lacking in 24 studies and information about allocation concealment and study blinding was not reported in most studies (6). Furthermore, the studies included were heterogeneous in terms of patient population and the characteristics of the intervention (i.e. intensity and duration, type of diet and physical activity program used) (6). Lastly, the authors needed to calculate the SD of weight change by imputation methods as this information was lacking in almost 40% of the studies (6).

Of the studies comparing lifestyle intervention with no treatment or a wait-listed control group, 18 of the 22 studies demonstrated a beneficial effect on weight loss (6). A meta-analysis of 12 studies that reported change in BMI and 7 studies that reported change in BMI z-score demonstrated that lifestyle interventions resulted in a significant reduction in BMI of -1.25 kg/m² (95% CI -2.18 to -0.32) and a significant reduction in BMI z-score of -0.10 (95% CI -0.18 to -0.02) compared to no-treatment control conditions. Interventions in this category that involved only adolescents with a mean age >12 years demonstrated a mean difference in BMI of -1.45 kg/m² (95% CI -3.02 to 0.12) and a mean difference in BMI z-score of -0.02 (95% CI -0.09 to 0.06) that were not statistically significant (6).

Of the studies comparing lifestyle intervention with usual care or minimal intervention, 8 of the 11 studies showed a positive effect on weight loss (6). A meta-analysis of 7 studies showed a significant reduction in BMI of -1.30 kg/m² (95% CI -1.58 to -1.03) at the end of the intervention (6). Pooled data from 4 studies that reported change in BMI z-score after the active intervention (duration 6 to 12 months) demonstrated a significant reduction of -0.09 (95% CI -0.15 to -0.02) in the intervention groups compared with participants receiving usual care (6). The authors found that interventions that lasted >6 months resulted in greater weight loss than interventions of a shorter duration (6). Four studies that reported outcomes after the active
treatment ended (7 months to one year from the start of the intervention) showed that weight loss was maintained with pooled data showing a significant change in BMI of -0.92 kg/m$^2$ (95% CI -1.31 to -0.54) (6).

Lastly, the authors compared the effects of lifestyle interventions to written educational materials in 5 studies. Pooled results from 3 studies that reported change in BMI z-score showed a greater reduction of -0.06 units (95% CI -0.10 to -0.02) for the lifestyle intervention programs compared to written educational materials over one year (6).

This systematic review was unique in that it considered the effect of lifestyle interventions on cardiometabolic outcomes. Fifteen of the 38 studies included at least one cardiometabolic outcome (6). Comparing lifestyle interventions with control groups, they found that lifestyle interventions significantly lowered low-density lipoprotein (LDL)-cholesterol (-0.30 mmol/L [-0.45 to -0.15]) up to 12 months from baseline, triglycerides (TGs) (-0.15 mmol/L [-0.24 to -0.07]) up to 2 years from baseline and fasting insulin (-55.1 pmol/L [-71.23 to -39.05]) up to one year from baseline (6). Diastolic BP lowered significantly only in the short-term studies (≤6 months duration) (-1.69 [-3.15 to -0.24]) and systolic BP lowered significantly only in studies with a duration of one year or more (-3.72 [-4.74 to -2.69]) (6). No differences were found for high-density lipoprotein (HDL)-cholesterol and fasting glucose (6). Interestingly, the cardiometabolic improvements were not always associated with the degree of weight loss or reduction in body fat (6). This suggests that the changes may not be due to weight loss but may be due to other effects of the intervention such as a change in dietary fat intake or an increase in physical activity (6).
The authors concluded that lifestyle interventions that include a dietary component are effective in treating childhood obesity as well as improving cardiometabolic outcomes at least up to one year (6).

1.6.2 Effectiveness of ‘Real-World’ Pediatric Weight Management Programs

The effectiveness of clinical pediatric weight management programs under real-life conditions is not yet fully evaluated, however, several groups have published retrospective results from their clinics. A table summary of these studies is outlined in Appendix 9.1.2.

A large study from Germany, Austria and Switzerland included 21,784 overweight children and adolescents ages 2-20 years who participated in 129 specialized pediatric obesity centres that offered an outpatient intervention of ≥6 months from 1999 to 2005 (44). At the start of treatment, the mean BMI was 30.4 ± 5.9 kg/m², the mean BMI-SDS was 2.51 ± 0.52 and the mean age was 12.6 ± 2.7 years (44). The authors found that complete follow-up data were available for only 24% of children at 6 months, 17% of children at 12 months and 8% of children at 24 months (44). Using an intention to treat analysis and baseline values for patients lost to follow-up, they found that 22% of patients reduced their BMI-SDS at 6 months, 15% at 12 months and 7% at 24 months (44). When they included only the 1060 patients with complete follow-up data at each time point, they found that 83% of patients reduced their BMI-SDS after 6 months, 82% after 12 months and 76% after 24 months (44). For this group, the mean change in BMI-SDS was -0.20 ± 0.32 at 6 months, -0.19 ± 0.40 at 12 months and -0.20 ± 0.54 at 24 months (44). Furthermore, when the authors evaluated the 5 centres with the highest success rate at 24 months with an intention to treat analysis and baseline values for patients lost to follow-up, they found that 83% of these 518 patients reduced their BMI-SDS after 6 months, 67% after 12 months and 51% after 24 months (44). These centres had a lower rate of attrition as data were
available for 57% of patients at 24 months (44). Compared to the other 124 centres studied, these 5 centres provided interventions that were longer and more intense. For example they provided more “units” or 45 minutes sessions on nutrition education, physical and exercise intervention, psychological intervention, parent sessions and medical lessons compared to the other centres (44).

The results from this large clinical study demonstrate the high frequency of incomplete follow-up data under real-world conditions as well as the heterogeneity of interventions and results, with a significant association between intensity of treatment and BMI-SDS reduction after 24 months in the entire population studied (44).

Skelton et al. also described the results from a real-world tertiary-care multidisciplinary pediatric weight management program: the NEW Kids Program at the Children’s Hospital of Wisconsin (45). The program is family-centred and provided CBT and nutrition and physical activity education and support (45). A retrospective chart review of patients who participated in the program for ≥9 months and had >4 visits to the clinic between 2003 to 2005 included 66 patients. However, of the 398 assessments completed during this time, 150 patients did not meet the inclusion criteria and 182 patients dropped out of the program (45).

The study patients had a mean BMI of 37 ± 10 kg/m² and a mean age of 11.8 ± 3.4 years; 50% were male (45). The population was ethnically diverse and 44% of the children were white, 39% African American and 11% Latino (45). After a mean follow-up of 13 ± 3 months, the 66 patients had a significant increase in mean BMI (1.0 ± 2.7 kg/m²) and a significant decrease in BMI z-score (-0.03 ± 0.16) (45). They also had significant improvements in total cholesterol (TC), TGs and LDL-cholesterol (45). Given the steep rate of weight gain in the patients prior to starting the program, the authors concluded that their results are clinically meaningful and that
multidisciplinary weight management programs can be an effective treatment for high-risk obese children (45).

A further study of a clinical weight management program examined results from the Michigan Pediatric Outpatient Weight Evaluation and Reduction (MPOWER) program at the University of Michigan (46). The MPOWER program started in 2007 and is a 6 month intensive, multidisciplinary program for adolescents ages 12-18 years with a BMI ≥95th percentile for age and gender (46). The program is family-centred and included medical assessments and nutrition and physical activity education in addition to an intense behavioural component that covered topics such as self-esteem, triggers of eating and problem solving (46). Motivational interviewing, a technique that aims to increase teens’ internal motivation and self-efficacy, was the primary skill used in the behavioural program (46).

A retrospective analysis of patients attending the program between 2007-2008 was conducted, excluding patients taking obesogenic medications such as steroids or with moderate to severe mental illness such as bipolar disorder or depression (46). The study population consisted of 67 patients of which 71% were female, 51% were Caucasian, 30% were African American, and 53% came from a household with an income <$25,000 per year (46). The mean age was 14.5 years and the mean baseline BMI was 40 kg/m² (range 29-70) (46).

Of the 48 patients who completed the program, the mean change in BMI was -2.3 kg/m² after 6 months and was not associated with age, gender, race or insurance status (46). The authors concluded that a multidisciplinary program can result in a clinically significant reduction in BMI after 6 months, but that more patients need to be studied and longer-term results are required and are in the process of being collected (46).
Madsen et al. also conducted a retrospective review of 214 children and adolescents ages 8 to 19 years attending a clinical weight management program between 2003 and 2006 (47). The University of California, San Francisco (UCSF) Weight Assessment for Teen and Child Health (WATCH) Clinic is an outpatient, interdisciplinary program for youth less than 21 years old with a BMI >95th percentile for age and gender (47). The program provided families with nutritional and physical activity recommendations including a low glycemic load diet, an individualized exercise prescription and decreasing sedentary activity (47). Patients were generally seen every 3 months (47). At baseline, the average age of participants with follow-up (n=156) was 13 ± 2.7 years and their average BMI and BMI z-score were 36.4 ± 10.1 kg/m$^2$ and 2.43 ± 0.37 respectively (47). Half of the participants were female and the study population was ethnically diverse (47). At the last follow-up visit (n=94), an average of 12.3 ± 6.3 months after intake, the overall mean change in BMI was -0.4 kg/m$^2$ and the mean change in BMI z-score was -0.11.

When the participants were divided into responders (n=64) and non-responders (n=30), the responders experienced a mean decrease in BMI and BMI z-score of -1.3 kg/m$^2$ and -0.19 respectively, whereas the non-responders had a mean increase in BMI and BMI z-score of 1.6 kg/m$^2$ and 0.06 respectively (47).

While this study demonstrated that clinical programs can improve weight status, the results also showed the heterogeneous response among participants and the high rate of attrition seen in clinical programs.

1.6.3 Current Status of Pediatric Weight Management Programs in Canada

In 2011, Ball et al. reported on the status of pediatric weight management programs in Canada (48). Data were collected on a national level in 2009 using an on-line survey tool and were then confirmed with program leaders by telephone or email the following year (48). At the
time of publication, 18 independent pediatric weight management programs were functioning in 6 provinces and 3 territories in Canada (48). The programs were all multidisciplinary and almost all required parental involvement (48). They enrolled a mean of 127 patients each year and the majority (83%) provided services for both children and youth (48). Half of the programs used an inclusion criteria of BMI ≥85th percentile whereas only 22% used an inclusion criteria of BMI ≥95th percentile (48). The majority (89%) provided lifestyle or behavioural counseling, 44% provided structured exercise plans, 33% used energy-reduced diets, 28% offered pharmacotherapy and one program provided bariatric surgery (48). Two thirds of the programs were funded by a hospital or health region and 72% were affiliated with an academic institution. At the time of publication, only 28% were evaluating their program, however 33% had plans to evaluate the program in the future (48).

The authors strongly recommended that program leaders of Canadian pediatric weight management programs conduct evaluations of their programs and also participate in a national data registry to create an evaluation framework that can be used across all centres (48).

Following this report, the first outcome evaluation of a Canadian pediatric weight management program, the Centre for Healthy Weights-Shapedown BC (CHW-SB), was published. The CHW-SB is a government-funded, multidisciplinary, family-centred program for overweight and obese children and their families that provided medical and psychosocial assessment, education and support (49). Families attended weekly 2 hour group sessions for 10 consecutive weeks. Topics included education on nutrition (e.g. label reading, portion sizes) and behaviour (e.g. goal-setting, dealing with teasing/bullying), and each session included 30 minutes of physical activity (49).
The referral criteria for the program included age 6-17 years and BMI >95\textsuperscript{th} percentile for age and gender or a BMI between the 85\textsuperscript{th} and 95\textsuperscript{th} percentile with at least one co-morbidity (49). At least one parent or caregiver was required to participate and needed to be able to read and understand English (49). Exclusion criteria included being non-ambulatory, receiving rigorous medical therapy or being diagnosed with a severe mental illness (49). Of the 144 families invited to join the program, 119 attended the first session (49). While 70.6\% of participants attended the first and last sessions of the program, only 32.8\% attended all 10 sessions (49).

At baseline, the study participants had a mean age of 11.6 ± 2.6 years, a mean BMI of 30.9 ± 6.2 kg/m\textsuperscript{2} and a mean BMI z-score of 2.3 ± 0.33; 57\% were male and 55\% were Caucasian (49). Almost one third of participants met criteria for the metabolic syndrome (49).

Participation in the CHW-SB program resulted in a significant decrease in weight trajectory after the start of the program; participants had an average increase in weight of 0.89\% monthly before the program started, followed by a 0.37\% decline monthly after the start of the program, resulting in a decrease of 1.26\% (49). Further, participants who attended the last visit experienced a significant decrease in BMI z-score (-0.06), waist circumference (-2 cm) and fasting insulin (-16 pmol/L) (49). Measures of self-reported physical activity, self-concept and anxiety also improved significantly (49).

The CHW-SB is the first obesity treatment program to be evaluated in Canada and showed significant improvements in the short-term. The study is limited by the lack of a control group and lack of full follow-up data; ongoing data collection is required to assess the long-term effects of this program (49).
1.7 ADOLESCENT BARIATRIC SURGERY

1.7.1 Overview of Adolescent Bariatric Surgery

The use of bariatric surgery in the treatment of adolescents with obesity and obesity-related co-morbidities has progressively increased over the past decade (50). In the United States, the annual number of adolescent inpatient bariatric surgery cases increased from 0.8 per 100,000 in 2000 to 2.3 per 100,000 in 2003 (328 vs. 987 procedures), and thereafter remained stable with a rate of 2.4 per 100,000 in 2009 (1009 procedures) (51). The support for a more aggressive treatment for a select group of adolescents comes from the knowledge that obese adolescents are likely to remain obese as adults with its associated risks, and that obesity-related co-morbidities are reduced after bariatric surgery (52). Despite the increase in adolescent bariatric surgery, adolescents represented only 0.73% of all patients receiving bariatric surgery in 2003 and the long-term effects of the procedures are still not known (50, 53).

1.7.2 Bariatric Surgery Options

There are currently three main types of bariatric surgeries performed in adolescents and weight loss is achieved by restricting oral intake by decreasing the stomach volume capacity and/or causing malabsorption. The Roux-en-Y procedure or gastric bypass is both a restrictive and malabsorptive procedure and involves joining a proximal gastric pouch to a loop of jejunum (53, 54). The laparoscopic adjustable gastric band (LAGB) is a restrictive procedure where an adjustable synthetic band is placed around the proximal stomach (53). The sleeve gastrectomy is also a restrictive procedure where most of the stomach along the greater curvature is resected and a narrow tube remains between the gastroesophageal junction and the pylorus (53, 55).
Complications associated with adolescent bariatric surgery vary by type of procedure. For the Roux-en-Y procedure, the most common complications reported are protein-calorie malnutrition and micronutrient deficiency, but also include more severe complications such as shock, pulmonary embolism and gastrointestinal obstruction (56). For the LAGB, the most frequently reported specific complication is band slippage; micronutrient deficiency is also a frequent outcome (56). After sleeve gastrectomy, reported complications from 3 studies included recurrent gastric ulceration in 2 patients who were heavy smokers, enlarged pouches in 2 patients and a disrupted staple line in one patient (56).

1.7.3 Candidates for Adolescent Bariatric Surgery

The consensus criteria for adolescent bariatric surgery are modified from adult guidelines and include adolescents with a BMI >35 kg/m² with a severe co-morbidity (i.e. T2DM, moderate to severe OSA, pseudotumor cerebri) or a BMI >40 kg/m² with a mild co-morbidity (i.e. hypertension, dyslipidemia, impairment of activities of daily living). Additional criteria include that the adolescent has attained 95% of his/her adult stature, he/she has demonstrated commitment to a psychological evaluation in the perioperative period, he/she has failed to achieved a healthy weight during prior attempts, females plan to avoid pregnancy for one year after surgery, he/she is capable of making a decision and will provide informed assent/consent, and he/she will adhere to the nutritional guidelines after surgery (53). The contraindications to adolescent bariatric surgery include having a cognitive disability that would interfere with adherence to treatment after surgery, if the teen is breastfeeding/pregnant or planning to become pregnant, or if the teen is not able to understand and acknowledge the potential outcomes of the surgery including possible post-operative nutritional deficiencies (53). Surgery is also contraindicated in the presence of untreated psychiatric issues such as an acute psychiatric
condition (e.g. active suicidal ideation), bulimia nervosa or self-induced vomiting, active substance use, a chronic mental condition resulting in emotional instability and significant conflict within the family (57).

1.7.4 Outcomes after Adolescent Bariatric Surgery

Outcomes after adolescent bariatric surgery are similar to outcomes in adults who have undergone bariatric surgery. In general, an average of 50-60% of excess weight is lost in the first year post-surgery, and up to 75% of excess weight is lost after the second year (53). Overall, this equates to a reduction in BMI of approximately 35% of original BMI (53).

A large retrospective study compared one year outcomes in 30 patients after Roux-en-Y gastric bypass surgery vs. a nonsurgical group of patients (n=12) participating in a pediatric weight management program (58). In the surgical patients, mean BMI decreased by 56% one year post-operatively (from 56.5 kg/m² before surgery to 35.8 kg/m² after surgery) vs. a decrease of 1.3% (47.2 kg/m² before the program to 46 kg/m² after the program) in the nonsurgical patients (58). The surgical patients experienced significant reductions in TC, TGs, fasting blood glucose and fasting insulin (58). The authors, however, noted that 2 patients began regaining weight during the first post-operative year and that 9 patients did not adhere to follow-up at the one year time point, highlighting the challenges in managing adolescents undergoing bariatric surgery (58).

A RCT comparing outcomes in adolescents after LAGB to a supervised lifestyle intervention found that 84% of adolescents in the gastric banding group lost more than 50% of excess weight compared with 12% in the lifestyle group (59). Of the 24 patients who underwent gastric banding, the mean weight lost was 34.6 kg or 12.7 BMI units, signifying an excess weight loss of 78.8% (59). In contrast, the 18 patients who completed the lifestyle program lost an
average of 3 kg or 1.3 BMI units, representing an excess weight loss of 13.2% (59). Furthermore, after 2 years, none of the patients who had surgery still had the metabolic syndrome compared with 22% of patients in the lifestyle group (59). The adolescents who underwent surgery also reported improvements in QOL, including physical functioning, general health self-esteem, family activities and change in health (59).

A systematic review in 2008 examined outcomes in adolescents after bariatric surgery and reported results in change in BMI units (56). Following LAGB surgery, with a follow-up time that ranged from 1-3 years, the 95% CI for change in BMI units was -13.7 to -10.6 at the longest point of follow-up. After Roux-en-Y gastric bypass surgery, after a mean length of follow-up of 1-6.3 years, the 95% CI for change in BMI units was -22.3 to -17.8 units.

Outcomes following sleeve gastrectomy were reported in 108 children and adolescents in a single centre by Alqahtani et al. (60). At 6 months, patients lost an average of 32.3 kg or 48.1% of excess weight; at 12 months, patients lost an average of 42.7 kg and 61.3% of excess weight; and at 24 months, they lost an average of 39.5 kg or 62.3% of excess weight (60). The majority of patients experienced a resolution in obesity-related co-morbidities (60). This program included children as young as 5 years of age and 43.5% of the surgeries were performed on children less than 14 years of age (60). This report has led to many concerns regarding the need for long-term follow-up.

1.8 SUMMARY OF THE LITERATURE

Results from randomized trials and clinical programs demonstrate that lifestyle interventions and clinical programs are effective in modestly reducing or stabilizing BMI, and
results are beginning to emerge on the benefits in cardiometabolic and psychological outcomes. In fact, these latter outcomes are likely more clinically relevant, as BMI itself is a proxy for measurement of other health parameters. Due to the heterogeneity of the programs and the quality of the data, it is not clear which components of the programs are most effective and which patient characteristics predict better outcomes. More recently, several studies have tried to determine predictors of treatment outcomes in pediatric obesity programs, with the aim of improving treatments and potentially tailoring therapies to the individual based on their baseline characteristics (61-64). A variety of different predictors have been studied, and the results have been heterogeneous. Positive predictors of weight loss or BMI reduction have included higher baseline adjusted BMI, older age, male gender, greater attendance, race/ethnicity and initial weight loss (61, 63). Within Canada, the evaluation of clinical programs will be an important way to try to answer these questions as well as assess the impact of these programs in treating children and adolescents with obesity and obesity-related co-morbidities.

In addition, adolescent bariatric surgery is increasingly performed in adolescents with similar outcomes to adult bariatric surgery and improvements in cardiometabolic and psychosocial outcomes post-operatively (53). Ongoing evaluation of outcomes after adolescent bariatric surgery is required to understand the long-term effects of this procedure in a younger population and to determine the most appropriate candidates for surgery (53).
Chapter 2 Aim, Objectives, Hypothesis and Outcome Rationale

2.1 AIM

The aim of this study is to evaluate and compare outcomes at 6 and 12 month of adolescents ages 12-17 years with severe obesity attending the SickKids Team Obesity Management Program (STOMP) at The Hospital for Sick Children (SickKids) to a comparison group of obese adolescents who are not enrolled in the STOMP program.

2.2 OBJECTIVES

The primary objective of the study is to evaluate whether adolescents participating in the STOMP experience a change in BMI at 6 months and at 12 months, compared to a group of obese adolescents not enrolled in the program.

The secondary objectives of the study are:

1. To evaluate whether adolescents participating in the STOMP program, compared to a group of obese adolescents not enrolled in the program, experience, at 6 and at 12 months:
   a. improvements in features related to the metabolic syndrome, including
      i. a change in waist circumference
      ii. a change in systolic and/or diastolic BP z-score
      iii. a change in TC, LDL-cholesterol, HDL-cholesterol, non-HDL cholesterol, TGs, and TG:HDL ratio
iv. a change in insulin resistance as measured by homeostatic measurement assessment-insulin resistance (HOMA-IR)

b. improvements in psychological health including
   i. a change in QOL as measured by the adolescent’s score on the Pediatric Quality of Life Inventory 4.0 (PedsQL 4.0) questionnaire and the Impact of Weight on Quality of Life (IWQOL)-Kids questionnaire
   ii. a change in the adolescent’s score on the Children’s Depression Inventory (CDI)

c. improvements in health behaviours including
   i. a change in the adolescent’s dietary readiness to change, as assessed by a dietician or STOMP team member (STOMP patients) or self-reported (comparison group)
   ii. a change in physical activity level as measured by the Habitual Activity Estimation Scale (HAES) questionnaire
   iii. a change in the adolescent’s and/or parent’s readiness to change as measured on the Readiness To Change questionnaire (teen and parent versions)

2. To determine baseline factors in STOMP patients associated with a greater reduction in BMI at 6 and 12 months.

3. To describe 6 month post-operative outcomes in STOMP patients who underwent bariatric surgery after participation in the lifestyle aspect of the program for 6 months.

2.3 HYPOTHESIS

We hypothesize that severely obese adolescents participating in the STOMP program will experience a reduction in BMI compared to obese adolescents not enrolled in the program. Adolescents enrolled in STOMP will also experience a reduction in cardiometabolic measures
including systolic and diastolic BP z-score, fasting cholesterol profile and HOMA-IR, an increase in psychological measures of QOL and a reduction in symptoms of depression, and an increase in health behaviour measures including dietary readiness to change, physical activity level and readiness to change compared to obese adolescents not enrolled in STOMP. Parents enrolled in STOMP will experience an increase in readiness to change compared to parents not enrolled in the program.

We hypothesize that STOMP patients and parents who are motivated to change at the start of the program, reflected in baseline Readiness to Change scores, will have a greater reduction in BMI over time. For STOMP patients who undergo bariatric surgery, we hypothesize that they will experience a significant decrease in BMI and improvements in cardiometabolic, psychological and health behaviour measures 6 months after surgery.

2.4 RATIONALE FOR PRIMARY OUTCOME

Change in BMI was chosen as the primary outcome because it has been used as the benchmark outcome parameter for the majority of studies of childhood obesity treatment (6-8). Change in BMI was selected rather than change in BMI z-score as the majority of patients enrolled in STOMP were post-pubertal and had completed linear growth. In addition, change in BMI z-score has been shown to be less effective in measuring adiposity change longitudinally in obese children and adolescents. For example, the child who has an increase in BMI z-score of one unit over one year can have a broad range of changes in BMI and in weight (65). Further, the BMI z-score growth charts have been smoothed statistically to remove outliers in the upper part of the BMI distribution, and lower centiles are closer together than upper centiles (66). As a
result, as one goes higher in the BMI percentile, a change in BMI is reflected by a smaller change in overall BMI z-score (66).
Chapter 3 Methods

3.1 STUDY DESIGN

This was a non-randomized prospective study comparing adolescents participating in the STOMP program to a comparison group not enrolled in the STOMP program.

3.2 OVERVIEW OF THE STOMP PROGRAM

3.2.1 Description of the STOMP Program

The STOMP program is a weight management program at The Hospital for Sick Children, a tertiary level pediatric hospital in Toronto, Ontario, Canada. The program was established in January 2010 and is an intensive 2 year program for adolescents with severe obesity ages 12 to 17 years (67). Fifty new patients are accepted into the program each year and a subset of patients undergo bariatric surgery (67). The goals of the program are to improve the health and QOL of adolescents struggling with obesity using a family-centred approach (67).

3.2.2 STOMP Program Referral Criteria

Adolescents can be referred to the STOMP program by a physician if they are between the ages of 12 to 17 years and have a BMI >99th percentile or a BMI >97th percentile (using the WHO definition of obesity) in addition to either a significant obesity-related co-morbidity requiring subspecialty care (e.g. hypertension requiring medication, technology dependent sleep disordered breathing, severe psychological impairment) or a significant co-existing illness (e.g. medication-induced obesity, hypothalamic obesity associated with a central nervous system (CNS) tumor) (68).
3.2.3 Interdisciplinary STOMP Team

The STOMP program comprises an interdisciplinary team including a pediatric endocrinologist, a pediatrician, a pediatric general surgeon, a nurse practitioner, a psychologist, a social worker, a dietitian, an exercise counselor and a clinic co-ordinator (69).

3.2.4 STOMP Program Intake Process

Referred adolescents who meet the program’s criteria are invited to a “Family Information Night” led by STOMP team members (69). Here, the teen and his/her family learn about the STOMP program and its structure. If families are interested in participating in STOMP, an intake assessment is booked. At the initial assessment, the family meets the entire STOMP team over the course of one half-day. This consists of a medical history and physical exam with the physician and nurse practitioner, a psychological assessment by the psychologist, a dietary assessment by the dietitian, an exercise assessment by the exercise counselor, and a social assessment by the social worker. Families complete baseline psychology questionnaires at this time. Following this, the teen and his/her family are invited to start the intensive phase of STOMP. The majority of families attend the core program, however, in exceptional cases where the family is keen to receive the intervention but is not able to attend the program at the usual frequency (i.e. due to extreme distance or due to other reasons precluding group participation, e.g. active mental health issues), alternative arrangements are made for the family to receive a shorter intensive curriculum with individual follow-up appointments thereafter.

3.2.5 Phases of STOMP Program

The STOMP program is divided into four phases (69). The first stage is an intensive educational curriculum. Patients and parents attend separate weekly 2 hour group sessions for 6 weeks. Patients also attend individual appointments with team members (nutrition, exercise
counseling, mental health) every other week prior to the group session during this time period to set goals and review progress of healthy lifestyle changes. Baseline blood work is completed during the first month after the intake assessment (69).

The second stage of treatment involves an ongoing intervention at a decreased frequency of visits. Patients and parents attend separate 1.5 hour biweekly group sessions, called “Mastery” sessions, where initial program content is expanded upon. Patients attend individual appointments or family therapy with the social worker and/or the psychologist and/or individual appointments with the dietitian and exercise counselor as required. Clinic visits take place at 3, 6 and 9 months with blood work and psychology questionnaires at 6 months (69).

The third phase begins at 12 months. Patients and parents now participate in separate 1.5 hour monthly “Mastery” group sessions. Here, the STOMP program also offers flexibility to meet the individual needs of the patient and his/her family. For example, if patients and families feel they would benefit from an increased frequency of visits in the second year of the program, they may continue to attend sessions biweekly. Patients attend individual appointments or family therapy with the social worker and/or the psychologist and/or individual appointments with the dietitian and exercise counselor as needed. Clinic visits take place at 12 and 18 months with repeat blood work and psychology questionnaires at these time points (69).

The fourth phase beginning at 18 months focuses on transition. Patients and parents may continue to attend 1.5 hour monthly “Mastery” group sessions or may reduce the frequency of sessions as they are transitioned to local community services. A final clinic visit takes place at 24 months with repeat blood work and psychology questionnaires (69).
3.3.6 STOMP Curriculum

The STOMP curriculum is delivered throughout the 2 year program. During the initial 6 weeks of the program, a number of topics are covered during the weekly patient and parent group sessions. These include sessions provided by the psychologist and the social worker (for ex: Thoughts-Feelings-Behaviour Cycles, Cognitive Distortions, Emotional Eating, Body Image, Relaxation Strategies, Coping Skills Toolbox), the dietitian (Healthy Lifestyle Approach, Hunger and Satiety, Canada’s Food Guide, Fibre and Protein) and the exercise counselor (Benefits and Types of Active Living, How to Become and Remain Physically Active). Families receive further education during the subsequent “Mastery” sessions, provided by the interdisciplin ary STOMP team. Topics covered include: Communicating with your Family, Responding to Bullying and Weight Bias, Fad Diets vs. Healthy Eating, Taste Testing, Surviving the Holidays, and Medical Complications of Obesity. Sessions include cooking with the dietitian and exercising with the exercise counselor. Families also receive education during clinic visits and individual appointments with STOMP team members.

3.3.7 Treatments Used in the STOMP Program

A large focus of the STOMP program is identifying and treating the underlying psychological co-morbidities that may be contributing to patients’ struggle with weight. The treatments used include CBT and motivational interviewing (67). Often, linkages are made with local community mental health centres to provide additional individual or family therapy. STOMP team members liaise with local mental health professionals to ensure consistency in treatment plans. In addition to providing all patients and families with education on healthy lifestyles, additional treatments are offered to STOMP participants depending on individual patient characteristics. This includes selective use of metformin, an oral antihyperglycemic
agent, and in one patient, short-term use of a specialized diet, the Protein Sparing Modified Fast (PSMF), a low carbohydrate, low fat, protein sparing nutrition plan, when severity of medical co-morbidities required expedient weight loss (69).

3.3.8 Bariatric Surgery

Bariatric surgery is performed in a subset of patients in the STOMP program. This process starts with the patient indicating interest in surgery, followed by a STOMP team member identifying and nominating a patient who meets the established criteria and does not meet the exclusion criteria, based on current consensus-based recommendations (53).

Patients then complete a standardized pre-operative protocol that includes education sessions on surgery and nutrition, a psychological evaluation to determine understanding of risks and benefits of the procedure, capacity for consent, and psychological readiness (i.e. absence of current, non-managed psychological disorders that could interfere with adherence to post-surgery recommendations), as well as assessments by the STOMP physician and nurse practitioner, the STOMP dietitian, a surgeon, an anesthesiologist and a thrombosis specialist. The patients and families meet with the pediatric general surgeon at SickKids and review the two options for bariatric surgery: laparoscopic Roux-en-Y gastric bypass or sleeve gastrectomy. Prior to surgery, patients follow a hypocaloric diet for 3-4 weeks consisting of 2 liquid meal replacement shakes and one healthy meal daily. Patients undergo surgery at SickKids and are admitted for 24-48 hours. Following this, they are closely monitored by the STOMP team. They attend monthly support group sessions with other patients who have had bariatric surgery and attend individual check-ins with the dietitian, nurse, exercise specialist, social worker and psychologist as needed. They are followed post-surgery for 2 years and are then transitioned to an adult bariatric surgery program.
3.4 STUDY VARIABLES AND DEFINITIONS

3.4.1. Anthropometric Measures

Anthropometric measures are taken at each medical clinic visit (baseline, 3, 6, 12, 18 and 24 month). These include patients’ height, weight and waist circumference (69). Height is measured in cm using a stadiometer and weight is measured in kg using a digital standing scale. Waist circumference is measured in cm midway between the lower ribs and the anterior superior iliac spine, using a measuring tape. Parents’ height and weight are also taken when possible. Between visits, weights are performed at the request of the patient. This was decided to allow for those who found tracking weight frequently helpful in monitoring progress, but also de-emphasizes the concept that weight equals success by focusing on healthy behaviour changes.

BMI and BMI z-scores are calculated using the WHO AnthroPlus anthropometric calculator for patients ≤19 years of age. For patients >19 years and parents, BMI is calculated by dividing weight in kg by height in m².

3.4.2. Physiologic Measures

Systolic and diastolic BP are measured at each clinic visit using an appropriate-sized cuff with either a manual or an automatic BP cuff (69). BP z-scores are calculated for patients ≤17 years of age using an on-line calculator created by the Baylor College of Medicine:
http://www.bcm.edu/bodycomplab/Flashapps/BPVAgeChartpage.html.

3.4.3 Biochemical Measures

Fasting blood work is performed at SickKids at intake and every 6 months. This includes fasting blood glucose, insulin, TC, LDL-cholesterol, HDL-cholesterol and TGs (69). HOMA-IR
is calculated by the following equation: (fasting blood sugar (mmol/L) x (insulin (pmol/L) /6.945))/22.5) (70). Non-HDL cholesterol is calculated by subtracting TC from HDL-cholesterol (37). TG:HDL ratio is calculated by dividing TG by HDL-cholesterol. A OGTT, with measurement of glucose fasting and 2 hours following glucose intake, is performed at baseline and every 12 months. Additional tests include measurement of ALT and AST levels (69).

3.4.4 Imaging
An abdominal ultrasound is completed at SickKids after the initial intake to assess for the presence of fat deposition in the liver (69).

3.4.5 Sleep Study
The majority of patients undergo a sleep study to assess for the presence of OSA. The sleep study takes place in the Sleep Lab at SickKids (69).

3.4.6 Dietary Measures
The dietitian performs individual dietary assessments with patients at intake and at subsequent clinic visits every 6 months. This consists of a 24 hour dietary recall and interview regarding intake of obesogenic foods (i.e. fast foods, sugar sweetened beverages, etc), eating patterns and changes made in overall eating behaviour. Based on this evaluation, the dietitian assigns a ‘dietary readiness to change score’: this represents her assessment of the patient’s stage of change with respect to nutrition. The dietary readiness to change score has 4 subscales (precontemplation, contemplation, action and maintenance), adapted from the Transtheoretical Model or Stages of Change Model (71). A copy of the dietary readiness to change score is available in Appendix 9.4.4.
3.4.7 Measures of Physical Activity

The exercise counselor completes the HAES questionnaire with patients at intake and at subsequent clinic visits every 6 months. The HAES questionnaire (Appendix 9.4.3) is an activity measurement tool that estimates the duration and intensity of daily activity of children (72). The questionnaire is delivered in interview format as a physical activity recall on a typical weekday (Tuesday, Wednesday or Thursday) and a typical Saturday during the past two weeks. It divides the day into four time periods based on wake-up, meal times and bedtime, and identifies four levels of intensity: inactive (i.e. lying down), somewhat inactive (i.e. sitting), somewhat active (i.e. walking) and very active (i.e. running) (72). The HAES questionnaire has been validated in healthy children and in those with chronic diseases (72).

3.4.8 Psychological Measures

Patients fill out the questionnaires listed in Table 1 at intake and every 6 months. A copy of these measures is available in Appendix 9.3 and 9.4.1.

Table 1: Adolescent Psychology Questionnaires

<table>
<thead>
<tr>
<th>Questionnaire Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PedsQL 4.0 (Pediatric Quality of Life Inventory Version 4.0)</td>
<td>A 23-item questionnaire that assesses Physical Functioning (8 items), Emotional Functioning (5 items), Social Functioning (5 items) and School Functioning (5 items) (73). A Psychosocial Health Summary Score (15 items) is calculated using the Emotional, Social and School Functioning scores, and a Total Score is calculated using all the scores. Scores range from 0 to 100, where a higher score indicates better HRQoL (73).</td>
</tr>
<tr>
<td>Impact of Weight on Quality of Life</td>
<td>A 27-item questionnaire that assesses Physical</td>
</tr>
<tr>
<td>Questionnaire Title</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>(IWQOL)-Kids</td>
<td>Comfort (6 items), Body Esteem (9 items), Social Life (6 items), Family Relations (6 items) and a Total Score (74). Scores range from 0 to 100, where 100 represents the best QOL (74).</td>
</tr>
<tr>
<td>Readiness To Change, Teen Version</td>
<td>A 6-item scale that assess the adolescent’s readiness to change his/her lifestyle.</td>
</tr>
<tr>
<td>Children’s Depression Inventory (CDI)</td>
<td>A 27-item scale for depression for youth 7 to 17 years of age. A CDI T-score ≥65 is considered clinically significant (75).</td>
</tr>
</tbody>
</table>

Parents fill out the questionnaire in Table 2 (Appendix 9.4.2) at intake and every 6 months.

### Table 2: Parent Psychology Questionnaires

<table>
<thead>
<tr>
<th>Questionnaire Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readiness To Change, Parent Version</td>
<td>A 6-item scale that assess the parent’s readiness to help the adolescent change his/her lifestyle.</td>
</tr>
</tbody>
</table>

### 3.4.9 Attendance

Patient and parent attendance at medical visits, individual appointments with STOMP team members, patient group sessions and parent group sessions are tracked through the hospital system.

### 3.4.10 Definitions of Obesity-Related Co-morbidities

As patients undergo assessments in the STOMP program, obesity-related co-morbidities are frequently newly diagnosed and treated. Table 3 lists the definitions used within this study for the most commonly diagnosed co-morbidities.
<table>
<thead>
<tr>
<th>Table 3: Definitions of Obesity-Related Co-morbidities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Impaired fasting glucose (IFG)</strong></td>
</tr>
<tr>
<td><strong>Impaired glucose tolerance (IGT)</strong></td>
</tr>
<tr>
<td><strong>Type 2 diabetes (T2DM)</strong></td>
</tr>
<tr>
<td><strong>Dyslipidemia</strong></td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
</tr>
<tr>
<td><strong>Non-alcoholic fatty liver disease (NAFLD)</strong></td>
</tr>
<tr>
<td><strong>Obstructive sleep apnea (OSA)</strong></td>
</tr>
<tr>
<td><strong>Polycystic ovarian syndrome (PCOS)</strong></td>
</tr>
<tr>
<td><strong>Musculoskeletal (MSK) complication</strong></td>
</tr>
<tr>
<td>Disorder</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Depression</td>
</tr>
<tr>
<td>Anxiety</td>
</tr>
<tr>
<td>Learning disorder (LD)</td>
</tr>
<tr>
<td>Attention deficit hyperactivity disorder (ADHD)</td>
</tr>
<tr>
<td>Disordered eating</td>
</tr>
</tbody>
</table>

### 3.5 EVALUATION OF THE STOMP PROGRAM

#### 3.5.1 Recruitment of STOMP Program Participants

STOMP program participants were recruited for this study during routine hospital visits by a graduate student (P.L.) or a research assistant (M.J.) until February 2012 to allow for a minimum of 12 month follow-up data to be collected. A copy of the adolescent and parent consent forms are available in Appendix 9.2.1 and 9.2.2 respectively. Patients enrolled in the STOMP program since its inception in January 2010 were eligible for the study.

#### 3.5.2 Recruitment of Comparison Participants

Comparison participants were recruited after attending the STOMP information night if they decided they were not able to attend the program. They were also recruited through flyers posted in SickKids, a notice posted on the hospital’s research website, from the Endocrine and
Endocrine-Gynecology clinics at SickKids, and by contacting adolescents who participated in research studies at SickKids and agreed to be contacted for future studies. Comparison participant recruitment started in July 2011 and ended in February 2012, to allow for a 12 month follow-up period. All comparison participants had a BMI ≥95th percentile. Participants were not excluded if they were receiving obesity management outside of STOMP as it was not deemed ethical to prevent adolescents in the comparison group from joining a community lifestyle program during the 12 months of this study. Among comparison participants, 40% were participating in a lifestyle program either prior to or during the study. A copy of the adolescent and parent consent forms are available in Appendix 9.2.3 and 9.2.4 respectively.

3.5.3 Comparison Participants’ Visits

Comparison participants visited the hospital at three time points: baseline, 6 months and 12 months. At each visit, participants completed fasting blood work including glucose, insulin and lipid profile. The adolescent’s anthropometric measures (height, weight, waist circumference) were taken together with his/her BP. The accompanying parent’s height and weight were measured by scale at each time point. If a parent did not attend a visit, his/her height and weight were reported at the initial visit. BMI and BMI z-scores were calculated using the WHO AnthroPlus anthropometric calculator for patients ≤19 years of age. For patients >19 years and parents, BMI was calculated by dividing weight in kg by height in m². BP z-scores were calculated for participants ≤17 years of age using an on-line calculator created by the Baylor College of Medicine (http://www.bcm.edu/bodycomplab/Flashapps/BPVAgeChartpage.html).

The participants and parents completed the following questionnaires: PedsQL 4.0, IWQOL-Kids, CDI and Readiness to Change (teen and parent versions). The HAES questionnaire was completed with the adolescents. Participants selected one of four sentences
that reflected their current dietary readiness to change (Appendix 9.4.5). Copies of the data collection forms used during the visits are available in Appendix 9.6.

Participants were compensated for their time with monetary reimbursement, a parking pass, a meal voucher and volunteer hours. The results of the blood work were mailed to the family after each visit and the results from the final visit were also mailed to the participant’s primary care physician.

3.6 RESEARCH ETHICS

This study received approval from the Research Ethics Board at The Hospital for Sick Children.

3.7 METHODOLOGICAL APPROACH

The aim of this study was to assess a number of outcomes for the STOMP program, including those classically measured in obesity program evaluations (i.e. change in BMI) and those increasingly recognized as important variables such as QOL outcomes. We selected change in BMI as the primary outcome and then explored several secondary outcomes in order to expand on what is already known about the impact of lifestyle programs in this patient population. We felt that carrying out a broad assessment of the program with numerous outcomes was advantageous, however, we also recognize that the risk of type 1 error increases with multiple comparisons and may limit the interpretation of some of the results.

In addition, it was not possible to perform repeated measures analysis (thereby reducing the variability from individual participants) for the entire population as a subset of STOMP
patients underwent bariatric surgery after 6 months and subsequent changes in outcomes could be attributed to surgery rather than the lifestyle program. As an alternative, we assessed change over time from baseline to 6 months for all STOMP patients and then assessed change over time from baseline to 12 months for STOMP patients who did not undergo bariatric surgery.

3.8 STATISTICAL ANALYSIS

3.8.1 Description of Statistical Analysis

Data were presented as means with SD. For all analyses, STOMP patients who eventually underwent bariatric surgery but were participating in the medical aspect of the program for at least 6 months were included at 6 months and excluded at 12 months.

Co-morbidities were grouped together in the analysis. Metabolic co-morbidity was defined as one or more of T2DM, hyperlipidemia, hypertension, NAFLD and PCOS. Psychiatric co-morbidity was defined as one or more of depression, anxiety, disordered eating, attention deficit hyperactivity disorder (ADHD) and learning disorder (LD). ADHD and LD were also combined separately into one group as were depression, anxiety and disordered eating. Other co-morbidities’ were defined as one or more of GERD, gallbladder disease, MSK complication, OSA, asthma, CNS tumor, developmental delay, difficulty ambulating, genetic syndrome and other. Medications were grouped into Metabolic (one or more of metformin, insulin, lipid-lowering and anti-hypertensive medication), Psychiatric (one or more of antidepressant and atypical antipsychotic) and Other Medication (one or more of medication for GERD, anti-inflammatory, inhaled corticosteroid, oral steroid, BiPAP, valproic acid and other medication).

Basic comparisons between STOMP patients and the comparison group were performed using Fisher’s exact chi-square and Student’s t-test (assuming unequal variance between
samples, Satterthwaite method). Student’s t-tests were conducted for ordinal variables as this method is more appropriate with small samples and many categories.

Comparison of the changes over time in outcomes between STOMP patients and the comparison group were performed using linear regression models (maximum likelihood for parameter estimation, (MLE)) adjusted for repeated measure through a compound symmetry covariance structure). Separate sets of models were created for change between baseline and 6 months and change between baseline and 12 months. Each model includes 3 parameters in the same regression model; 1) the baseline difference between groups, 2) the common change between baseline and follow-up which adjusts for change over time regardless of intervention and 3) the interaction between study groups and time. The interaction term represents the attributable effect which is the difference between the changes in STOMP patients vs. the changes in the comparison group. The regression models were also used to estimate within-group changes over time. Within-group changes and attributable effect were transformed to relative change using baseline values as benchmark in order for a common scale to be used in forest plots for graphical representation of the results. Results were adjusted for baseline variables of BMI, HOMA-IR, TG, IWQOL-Kids Total score, CDI T-score and dietary readiness to change. Adjusted results are presented in all cases except in Figures 12-14 (forest and box plots) where raw results are shown.

For STOMP patients only, an exploratory analysis was conducted to evaluate baseline clinical predictors contributing to BMI change over 6 and 12 months. Potential predictors were selected based on clinical relevance, thereafter, all selected predictors were modelled against change in BMI using univariable linear regression models with maximum likelihood method for parameter estimation. Factors with univariable association with p-value <0.20 were then
included in a multivariable linear regression model with backward selection of variables to obtain a final model.

Lastly, outcomes in STOMP patients who underwent bariatric surgery after 6 months in the program were assessed using a paired t-test at three time points: between baseline and 6 months (lifestyle aspect of the program only), between baseline and 6 months post-surgery and between 6 months and 6 months post-surgery.

All statistical analyses were performed using SAS v9.3 (The SAS Institute, Cary, NC). Given the limited sample size, some ordinal variables had to be treated as continuous variables (for example, 6 point Likert scale of Readiness to Change). Mean imputation was used to handle missing values in multivariable regression models. As a general rule, parameter estimates represent the change in the dependent variable for each increment of 1 unit in the independent variable.

3.8.2 Sample Size Calculation

The sample size calculation was based on results from a one year RCT of lifestyle intervention by Diaz et al (78). We chose to base the sample size on an RCT as the published clinical program outcome reports do not contain a comparison group. The intervention by Diaz et al. was similar to the STOMP program in that participants were between 9-17 years of age and needed to have a BMI >95th percentile or BMI and waist circumference >90th percentile (78). They attended 12 consecutive, weekly 2 hour group sessions, led by a registered dietitian. During this time, health behaviour goals were set and revised. Participants and their parents also had individual weekly appointments with the dietitian for 12 weeks and then monthly; they also met monthly with a primary care physician (78). Parents attended 6 education sessions during the intervention (78). In the control group, participants and parents received monthly consultations.
with a primary care physician who monitored BMI and provided general advice on healthy lifestyle changes (78). The attrition rates at 12 months were quite high (45% and 42% for the intervention and control groups respectively) (78). Change in BMI at 12 months in the intervention participants was -1.8±1.9 kg/m² and in the control group was 0.4±2.1 kg/m². Based on the change in BMI at 12 months in the intervention group and in the control group in this study, an α of 0.05 and β of 0.20, the sample size required for the STOMP treatment group is 22 and the sample size required for the comparison group is 11.

We recruited 75 STOMP patients and 42 comparison participants in anticipation of high attrition rates (40-50% based on the literature) and with the recognition that a proportion (up to 10 per year) may undergo bariatric surgery. In addition, the evaluation of the STOMP program was performed in parallel by a government-funded agency who requested and provided funding for the completion of 42 comparison visits.

The sample size calculation was based on change in BMI over 12 months. This endpoint was chosen as the majority of studies demonstrate greater BMI reduction at 6 months, however, effects of the intervention tend to attenuate from 6-12 months.
Chapter 4 Results

4.1 PARTICIPANTS

4.1.1 Baseline Demographic, Anthropometric, Cardiometabolic, Psychological and Health Behaviour Characteristics of STOMP and Comparison Participants

Of the 75 STOMP patients approached to participate in the study, all consented and completed baseline investigations and intake assessments (Figure 2). In the comparison group, 41 adolescents met criteria for the study and completed baseline investigations. The number of STOMP and comparison participants who completed 6 and 12 month assessments are shown in Figure 2.

Tables 4-8 and Figures 3-11 describe the baseline characteristics of STOMP patients (n=75) and comparison participants (n=41). STOMP participants had severe obesity (mean BMI 44.8±7.8 kg/m$^2$) and 84% had at least one metabolic co-morbidity. At the start of the program, 17% had a diagnosis of OSA. The degree of psychiatric co-morbidity was also high with 45% of STOMP patients having at least one psychiatric co-morbidity. QOL scores were lower than those reported in healthy youth in the literature (73, 74) and 16% reported a CDI T-score suggestive of clinical depression (data not shown). STOMP patients and parents reported being ready for healthy behaviour change at the start of the program with a mean ‘preparation stage’ score on the Readiness to Change questionnaire. In contrast, the mean assessment of dietary readiness to change by the STOMP dietitian at baseline was at the ‘precontemplation stage’. STOMP parents’ mean maternal and paternal BMI levels were in the obese range. Mean annual household income was between $25,000-50,000 and 30% of families reported an annual income <$25,000.

Although the comparison participants met criteria for severe complex obesity (i.e. BMI percentile >99th percentile), their BMI values were significantly lower than STOMP participants.
Additional significant differences, including demographic, anthropometric, cardiometabolic, psychological and health behaviour measures, are outlined in Tables 4-8 and Figures 6-8.

**Figure 2: Recruitment, Enrollment and Follow-up of STOMP and Comparison Participants**

- 75 STOMP patients approached to participate in study
- 75 STOMP patients consented to participate in study
- 75 STOMP patients completed baseline intake and investigations

**Status at 6 month follow-up**
- 66 in program and completed investigations
- 7 dropped out (9% attrition rate)
- 1 excluded due to pregnancy
- 1 family moved

- 42 participants recruited from STOMP information night (24%), hospital flyers, hospital clinics and contacts from previous studies; 15/42 or 40% in community lifestyle program
- 42 participants consented to participate in study
- 42 participants completed baseline visit

**Status at 6 month follow-up**
- 35 completed 6 month visit
- 6 dropped out (15% attrition rate)

- 75 STOMP patients approached to participate in study
- 75 STOMP patients consented to participate in study
- 75 STOMP patients completed baseline intake and investigations

**Status at 12 month follow-up**
- 60 in program and 54 (47 non-bariatric sx pts, 7 bariatric sx pts) completed investigations*
- 4 dropped out (15% overall attrition rate)
- 1 discharged early by program
- 1 admitted to inpatient housing complex

*6 pts did not have 12 month medical visit at time of data analysis

- 35 completed 12 month visit (15% attrition rate)

1 participant excluded-Did not meet study criteria
Table 4: Baseline Demographic and Anthropometric Characteristics of STOMP and Comparison Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>STOMP</th>
<th>n</th>
<th>Comparison</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>75</td>
<td>15.1±1.8</td>
<td>41</td>
<td>14.9±2.0</td>
<td>0.53</td>
</tr>
<tr>
<td>Gender</td>
<td>75</td>
<td>65% female</td>
<td>41</td>
<td>59% female</td>
<td>0.48</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>75</td>
<td>44.8±7.8</td>
<td>41</td>
<td>34.5±8.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BMI z-score</td>
<td>75</td>
<td>4.5±1.1</td>
<td>41</td>
<td>3.1±1.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>68</td>
<td>127.9±19.5</td>
<td>41</td>
<td>104.6±16.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Systolic BP z-score</td>
<td>60</td>
<td>0.9±1.2</td>
<td>34</td>
<td>0.6±0.9</td>
<td>0.10</td>
</tr>
<tr>
<td>Diastolic BP z-score</td>
<td>60</td>
<td>0.7±0.7</td>
<td>34</td>
<td>0.01±0.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Paternal BMI (kg/m²)</td>
<td>30</td>
<td>33.6±7.4</td>
<td>36</td>
<td>30.1±5.9</td>
<td>0.03</td>
</tr>
<tr>
<td>Maternal BMI (kg/m²)</td>
<td>47</td>
<td>33.6±7.6</td>
<td>38</td>
<td>30.6±7.6</td>
<td>0.07</td>
</tr>
<tr>
<td>Paternal education</td>
<td>61</td>
<td>2.9±1.1</td>
<td>40</td>
<td>2.7±1.2</td>
<td>0.35</td>
</tr>
<tr>
<td>Maternal education</td>
<td>69</td>
<td>3.0±1.0</td>
<td>41</td>
<td>3.3±1.1</td>
<td>0.24</td>
</tr>
<tr>
<td>Income</td>
<td>66</td>
<td>2.8±1.6</td>
<td>41</td>
<td>3.2±1.3</td>
<td>0.20</td>
</tr>
</tbody>
</table>

(Education: 1=less than high school; 2=high school; 3=college; 4=university (undergraduate); 5=university (graduate). Income: 1=<$25,000; 2=$25,001-50,000; 3=$50,001-75,000; 4=$75,001-100,000; 5=>$100,001).

Figure 3: Parental Education Levels
Figure 4: Annual Household Income

Table 5: Baseline Co-Morbidities of STOMP and Comparison Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>STOMP</th>
<th>n</th>
<th>Comparison</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>%Metabolic co-morbidity</td>
<td>75</td>
<td>84%</td>
<td>38</td>
<td>61%</td>
<td>0.004</td>
</tr>
<tr>
<td>%Depression/anxiety/disordered eating</td>
<td>75</td>
<td>27%</td>
<td>41</td>
<td>10%</td>
<td>0.03</td>
</tr>
<tr>
<td>%Learning disability/ADHD</td>
<td>73</td>
<td>30%</td>
<td>40</td>
<td>43%</td>
<td>0.18</td>
</tr>
<tr>
<td>%Psychiatric co-morbidity</td>
<td>74</td>
<td>45%</td>
<td>40</td>
<td>43%</td>
<td>0.83</td>
</tr>
<tr>
<td>%Other co-morbidity</td>
<td>73</td>
<td>92%</td>
<td>41</td>
<td>46%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>%Medication for metabolic co-morbidity</td>
<td>75</td>
<td>12%</td>
<td>41</td>
<td>5%</td>
<td>0.21</td>
</tr>
<tr>
<td>%Medication for psychiatric co-morbidity</td>
<td>75</td>
<td>15%</td>
<td>41</td>
<td>5%</td>
<td>0.11</td>
</tr>
<tr>
<td>%Medication for other co-morbidity</td>
<td>75</td>
<td>56%</td>
<td>41</td>
<td>66%</td>
<td>0.30</td>
</tr>
</tbody>
</table>
Figure 5: Baseline Co-Morbidities of STOMP and Comparison Participants

![Figure 5: Baseline Co-Morbidities of STOMP and Comparison Participants](image)

Table 6: Baseline Cardiometabolic Characteristics of STOMP and Comparison Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>STOMP</th>
<th>n</th>
<th>Comparison</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol (mmol/L)</td>
<td>75</td>
<td>4.38±1.08</td>
<td>39</td>
<td>4.24±0.78</td>
<td>0.45</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>75</td>
<td>1.53±0.76</td>
<td>39</td>
<td>1.19±0.45</td>
<td><strong>0.008</strong></td>
</tr>
<tr>
<td>HDL-cholesterol (mmol/L)</td>
<td>75</td>
<td>1.11±0.24</td>
<td>39</td>
<td>1.17±0.27</td>
<td>0.18</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/L)</td>
<td>74</td>
<td>2.59±0.89</td>
<td>39</td>
<td>2.53±0.73</td>
<td>0.68</td>
</tr>
<tr>
<td>TG:HDL ratio</td>
<td>75</td>
<td>1.50±0.93</td>
<td>39</td>
<td>1.08±0.52</td>
<td><strong>0.009</strong></td>
</tr>
<tr>
<td>Non-HDL cholesterol (mmol/L)</td>
<td>75</td>
<td>3.28±1.06</td>
<td>39</td>
<td>3.06±0.79</td>
<td>0.26</td>
</tr>
<tr>
<td>Fasting glucose (mmol/L)</td>
<td>73</td>
<td>5.1±1.8</td>
<td>39</td>
<td>4.7±0.4</td>
<td>0.14</td>
</tr>
<tr>
<td>Fasting insulin (pmol/L)</td>
<td>70</td>
<td>191.8±158.3</td>
<td>39</td>
<td>89.9±66.1</td>
<td><strong>&lt;0.001</strong></td>
</tr>
<tr>
<td>Homeostatic measurement assessment- insulin resistance (HOMA-IR)</td>
<td>68</td>
<td>6.1±5.3</td>
<td>39</td>
<td>2.8±2.1</td>
<td><strong>&lt;0.001</strong></td>
</tr>
</tbody>
</table>
Figure 6: Baseline Cardiometabolic Measures of STOMP and Comparison Participants

Table 7: Baseline Psychological Measures of STOMP and Comparison Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>STOMP</th>
<th>Comparison</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PedsQL 4.0 Physical Functioning</td>
<td>69</td>
<td>68.0±18.4</td>
<td>39 82.1±14.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PedsQL 4.0 Emotional Functioning</td>
<td>69</td>
<td>63.4±23.1</td>
<td>39 73.6±18.0</td>
<td>0.02</td>
</tr>
<tr>
<td>PedsQL 4.0 Social Functioning</td>
<td>69</td>
<td>74.7±16.3</td>
<td>39 81.9±15.3</td>
<td>0.02</td>
</tr>
<tr>
<td>PedsQL 4.0 School Functioning</td>
<td>68</td>
<td>61.9±20.4</td>
<td>39 67.3±19.5</td>
<td>0.17</td>
</tr>
<tr>
<td>PedsQL 4.0 Psychosocial Health</td>
<td>69</td>
<td>66.6±15.5</td>
<td>39 74.3±14.5</td>
<td>0.01</td>
</tr>
<tr>
<td>PedsQL 4.0 Total Score</td>
<td>69</td>
<td>67.1±14.6</td>
<td>39 77.0±14.1</td>
<td>0.001</td>
</tr>
<tr>
<td>IWQOL-Kids Physical Comfort</td>
<td>65</td>
<td>66.4±22.4</td>
<td>39 84.7±17.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IWQOL-Kids Body Esteem</td>
<td>65</td>
<td>53.3±27.6</td>
<td>35 68.9±28.9</td>
<td>0.007</td>
</tr>
<tr>
<td>IWQOL-Kids Social Life</td>
<td>65</td>
<td>73.3±24.5</td>
<td>38 85.8±21.2</td>
<td>0.008</td>
</tr>
<tr>
<td>IWQOL-Kids Family Relations</td>
<td>64</td>
<td>89.8±13.4</td>
<td>38 93.2±17.6</td>
<td>0.27</td>
</tr>
<tr>
<td>IWQOL-Kids Total Score</td>
<td>65</td>
<td>68.6±17.4</td>
<td>38 81.9±17.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Children’s Depression Inventory T-score</td>
<td>69</td>
<td>50.8±11.9</td>
<td>39 46.0±9.0</td>
<td>0.03</td>
</tr>
</tbody>
</table>

PedsQL 4.0=Pediatric Quality of Life 4.0 Inventory; IWQOL-Kids=Impact of Weight on Quality of Life-Kids.
Figure 7: Baseline PedsQL 4.0 Scores of STOMP and Comparison Participants Vs. Healthy Youth (73)

*P-value <0.05 comparing STOMP and comparison participants

Figure 8: Baseline IWQOL-Kids Scores of STOMP and Comparison Participants Vs. Healthy Youth (74)

*P-value <0.05 comparing STOMP and comparison participants
Table 8: Baseline Measures of Health Behaviour in STOMP and Comparison Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>STOMP</th>
<th>n</th>
<th>Comparison</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teen Readiness to Change score</td>
<td>62</td>
<td>4.2±1.2</td>
<td>38</td>
<td>4.4±1.2</td>
<td>0.31</td>
</tr>
<tr>
<td>Parent Readiness to Change score</td>
<td>62</td>
<td>4.7±0.8</td>
<td>41</td>
<td>4.5±1.4</td>
<td>0.25</td>
</tr>
<tr>
<td>HAES WK (hours)</td>
<td>73</td>
<td>4.0±2.4</td>
<td>41</td>
<td>4.1±2.3</td>
<td>0.78</td>
</tr>
<tr>
<td>HAES WE (hours)</td>
<td>73</td>
<td>4.5±3.0</td>
<td>41</td>
<td>4.5±2.7</td>
<td>0.96</td>
</tr>
<tr>
<td>HAES ALL (hours)</td>
<td>73</td>
<td>8.3±4.5</td>
<td>41</td>
<td>8.6±4.2</td>
<td>0.73</td>
</tr>
<tr>
<td>Dietary readiness to change</td>
<td>72</td>
<td>1.4±0.5</td>
<td>41</td>
<td>3.2±0.7</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

HAES WK= Habitual Activity Estimation Scale (HAES) weekday somewhat active (SA) + HAES weekday very active (VA); HAES WE= HAES weekend SA+ HAES weekend VA; HAES ALL = HAES WK+HAES WE.

Figure 9: Baseline Teen Readiness to Change Scores

![Pie chart showing teen readiness to change scores in STOMP and Comparison groups.](chart1)

Figure 10: Baseline Parent Readiness to Change Scores

![Pie chart showing parent readiness to change scores in STOMP and Comparison groups.](chart2)
4.2 TREATMENT EFFECT

4.2.1 Changes in Anthropometric Measures From Baseline to 6 Months and 12 Months

Table 9 describes the anthropometric changes from baseline to 6 and 12 months for STOMP and comparison participants, and the attributable effect of the intervention. After 6 months in the program, STOMP patients’ BMI had not changed significantly (change of 0.08±0.3 kg/m$^2$; p=0.79). In contrast, comparison participants had a significant increase in BMI at 6 months of 0.7±0.2 kg/m$^2$ (p=0.004). After 12 months in the program, STOMP participants experienced a non-significant increase in BMI of 0.8±0.5 kg/m$^2$ (p=0.07) and comparison participants had a significant increase in BMI of 1.2±0.4 kg/m$^2$ (p=0.001). The change in BMI between the two groups was not significant at 6 or 12 months (p=0.10 and 0.53 respectively).

At 12 months, STOMP participants experienced a significant decrease in waist circumference compared to baseline and compared to the comparison group.

BP z-scores did not improve at 6 or 12 months in STOMP patients, whereas the comparison participants had a significant increase in systolic BP z-score at 6 months compared to baseline and compared to STOMP participants.
Table 9: Within Group and Between Group Change in Anthropometric Measures from Baseline to 6 and 12 Months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mo</th>
<th>n</th>
<th>Δ within STOMP Est±SE</th>
<th>P-value</th>
<th>n</th>
<th>Δ within Comparison Est±SE</th>
<th>P-value</th>
<th>Attributable Effect Est±SE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>6</td>
<td>66</td>
<td>1.1±0.8</td>
<td>0.19</td>
<td>35</td>
<td>2.9±0.7</td>
<td>&lt;0.001</td>
<td>-1.8±1.1</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>47</td>
<td>4.0±1.3</td>
<td>0.002</td>
<td>35</td>
<td>4.8±1.0</td>
<td>&lt;0.001</td>
<td>-0.8±1.6</td>
<td>0.64</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>6</td>
<td>66</td>
<td>0.7±0.2</td>
<td>&lt;0.001</td>
<td>35</td>
<td>1.0±0.2</td>
<td>&lt;0.001</td>
<td>-0.2±0.3</td>
<td>0.44</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>47</td>
<td>1.3±0.3</td>
<td>&lt;0.001</td>
<td>35</td>
<td>1.6±0.5</td>
<td>0.001</td>
<td>-0.3±0.6</td>
<td>0.65</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>6</td>
<td>66</td>
<td>0.08±0.3</td>
<td>0.79</td>
<td>35</td>
<td>0.7±0.2</td>
<td>0.004</td>
<td>-0.6±0.4</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>47</td>
<td>0.8±0.5</td>
<td>0.07</td>
<td>35</td>
<td>1.2±0.4</td>
<td>0.001</td>
<td>-0.4±0.6</td>
<td>0.53</td>
</tr>
<tr>
<td>BMI z-score</td>
<td>6</td>
<td>66</td>
<td>-0.04±0.04</td>
<td>0.32</td>
<td>34</td>
<td>0.04±0.05</td>
<td>0.50</td>
<td>-0.08±0.07</td>
<td>0.26</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>47</td>
<td>0.03±0.07</td>
<td>0.66</td>
<td>34</td>
<td>0.08±0.06</td>
<td>0.22</td>
<td>-0.05±0.09</td>
<td>0.61</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>6</td>
<td>21</td>
<td>-3.6±2.2</td>
<td>0.11</td>
<td>34</td>
<td>-0.4±0.9</td>
<td>0.68</td>
<td>-3.2±2.4</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>28</td>
<td>-7.4±2.1</td>
<td>0.001</td>
<td>35</td>
<td>-1.5±1.0</td>
<td>0.15</td>
<td>-5.9±2.4</td>
<td>0.01</td>
</tr>
<tr>
<td>Systolic BP z-score</td>
<td>6</td>
<td>21</td>
<td>-0.1±0.2</td>
<td>0.56</td>
<td>24</td>
<td>0.4±0.2</td>
<td>0.03</td>
<td>-0.6±0.3</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>17</td>
<td>-0.3±0.2</td>
<td>0.22</td>
<td>21</td>
<td>0.1±0.2</td>
<td>0.60</td>
<td>-0.4±0.3</td>
<td>0.21</td>
</tr>
<tr>
<td>Diastolic BP z-score</td>
<td>6</td>
<td>21</td>
<td>-0.2±0.2</td>
<td>0.18</td>
<td>24</td>
<td>-0.08±0.2</td>
<td>0.69</td>
<td>-0.2±0.3</td>
<td>0.55</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>17</td>
<td>-0.3±0.2</td>
<td>0.09</td>
<td>21</td>
<td>-0.1±0.1</td>
<td>0.50</td>
<td>-0.2±0.2</td>
<td>0.37</td>
</tr>
</tbody>
</table>

*First p-value is within group change for Stomp patients, second p-value is within group change for Comparison group, third p-value is between group change after adjustment for significant baseline variables.

4.2.2 Cardiometabolic Change From Baseline to 6 Months and 12 Months

Table 10 outlines the adjusted cardiometabolic changes from baseline to 6 and 12 months. Fasting lipid profiles did not improve significantly in STOMP or comparison participants at 6 months or 12 months. Fasting insulin and HOMA-IR values decreased significantly in STOMP patients at 12 months and increased significantly in the comparison group at 6 and 12 months. The change in fasting insulin and HOMA-IR between the two groups was significant at 6 and 12 months.
Table 10: Within Group and Between Group Change in Cardiometabolic Measures from Baseline to 6 and 12 Months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mo</th>
<th>n</th>
<th>Δ within STOMP Est±SE</th>
<th>P-value</th>
<th>n</th>
<th>Δ within Comparison Est±SE</th>
<th>P-value</th>
<th>Attributable Effect Est±SE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol (mmol/L)</td>
<td>6</td>
<td>66</td>
<td>0.01±0.11</td>
<td>0.92</td>
<td>35</td>
<td>0.15±0.09</td>
<td>0.10</td>
<td>-0.14±0.15</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>43</td>
<td>-0.10±0.14</td>
<td></td>
<td></td>
<td>0.12±0.09</td>
<td>0.21</td>
<td>-0.22±0.17</td>
<td></td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>6</td>
<td>66</td>
<td>0.04±0.07</td>
<td>0.56</td>
<td>35</td>
<td>0.09±0.06</td>
<td>0.15</td>
<td>-0.04±0.09</td>
<td>0.63</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>43</td>
<td>-0.10±0.10</td>
<td></td>
<td></td>
<td>0.01±0.07</td>
<td>0.92</td>
<td>-0.11±0.12</td>
<td></td>
</tr>
<tr>
<td>HDL-cholesterol (mmol/L)</td>
<td>6</td>
<td>66</td>
<td>0.00±0.03</td>
<td>0.97</td>
<td>35</td>
<td>0.01±0.02</td>
<td>0.59</td>
<td>-0.01±0.03</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>43</td>
<td>0.00±0.03</td>
<td></td>
<td></td>
<td>0.01±0.02</td>
<td>0.74</td>
<td>-0.00±0.04</td>
<td></td>
</tr>
<tr>
<td>TG:HDL ratio</td>
<td>6</td>
<td>66</td>
<td>0.04±0.07</td>
<td>0.53</td>
<td>35</td>
<td>0.07±0.06</td>
<td>0.28</td>
<td>-0.02±0.09</td>
<td>0.81</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>43</td>
<td>-0.09±0.09</td>
<td></td>
<td></td>
<td>0.00±0.07</td>
<td>0.97</td>
<td>-0.10±0.12</td>
<td></td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/L)</td>
<td>6</td>
<td>64</td>
<td>-0.03±0.09</td>
<td>0.73</td>
<td>35</td>
<td>0.10±0.07</td>
<td>0.15</td>
<td>-0.14±0.12</td>
<td>0.24</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>43</td>
<td>-0.07±0.12</td>
<td></td>
<td></td>
<td>0.12±0.09</td>
<td>0.19</td>
<td>-0.18±0.15</td>
<td></td>
</tr>
<tr>
<td>Non-HDL cholesterol (mmol/L)</td>
<td>6</td>
<td>66</td>
<td>0.01±0.11</td>
<td>0.90</td>
<td>35</td>
<td>0.14±0.09</td>
<td>0.10</td>
<td>-0.13±0.14</td>
<td>0.34</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>43</td>
<td>-0.10±0.13</td>
<td></td>
<td></td>
<td>0.12±0.09</td>
<td>0.20</td>
<td>-0.22±0.16</td>
<td></td>
</tr>
<tr>
<td>Fasting glucose (mmol/L)</td>
<td>6</td>
<td>56</td>
<td>-0.03±0.09</td>
<td>0.71</td>
<td>35</td>
<td>-0.1±0.06</td>
<td><strong>0.03</strong></td>
<td>0.1±0.1</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>39</td>
<td>-0.1±0.1</td>
<td></td>
<td></td>
<td>-0.02±0.06</td>
<td>0.72</td>
<td>-0.08±0.1</td>
<td></td>
</tr>
<tr>
<td>Fasting insulin (pmol/L)</td>
<td>6</td>
<td>62</td>
<td>-36.2±19.7</td>
<td>0.07</td>
<td>35</td>
<td>53.9±21.2</td>
<td><strong>0.01</strong></td>
<td>-90.1±29.2</td>
<td><strong>0.002</strong></td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>39</td>
<td>-45.7±15.1</td>
<td><strong>0.003</strong></td>
<td>35</td>
<td>34.0±11.1</td>
<td><strong>0.002</strong></td>
<td>-79.6±18.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>6</td>
<td>54</td>
<td>-1.2±0.7</td>
<td>0.09</td>
<td>35</td>
<td>1.6±0.7</td>
<td><strong>0.03</strong></td>
<td>-2.7±1.0</td>
<td><strong>0.007</strong></td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>35</td>
<td>-1.9±0.6</td>
<td><strong>0.002</strong></td>
<td>35</td>
<td>1.0±0.4</td>
<td><strong>0.01</strong></td>
<td>-2.9±0.7</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*First p-value is within group change for Stomp patients, second p-value is within group change for Comparison group, third p-value is between group change after adjustment for significant baseline variables; HOMA-IR=homeostatic measurement assessment-insulin resistance.
4.2.3 Change in Psychological Measures From Baseline to 6 Months and 12 Months

Among STOMP participants, significant improvements on the CDI, PedsQL 4.0 Emotional Functioning subscale and IWQOL-Kids questionnaires (Physical Comfort, Body Esteem and Total score) were reported at 6 months (Table 11). QOL and depression scores did not improve significantly among comparison participants. STOMP CDI T-scores improved significantly from baseline and vs. the comparison group at 6 months.

Table 11: Within Group and Between Group Change in Psychological Measures from Baseline to 6 and 12 Months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mo</th>
<th>n</th>
<th>Δ within STOMP Est±SE</th>
<th>P-value</th>
<th>n</th>
<th>Δ within Comparison Est±SE</th>
<th>P-value</th>
<th>Attributable Effect Est±SE</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PedsQL 4.0 Physical Functioning</td>
<td>6</td>
<td>39</td>
<td>2.0±2.2</td>
<td>0.34</td>
<td>35</td>
<td>-0.6±1.6</td>
<td>0.72</td>
<td>2.6±2.7</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>0.6±3.7</td>
<td>0.88</td>
<td>35</td>
<td>-0.3±1.8</td>
<td>0.85</td>
<td>0.9±4.1</td>
<td>0.82</td>
</tr>
<tr>
<td>PedsQL 4.0 Emotional Functioning</td>
<td>6</td>
<td>39</td>
<td>7.5±3.0</td>
<td>0.01</td>
<td>35</td>
<td>3.8±2.6</td>
<td>0.13</td>
<td>3.7±3.9</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>2.1±3.9</td>
<td>0.59</td>
<td>35</td>
<td>1.9±3.0</td>
<td>0.52</td>
<td>0.2±4.9</td>
<td>0.98</td>
</tr>
<tr>
<td>PedsQL 4.0 Social Functioning</td>
<td>6</td>
<td>39</td>
<td>0.7±2.3</td>
<td>0.77</td>
<td>35</td>
<td>3.6±2.0</td>
<td>0.07</td>
<td>-2.9±3.1</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>3.6±2.9</td>
<td>0.21</td>
<td>35</td>
<td>4.2±2.2</td>
<td>0.06</td>
<td>-0.5±3.7</td>
<td>0.89</td>
</tr>
<tr>
<td>PedsQL 4.0 School Functioning</td>
<td>6</td>
<td>39</td>
<td>2.6±2.7</td>
<td>0.33</td>
<td>35</td>
<td>0.4±2.4</td>
<td>0.85</td>
<td>2.2±3.6</td>
<td>0.55</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>-3.1±3.9</td>
<td>0.42</td>
<td>35</td>
<td>0.5±2.2</td>
<td>0.83</td>
<td>-3.6±4.4</td>
<td>0.42</td>
</tr>
<tr>
<td>PedsQL 4.0 Psychosocial Health</td>
<td>6</td>
<td>39</td>
<td>3.5±2.1</td>
<td>0.09</td>
<td>35</td>
<td>2.5±1.8</td>
<td>0.16</td>
<td>1.1±2.8</td>
<td>0.70</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>0.9±2.9</td>
<td>0.76</td>
<td>35</td>
<td>2.3±1.8</td>
<td>0.21</td>
<td>-1.4±3.4</td>
<td>0.69</td>
</tr>
<tr>
<td>PedsQL 4.0 Total Score</td>
<td>6</td>
<td>39</td>
<td>3.0±1.8</td>
<td>0.09</td>
<td>35</td>
<td>1.5±1.6</td>
<td>0.35</td>
<td>1.5±2.4</td>
<td>0.51</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>0.9±2.9</td>
<td>0.76</td>
<td>35</td>
<td>0.9±1.5</td>
<td>0.54</td>
<td>-0.03±3.3</td>
<td>0.99</td>
</tr>
<tr>
<td>IWQOL-Kids</td>
<td>6</td>
<td>41</td>
<td>5.7±2.3</td>
<td>0.02</td>
<td>35</td>
<td>2.7±1.5</td>
<td>0.06</td>
<td>2.9±2.8</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>26</td>
<td>6.5±4.0</td>
<td>0.11</td>
<td>35</td>
<td>1.6±1.8</td>
<td>0.36</td>
<td>4.9±4.4</td>
<td>0.27</td>
</tr>
</tbody>
</table>
### Physical Comfort

<table>
<thead>
<tr>
<th>IWQOL-Kids Body Esteem</th>
<th>6</th>
<th>12</th>
<th>41</th>
<th>26</th>
<th>7.6±3.5</th>
<th>8.5±4.7</th>
<th>0.07</th>
<th>35</th>
<th>4.1±2.9</th>
<th>3.2±2.6</th>
<th>0.16</th>
<th>35</th>
<th>3.5±4.5</th>
<th>0.44</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>IWQOL-Kids Social Life</th>
<th>6</th>
<th>12</th>
<th>41</th>
<th>26</th>
<th>6.6±3.5</th>
<th>5.3±4.7</th>
<th>0.06</th>
<th>35</th>
<th>3.7±2.6</th>
<th>1.9±1.9</th>
<th>0.15</th>
<th>35</th>
<th>2.9±4.3</th>
<th>0.51</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>IWQOL-Kids Family Relations</th>
<th>6</th>
<th>12</th>
<th>41</th>
<th>26</th>
<th>2.1±1.8</th>
<th>-3.3±2.8</th>
<th>0.25</th>
<th>35</th>
<th>1.4±2.8</th>
<th>-0.9±2.3</th>
<th>0.63</th>
<th>35</th>
<th>0.7±3.4</th>
<th>0.83</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>IWQOL-Kids Total Score</th>
<th>6</th>
<th>12</th>
<th>41</th>
<th>26</th>
<th>5.5±2.0</th>
<th>4.5±3.5</th>
<th>0.20</th>
<th>35</th>
<th>2.4±1.8</th>
<th>1.1±1.3</th>
<th>0.39</th>
<th>35</th>
<th>3.0±2.7</th>
<th>0.26</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Children’s Depression Inventory T-score</th>
<th>6</th>
<th>12</th>
<th>38</th>
<th>24</th>
<th>-3.6±1.4</th>
<th>-1.1±2.6</th>
<th>0.66</th>
<th>35</th>
<th>-0.09±1.0</th>
<th>-0.8±1.3</th>
<th>0.93</th>
<th>35</th>
<th>-3.5±1.7</th>
<th>0.04</th>
</tr>
</thead>
</table>

*First p-value is within group change for Stomp patients, second p-value is within group change for Comparison group, third p-value is between group change after adjustment for significant baseline variables

PedsQL 4.0=Pediatric Quality of Life 4.0 Inventory; IWQOL-Kids=Impact of Weight on Quality of Life-Kids

### 4.2.4 Change in Health Behaviours From Baseline to 6 and 12 Months

Among STOMP families, teen and parent Readiness to Change scores increased significantly at 6 and 12 months (Table 12). Comparison participants reported an increase in Readiness to Change scores at 6 months only.

At 6 months, STOMP participants significantly increased the number of hours spent active on the weekend vs. the comparison group (Table 12).

STOMP patients’ dietary readiness to change, as assessed by the STOMP dietitian, increased significantly from baseline to 6 months and from baseline to 12 months, and increased
significantly vs. the comparison participants’ self-reported dietary readiness to change at each time point (Table 12).

**Table 12: Within Group and Between Group Change in Health Behaviours from Baseline to 6 and 12 Months**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Mo</th>
<th>n</th>
<th>Δ within STOMP</th>
<th>P-value</th>
<th>n</th>
<th>Δ within Comparison</th>
<th>P-value</th>
<th>Attributable Effect</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teen Readiness to Change score</td>
<td>6</td>
<td>38</td>
<td>0.6±0.2</td>
<td>&lt;0.001</td>
<td>35</td>
<td>0.4±0.2</td>
<td>0.05</td>
<td>0.3±0.3</td>
<td>0.33</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>24</td>
<td>0.6±0.2</td>
<td>0.003</td>
<td>35</td>
<td>0.02±0.3</td>
<td>0.94</td>
<td>0.6±0.3</td>
<td>0.07</td>
</tr>
<tr>
<td>Parent Readiness to Change score</td>
<td>6</td>
<td>36</td>
<td>0.5±0.2</td>
<td>&lt;0.001</td>
<td>35</td>
<td>0.4±0.2</td>
<td>0.07</td>
<td>0.1±0.3</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>23</td>
<td>0.6±0.2</td>
<td>&lt;0.001</td>
<td>34</td>
<td>0.3±0.3</td>
<td>0.23</td>
<td>0.3±0.3</td>
<td>0.38</td>
</tr>
<tr>
<td>HAES WK (hours)</td>
<td>6</td>
<td>52</td>
<td>0.4±0.3</td>
<td>0.28</td>
<td>35</td>
<td>-0.1±0.4</td>
<td>0.80</td>
<td>0.5±0.5</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>35</td>
<td>0.1±0.4</td>
<td>0.72</td>
<td>35</td>
<td>0.4±0.4</td>
<td>0.31</td>
<td>-0.3±0.6</td>
<td>0.61</td>
</tr>
<tr>
<td>HAES WE (hours)</td>
<td>6</td>
<td>52</td>
<td>0.5±0.4</td>
<td>0.16</td>
<td>35</td>
<td>-0.6±0.4</td>
<td>0.17</td>
<td>1.1±0.6</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>35</td>
<td>0.5±0.5</td>
<td>0.26</td>
<td>35</td>
<td>-0.3±0.6</td>
<td>0.65</td>
<td>0.8±0.7</td>
<td>0.28</td>
</tr>
<tr>
<td>HAES ALL (hours)</td>
<td>6</td>
<td>52</td>
<td>1.1±0.6</td>
<td>0.07</td>
<td>35</td>
<td>-0.7±0.6</td>
<td>0.28</td>
<td>1.7±0.9</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>35</td>
<td>1.0±0.7</td>
<td>0.15</td>
<td>35</td>
<td>0.2±0.8</td>
<td>0.82</td>
<td>0.8±1.0</td>
<td>0.43</td>
</tr>
<tr>
<td>Dietary readiness to change</td>
<td>6</td>
<td>64</td>
<td>0.6±0.07</td>
<td>&lt;0.001</td>
<td>35</td>
<td>0.05±0.1</td>
<td>0.73</td>
<td>0.6±0.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>42</td>
<td>1.0±0.10</td>
<td>&lt;0.001</td>
<td>35</td>
<td>0.1±0.1</td>
<td>0.41</td>
<td>0.9±0.2</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*First p-value is within group change for Stomp patients, second p-value is within group change for Comparison group, third p-value is between group change after adjustment for significant baseline variables.

HAES WK= Habitual Activity Estimation Scale (HAES) weekday somewhat active (SA) + HAES weekday very active (VA); HAES WE= HAES weekend SA+ HAES weekend VA; HAES ALL = HAES WK+HAES WE.

### 4.2.5 Summary of Treatment Effect

Figure 12 and Figure 13 demonstrate unadjusted changes in anthropometric, cardiometabolic, psychological and health behaviours within and between STOMP and
comparison participants at 6 and 12 months respectively. Figure 14 illustrates the unadjusted change in HOMA-IR within and between STOMP and comparison participants at 6 and 12 months. Unadjusted results were similar to adjusted results except for three results: the within STOMP change on the IWQOL-Kids Social subscale at 6 months and the within STOMP change on the IWQOL-Kids Body Esteem subscale at 12 months were only significant when raw data was used, and the between group change in systolic BP z-score at 6 months was not significant when raw data was used.
Figure 12: Between and Within Group Changes From Baseline to 6 Months

Red line: change with STOMP; Black line: change within Comparison group.
Top p-value: change within STOMP patients; Middle p-value: change within Comparison group; Bottom p-value (red): attributable effect; *For BP z-score only, units are change in z-score x 10, not percent change (transformed to conserve scale). SBP=systolic blood pressure; DBP=diastolic blood pressure; IWQOL-Kids=Impact of Weight on Quality of Life-Kids; CDI=Children’s Depression Inventory; RTC=Readiness to Change; HAES weekday=Habitual Activity Estimation Scale (HAES) weekday somewhat active (SA) + HAES weekday very active (VA); HAES weekend=HAES weekend SA+ HAES weekend VA; HAES combined = HAES WK+HAES WE; Diet RTC=dietary readiness to change.
Figure 13: Between and Within Group Changes From Baseline to 12 Months

Red line: change with STOMP; Black line: change within Comparison group.
Top p-value: change within STOMP; Middle p-value: change within Comparison group; Bottom p-value (red): attributable effect; *For BP z-score only, units are change in z-score x 10, not percent change (transformed to conserve scale). SBP=systolic blood pressure; DBP=diastolic blood pressure; IWQOL-Kids=Impact of Weight on Quality of Life-Kids; CDI=Children’s Depression Inventory; RTC=Readiness to Change; HAES weekday=Habitual Activity Estimation Scale (HAES) weekday somewhat active (SA) + HAES weekday very active (VA); HAES weekend= HAES weekend SA+ HAES weekend VA; HAES combined = HAES WK+HAES WE; Diet RTC=dietary readiness to change.
4.3 FACTORS ASSOCIATED WITH A REDUCTION IN BMI AT 6 AND 12 MONTHS IN STOMP PATIENTS

The proportion of STOMP patients who decreased their BMI at 6 months was 50% (n=33, change of -1.6 kg/m²) and 50% increased their BMI (n=33, change of 1.7 kg/m²). In contrast, at 6 months, 29% of comparison participants decreased their BMI (n=10, change of -1.1 kg/m²) and 71% increased their BMI (n=25, change of 1.4 kg/m²). At 12 months, 32% of STOMP patients decreased their BMI (n=15, change of -2.4 kg/m²) and 68% increased their BMI (n=32, change of 2.4 kg/m²). Similarly, 31% of comparison participants decreased their BMI (n=11, change of -1.1 kg/m²) and 69% increased their BMI (n=24, change of 2.2 kg/m²) at 12 months.
Results of a linear regression model looking at factors associated with a greater reduction in BMI between baseline and 6 months are outlined in Table 13 and graphically displayed in Figure 15. These included a higher teen Readiness to Change score at baseline, lower attendance at parent group sessions at 6 months, a greater reduction in BMI over the time between the intake assessment and the official start of the STOMP group sessions (a time period that ranged from 6 days to 181 days, mean of 46 days), and a lower maternal education level.

Table 13: Regression Model of Factors Associated with a Greater Reduction in BMI Between Baseline and 6 Months

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate</th>
<th>Standard Error</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-0.34</td>
<td>1.23</td>
<td>0.78</td>
</tr>
<tr>
<td>Higher baseline teen Readiness to Change score</td>
<td>-0.62</td>
<td>0.22</td>
<td>0.005</td>
</tr>
<tr>
<td>Lower attendance at 6 months for parent group sessions</td>
<td>0.15</td>
<td>0.04</td>
<td>0.0007</td>
</tr>
<tr>
<td>Greater reduction in BMI/time before start of STOMP group</td>
<td>1.41</td>
<td>0.36</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Lower maternal education</td>
<td>0.52</td>
<td>0.25</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Baseline variables that were assessed for the model include: BMI, change in BMI/time, age, gender, maternal BMI, paternal BMI, maternal education, paternal education, annual income, HOMA-IR, teen Readiness to Change score, parent Readiness to Change score, PedsQL 4.0 Physical Functioning, Psychosocial Health and Total Score, IWQOL-Kids Physical Comfort, Body Esteem, Social life and Family Relations, Children’s Depression Inventory T-score, dietary readiness to change, HAES WK, HAES WE, attendance at 6 months for individual appointments with health care providers, patient group sessions and parent group sessions. HOMA-IR=homeostatic measurement assessment-insulin resistance; PedsQL 4.0=Pediatric Quality of Life 4.0 Inventory; IWQOL-Kids=Impact of Weight on Quality of Life-Kids; HAES WE= HAES weekend SA+ HAES weekend VA.
Figure 15: Factors Associated with Greater Reduction in BMI at 6 Months*

Graphs in Figure 15 represent univariable associations.

Baseline factors associated with a greater reduction in BMI between baseline and 12 months are shown in Table 14 and illustrated in Figure 16. These included an older age at the start of the program, a higher teen Readiness to Change score, a lower parent Readiness to Change score, a higher teen dietary readiness to change, a lower baseline score on the IWQOL-Kids Physical Comfort subscale (indicating worse QOL), and a higher baseline score on the PedsQL 4.0 Psychosocial Health subscale (indicating higher QOL in Emotional, Social and School Functioning).
Table 14: Regression Model of Factors Associated with a Greater Reduction in BMI Between Baseline and 12 Months

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate</th>
<th>Standard Error</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interception</td>
<td>8.67</td>
<td>5.01</td>
<td>0.08</td>
</tr>
<tr>
<td>Older age (per years)</td>
<td>-0.04</td>
<td>0.02</td>
<td>0.02</td>
</tr>
<tr>
<td>Higher baseline teen Readiness to Change score</td>
<td>-0.60</td>
<td>0.32</td>
<td>0.06</td>
</tr>
<tr>
<td>Lower baseline parent Readiness to Change score</td>
<td>1.09</td>
<td>0.53</td>
<td>0.04</td>
</tr>
<tr>
<td>Higher baseline dietary readiness to change</td>
<td>-1.54</td>
<td>0.77</td>
<td>0.04</td>
</tr>
<tr>
<td>Lower baseline IWQOL-Kids Physical Comfort score</td>
<td>0.05</td>
<td>0.02</td>
<td>0.04</td>
</tr>
<tr>
<td>Higher baseline PedsQL 4.0 Psychosocial Health</td>
<td>-0.06</td>
<td>0.03</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Baseline variables that were assessed for the model include: BMI, change in BMI/time, age, gender, maternal BMI, paternal BMI, maternal education, paternal education, annual income, HOMA-IR, teen Readiness to Change score, parent Readiness to Change score, PedsQL 4.0 Physical Functioning, Psychosocial Health and Total Score, IWQOL-Kids Physical Comfort, Body Esteem, Social life and Family Relations, Children’s Depression Inventory T-score, dietary readiness to change, HAES WK, HAES WE, attendance at 12 months for individual appointments with health care providers, patient group sessions and parent group sessions. HOMA-IR=homeostatic measurement assessment-insulin resistance; PedsQL 4.0=Pediatric Quality of Life 4.0 Inventory; IWQOL-Kids=Impact of Weight on Quality of Life-Kids; HAES WE= HAES weekend SA+ HAES weekend VA.
Figure 16: Factors Associated with Greater Reduction in BMI at 12 Months*

*Graphs in Figure 16 represent univariable associations.

4.4 BARIATRIC SURGERY

4.4.1 Bariatric Surgery Patients

Seven patients underwent bariatric surgery after 6 months of participation in the STOMP program. Three patients underwent LAGB surgery and 4 patients underwent sleeve gastrectomy.
One patient who had LAGB went on to have a second bariatric surgery due to defective problems with the band that did not inflate appropriately. There were no other peri- or post-operative complications. Mean age at entry into the program was 16.7±0.8 years and mean BMI was 51.4±7.4 kg/m²; 57% were female. Compared to patients who did not undergo surgery in the first 12 months of the program, they were significantly older (16.7±0.8 years vs. 15.0±1.8 years; p=0.001), had a significantly higher BMI (51.4±7.4 vs. 44.1±7.6 kg/m²; p=0.01) and waist circumference (149.7±20.8 vs. 125.4±17.9; p=0.001), and reported significantly worse QOL on the IWQOL-Kids Physical Comfort score (36.9±23.8 vs. 70.0±19.6; p<0.001) and Total score (55.4±13.0 vs. 70.2±17.3; p=0.03).

4.4.2 Outcomes in Bariatric Surgery Patients

Table 15 reports the anthropometric changes over time for STOMP patients who underwent bariatric surgery. Not surprisingly, there was a significant decrease in BMI after surgery (-10.4 kg/m²). Among the four patients who had sleeve gastrectomy, the mean reduction in BMI was -13.6 kg/m², and among the two patients who had the LAGB (excluding one patient who went on to have a second surgery), the mean reduction in BMI was -7.1 kg/m². This was accompanied by a significant decrease in fasting insulin and LDL-cholesterol (Table 16).

Changes in QOL post-operative were not analysed as the number of measures completed was small (Table 17). After surgery, STOMP patients did not demonstrate a significant change in physical activity or dietary readiness to change (Table 18).

Of note, this subset of STOMP patients demonstrated significant improvements after participating in the lifestyle program for the first 6 months, including a significant decrease in BMI (-2.2 kg/m², p=0.02) (Table 15) and a significant increase in dietary readiness to change (Table 18). They also showed a trend for an increase in teen Readiness to Change scores and an
increase in QOL reflected by their scores on the IWQOL-Kids Body Esteem and Total subscales and CDI questionnaire (data not shown).

Table 15: Anthropometric Measures At Baseline, 6 Months and 6 Months Post-Operative

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n</th>
<th>Baseline (T1)</th>
<th>n</th>
<th>6 Months Lifestyle (T2)</th>
<th>N</th>
<th>6 Months Post-op (T3)</th>
<th>P-value (T2-T3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
<td>7</td>
<td>152.7±29.4</td>
<td>7</td>
<td>145.7±30.1*</td>
<td>7</td>
<td>114.9±23.6**</td>
<td>0.001</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>7</td>
<td>171.9±9.4</td>
<td>7</td>
<td>171.7±9.2</td>
<td>7</td>
<td>171.8±9.0</td>
<td>0.65</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>7</td>
<td>51.4±7.4</td>
<td>7</td>
<td>49.2±7.9*</td>
<td>7</td>
<td>38.8±6.7**</td>
<td>0.001</td>
</tr>
<tr>
<td>BMI z-score</td>
<td>7</td>
<td>5.3±1.1</td>
<td>7</td>
<td>5.0±1.1*</td>
<td>7</td>
<td>3.5±1.0**</td>
<td>0.001</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>7</td>
<td>149.7±20.8</td>
<td>0</td>
<td>N/A</td>
<td>2</td>
<td>128.5±12.0</td>
<td>N/A</td>
</tr>
<tr>
<td>Systolic BP z-score</td>
<td>4</td>
<td>0.8±0.8</td>
<td>0</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Diastolic BP z-score</td>
<td>4</td>
<td>0.7±0.4</td>
<td>0</td>
<td>N/A</td>
<td>0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*P-value <0.05 comparing T1-T2; **p-value <0.05 comparing T1-T3.

Table 16: Cardiometabolic Measures At Baseline, 6 Months and 6 Months Post-Operative

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n</th>
<th>Baseline (T1)</th>
<th>n</th>
<th>6 Months Lifestyle (T2)</th>
<th>N</th>
<th>6 Months Post-op (T3)</th>
<th>P-value (T2-T3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol (mmol/L)</td>
<td>7</td>
<td>4.20±0.89</td>
<td>7</td>
<td>4.13±0.74</td>
<td>7</td>
<td>3.84±0.98</td>
<td>0.19</td>
</tr>
<tr>
<td>Triglycerides (mmol/L)</td>
<td>7</td>
<td>1.23±0.38</td>
<td>7</td>
<td>1.12±0.25</td>
<td>7</td>
<td>1.11±0.45</td>
<td>0.98</td>
</tr>
<tr>
<td>HDL-cholesterol (mmol/L)</td>
<td>7</td>
<td>1.20±0.07</td>
<td>7</td>
<td>1.11±0.15</td>
<td>7</td>
<td>1.17±0.22</td>
<td>0.55</td>
</tr>
<tr>
<td>TG:HDL ratio</td>
<td>7</td>
<td>1.03±0.34</td>
<td>7</td>
<td>1.01±0.19</td>
<td>7</td>
<td>0.99±0.45</td>
<td>0.94</td>
</tr>
<tr>
<td>LDL-cholesterol (mmol/L)</td>
<td>7</td>
<td>2.45±0.76</td>
<td>7</td>
<td>2.50±0.65</td>
<td>7</td>
<td>2.16±0.84</td>
<td>0.02</td>
</tr>
<tr>
<td>Non-HDL cholesterol (mmol/L)</td>
<td>7</td>
<td>3.00±0.88</td>
<td>7</td>
<td>3.01±0.68</td>
<td>7</td>
<td>2.67±1.02</td>
<td>0.10</td>
</tr>
<tr>
<td>Fasting glucose (mmol/L)</td>
<td>7</td>
<td>4.9±0.5</td>
<td>5</td>
<td>4.7±0.4</td>
<td>5</td>
<td>4.2±0.1</td>
<td>0.09</td>
</tr>
<tr>
<td>Fasting insulin (pmol/L)</td>
<td>6</td>
<td>127.8±55.5</td>
<td>6</td>
<td>115.8±53.0</td>
<td>7</td>
<td>46.7±23.7**</td>
<td>0.01</td>
</tr>
<tr>
<td>HOMA-IR</td>
<td>6</td>
<td>4.0±1.9</td>
<td>5</td>
<td>3.3±1.8</td>
<td>5</td>
<td>1.0±0.6</td>
<td>0.18</td>
</tr>
</tbody>
</table>

**P-value <0.05 comparing T1-T3; HOMA-IR=homeostatic measurement assessment-insulin resistance.
Table 17: Psychological Measures At Baseline, 6 Months and 6 Months Post-Operative

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n</th>
<th>Baseline (T1)</th>
<th>n</th>
<th>6 Months Lifestyle (T2)</th>
<th>N</th>
<th>6 Months Post-op (T3)</th>
<th>P-value (T2-T3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PedsQL 4.0 Physical Functioning</td>
<td>7</td>
<td>62.1±21.8</td>
<td>4</td>
<td>62.5±32.2</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>PedsQL 4.0 Emotional Functioning</td>
<td>7</td>
<td>63.2±18.4</td>
<td>4</td>
<td>82.5±11.9</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>PedsQL 4.0 Social Functioning</td>
<td>7</td>
<td>68.8±18.4</td>
<td>4</td>
<td>65.0±19.6</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>PedsQL 4.0 School Functioning</td>
<td>7</td>
<td>59.3±9.8</td>
<td>4</td>
<td>62.2±28.6</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>PedsQL 4.0 Psychosocial Health</td>
<td>7</td>
<td>63.8±11.4</td>
<td>4</td>
<td>69.7±15.6</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>PedsQL 4.0 Total Score</td>
<td>7</td>
<td>63.2±12.4</td>
<td>4</td>
<td>67.2±21.4</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>IWQOL-Kids Physical Comfort</td>
<td>7</td>
<td>36.9±23.8</td>
<td>4</td>
<td>40.6±32.5</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>IWQOL-Kids Body Esteem</td>
<td>7</td>
<td>39.7±17.0</td>
<td>4</td>
<td>63.9±19.4</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>IWQOL-Kids Social Life</td>
<td>7</td>
<td>71.4±22.1</td>
<td>4</td>
<td>75±28.3</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>IWQOL-Kids Family Relations</td>
<td>6</td>
<td>86.1±10.1</td>
<td>4</td>
<td>91.7±9.0</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
<tr>
<td>IWQOL-Kids Total Score</td>
<td>7</td>
<td>55.4±13.0</td>
<td>4</td>
<td>67.4±17.5</td>
<td></td>
<td></td>
<td>Not yet administered</td>
</tr>
</tbody>
</table>
Table 18: Measures of Health Behaviour At Baseline, 6 Months and 6 Months Post-Operative

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n</th>
<th>Baseline (T1)</th>
<th>n</th>
<th>6 Months Lifestyle (T2)</th>
<th>N</th>
<th>6 Months Post-op (T3)</th>
<th>P-value (T2-T3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teen Readiness to Change score</td>
<td>7</td>
<td>4.7±0.8</td>
<td>4</td>
<td>6.0±0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent Readiness to Change score</td>
<td>7</td>
<td>5.0±0</td>
<td>3</td>
<td>5.3±0.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HAES WK (hours)</td>
<td>7</td>
<td>3.8±2.3</td>
<td>6</td>
<td>6.0±3.2</td>
<td>6</td>
<td>4.7±2.8</td>
<td>0.97</td>
</tr>
<tr>
<td>HAES WE (hours)</td>
<td>7</td>
<td>5.0±4.0</td>
<td>6</td>
<td>6.1±3.3</td>
<td>6</td>
<td>5.5±2.4</td>
<td>0.57</td>
</tr>
<tr>
<td>HAES ALL (hours)</td>
<td>7</td>
<td>8.8±4.7</td>
<td>6</td>
<td>12.1±6.4</td>
<td>6</td>
<td>10.1±5.0</td>
<td>0.80</td>
</tr>
<tr>
<td>Dietary readiness to change</td>
<td>7</td>
<td>1.1±0.4</td>
<td>7</td>
<td>2.3±0.8*</td>
<td>6</td>
<td>2.2±0.8**</td>
<td>1.00</td>
</tr>
</tbody>
</table>

*P-value <0.05 comparing T1-T2; **p-value <0.05 comparing T1-T3; HAES WK= Habitual Activity Estimation Scale (HAES) weekday somewhat active (SA) + HAES weekday very active (VA); HAES WE= HAES weekend SA+ HAES weekend VA; HAES ALL = HAES WK+HAES WE.

4.5 ATTRITION RATES

The attrition rate among STOMP patients at 6 months was 9% and at 12 months was 15% (Figure 2). Within the comparison group, the attrition rate was 15% at 6 and at 12 months (Figure 2).
Chapter 5 Discussion

We assessed 6 and 12 month anthropometric, cardiometabolic, psychological and health behaviour change outcomes among a group of severely obese adolescents enrolled in a tertiary care weight management program, STOMP, at The Hospital for Sick Children in Toronto, and compared outcomes to a group of obese adolescents not enrolled in the program.

We found that STOMP participants stabilized their BMI at 6 and 12 months and significantly decreased their waist circumference and insulin resistance at 12 months. QOL and depression scores improved at 6 months. STOMP patients and parents significantly increased their readiness to change at 6 and 12 months and patients’ dietary readiness to change significantly increased at 6 and 12 months.

In contrast, the comparison group experienced a significant increase in BMI at 6 and 12 months, an increase in systolic BP z-score at 6 months and an increase in insulin resistance at 6 and 12 months. They did not report significant changes in QOL, physical activity or dietary readiness to change.

The attributable effect of the STOMP program, comparing STOMP and comparison participants, was significant at 6 months for improving depression scores, insulin resistance, dietary readiness to change and physical activity, and decreasing systolic BP z-scores. At 12 months, the intervention significantly decreased waist circumference, decreased insulin resistance and increased dietary readiness to change among STOMP participants vs. comparison participants.

After bariatric surgery, STOMP patients had a significant reduction in BMI and cardiometabolic outcomes including fasting insulin and LDL-cholesterol. These patients also
showed significant improvements after participating in the lifestyle program for 6 months, which was expected as the adolescents who desire and are selected for bariatric surgery tend to be motivated and engaged.

5.1 STABILIZATION IN BMI AMONG STOMP PARTICIPANTS VS. INCREASE IN BMI AMONG COMPARISON PARTICIPANTS

5.1.1 BMI Outcomes at 6 and 12 Months in STOMP and Comparison Participants

We found that severely obese adolescents enrolled in STOMP stabilized their BMI whereas a comparison group of obese adolescents significantly increased their BMI over 6 and 12 months. The purpose of including a comparison group was to assess the natural history of weight change in severely obese adolescents who do not participate in STOMP, however, the comparison group was significantly different from STOMP participants at baseline, including a 10 point lower BMI, less insulin resistance and better QOL. In addition, 40% were enrolled in a community lifestyle program. As such, their weight gain likely does not reflect what may have happened to STOMP patients without an intervention and limits the interpretation of the results. Although there was no significant decrease in BMI, the plateau in weight gain among STOMP participants may be considered clinically significant for several reasons. Firstly, it is likely that without an intervention, STOMP participants would have continued to experience a rapid and progressive weight gain. By history, these participants had experienced significant ongoing weight gain prior to entry, however, as they were the first enrolled patients in the new program, we did not have access to prior weights as one might see with a ‘wait-list’ control group. An alternative explanation is that the stabilization in BMI in STOMP patients represents a regression to the mean among this population, and therefore explains the improvement over time relative to the comparison group. The literature on severely obese adolescents, however, shows that this
population does not typically decrease their BMI-SDS despite interventions of 1, 2 and 3 year duration and, in one particular study, only 2% experienced clinically significant weight loss after 3 years (79).

On further analyses, we demonstrated that, at 6 months, 50% of STOMP patients decreased their BMI by a mean of -1.6 kg/m² and 50% increased their BMI by a mean of 1.7 kg/m², suggesting that the intervention had a greater effect on a subgroup of patients. Although this effect waned towards one year follow-up (32% decreased BMI overall), this may have been impacted by the exclusion of the patients who had gone on to bariatric surgery and had demonstrated clear behaviour change and weight loss. Although it is not possible to know the true impact of this exclusion on 12 month results, it is possible that if these patients had not undergone surgery, the proportion of those reducing BMI at 12 months may have been greater.

5.1.2 Factors Associated with BMI Reduction at 6 and 12 Months Among STOMP Patients

We attempted to determine baseline characteristics that may have predicted those who would reduce BMI in the program. Readiness to change and motivation are factors thought to be important for changes in lifestyle behaviours, although results in pediatric studies are mixed (64, 80). In our adolescent population with severe obesity, self-reported readiness to change did appear to be an important factor as it was associated with a greater reduction in BMI at 6 and 12 months. Similarly, gaining less weight between the initial intake assessment and the start of STOMP group sessions was associated with a greater reduction in BMI during the first 6 months, and a higher dietary stage of change was associated with a greater reduction in BMI at 12 months. At 12 months, lower scores on the IWQOL-Kids Physical Comfort subscale (Appendix 9.3.2) appeared to be an important predictor of BMI reduction and this may also reflect patients’ motivation. In particular, the IWQOL-Kids Physical Comfort subscale asks about difficulties in
social situations, such as fitting into seats in public places, which may be particular goals for adolescents starting the program. Surprisingly, lower parent readiness to change, decreased parental attendance at group sessions at 6 months and lower maternal education were predictors of BMI reduction. This may reflect a group of adolescents who were really engaged in starting the STOMP program, independent of parental concern and pressure. Lastly, adolescents who reported better psychosocial health (i.e. emotional, social and school functioning) at baseline had greater reduction in BMI at 12 months. This suggests that a stable social situation may enable teens to focus on making lifestyle changes. Further exploration of the characteristics of patients who respond to treatment is important as this may allow tailoring of interventions to patients and/or predicting response.

5.1.3 Comparison of BMI Outcomes to the Published Literature

Comparing outcomes from this study to published interventions highlights the variability in weight management programs and patient populations studied, thus making direct comparisons between these studies and the STOMP program difficult. For example, among studies combined in either the Cochrane review or the meta-analysis by Ho et al., mean ages of participants were generally younger than STOMP participants (e.g. mean age of 11-12 years), and thus parental control over food intake and behaviour changes may be more reflective of outcomes (78, 81-83). Mean baseline BMI z-scores were also lower than those of STOMP participants (78, 81-83). As a representative example, in one study, the mean baseline BMI z-score of the intervention group was 2.47 and of the control group was 2.48, whereas STOMP participants had a baseline BMI z-score of 4.5 and the comparison group had a baseline BMI z-score of 3.09 (81). Given that with increasing BMI, the prevalence of obesity-related co-
morbidities increases and weight-related QOL worsens (15, 74), patients within the STOMP program likely represent a different patient population than those studied in these reviews.

Adding to the heterogeneity between studies is the fact that published interventions were often targeted for varying ethnic populations and delivered in various settings and at different intensities. For example, the Yale Bright Bodies Weight Management Program was developed for obese, inner-city children and approximately one quarter of their participants were Hispanic (81). An intensive school-based weight loss program published by Johnston et al. was targeted specifically for overweight Mexican American children and the intervention was delivered in a school on a daily basis for the first 12 weeks (83).

Similar issues with variability among patient populations, programs and outcomes are present in the evaluation of clinical programs. For example, the evaluation of a Canadian weight management program, the CHW-SB, looked at 10 week outcomes in children with a mean age of 11.6 years and mean BMI z-score of 2.3 (49). Despite differences in this population (younger, lower BMI z-score) compared to STOMP participants, outcomes between the two programs were similar. Shapedown BC participants had a change in BMI z-score of -0.06 units after 10 weeks vs. -0.04 units among STOMP patients after 6 months (49). Other clinical programs that were structured similarly to STOMP have reported a change in BMI that varied from -2.3 kg/m² after 6 months to +1 kg/m² after a mean follow-up period of 13 months (45, 46). In the former case, patients were excluded if they were taking obesogenic medications or had moderate to severe mental illness including depression, which may have played a factor in BMI outcomes (46). In comparison, almost half of the STOMP patients had at least one psychiatric co-morbidity, increasing the complexity of the patient population.
5.2 DECREASE IN INSULIN RESISTANCE AMONG STOMP PARTICIPANTS

The STOMP program had a significant effect on HOMA-IR and fasting insulin in STOMP participants vs. the comparison group, with an effect size of -2.7±1.0 and -2.9±0.7 for HOMA-IR at 6 and 12 months respectively, and -90.1±29.2 and -79.6±18.8 pmol/L for fasting insulin at 6 and 12 months respectively.

These results are similar to those reported by Ho et al. (6). Here, meta-analyses of three RCTs showed a significant improvement in HOMA-IR (-2.3 [-3.3 to -1.4]) in favour of lifestyle intervention after 1 year, although the heterogeneity between studies was high. Meta-analyses of four RCTs demonstrated a significant improvement in fasting insulin (-55.1 pmol/L [-71.2 to -39.1]) with respect to lifestyle interventions after 1 year.

Clinical programs have also demonstrated a reduction in insulin resistance among participants. After 10 weeks in the clinical program at the Centre for Healthy Weights-Shapedown BC, youth had a significant decrease in fasting insulin (-16 pmol/L) and a trend for a decrease in HOMA-IR (-0.5 units) (49). Reinehr et al. also looked at insulin resistance from the perspective of the long-term impact of an obesity intervention on CVD risk factors (84). Following the completion of a one-year obesity program, children (mean age 10.4 years) who reduced their BMI z-score had an improvement in HOMA-IR by 17%. This was sustained one year after the intervention ended as children with a reduction in BMI z-score had a 28% lower HOMA-IR compared to the control group of obese children who lived too far to attend their clinic (84).

The potential impact of decreasing insulin resistance among obese children and adolescents is highlighted by the results of a 10 year prospective study by Morrison et al. where insulin and HOMA-IR levels at age 9-10 years predicted the development of T2DM at age 18-19
years (85). In addition, it has been suggested that insulin resistance is the single mechanism behind the features of the metabolic syndrome including obesity, hypertension, dyslipidemia, dysglycemia, and related conditions such as PCOS, NAFLD and OSA (86). Further, Lustig proposed that hyperinsulinism can be a primary cause of obesity (87). From these perspectives, decreasing insulin resistance is a very important outcome in the management of overweight and obese children and adolescents.

5.3 IMPROVEMENTS IN PSYCHOLOGICAL MEASURES AMONG STOMP PARTICIPANTS

QOL is increasingly recognized as an important endpoint in clinical trials in addition to medical outcomes (74). This is particularly relevant for children and adolescents with obesity as they are known to have lower HRQoL compared to youth of normal weight (22), which may be related to negative social and economic consequences in adulthood (30).

Reasons to assess QOL within pediatric weight management programs include the ability to help clinicians address concerns that are of importance to patients and for increased recognition of its contribution to the burden of obesity (74). From a management perspective, those participants who demonstrate improvement of QOL and other mental health measures may be more likely to adopt healthy behaviour changes in the long-term (82).

We assessed QOL using two scales, a generic questionnaire (PedsQL 4.0) reported frequently in the literature, and a second one focusing specifically on issues pertaining to obesity-related QOL (IWQOL-Kids). Overall, participants in the STOMP program improved QOL scores on the IWQOL-Kids Physical Comfort, Body Esteem and Total score, the PedsQL 4.0 Emotional subscale, and the CDI after 6 months.
Modi and Zeller recently established minimal clinically important difference (MCID) scores for the IWQOL-Kids questionnaire (88). The MCID represents the smallest clinically relevant change perceived by a patient and were calculated using the standard error of measurement of IWQOL-Kids subscale results from 263 obese youth (88). STOMP patients’ results on the IWQOL-Kids Body Esteem and Total subscales are consistent with MCID scores at 6 and 12 months (88).

Comparing the QOL changes seen within STOMP to other programs is limited as QOL measures have typically not been included in the evaluation of weight management programs. The available results, however, are promising. For example, among overweight and obese Mexican-American children randomized to either intensive-instructor-led intervention (ILI) or self-help (SH), children in the ILI group had significantly greater improvement in physical QOL at 6 months in addition to significantly greater weight loss (BMI z-score -0.13) (89). The increase in physical QOL was associated with a reduction in BMI z-score, however, in contrast, psychosocial and total QOL were not significantly affected by the type of intervention or change in BMI z-score (89).

Kolotkin et al. also examined changes in IWQOL-Kids scores in teens after participating in a weight loss camp (74). After the intervention, all IWQOL-Kids scales significantly improved, with changes that ranged from 9.8 to 17.9, exceeding the MCID for the IWQOL-Kids subscales (74, 88). The mean decrease in BMI among teens was 3 points (range -0.5 to -7.4 kg/m²) (74).

With the development of weight-specific questionnaires for youth, such as the IWQOL-Kids questionnaire, it is expected that weight management interventions will begin to incorporate QOL outcomes in their study. In addition to short-term changes in QOL, the long-term effects of
improving QOL in obese youth remains to be seen, including its impact on adherence to healthy behaviour changes as well as social and economic outcomes in adulthood.

5.4 IMPROVEMENTS IN HEALTH BEHAVIOURS (READINESS TO CHANGE, DIETARY READINESS TO CHANGE) AMONG STOMP PARTICIPANTS

Health behaviour changes were seen among STOMP patients at 6 and 12 months, including increases in teen and parent readiness to change and increases in dietary readiness to change.

These results may be a reflection of the use of motivational interviewing and CBT methods within the STOMP program. Within each component of the STOMP program (i.e. nutritional education by the dietitian, exercise counseling by the exercise counselor, therapy by the psychologist), STOMP team members assess patients’ and parents’ stage of change according to Prochaska’s Stages of Change Model (precontemplation, contemplation, preparation, action and maintenance) (71). This is an important step in the assessment process in order to design an intervention appropriate to the individual’s readiness to change (90). With the use of motivational interviewing techniques, STOMP specialists then assist the patients in exploring their own reasons for either staying the same or making changes in an attempt to increase intrinsic motivation (91). Similarly, CBT explores a “patient’s attitudes and beliefs about weight loss, builds a partnership with the patients, sets achievable behavioural goals, and assists the patients to modify current behaviours.” (90).

Adult and pediatric studies have highlighted the importance of considering stage of change in the management of chronic conditions including obesity, and have shown that stage of change can be a predictor of positive dietary changes and physical activity (92). Results from
STOMP are consistent with this as patients increased their readiness to change throughout the first year of the program while also making positive changes to their dietary intake at 6 and 12 months.

5.5 OUTCOMES POST-BARIATRIC SURGERY

The 7 STOMP patients who underwent bariatric surgery had significant reductions in BMI and improvement in cardiometabolic outcomes after surgery, similar to outcomes reported in the literature on adolescent bariatric surgery.

Four STOMP patients underwent sleeve gastrectomy and had a mean reduction in BMI of -13.6 kg/m² after 6 months. There are limited reports of outcomes after sleeve gastrectomy in adolescents. In the largest study by Alqahtani et al, 6 month outcomes are described in 8 patients after the sleeve gastrectomy; they had a reduction in BMI of -16 kg/m² (60). Overall, patients had a 70% or greater resolution of co-morbidities including dyslipidemia, hypertension, diabetes and prediabetes (60). Till et al. reported a mean decrease in BMI of -11.2 kg/m² in 4 children (mean age 14.5 years) after a mean follow-up of 12 months (range 6-19 years) post-sleeve gastrectomy (93). Of note, however, is that both studies describe children as young as 8 years of age who had bariatric surgery, which remains very controversial (60, 93).

Three STOMP patients underwent LAGB, however, one patient went on to have a second bariatric surgery due to defective problems with the band in that it would not inflate properly to reduce the size of the stomach pouch. Looking at the remaining two patients who had LAGB surgery, they had a mean decrease in BMI of -7.1 kg/m² after 6 months. Similar outcomes were reported by Holterman et al (94). Among 20 adolescents with a mean age of 16 years and mean baseline BMI of 50 kg/m², they reduced their BMI by -6.6 kg/m² 6 months after LAGB (94).
Resolution of insulin resistance occurred in 45% and 72% of patients at 12 and 18 months respectively (94). In an RCT of LAGB vs. lifestyle intervention, adolescents who underwent surgery had a mean reduction in BMI of -12.7 kg/m² after 2 years (59). They also experienced resolution of the metabolic syndrome and insulin resistance as well as improvements in QOL (59).

5.6 SYNTHESIS

The results of this evaluation demonstrate that an intensive intervention in adolescents with severe obesity was able to stabilize BMI and improve cardiometabolic and psychological outcomes as well as health behaviour changes over 6-12 months. The comparison group participants, in contrast, continued to experience a significant increase in BMI and insulin resistance, despite, in some instances, participating in community lifestyle programs. Although the differences between groups were largely nonsignificant, there were many differences between the two populations that may have influenced these results. These short-term effects, together with the STOMP program components, delivery and long-term goals, are illustrated in Figure 17.

We also identified factors associated with a reduction in BMI in STOMP patients at 6 and 12 months. These factors highlight a common theme: the importance of adolescents’ readiness to change at the start of an obesity program. Exploring motivation and readiness to change with adolescents prior to the initiation of an intensive program may guide the treatment plan and goals. In addition, the finding that adolescents with parents who were less ready to change or who attended fewer sessions had a greater reduction in BMI may represent a group of patients
who are highly engaged, independent of their family. This is in comparison to studies in younger children where parental involvement has been found to play an important role in obesity treatment (95). For example, an intervention that targeted both child and parent weight loss and behaviour change resulted in a significant decrease in percentage overweight after 5 and 10 years vs. a nonspecific control group where only family attendance was reinforced (96). These differences may be a reflection of the older patient population treated in STOMP, and suggests that a modified approach is required in treating adolescents with severe obesity.

The importance of considering readiness to change in adolescents has been explored in several intervention studies. For example, a non-randomized study of motivational interviewing in adolescents with Type 1 diabetes who identified themselves as “contemplators” resulted in a significant reduction in hemoglobin A1C during and after the intervention (97). On the Diabetes Readiness to Change Questionnaire, 39% of scores changed, of which 64% demonstrated a change towards action (97). Similarly, in a dietary intervention, the focus shifted from a family-based group approach to an individual-level motivational intervention after age 13 years in order to increase adherence at a time when adolescents are becoming more independent from their parents and family (98). Adolescents were asked to rate their readiness to change at an initial in-person motivational interviewing session and the intervention was then tailored to the reported stage. While this was a preliminary study of motivational interviewing without a control group, at follow-up 4-8 weeks later, adolescents had a significant decrease in dietary fat and cholesterol intake and reported an increase in readiness to change scores (98). Interventionists noted that the adolescents appreciated the opportunity to have control over their dietary choices (98). These studies support the utility of assessing adolescents’ readiness to change in the delivery of an intervention.
Similar to our study, baseline adolescent and parent readiness to change were assessed as predictors of change in BMI in overweight and obese adolescent females with PCOS and comorbid depression who received CBT and motivational interviewing for six months (92). In contrast to our findings, neither adolescent nor parent baseline stage of change scores predicted change in adolescent BMI after six months (92). Change in adolescent stage of change also did not predict adolescent change in BMI, however, change in parent stage of change was a predictor of adolescent change in BMI (92). The differences in our findings may be due to the patient population (females only), the presence of comorbid depression in each patient with PCOS (as this may have affected the adolescents’ motivation to make changes), and the use of a different readiness to change questionnaire.

**Figure 17: Overview of STOMP Program: Components, Delivery, Short-Term Impact and Long-Term Goals**

![Diagram of STOMP Program](image-url)
5.7 STRENGTHS AND LIMITATIONS

This study contributes to the small number of reports of outcomes from ‘real world’ clinical programs. While RCTs are considered the gold standard to study an intervention, studying outcomes from clinical practice is important to understand the clinical effectiveness of these programs. However, we also recognize the limitations of studying a clinical program without a control group, and recruited a comparison group of adolescents who completed several of the same variables as STOMP patients over three time points.

A further strength of the evaluation of the STOMP program is the inclusion of QOL and health behaviour outcomes in a large group of severely obese adolescents at 6 and 12 months. Changes in these outcomes may have a long-lasting impact on participants and may contribute to sustaining lifestyle changes over time.

In addition, there was a very low attrition rate of 15% in the STOMP program at 12 months, in comparison to the majority of ‘real-world’ pediatric obesity outcome studies that report much higher drop-out rates. Unfortunately, analyses had to proceed due to timelines prior to 12 month clinic visits for 6 STOMP participants who had delayed their appointments. We also excluded, at 12 months, patients who underwent bariatric surgery and we did not have results on one patient who was discharged early by the program and one patient who was admitted to an inpatient housing complex. However, despite this, data were captured on 63% of participants at endpoint. The impact of the low attrition rate on outcomes can be seen from two different perspectives. On one hand, it may have biased results towards the null hypothesis if patients who continued to increase their BMI continued to attend STOMP. On the other hand, the low rate
may indicate that adolescent participants were motivated to change and continued to attend the program, thereby biasing results toward a treatment effect.

While inclusion of a comparison group provided information about a group of obese adolescents not participating in STOMP, this was limited by the significant differences between STOMP patients and comparison participants at baseline. Due to the study’s relatively short timeline for recruitment, we did not have a sufficient number of comparison participants recruited from the STOMP information night (i.e. adolescents who were interested in joining STOMP but were not able to participate due to distance, time conflicts, etc). As a result, we expanded our recruitment to include adolescents who met criteria for the study who were attending clinics within the hospital, who responded to flyers posted on-line and in the hospital and who participated in previous studies. Of these adolescents, 40% were enrolled in a community lifestyle program at some point. We attempted to control for these differences between the two groups by adjusting for baseline differences in BMI, HOMA-IR, TG, IWQOL-Kids Total score, CDI and dietary readiness to change, however, it is quite likely these groups represent inherently different populations of adolescents. Although there were few significant ‘between group’ differences in outcomes, it was encouraging to see many within group improvements in multiple measures for STOMP participants.

A further limitation is that the initial sample size calculation was based on a RCT that achieved a greater reduction in BMI (-1.8±1.9 kg/m²) in their treatment group, and as a result, our study was underpowered. Limitations in our measures include the subjective nature of the dietary and activity measurements used. Alternative objective assessments of behaviour change, such as dietary food records and accelerometer data, were not available for STOMP patients and, thus, not collected in the comparison group. In addition, the dietary readiness to change score
was completed by the STOMP dietitian in the treatment group and was self-assessed in the comparison group as a dietitian was not available to attend the comparison participants’ visits. Determining the diagnosis of NAFLD and IGT or T2DM among comparison participants was limited as they did not undergo abdominal ultrasounds, liver enzyme testing or OGTTs.

Further, a subset of patients underwent bariatric surgery after 6 months in the program and they represent highly engaged and motivated patients in the program. Their post-operative outcomes are excluded from the 12 month analysis, however, had they remained in the lifestyle program, the 12 month outcomes may have been altered. In addition, as this was a clinical study, the time points at which data was collected did not fall exactly at 6 and 12 months and we did not have complete data for each participant at each time point.

Lastly, data included in the study were collected while the STOMP program was under development. During this time, the curriculum was in the process of being created and STOMP team members were new to their roles. During the course of this study, there were also several maternity leave absences, resulting in increased staff turnover. Ongoing evaluation is needed to determine outcomes after the establishment of a fully developed STOMP team and curriculum.
Chapter 6 Conclusions and Future Directions

In summary, participation in the STOMP program was effective in stabilizing BMI in adolescents with severe obesity and significantly improved several important outcomes including cardiometabolic, psychological and health behaviours. In contrast, a comparison group of obese adolescents experienced a significant increase in BMI and insulin resistance over time. There were few between group differences in outcomes, however, these results were limited by the significant differences between the STOMP and comparison participants at baseline. As expected, adolescents who underwent bariatric surgery experienced significant reductions in BMI and improvements in cardiometabolic measures 6 months after surgery.

This study contributes to the knowledge of outcomes from weight management programs for adolescents with severe obesity. In particular, it sheds light on the clinical effectiveness of a tertiary care program treating an older, more obese population compared to the majority of reported RCTs. It also included a broad range of variables, such as QOL and readiness to change, that are increasingly recognized as important outcomes of obesity management programs. Several of these variables appeared to be important baseline factors associated with a greater reduction in BMI over time, highlighting the importance of exploring readiness to change and QOL with adolescents at the onset of participation in an obesity program. These discussions may subsequently guide the intervention and treatment goals.

While the long-term impact of the STOMP program on participants requires further study, the improvements in insulin resistance, psychological and health behaviours in STOMP patients are promising that the trajectory of these adolescents may be modified and that obesity-related co-morbidities may be prevented/improved and behaviour changes sustained.
Within the field of pediatric obesity management programs, several questions remain. The long term impact of the programs on adolescents (i.e. 5-10 years after program completion) is not clear, and the impact of programs on psychological and health behaviour outcomes needs further exploration. Similarly, the long-term outcomes after adolescent bariatric surgery, including mental health parameters, need to be studied carefully. It is also not clear which components within pediatric weight management programs are most effective as programs are heterogeneous in structure and delivery, thus making comparisons difficult. In addition, the optimal treatment of adolescents with severe obesity is not known as this patient population is likely quite different from those with less severe obesity who have been studied in more detail.

Future directions to address these questions include the ongoing evaluation of the STOMP program. Outcomes are being collected up to 2 years after the start of the program and there is opportunity to collect measures from these patients in the future. This could provide important information on the development of co-morbidities as well as social and economic outcomes post-participation in STOMP. In addition, the ongoing evaluation of the program provides a chance to evaluate newer measures, such as the waist/height ratio, recently shown to identify obese children with abnormal cardiometabolic risk factor levels (99). Another important future component of the evaluation of the program is an assessment of cost-effectiveness.

As the STOMP program continues to offer bariatric surgery to a select group of patients, there is an opportunity to assess post-operative outcomes in a larger group of patients over several years. In particular, it will be interesting to assess the psychological changes that may occur after bariatric surgery.

In addition, current plans are in place to develop a national registry of pediatric lifestyle programs within Canada. Program directors across the country have selected a standardized list
of outcomes (anthropometric, cardiometabolic, psychological and health behaviour) to collect in a central database in order to make the results comparable. It will be important for programs to maintain components that are important for the patient populations served, such as cultural differences in the curriculum. However, having a more standardized approach to evaluation will allow for comparison of participant characteristics and outcomes between programs.

Lastly, another area for further exploration is the determination of characteristics of patients who respond to weight management programs with reduction in BMI and cardiometabolic/psychological co-morbidities. Certainly, the ability to predict who will respond to a treatment program will be helpful as it can help team members tailor the intervention to patients as well as identify patients who may not be ready to start an intensive program and may benefit from strategies to increase his/her stage of change. This will also result in cost effectiveness, as treatment strategies can be directed to underlying barriers in those not ready to fully participate.

Tertiary care pediatric clinical obesity management programs play an important role in the management of severely obese children and adolescents. Evaluating the clinical effectiveness of these programs is a key step in the process of improving the outcomes of the patients they serve.
References


102


Varni JW, Limbers CA, Burwinkle TM. Impaired health-related quality of life in children and adolescents with chronic conditions: a comparative analysis of 10 disease clusters and 33 disease categories/severities utilizing the PedsQL 4.0 Generic Core Scales. Health and quality of life outcomes.


Appendices
9.1 SUMMARY OF STUDY RESULTS

9.1.1 Summary of Randomized Controlled Trials/Clinical Controlled Trials of Pediatric Obesity Interventions

9.1.2 Summary of Evaluations of Pediatric Clinical Obesity Management Programs

9.2 CONSENT FORMS

9.2.1 Letter of Consent for STOMP Participants

9.2.2 Letter of Consent for STOMP Parents

9.2.3 Letter of Consent for Comparison Participants

9.2.4 Letter of Consent for Comparison Parents

9.3 PSYCHOLOGY QUESTIONNAIRES

9.3.1 PedsQL 4.0 Questionnaire

9.3.2 IWQOL-Kids Questionnaire

9.3.3 CDI Questionnaire

9.4 HEALTH BEHAVIOUR CHANGE QUESTIONNAIRES

9.4.1 Teen Readiness to Change

9.4.2 Parent Readiness to Change

9.4.3 HAES Questionnaire

9.4.4 STOMP Participants’ Dietary Readiness to Change Assessment by STOMP Dietitian

9.4.5 Comparison Participants’ Dietary Readiness to Change Questionnaire

9.6 DATA COLLECTION FORMS

9.6.1 Intake Form

9.6.2 Co-Morbidity and Medication Checklists
9.6.3 Comparison Participants’ Data Collection Form
### 9.1 SUMMARY OF STUDY RESULTS

#### 9.1.1. Summary of Randomized Controlled Trials/Clinical Controlled Trials of Pediatric Obesity Interventions

#### SUMMARY OF RANDOMIZED CONTROLLED TRIALS/CLINICAL CONTROLLED TRIALS OF PEDIATRIC OBESITY INTERVENTIONS

<table>
<thead>
<tr>
<th>Study, Program Name, Setting, Country</th>
<th>Study Design</th>
<th>Number of Participants</th>
<th>Participant Characteristics</th>
<th>Intervention</th>
<th>Intervention Length</th>
<th>Attrition Rate</th>
<th>Outcome</th>
<th>Difference Between Groups (*=p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cochrane review; Oude Luttikhuis et al. 2009; 64 RCTs; majority took place in North America; community, school or clinic-based; search dates 1985 to May 2008</td>
<td>RCTs, designed to treat obesity in children, observed participants for minimum of 6 mths</td>
<td>5230 (3806 in lifestyle intervention, 1424 in drug trials)</td>
<td>Participants had mean age &lt;18 yrs at start of intervention (range 3 to 21 yrs)</td>
<td>Lifestyle interventions (dietary, physical activity and/or behavioural therapy), drug interventions also studied</td>
<td>Duration of lifestyle intervention 1 mth to 24 mths</td>
<td>Variable</td>
<td>Combined behavioural lifestyle interventions vs. standard care or self-help can result in a significant reduction in overweight in children and adolescents</td>
<td>N/A</td>
</tr>
<tr>
<td>Subset of studies (n=4) within Cochrane review 2009</td>
<td>RCTs, 6 month f/u</td>
<td>362</td>
<td>Children &gt;12 yrs</td>
<td>Behavioural intervention vs. self help or control</td>
<td>N/A</td>
<td>N/A</td>
<td>Change in BMI</td>
<td>Mean difference -3.04 kg/m² [-3.14 to -2.94]*</td>
</tr>
<tr>
<td>Subset of studies (n=3) within Cochrane</td>
<td>RCTs, 6 month f/u</td>
<td>291</td>
<td>Children &gt;12 yrs</td>
<td>Behavioural intervention vs. self help or control</td>
<td>N/A</td>
<td>N/A</td>
<td>Change in BMI z-score</td>
<td>Mean difference -0.14 [-0.17 to</td>
</tr>
<tr>
<td>Study, Program Name, Setting, Country</td>
<td>Study Design</td>
<td>Number of Participants</td>
<td>Participant Characteristics</td>
<td>Intervention</td>
<td>Intervention Length</td>
<td>Attrition Rate</td>
<td>Outcome</td>
<td>Difference Between Groups (*=p&lt;0.05)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>--------------</td>
<td>------------------------</td>
<td>--------------------------</td>
<td>--------------</td>
<td>---------------------</td>
<td>---------------</td>
<td>---------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Subset of studies (n=2) within Cochrane review 2009</td>
<td>RCTs, 12 month f/u</td>
<td>231</td>
<td>Children &gt;12 yrs</td>
<td>Behavioural intervention vs. self help or control</td>
<td>N/A</td>
<td>N/A</td>
<td>Change in BMI</td>
<td>Mean difference -3.27 kg/m² [-3.38 to -3.17]*</td>
</tr>
<tr>
<td>Subset of studies (n=2) within Cochrane review 2009</td>
<td>RCTs, 12 month f/u</td>
<td>231</td>
<td>Children &gt;12 yrs</td>
<td>Behavioural intervention vs. self help or control</td>
<td>N/A</td>
<td>N/A</td>
<td>Change in BMI z-score</td>
<td>Mean difference -0.14 [-0.18 to -0.10]*</td>
</tr>
<tr>
<td>Systematic Review for the US Preventive Services Task Force (USPSTF); Whitlock et al. (2010); 15 RCTs and CCTs; study dates 1985 to 2008</td>
<td>RCTs and CCTs</td>
<td>N/A</td>
<td>Children and adolescents ages 4 to 18 years, overweight or obese</td>
<td>Behavioural interventions</td>
<td>N/A</td>
<td>Variable</td>
<td>Comprehensive medium to high intensity behavioural interventions in obese children and adolescents have short-term benefits</td>
<td>N/A</td>
</tr>
<tr>
<td>Subset of studies within Whitlock et al. (2010)</td>
<td>10 RCTs, 1 CCTs, 6-12 mth f/u</td>
<td>1099</td>
<td>4 to 18 years, majority had BMI &gt;95th percentile</td>
<td>Behavioural interventions</td>
<td>N/A</td>
<td>Variable</td>
<td>Change in BMI</td>
<td>Mean difference -3.3 to -0.3 kg/m² (p&lt;0.00001 to 0.31)</td>
</tr>
<tr>
<td>Study, Program Name, Setting, Country</td>
<td>Study Design</td>
<td>Number of Participants</td>
<td>Participant Characteristics</td>
<td>Intervention</td>
<td>Intervention Length</td>
<td>Attrition Rate</td>
<td>Outcome</td>
<td>Difference Between Groups (*=p&lt;0.05)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>-------------</td>
<td>------------------------</td>
<td>----------------------------</td>
<td>--------------</td>
<td>---------------------</td>
<td>----------------</td>
<td>---------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Subset of studies (n=7 interventions) within Ho et al. (2012)</td>
<td>RCTs</td>
<td>200</td>
<td>Children &gt;12 yrs</td>
<td>Lifestyle intervention vs. no-treatment control</td>
<td>2 mths to 2 yrs</td>
<td>N/A</td>
<td>Change in BMI</td>
<td>Mean difference -1.45 kg/m² [-3.02 to 0.12]</td>
</tr>
<tr>
<td>Subset of studies (n=4 interventions) within Ho et al. (2012)</td>
<td>RCTs</td>
<td>66</td>
<td>Children &gt;12 yrs</td>
<td>Lifestyle intervention vs. no-treatment control</td>
<td>≤6 mths</td>
<td>N/A</td>
<td>Change in BMI z-score</td>
<td>Mean difference -0.02 [-0.09 to 0.06]</td>
</tr>
<tr>
<td>Subset of studies (n=7 interventions) within Ho et al. (2012)</td>
<td>RCTs</td>
<td>586</td>
<td>Children and adolescents</td>
<td>Lifestyle intervention vs. usual care</td>
<td>3 mths to 1 yr</td>
<td>N/A</td>
<td>Change in BMI</td>
<td>Mean difference -1.30 kg/m² [-1.58 to -1.03] *</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>------</td>
<td>-----</td>
<td>--------------------------</td>
<td>--------------------------------------</td>
<td>----------------</td>
<td>-----</td>
<td>----------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Subset of studies (n=2 interventions) within Ho et al. (2012)</td>
<td>RCTs</td>
<td>137</td>
<td>Children and adolescents</td>
<td>Lifestyle intervention vs. minimal advice or written diet and physical activity material</td>
<td>6-12 mths</td>
<td>N/A</td>
<td>Change in BMI</td>
<td>Mean difference -2.52 kg/m² [-5.95 to 0.91]</td>
</tr>
<tr>
<td>Subset of studies (n=4 interventions) within Ho et al. (2012)</td>
<td>RCTs</td>
<td>354</td>
<td>Children and adolescents</td>
<td>Lifestyle intervention vs. minimal advice or written diet and physical activity material</td>
<td>6-12 mths</td>
<td>N/A</td>
<td>Change in BMI z-score</td>
<td>Mean difference -0.06 kg/m² [-0.10 to -0.02] *</td>
</tr>
</tbody>
</table>
## 9.1.2 Summary of Evaluations of Pediatric Clinical Obesity Management Programs

<table>
<thead>
<tr>
<th>Study, Program Name, Setting, Country</th>
<th>Study Design</th>
<th>Number of Participants</th>
<th>Participant Characteristics</th>
<th>Intervention</th>
<th>Intervention Length</th>
<th>Attrition Rate</th>
<th>Outcome</th>
<th>Difference Between Groups (*=p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reinehr et al. (2009); 129 centers specialized in pediatric obesity care in Germany, Austria and Switzerland; 1999-2005</td>
<td>Prospective study using data collected for a quality control program</td>
<td>21,784 (complete data for 10,600 children)</td>
<td>Mean age 12.6 yrs (range 2-20 yrs), 45% male, mean baseline BMI-SDS 2.51±0.52, 14% overweight, 44% obese, 42% extremely obese. Excluded children with anti-obesity medications or bariatric surgery.</td>
<td>Outpatient intervention for at least 6 mths, included nutrition education, physical and exercise intervention, psychological intervention, parent sessions and/or medical lessons</td>
<td>At least 6 mths</td>
<td>76% at 6 mths, 83% at 12 mths, 92% at 2 yrs</td>
<td>For participants with complete data only: Mean change in BMI z-score -0.20±0.32 at 6 mths, -0.19±0.40 at 12 mths, -0.20 ± 0.54 at 24 mths</td>
<td>N/A</td>
</tr>
<tr>
<td>Skelton et al. (2008); NEW Kids Program, the Children’s Hospital of Wisconsin, United States; June 2003-April 2005</td>
<td>Retrospective chart review of a clinical program</td>
<td>66 study participants 398 participants had initial evaluations, 150 did not meet study</td>
<td>Mean age 11.8 yrs, mean BMI 37 kg/m², 50% female, 44% Caucasian. Program open to 2 to 18 yr old children who are overweight or</td>
<td>Family-based multidisciplinary weight management clinic; team consists of a pediatrician, nurse practitioner, dietician, psychologist and physical therapist;</td>
<td>Mean follow-up 13 ± 3 mths</td>
<td>73%</td>
<td>Mean change in BMI +1.0±2.7 kg/m²* Mean change in BMI z-score</td>
<td>N/A</td>
</tr>
<tr>
<td>Study, Program Name, Setting, Country</td>
<td>Study Design</td>
<td>Number of Participants</td>
<td>Participant Characteristics</td>
<td>Intervention</td>
<td>Intervention Length</td>
<td>Attrition Rate</td>
<td>Outcome</td>
<td>Difference Between Groups (*=p&lt;0.05)</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>--------------</td>
<td>------------------------</td>
<td>-----------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------</td>
<td>----------------</td>
<td>---------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Woolford et al. (2011); Michigan Pediatric Outpatient Weight Evaluation and Reduction program (MPOWER), the University of Michigan, United States; April 2007-June 2008</td>
<td>Retrospective chart review of clinical program</td>
<td>67 adolescents enrolled in program, 48 completed 6 mth program</td>
<td>Mean age 14.5 yrs, mean BMI 40 kg/m², (29-70), 71% female, 51% Caucasian. Program open to adolescents 12 to 18 yrs old with BMI ≥95th percentile for age and gender. Study inclusion: enrolled between April 2007 and June 2008. Study exclusion: taking obesogenic medications, moderate to severe obesity, taking obesogenic medications, severe obesity, taking obesogenic medications, moderate obesity and comorbid conditions.</td>
<td>Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths</td>
<td>6 months</td>
<td>28%</td>
<td>Mean change in BMI -2.3 kg/m² in 48 participants who completed the program*</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<p>| Study inclusion: participation in program ≥9 mths and &gt;4 visits to clinic. | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | Study inclusion: enrolled between April 2007 and June 2008. Study exclusion: taking obesogenic medications, moderate to severe obesity, taking obesogenic medications, severe obesity, taking obesogenic medications, moderate obesity and comorbid conditions. | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | Individualized care plans created for family; uses a cognitive behavioural approach and provides nutrition and physical activity education; visits every 1-3 mths | N/A |</p>
<table>
<thead>
<tr>
<th>Study, Program Name, Setting, Country</th>
<th>Study Design</th>
<th>Number of Participants</th>
<th>Participant Characteristics</th>
<th>Intervention</th>
<th>Intervention Length</th>
<th>Attrition Rate</th>
<th>Outcome</th>
<th>Difference Between Groups (*=p&lt;0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Madsen et al. (2009); WATCH clinic, University of California and San Francisco, United States; August 2003-February 2006</td>
<td>Retrospective chart review of clinical program</td>
<td>156 participants</td>
<td>Mean baseline BMI 36.4 kg/m², mean baseline BMI z-score 2.43, mean age 13 yrs, 51% female, ethnically diverse. Patients referred if BMI &gt;95th percentile for age and gender, &lt;21 yrs.</td>
<td>Hospital-associated outpatient lifestyle intervention clinic; Team included pediatric endocrinologist, gastroenterologist, cardiologist, general pediatricians, dietitians and a psychologist. Modeled after low glycemic load diet. Advice provided on nutrition, reduced television viewing, increased physical activity. Follow-up visits every 3 mths.</td>
<td>Mean 12.1 ± 6.3 mths</td>
<td>27% after initial visit; 56% at ultimate f/u visit</td>
<td>Mean change in BMI at ultimate f/u visit (mean 12.1 mths) -0.4 [-0.8 to 0.1]</td>
<td>Mean change in BMI z-score at ultimate f/u visit -0.11 [-0.16 to -0.07]</td>
</tr>
<tr>
<td>Panagiotopoulos et al. (2011); Centre for Healthy Weights-Shapedown BC, Canada; March 2007-March</td>
<td>Prospective evaluation of a clinical program</td>
<td>119 participants</td>
<td>Mean age 11.6 yrs, 57% male, 55.6% Caucasian, mean BMI 30.9±6.2 kg/m², mean BMI z-score 2.3±0.33.</td>
<td>Family-centred, multidisciplinary behavioural weight mgmt program; provided medical and psychosocial assessment, 10 consecutive weeks followed by monthly follow-ups</td>
<td>67.2% (for all 10 sessions)</td>
<td>Mean change in BMI z-score -0.06* (secondary outcome)</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>sessions, 39 attended all 10 sessions</td>
<td>Program participants referred by physicians, eligible if 6-17 yrs old, BMI ( \geq 95^{th} ) percentile or ( \geq 85^{th} ) percentile with ( \geq 1 ) co-morbidity, one caregiver able to participate and read and understand English. Excluded if non-ambulatory, receiving rigorous medical therapy, diagnosed with a severe mental illness.</td>
<td>education and support. Team included a dietitian, a psychologist and a physician. An exercise specialist was available through YMCA. Intervention was 10 weekly group sessions (2 hrs each) for 6-10 families with separate child and parent sessions + 30 min physical activity for children.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9.2 CONSENT FORMS
9.2.1 Letter of Consent for STOMP Participants
Consent Form (Participant STOMP)

Title of Research Project:
Evaluation of the SickKids Team Obesity Management Program (STOMP)

Principal Investigator:
Dr. Jill Hamilton 416.813.5115

Co-Investigators:
Dr. Catherine Birken 416.813.5115
Elizabeth Dettmer, Psychologist 416.813.5115
Preeti Grewal, Nurse Practitioner 416.813.7654 x 28366
Allison Jeffery, Exercise Therapist 416.813.7654 x 4495
Dianne Knox, Social Worker 416.813.7654 x 28750
Alisa Bar-Dayan, Dietitian 416.813.7654 x 28368
Christopher Incognito, Information Coordinator
Marilyn Booth, Provincial Council for Maternal and Child Health

Research Team Member:
Dr. Paola Luca
Pediatric Endocrinology Fellow 416.813.7116

Research Coordinators:
Munaza Jamil 416.813.7654 x 28363
Rachel Steger 416.813.7654 x1931
Sahar Ehtesham 416.813.7654 x1931

Purpose of the Research:
There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with obesity, and may form the basis for changes in clinical practice in this population of children.

The purpose of this study is to see if and how the STOMP clinic changes health (body weight, risk for diabetes and heart disease) and the quality of life of patients diagnosed with obesity, compared with a control group of those who are not provided similar care. The control group consist of patients who decline entry into the STOMP program. The estimated total number of participants in the study will be 87 (50 in the STOMP program, 37 in the control group).
We also want to find out how the STOMP clinic influences your satisfaction with the medical care provided to you. Finally, we are interested in how the clinic influences your knowledge with health issues related to your condition.

**Description of the Research:**

In January 2010 a new clinic (STOMP) was created to provide care for children and adolescents with obesity. STOMP incorporates an interdisciplinary team, frequent visits, individualized care plans for medically-complex adolescents, psychosocial intervention and involvement of a “key worker” (nurse practitioner) to support families. We would like to evaluate how our program is working. Funding has been obtained for the program from the Ministry of Health with the expectation of a report of outcomes of the program.

Prior to acceptance into the program, children and their parents attend an information night run by the STOMP team which describes the program and the commitment required of families. Approximately 50% of attendees choose not to book into the program, for reasons including difficulty attending the frequent appointments due to distance or inability to leave work early. Families not participating will serve as the comparison group for the evaluation.

As part of your clinical care, families enrolled in the STOMP program complete diet, physical activity, and psychology questionnaires (e.g., screening for depression, eating disorders, quality of life). This is done as part of the routine clinic visit (e.g., check up, bloodwork). In addition, at the time of the clinic visit, we will be conducting a test called BODPOD, which measure your child’s body fat and muscle. Your child will sit in a special chamber for 5-7 minutes. This test does not cause discomfort. The diet, physical activity, and psychology questionnaires are designed to help us better understand the current and past medical complications of your condition as well as information related to psychosocial well-being, dietary and activity levels. These measures are repeated every 6 months so that we may evaluate whether participation in this clinic results in changes in quality of life, knowledge and your medical condition. We would like to collect this information to compare how you progress through the program, and to compare to a group of children who choose not to join STOMP.

We would also like to ask you to complete an additional questionnaire regarding your knowledge and satisfaction with regard to both your overall health care and this clinic. This additional questionnaire will allow us to evaluate what you like and don’t like about the clinic and whether increased satisfaction in your healthcare and improved sense of knowledge of your condition has resulted from participation in the STOMP clinic. This questionnaire will take approximately 5 minutes to complete.

The anticipated duration of the STOMP clinic evaluation is 2 years including the initial assessment with visits occurring approximately every six months.

**Potential Harms:**
We know of no harm that taking part in this study could cause you.

**Potential Benefits:**

What we learn from this evaluation study may also help other children with obesity and help us to design better programs and secure long term funding for obesity programs in Ontario. This study will hopefully lead to improvements in your healthcare delivery.

**To individual subjects:**

Previous evaluations on clinical outcomes of children attending an outpatient interdisciplinary program at SickKids found significant benefit to those attending, including reduction of weight gain and improved psychosocial functioning, as well as increased care satisfaction. A summary of results will be provided to you.

**To society:**

There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with severe complex obesity, and may form the basis for changes in clinical practice in this vulnerable population of children.

**Alternatives to participation:**

Taking part in the study is entirely your choice. The alternative to joining the study is to continue with the usual comprehensive care clinic at The Hospital for Sick Children. Whether or not you decide to participate in this research study, this decision will not affect any future care you may receive.

**Confidentiality:**

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless the law makes us do this. For example, the law could make us give information about you:

- If you have been abused
- If you have an illness that could spread to others
- If you or someone else talks about suicide (killing themselves), or
- If the court orders us to give them the study papers

SickKids Clinical Research Office Monitor or the regulator of the study may see your health record to check on the study. For example, people from Health Canada Health Products and Food Branch or Canadian Institute of Health Research may look at your records.

By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your patient health records.
The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by Sick Kids policy. Published study results will not reveal your identity.

The results of the tests we describe in this form will be used only for this study. If another doctor or caregiver caring for your needs to see these results, you will have to give us your permission. We will ask you to sign a form saying that you agree that this person can see your results. We recommend that only a registered psychologist or doctor tell you what the results of these tests mean.

**Reimbursement:**

There is no reimbursement for this study.

**Participation:**

Participation in research is voluntary. It is your choice for you to take part in this study. You can stop at any time. The care you get at SickKids will not be affected in any way by whether you take part in this study. New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study. During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.

We will give you a copy of this consent form for your records.

In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the medicine [or treatment] given in the study is helping you. If this happens, the study doctor will talk to you about what will happen next.

If you become ill or are harmed because you took part in this study, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

**Sponsorship:**

The sponsor of this study is Dr. Jill Hamilton and The Hospital for Sick Children and the funder of this study is the Provincial Council for Child and Maternal Health (PCMCH).

**Conflict of Interest:**

Dr. Jill Hamilton and the other research team members have no conflict of interest to declare.
Future Contact:
Do you give permission to be contacted for future follow up studies are conducted?
Yes, I do [ ]  No, I do not [ ]

Consent:
By signing this form, I agree that:
1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care at Sick Kids.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my medical records will be kept private except as described to me.
6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7) I have read pages 1 to 7 and I agree, or consent, to take part in this study.

Printed Name of Subject & Age  Subject’s Signature and Date
Printed Name of person who explained consent  Signature of Person who explained consent & date
Printed Witness’ name (if the parent/legal guardian does not read English)  Witness’ signature & date

If you have any questions about this study, please call Jill Hamilton at 416.813.5115

If you have questions about your rights as a research subject in a study or injuries during a study, please call the Research Ethics Manager at 416.813.5718 at SickKids.
Consent Form (Parent/Caregiver of STOMP Participant)

**Title of Research Project:**
Evaluation of the SickKids Team Obesity Management Program (STOMP)

**Principal Investigator:**
Dr. Jill Hamilton 416.813.5115

**Co-Investigators:**
Dr. Catherine Birken 416.813.5115  
Elizabeth Dettmer, Psychologist 416.813.5115  
Preeti Grewal, Nurse Practitioner 416.813.7654 x 28366  
Allison Jeffery, Exercise Therapist 416.813.7654 x 4495  
Dianne Knox, Social Worker 416.813.7654 x 28750  
Alisa Bar-Dayan, Dietitian 416.813.7654 x 28368  
Christopher Incognito, Information Coordinator  
Marilyn Booth, Provincial Council for Maternal and Child Health

**Research Team Member:**
Dr. Paola Luca, Pediatric Endocrinology Fellow 416.813.7116

**Research Coordinators:**
Munaza Jamil 416.813.7654 x 28363  
Rachel Steger 416.813.7654 x 1931  
Sahar Ehtesham 416.813.7654 x 1931

**Purpose of the Research:**
There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with obesity, and may form the basis for changes in clinical practice in this population of children.

The purpose of this study is to see if and how the STOMP clinic changes health (body weight, risk for diabetes and heart disease) and the quality of life of patients diagnosed with obesity, compared with a control group of those who are not provided similar care. The control group will be of those patients who decline entry into the STOMP program. The estimated total number of participants in the study will be 87 (50 in the STOMP program, 37 in the control group).
We also want to find out how the STOMP clinic influences your satisfaction with the medical care provided to your child. Finally, we are interested in how the clinic influences your knowledge with health issues related to your child’s condition.

**Description of the Research:**

In January 2010 a new clinic (STOMP) was created to provide care for children and adolescents with obesity. STOMP incorporates an interdisciplinary team, frequent visits, individualized care plans for medically-complex adolescents, psychosocial intervention and involvement of a “key worker” (nurse practitioner) to support families. We would like to evaluate how our program is working. Funding has been obtained for the program from the Ministry of Health with the expectation of a report of outcomes of the program.

Prior to acceptance into the program, children and their parents attend an information night run by the STOMP team which describes the program and the commitment required of families. Approximately 50% of attendees choose not to book into the program, for reasons including difficulty attending the frequent appointments due to distance or inability to leave work early. Families not participating will serve as the comparison group for the evaluation.

As part of your child’s clinical care, families enrolled in the STOMP program complete diet, physical activity, and psychology questionnaires (e.g., screening for depression, eating disorders, quality of life). This is done as part of the routine clinic visit (eg check up, bloodwork). In addition, at the time of the clinic visit, we will be conducting a test called BODPOD, which measure your child’s body fat and muscle. Your child will sit in a special chamber for 5-7 minutes. This test does not cause discomfort. The diet, physical activity, and psychology questionnaires are designed to help us better understand the current and past medical complications of your child’s condition as well as information related to psychosocial well-being, dietary and activity levels. These measures are repeated every 6 months so that we may evaluate whether participation in this clinic results in changes in quality of life, knowledge and your child’s medical condition. We would like to collect this information to compare how your child progresses through the program, and to compare to a group of children who choose not to join STOMP.

We would also like to ask you to complete an additional questionnaire regarding your knowledge and satisfaction with regard to both your child’s overall health care and this clinic. This additional questionnaire will allow us to evaluate what you like and don’t like about the clinic and whether increased satisfaction in your child’s healthcare and improved sense of knowledge of your condition has resulted from participation in the STOMP clinic. This questionnaire will take approximately 5 minutes to complete.

The anticipated duration of the STOMP clinic evaluation is 2 years including the initial assessment with visits occurring approximately every 6 months.

**Potential Harms:**
We know of no harm that taking part in this study could cause you or your child.

**Potential Benefits:**

What we learn from this evaluation study may also help other children with obesity and help us to design better programs and secure long term funding for obesity programs in Ontario. This study will hopefully lead to improvements in your child’s healthcare delivery.

**To individual subjects:**

Previous evaluations on clinical outcomes of children attending an outpatient interdisciplinary program at SickKids found significant benefit to those attending, including reduction of weight gain and improved psychosocial functioning, as well as increased care satisfaction. A summary of results will be provided to families who participate in the program evaluation.

**To society:**

There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with severe complex obesity, and may form the basis for changes in clinical practice in this vulnerable population of children.

**Alternatives to participation:**

Taking part in the study is entirely yours and your child’s choice. The alternative to joining the study is to continue with the usual care in STOMP at The Hospital for Sick Children. Whether or not you and your child decide to participate in this research study, this decision will not affect any future care your child may receive.

**Confidentiality:**

We will respect your child’s privacy. No information about who your child is will be given to anyone or be published without your permission, unless the law makes us do this. For example, the law could make us give information about your child:

- If a child has been abused
- If you have an illness that could spread to others
- If you or someone else talks about suicide (killing themselves), or
- If the court orders us to give them the study papers

SickKids Clinical Research Office Monitor or the regulator of the study may see your child’s health record to check on the study. For example, people from Health Canada Health Products and Food Branch or Canadian Institute of Health Research may look at your records.
By signing this consent form, you agree to let these people look at your child’s records. We will put a copy of this research consent form in your child’s patient health records.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by Sick Kids policy. Published study results will not reveal your child’s identity.

The results of the tests we describe in this form will be used only for this study. If another doctor or caregiver caring for your child needs to see these results, you will have to give us your permission. We will ask you to sign a form saying that you agree that this person can see your (your child’s) results. We recommend that only a registered psychologist or doctor tell you what the results of these tests mean.

Reimbursement:

There is no reimbursement for this study.

Participation:

Participation in research is voluntary. It is your choice for your child to take part in this study. You can stop at any time. The care your child gets at SickKids will not be affected in any way by whether you take part in this study. New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want your child to be in the study. During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you [or your child] any of this money now or in the future because you [or your child] took part in this study.

We will give you a copy of this consent form for your records.

In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the medicine [or treatment] given in the study is helping your child. If this happens, the study doctor will talk to you about what will happen next. If your child becomes ill or is harmed because you took part in this study, we will treat your child for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

Sponsorship:

The sponsor of this study is Dr. Jill Hamilton and The Hospital for Sick Children and the funder of this study is the Provincial Council for Child and Maternal Health (PCMCH)

Conflict of Interest:
Dr. Jill Hamilton and the other research team members have no conflict of interest to declare

**Future Contact:**
Do you give permission to be contacted for future follow up studies are conducted?

Yes, I do  ☐  No, I do not  ☐

**Consent:**

By signing this form, I agree that:
1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time. My decision about my child taking part in the study will not affect my child’s health care at Sick Kids.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my child’s medical records will be kept private except as described to me.
6) I understand that no information about my child will be given to anyone or be published without first asking my permission.
7) I have read pages 1 to 7 and I agree, or consent, that my child____________ may take part in this study.

______  Printed Name of Parent/Legal Guardian  ________________  Parent/Legal Guardian’s signature & date

______  Printed Name of person who explained consent  ________________  Signature of Person who explained consent & date

______  Printed Witness’ name (if the parent/legal guardian does not read English)  ________________  Witness’ signature & date

If you have any questions about this study, please call Jill Hamilton at 416.813.5115

If you have questions about your child’s rights as a research subject in a study or injuries during a study, please call the Research Ethics Manager at 416.813.5718 at SickKids.
Control Consent Form (Participant)

Title of Research Project:
Evaluation of the SickKids Team Obesity Management Program (STOMP)

Principle Investigator
Dr. Jill Hamilton 416.813.5115

Co-Investigators
Dr. Catherine Birken 416.813.5115
Elizabeth Dettmer, Psychologist 416.813.5115
Preeti Grewal, Nurse Practitioner 416.813.7654 x 28366
Allison Jeffery, Exercise Therapist 416.813.7654 x 4495
Dianne Knox, Social Worker 416.813.7654 x 28750
Alisa Bar-Dayan, Dietitian 416.813.7654 x 28368
Christopher Incognito 416.813.7654 x 28367
Melissa McGuire, Cathexis
Marilyn Booth, Provincial Council for Maternal and Child Health

Research Team Member:
Dr. Paola Luca,
Pediatric Endocrinology Fellow 416.813.7116

Research Coordinators:
Munaza Jamil 416.813.7654 x 28363
Rachel Steger 416.813.7654 x1931
Sahar Ehtesham 416.813.7654 x1931

Purpose of the Research:
There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with obesity, and may form the basis for changes in clinical practice.
The purpose of this study is to see if and how the STOMP clinic changes the quality of life of patients and families diagnosed with obesity, compared with a control group of those who are not provided similar care. The control group will be those patients who declined entry into the STOMP program. The estimated total number of participants in the study will be 87 (50 in the STOMP program, 37 in the control group).

**Description of the Research:**

In January 2010 a new interdisciplinary clinic (STOMP) was created to provide care for children and adolescents with severe ‘complex’ obesity. STOMP incorporates frequent visits, individualized care plans for medically-complex adolescents, psychosocial intervention and involvement of a “key worker” (nurse practitioner) to support families.

Prior to acceptance into the program, prospective patients and their parents attend an information night run by the STOMP team which describes the program and the commitment required of families. Approximately 50% of attendees choose not to book into the program, for reasons including difficulty attending the frequent appointments due to distance or inability to leave work early. This population will serve as the control group for the evaluation. We are hoping to enroll 37 participants in the control group.

As a member of the control group, you will be asked to attend three clinic appointments at SickKids over a period of 18 months. Each visit will be 6 months apart. For these research visits, you will be fasting so we will provide a meal voucher for you to purchase lunch in the hospital cafeteria. These visits are in addition to any other appointments or regular hospital visits you may have.

You will be asked to complete diet, physical activity, and psychology questionnaires (e.g., screening for depression, eating disorders, quality of life). These questionnaires are designed to help us better understand the current and past medical complications of your condition as well as information related to psychosocial well-being, dietary and activity levels. They take approximately one hour to complete. From these assessments, a summary and recommendations for follow-up will be provided to you. These measures will be repeated at 6-month intervals for 18 months, so that we may evaluate any changes in your child’s medical condition.

A comprehensive assessment will be completed at each clinic visit. We will ask you questions about your health. We will measure your height and weight, as well as waist and hip circumference.

We will then take a fasting blood sample for to measure your cholesterol (blood fats) and risk for diabetes. The volume of blood collected will be 5 mLs (1 teaspoon).

**Potential Harms:**

We know of no harm that taking part in this study could cause you.
**Potential Discomforts or Inconvenience:**

During the visits, we will take a blood test. There may be a small amount of bleeding when blood is taken from a vein and there may be slight discomfort and bruising or redness that will usually disappear in a few days. We will offer a special cream (EMLA) that can be applied to the skin to numb it and reduce the discomfort prior to the needle poke.

**Potential Benefits:**

What we learn from this evaluation study may also help other children with obesity and help us to design better programs and secure long term funding for new obesity programs in Ontario. This study will hopefully lead to improvements in your healthcare delivery.

**To individual subjects:**

There is no guarantee that you will personally experience any benefits from joining this study. If any abnormalities are detected, we will ensure that the results are discussed with you and a copy sent to your family doctor or pediatrician. If further treatment is required, we will refer you to the appropriate pediatric specialty doctor. You will receive a summary of your results after the study is complete.

**To society:**

There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with severe complex obesity, and may form the basis for changes in clinical practice in this vulnerable population of children.

**Alternatives to participation:**

Taking part in the study is entirely your choice. Whether or not you decide to participate in this research study, this decision will not affect any future care you may receive.

**Confidentiality:**

We will respect your privacy. No information about who you are will be given to anyone or be published without your permission, unless the law makes us do this. For example, the law could make us give information about you:
- If you have been abused
- If you have an illness that could spread to others
- If you or someone else talks about suicide (killing themselves), or
- If the court orders us to give them the study papers
SickKids Clinical Research Office Monitor or the regulator of the study may see your health record to check on the study. For example, people from Health Canada Health Products and Food Branch, or Canadian Institute of Health Research may look at your records.

By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your patient health records.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by SickKids policy. Published study results will not reveal your identity.

The results of the tests we describe in this form will be used only for this study. If another doctor or caregiver caring for your needs to see these results, you will have to give us your permission. We will ask you to sign a form saying that you agree that this person can see your results. We recommend that only a registered psychologist or doctor tell you what the results of these tests mean.

Reimbursement:
You will be offered $300 total for participation in the study as compensation for their time, discomfort, and travel costs.

Participation:
Participation in research is voluntary. It is your choice for you to take part in this study. You can stop at any time. The care you get at SickKids will not be affected in any way by whether you take part in this study. New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want to be in the study. During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you any of this money now or in the future because you took part in this study.

We will give you a copy of this consent form for your records.

In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the medicine [or treatment] given in the study is helping you. If this happens, the study doctor will talk to you about what will happen next.

If you become ill or are harmed because you took part in this study, we will treat you for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.
Sponsorship:

The sponsor of this study is Dr. Jill Hamilton and the Hospital for Sick Children and the funder of this study is the Provincial Council for Child and Maternal Health (PCMCH).

Conflict of Interest:

Dr. Jill Hamilton and the other research team members have no conflict of interest to declare.

Future Contact:

Do you give permission to be contacted for future follow up studies are conducted?

Yes, I do ☐ No, I do not ☐

Consent:

By signing this form, I agree that:

1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of taking part in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care at Sick Kids.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my medical records will be kept private except as described to me.
6) I understand that no information about who I am will be given to anyone or be published without first asking my permission.
7) I have read pages 1 to 5 and I agree, or consent, to take part in this study.

Printed Name of Subject & Age ___________________________ Subject’s Signature and Date ___________________________

Printed Name of person who explained consent ___________________________ Signature of Person who explained consent
& date ___________________________

Additional Consent:

I give permission for my OHIP number to be stored for a future study of health care use.

Printed Name of Subject & Age ___________________________ Subject’s Signature and Date ___________________________

Printed Name of person who explained consent ___________________________ Signature of Person who explained consent
& date ___________________________

If you have any questions about this study, please call Jill Hamilton at 416.813.5115. If you have questions about your rights as a research subject in a study or injuries during a study, please call the Research Ethics Manager at 416.813.5718 at SickKids.

Consent Form, Version Date 01 Nov 2011

9.2.4 Letter of Consent for Comparison Parents

133
Control Consent Form (Parent/Caregiver)

Title of Research Project:
Evaluation of the SickKids Team Obesity Management Program (STOMP)

Principal Investigator:
Dr. Jill Hamilton 416.813.5115

Co-Investigators:
Dr. Catherine Birken 416.813.5115
Elizabeth Dettmer, Psychologist 416.813.5115
Preeti Grewal, Nurse Practitioner 416.813.7654 x 28366
Allison Jeffery, Exercise Therapist 416.813.7654 x 4495
Dianne Knox, Social Worker 416.813.7654 x 28750
Alisa Bar-Dayan, Dietitian 416.813.7654 x 28368
Christopher Incognito 416.813.7654 x 28367
Melissa McGuire, Cathexis
Marilyn Booth, Provincial Council for Maternal and Child Health

Research Team Member:
Dr. Paola Luca, Pediatric Endocrinology Fellow 416.813.7654 x 8088

Research Coordinators:
Munaza Jamil 416.813.7654 x 28363
Rachel Steger 416.813.7654 x 1931
Sahar Ehtesham 416.813.7654 x1931

Purpose of the Research:
There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with obesity, and may form the basis for changes in clinical practice.

The purpose of this study is to see if and how the STOMP clinic changes the quality of life of patients and families diagnosed with obesity, compared with a control group of those who are not provided similar care. The control group will be those patients who declined entry into
the STOMP program. The estimated total number of participants in the study will be 87 (50 in the STOMP program, 37 in the control group).

**Description of the Research:**

In January 2010 a new interdisciplinary clinic (STOMP) was created to provide care for children and adolescents with severe ‘complex’ obesity. STOMP incorporates frequent visits, individualized care plans for medically-complex adolescents, psychosocial intervention and involvement of a “key worker” (nurse practitioner) to support families.

Prior to acceptance into the program, prospective patients and their parents attend an information night run by the STOMP team which describes the program and the commitment required of families. Approximately 50% of attendees choose not to book into the program, for reasons including difficulty attending the frequent appointments due to distance or inability to leave work early. This population will serve as the control group for the evaluation. We are hoping to enroll 37 participants in the control group.

As the control group, you and your child will be asked to attend three clinic appointments at SickKids over a period of 18 months. Each visit will be 6 months apart. For these research visits, your child will be fasting so we will provide a meal voucher for you to purchase lunch in the hospital cafeteria. These visits are in addition to any other appointments or regular hospital visits you may have.

You and your child will be asked to complete diet, physical activity, and psychology questionnaires (e.g., screening for depression, eating disorders, quality of life). These questionnaires are designed to help us better understand the current and past medical complications of your condition as well as information related to psychosocial well-being, dietary and activity levels. They take approximately one hour to complete and will be mailed to you in advance of the clinic appointment. From these assessments, a summary and recommendations for follow-up will be provided to you. These measures will be repeated at 6-month intervals for 18 months, so that we may evaluate any changes in your child’s medical condition.

A comprehensive assessment will be completed at each clinic visit. We will ask you questions about your child and family’s medical history. We will review your child’s health record at this time. We will take your child’s height and weight, as well as waist and hip circumferences.

We will then take a fasting blood sample for to measure your child’s cholesterol (blood fats) and risk for diabetes. The volume of blood collected will be 5 mLs (1 teaspoon).

**Potential Harms:**

We know of no harm that taking part in this study could cause you or your child.
Potential Discomforts or Inconvenience:

During the visits, we will take blood from your child. There may be a small amount of bleeding when blood is taken from a vein and there may be slight discomfort and bruising or redness that will usually disappear in a few days. We will offer a special cream (EMLA) that can be applied to the skin to numb it and reduce the discomfort prior to the needle poke.

Potential Benefits:

What we learn from this evaluation study may also help other children with obesity and help us to design better programs and secure long term funding for new obesity programs in Ontario. This study will hopefully lead to improvements in your child’s healthcare delivery.

To individual subjects:

There is no guarantee that your child will personally experience any benefits from joining this study. If any abnormalities are detected, we will ensure that the results are discussed with you and your child and a copy sent to your child’s family doctor or pediatrician. If further treatment is required, we will refer your child to the appropriate pediatric specialty doctor.

You will receive a summary of your child’s results after the study is complete.

To society:

There is little information available regarding benefit to children and adolescents who participate in obesity programs. The results from this study will improve our understanding of the complex medical and psychosocial issues associated with severe complex obesity, and may form the basis for changes in clinical practice in this vulnerable population of children.

Alternatives to participation:

Taking part in the study is entirely yours and your child’s choice. Whether or not you and your child decide to participate in this research study, this decision will not affect any future care your child may receive.

Confidentiality:

We will respect your child’s privacy. No information about who your child is will be given to anyone or be published without your permission, unless the law makes us do this. For example, the law could make us give information about your child:

- If a child has been abused
- If you have an illness that could spread to others
- If you or someone else talks about suicide (killing themselves), or
- If the court orders us to give them the study papers
SickKids Clinical Research Office Monitor or the regulator of the study may see your child’s health record to check on the study. For example, people from Health Canada Health Products and Food Branch, or Canadian Institute of Health Research may look at your child’s records.

By signing this consent form, you agree to let these people look at your child’s records. We will put a copy of this research consent form in your child’s patient health records.

The data produced from this study will be stored in a secure, locked location. Only members of the research team (and maybe those individuals described above) will have access to the data. This could include external research team members. Following completion of the research study the data will be kept as long as required then destroyed as required by Sick Kids policy. Published study results will not reveal your child’s identity.

The results of the tests we describe in this form will be used only for this study. If another doctor or caregiver caring for your child needs to see these results, you will have to give us your permission. We will ask you to sign a form saying that you agree that this person can see your (your child’s) results. We recommend that only a registered psychologist or doctor tell you what the results of these tests mean.

**Reimbursement:**

Patients will be offered $300 total for participation in the study as compensation for their time, discomfort, and travel costs.

**Participation:**

Participation in research is voluntary. It is your choice for your child to take part in this study. You can stop at any time. The care your child gets at SickKids will not be affected in any way by whether you take part in this study. New information that we get while we are doing this study may affect your decision to take part in this study. If this happens, we will tell you about this new information. And we will ask you again if you still want your child to be in the study. During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you [or your child] any of this money now or in the future because you [or your child] took part in this study.

We will give you a copy of this consent form for your records.

In some situations, the study doctor or the company paying for the study may decide to stop the study. This could happen even if the medicine [or treatment] given in the study is helping your child. If this happens, the study doctor will talk to you about what will happen next.

If your child becomes ill or is harmed because you took part in this study, we will treat your child for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.
Sponsorship:

The sponsor of this study is Dr. Jill Hamilton and the Hospital for Sick Children and the funder of this study is the Provincial Council for Child and Maternal Health (PCMCH)

Conflict of Interest:

Dr. Jill Hamilton and the other research team members have no conflict of interest to declare

Future Contact:

Do you give permission to be contacted for future follow up studies are conducted?

Yes, I do ☐  No, I do not ☐

Consent:

By signing this form, I agree that:
1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study, I also have the right to take my child out of the study at any time. My decision about my child taking part in the study will not affect my child’s health care at Sick Kids.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my child’s medical records will be kept private except as described to me.
6) I understand that no information about my child will be given to anyone or be published without first asking my permission.
7) I have read pages 1 to 6 and I agree, or consent, that my child __________________________ may take part in this study.

Printed Name of Parent/Legal Guardian  Parent/Legal Guardian’s signature & date

Printed Name of person who explained consent  Signature of Person who explained consent & date

Printed Witness’ name (if the parent/legal guardian does not read English)  Witness’ signature & date
**Additional Consent:**

I give permission for my child’s OHIP number to stored for a future study of health care use.

<table>
<thead>
<tr>
<th>Printed Name of Parent/Legal Guardian</th>
<th>Parent/Legal Guardian’s signature &amp; date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed Name of person who explained consent</td>
<td>Signature of Person who explained consent &amp; date</td>
</tr>
<tr>
<td>Printed Witness’ name (if the parent/legal guardian does not read English)</td>
<td>Witness’ signature &amp; date</td>
</tr>
</tbody>
</table>

If you have any questions about this study, please call Jill Hamilton at 416.813.5115
If you have questions about your child’s rights as a research subject in a study or injuries during a study, please call the Research Ethics Manager at 416.813.5718 at SickKids.
PedsQL™
Pediatric Quality of Life Inventory
Version 4.0

TEEN REPORT (ages 13-18)

DIRECTIONS
On the following page is a list of things that might be a problem for you. Please tell us how much of a problem each one has been for you during the past ONE month by circling:

0 if it is never a problem
1 if it is almost never a problem
2 if it is sometimes a problem
3 if it is often a problem
4 if it is almost always a problem

There are no right or wrong answers. If you do not understand a question, please ask for help.
In the past ONE month, how much of a problem has this been for you ...

### About My Health and Activities (problems with...)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is hard for me to walk more than one block</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>It is hard for me to run</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>It is hard for me to do sports activity or exercise</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>It is hard for me to lift something heavy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>It is hard for me to take a bath or shower by myself</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>It is hard for me to do chores around the house</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I hurt or ache</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have low energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### About My Feelings (problems with...)

<table>
<thead>
<tr>
<th>Feeling</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel afraid or scared</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel sad or blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I feel angry</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble sleeping</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I worry about what will happen to me</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### How I Get Along with Others (problems with...)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have trouble getting along with other teens</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Other teens do not want to be my friend</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Other teens tease me</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I cannot do things that other teens my age can do</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>It is hard to keep up with my peers</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### About School (problems with...)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Never</th>
<th>Almost Never</th>
<th>Sometimes</th>
<th>Often</th>
<th>Almost Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is hard to pay attention in class</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I forget things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I have trouble keeping up with my schoolwork</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I miss school because of not feeling well</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>I miss school to go to the doctor or hospital</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
**IWQOL-Kids**

Please answer the following statements by circling the number that best applies to you in the past seven days. Be as open as possible. There are no right or wrong answers.

<table>
<thead>
<tr>
<th>Physical Comfort</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Because of my weight I avoid using stairs whenever possible.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2. Because of my weight it is hard for me to bend over to tie my shoes or to pick something up off the floor.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. Because of my weight it is hard for me to move around.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Because of my weight it is hard for me to fit into seats in public places (e.g., movie theaters, desks at school, booths in restaurants).</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. Because of my weight my knees or ankles hurt.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. Because of my weight it is hard for me to cross my legs.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Body Esteem</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Because of my weight I am ashamed of my body.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8. Because of my weight I don’t like myself very much.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9. Because of my weight I try not to look at myself in mirrors or in photographs.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10. Because of my weight I have a hard time believing compliments that I receive from others.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11. Because of my weight I am lacking in self-confidence.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12. Because of my weight I avoid activities that involve wearing shorts or a bathing suit.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13. Because of my weight it is very difficult for me to buy clothing.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. Because of my weight I don’t like to change my clothes or undress in front of others.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. Because of my weight I am embarrassed to try out for activities at school.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

*Copyright 2002, Rouchell, L., & Boles, K. Obesity and Quality of Life Consulting, Durham, NC and Children’s Hospital Medical Center, Cincinnati, OH.
All rights reserved. Do not use without permission.
For permission to use contact Rouchell@obesityqualityoflifeconsulting.com or telephone (919) 493-0995*
<table>
<thead>
<tr>
<th>Social Life</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>16. Because of my weight people tease me or make fun of me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. Because of my weight people talk about me behind my back</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. Because of my weight people avoid spending time with me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. Because of my weight people stare at me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. Because of my weight I have trouble making or keeping friends</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21. Because of my weight people don’t think I’m very smart</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Family Relations</th>
<th>ALWAYS TRUE</th>
<th>USUALLY TRUE</th>
<th>SOMETIMES TRUE</th>
<th>RARELY TRUE</th>
<th>NEVER TRUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>22. Because of my weight family members treat me differently from the way they treat other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>23. Because of my weight family members talk about me behind my back</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>24. Because of my weight one or more people in my family reject me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>25. Because of my weight my parents aren’t proud of me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>26. Because of my weight family members make fun of me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>27. Because of my weight family members don’t want to be seen with me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

9.3.3 CDI Questionnaire
Kids sometimes have different feelings and ideas.

This form lists the feelings and ideas in groups. From each group of three sentences, pick one sentence that describes you best for the past two weeks. After you pick a sentence from the first group, go on to the next group.

There is no right or wrong answer. Just pick the sentence that best describes the way you have been recently. Put a mark like this ☑️ next to your answer. Put the mark in the box next to the sentence that you pick.

Here is an example of how this form works. Try it. Put a mark next to the sentence that describes you best.

Example:

- ☐ I read books all the time.
- ☑️ I read books once in a while.
- ☐ I never read books.

Remember, pick out the sentences that describe you best in the PAST TWO WEEKS.

<table>
<thead>
<tr>
<th>Item 1</th>
<th>Item 2</th>
<th>Item 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I am sad once in a while.</td>
<td>☐ Nothing will ever work out for me.</td>
<td>☐ I do most things O.K.</td>
</tr>
<tr>
<td>☐ I am sad many times.</td>
<td>☐ I am not sure if things will work out for me.</td>
<td>☐ I do many things wrong.</td>
</tr>
<tr>
<td>☜ I am sad all the time.</td>
<td>☐ Things will work out for me O.K.</td>
<td>☐ I do everything wrong.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 4</th>
<th>Item 5</th>
<th>Item 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I have fun in many things.</td>
<td>☐ I hate myself.</td>
<td>☐ I think about bad things happening to me once in a while.</td>
</tr>
<tr>
<td>☐ I have fun in some things.</td>
<td>☐ I do not like myself.</td>
<td>☐ I worry that bad things will happen to me.</td>
</tr>
<tr>
<td>☐ Nothing is fun at all.</td>
<td>☐ I like myself.</td>
<td>☐ I am sure that terrible things will happen to me.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 7</th>
<th>Item 8</th>
<th>Item 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I am bad all the time.</td>
<td>☐ Many bad things are my fault.</td>
<td>☐ I do not think about killing myself.</td>
</tr>
<tr>
<td>☐ I am bad many times.</td>
<td>☐ Many bad things are my fault.</td>
<td>☐ I think about killing myself but I would not do it.</td>
</tr>
<tr>
<td>☜ I am bad once in a while.</td>
<td>☐ Bad things are not usually my fault.</td>
<td>☐ I want to kill myself.</td>
</tr>
</tbody>
</table>

Turn over and fill out the other side.
<table>
<thead>
<tr>
<th>Item</th>
<th>Question</th>
<th>Item</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 10</td>
<td>I feel like crying every day.</td>
<td>Item 19</td>
<td>I do not worry about aches and pains.</td>
</tr>
<tr>
<td>Item 11</td>
<td>Things bother me all the time.</td>
<td>Item 20</td>
<td>I do not feel alone.</td>
</tr>
<tr>
<td>Item 12</td>
<td>I like being with people.</td>
<td>Item 21</td>
<td>I never have fun at school.</td>
</tr>
<tr>
<td>Item 13</td>
<td>I cannot make up my mind about things.</td>
<td>Item 22</td>
<td>I have plenty of friends.</td>
</tr>
<tr>
<td>Item 14</td>
<td>I look O.K.</td>
<td>Item 23</td>
<td>My schoolwork is alright.</td>
</tr>
<tr>
<td>Item 15</td>
<td>I have to push myself all the time to do my schoolwork.</td>
<td>Item 24</td>
<td>I can never be as good as other kids.</td>
</tr>
<tr>
<td>Item 16</td>
<td>I have trouble sleeping every night.</td>
<td>Item 25</td>
<td>Nobody really loves me.</td>
</tr>
<tr>
<td>Item 17</td>
<td>I am tired once in a while.</td>
<td>Item 26</td>
<td>I usually do what I am told.</td>
</tr>
<tr>
<td>Item 18</td>
<td>Most days I do not feel like eating.</td>
<td>Item 27</td>
<td>I get along with people.</td>
</tr>
</tbody>
</table>

**9.4 HEALTH BEHAVIOUR CHANGE QUESTIONNAIRES**
9.4.1 Teen Readiness to Change

Readiness to Change Questionnaire
(Child Version - adapted from Heinmäe, 2003)

Please read each of the following 5 statements about yourself. Check the box for ONE statement that best describes how you presently think about your own readiness to change your lifestyle (i.e., eating behaviour & attitudes & activity level)

1. I am here only because someone else thinks I have an unhealthy lifestyle.
2. I don't believe that I have any problems with an unhealthy lifestyle.
3. I might have an unhealthy lifestyle and I have been thinking about what to do about it.
4. I am ready to do something about my unhealthy lifestyle, but haven't yet.
5. I have actively been trying to do things to change my unhealthy lifestyle.
6. I have successfully made changes to address my unhealthy lifestyle.

Check the box for the statement (below) that best describes how your mother and father think about your readiness to change your lifestyle (i.e., eating behaviour & attitudes & activity level)

1. I am here only because other people believe my child has an unhealthy lifestyle.
2. I am here because I'm not sure if my child has an unhealthy lifestyle.
3. My child has an unhealthy lifestyle and I have been thinking about what to do about it.
4. I am ready to do something about my child's unhealthy lifestyle, but haven't yet.
5. I have actively been doing or changing things to help my child address his/her unhealthy lifestyle.
6. I have successfully made changes that are helping to address my child's unhealthy lifestyle.

9.4.2 Parent Readiness to Change
Readiness to Change Questionnaire
(Parent Version - adapted from Heinmaa, 2003)

Check the box for **ONE** statement that best describes **how you** presently think about your own readiness to help your child to change his/her lifestyle (i.e., eating behaviour & attitudes & activity level).

1. I am here only because other people believe my child has an unhealthy lifestyle.
2. I am here because I'm not sure if my child has an unhealthy lifestyle.
3. My child has an unhealthy lifestyle and I have been thinking about what to do about it.
4. I am ready to do something about my child's unhealthy lifestyle, but haven't yet.
5. I have actively been doing or changing things to help my child address his/her unhealthy lifestyle.
6. I have successfully made changes that are helping to address my child's unhealthy lifestyle.

Please read each of the following 6 statements (below) about your child: Check the box for the **ONE** statement that best describes how your child thinks about his/her readiness to change his/her lifestyle (i.e., eating behaviour & attitudes & activity level).

1. I am here only because someone else thinks I have an unhealthy lifestyle.
2. I don’t believe that I have any problems with an unhealthy lifestyle.
3. I might have an unhealthy lifestyle and I have been thinking about what to do about it.
4. I am ready to do something about my unhealthy lifestyle, but haven’t yet.
5. I have been actively trying to do things to change my unhealthy lifestyle.
6. I have successfully made changes to address my unhealthy lifestyle.

9.4.3 HAES Questionnaire
THE HAES (HABITUAL ACTIVITY ESTIMATION SCALE)  SickKids

Age: _______ years  Date: __________ Study ID#: __________

Male  Female (Circle)

The following questions will ask you about your daily activity levels. Please read all of the instructions carefully and answer each question as truthfully as you can.

INSTRUCTIONS (Please Read!)
Please recall the activities of one typical weekday (choose from a Tuesday, Wednesday, or Thursday) and one typical Saturday within the past two weeks. For each time period described please estimate the percentage of time that you spent in each different activity level. For each time period, the total time spent in all activity levels must add up to 100%.

The different activity levels are described below:

<table>
<thead>
<tr>
<th>ACTIVITY LEVEL DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>These descriptions give you examples of activities that are typical of each activity level. Please refer back to these descriptions as often as you need when completing your estimates.</td>
</tr>
<tr>
<td>a)  <strong>Inactive</strong> – lying down, sleeping, resting, napping</td>
</tr>
<tr>
<td>b)  <strong>Somewhat inactive</strong> – sitting, reading, watching television, playing video games, time in front of the computer, playing games or activities that are mostly done sitting down.</td>
</tr>
<tr>
<td>c)  <strong>Somewhat active</strong> – walking, shopping, light household chores</td>
</tr>
<tr>
<td>d)  <strong>Very active</strong> – running, jumping, skipping, bicycling, skating, swimming, games that require lots of movement and make you breathe/sweat hard</td>
</tr>
</tbody>
</table>

Following is a sample of a completed time period:

<table>
<thead>
<tr>
<th>SAMPLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>From when your child finished supper until bedtime, please estimate the percentage of time that you spent in each of the following activity levels?</td>
</tr>
<tr>
<td>a) Inactive  5 % (e.g., having a nap)</td>
</tr>
<tr>
<td>b) Somewhat inactive  60 % (e.g., watching TV)</td>
</tr>
<tr>
<td>c) Somewhat active  25 % (e.g., going for a walk)</td>
</tr>
<tr>
<td>d) Very Active  10 % (e.g., riding a bike fast)</td>
</tr>
<tr>
<td><strong>TOTAL 100 %</strong></td>
</tr>
</tbody>
</table>
**WEEKDAY ACTIVITY**

For *one typical weekday in the past 2 weeks* (choose from one of Tuesday, Wednesday or Thursday), please estimate the percentage of time you spent in each activity level.

1. **After getting out of bed until starting breakfast:**
   - a) Inactive ______%  
   - b) Somewhat inactive ______%  
   - c) Somewhat active ______%  
   - d) Very Active ______%  
   **TOTAL** 100 %

2. **After finishing breakfast until starting lunch:**
   - a) Inactive ______%  
   - b) Somewhat inactive ______%  
   - c) Somewhat active ______%  
   - d) Very Active ______%  
   **TOTAL** 100 %

3. **After finishing lunch until starting supper:**
   - a) Inactive ______%  
   - b) Somewhat inactive ______%  
   - c) Somewhat active ______%  
   - d) Very Active ______%  
   **TOTAL** 100 %

4. **After finishing supper until bedtime:**
   - a) Inactive ______%  
   - b) Somewhat inactive ______%  
   - c) Somewhat active ______%  
   - d) Very Active ______%  
   **TOTAL** 100 %
For the typical weekday that you are describing, please answer the following questions as accurately as possible in the spaces provided.

5. When did you get out of bed in the morning?

6. When did you start eating breakfast?

7. How long did you spend eating breakfast?

8. When did you start eating lunch?

9. How long did you spend eating lunch?

10. When did you start eating supper?

11. How long did you spend eating supper?

12. At what time did you go to bed?

13. For the typical weekday that this questionnaire has asked you about, please rate your overall level of activity (Please circle one response only):

   a) Very inactive
   b) Inactive
   c) Somewhat inactive
   d) Somewhat active
   e) Active
   f) Very active

14. Please complete the following sentence by putting a circle around your choice:

   The weekday I described in this form is:

   a) Very much like most weekdays
   b) A little bit like most weekdays
   c) A little bit different from most weekdays
   d) Very different from most weekdays
SATURDAY ACTIVITY

For one typical Saturday in the past 2 weeks, please estimate the percentage of time you spent in each activity level.

1. After getting out of bed until starting breakfast:
   a) Inactive
   b) Somewhat inactive
   c) Somewhat active
   d) Active
   **TOTAL 100 %**

2. After finishing breakfast until starting lunch:
   a) Inactive
   b) Somewhat inactive
   c) Somewhat active
   d) Active
   **TOTAL 100 %**

3. After finishing lunch until starting supper:
   a) Inactive
   b) Somewhat inactive
   c) Somewhat active
   d) Active
   **TOTAL 100 %**

4. After finishing supper until bedtime:
   a) Inactive
   b) Somewhat inactive
   c) Somewhat active
   d) Active
   **TOTAL 100 %**
For the typical Saturday that you are describing, please answer the following questions as accurately as possible in the spaces provided.

5. When did you get out of bed in the morning?

6. When did you start eating breakfast?


8. When did you start eating lunch?


10. When did you start eating supper?

11. How long did you spend eating supper? _______ min.

12. At what time did you go to bed?

13. For the typical Saturday that this questionnaire has asked you about, please rate your overall level of activity (Please circle one response only):

   a) Very inactive
   b) Inactive
   c) Somewhat inactive
   d) Somewhat active
   e) Active
   f) Very active

14. Is this “typical” Saturday that you described in this questionnaire (please circle one response only):

   a) Very much like most Saturdays
   b) A little bit like most Saturdays
   c) A little bit different from most Saturdays
   d) Very different from most Saturdays
QUALITY OF PATIENT’S DIET AND EATING BEHAVIOURS – RUBRIC

Instructions

To be completed by the dietitian for treatment and comparison group participants at intake, 6 months, 12 months, 18 months, and 24 months.

Purpose
The purpose of this rubric is to provide an overall assessment of the quality of the patient’s diet and eating behaviours based on the dietitian’s expert opinion.

Basis of Assessment
When assessing the quality of a patient’s diet and eating behaviours, please base your expert assessment on the following information:

- Treatment group participants (SickKids and CHEO) – All information acquired from the patient during appointments and group sessions.
- Comparison group participants (SickKids only) – Information from a 2-day food record recall form completed by participants.
- Comparison group participants (CHEO only) – Information from the patient’s usual intake at their follow-up clinic visits.

During your assessment, also note that for the purposes of this rubric, the elements of a ‘good diet’ and ‘good eating habits’ for this group of patients (i.e., those with severe complex obesity) include:

- Ultimately want patients to follow guidelines of Canada’s Food Guide
- Reduced intake of high sugar food
- Reduced intake of fast food/fried food
- Reduced intake of juice/pop
- Reduced intake of junk food
- Increased intake of fruits and vegetables

Scoring
The quality of a patient’s diet and eating behaviours will be scored as follows. A higher score indicates increased nutrition status.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1 (Pre-Contemplative)</td>
<td>1</td>
</tr>
<tr>
<td>Stage 2 (Contemplative)</td>
<td>2</td>
</tr>
<tr>
<td>Stage 3 (Action)</td>
<td>3</td>
</tr>
<tr>
<td>Stage 4 (Maintenance)</td>
<td>4</td>
</tr>
</tbody>
</table>
Stage 1 (Pre-Contemplative)
- Poor eating habits given known medical conditions. Does not recognize or acknowledge that eating behaviour needs to change, or feels that nothing can be done to change the situation. Therefore, does not act on plans.

Stage 2 (Contemplative)
- Poor eating habits given known medical conditions. Does recognize or acknowledge that his/her eating behaviour needs to change, but does not know how to change the situation or is not motivated to change. Therefore, does not act on plans.

Stage 3 (Action)
- Fair eating habits given known medical conditions. Begins to see that change can occur, and sometimes follows through on plans. Willing to learn new eating behaviours and feels that he/she can change the situation although requires frequent monitoring and encouragement from others. Has not fully adopted behaviours on his/her own yet.

Stage 4 (Maintenance)
- Good eating habits given known medical conditions. Has followed through with these positive eating behaviour changes for at least six months. If a setback is experienced, is motivated to get back on track with plans and takes action to get back on track.

Patient Score: __________

9.4.5 Comparison Participants’ Dietary Readiness to Change Questionnaire
Stages of Change Dietary Assessment

Read 4 statements to patient and ask which one fits best. Place a check beside the statement selected.

Patient ID: ____________  Date: ____________

☐ I have no plans to change my eating behavior

☐ I am starting to think about changing my eating behavior to include healthier food choices

☐ I have made some changes to my eating behavior and have chosen healthier foods some of the time

☐ I have made many changes to my eating behavior and generally choose healthy food options

9.6 DATA COLLECTION FORMS
9.6.1 Intake Form
INTAKE FORM – COMPARISON GROUP

ABOUT YOUR CHILD’S FAMILY

The purpose of this form is to get to know about your child and his/her family. The information will help us understand who is and who is not receiving services through STOMP. This form is to be completed by the child’s parent/guardian.

Date:
Form completed by: Insert Patient ID
Relationship to child:

Patient ID:

Child’s month and year of birth

Child’s gender:

Child’s grade level at school:

Number of people in the child’s family:

Highest level of education of the child’s mother:
☐ Less than high school
☐ High school
☐ College
☐ University (undergraduate)
☐ University (graduate, post-graduate)

Highest level of education of the child’s father:
☐ Less than high school
☐ High school
☐ College
☐ University (undergraduate)
☐ University (graduate, post-graduate)

The combined total income per year of the household in which the child lives: (If the child lives in more than one household, select the household in which he/she spends the most time.)
☐ $25,000 and less
☐ $25,001 - $50,000
☐ $50,001 - $75,000
☐ $75,001 - $100,000
☐ $100,001 and above
9.6.2 Co-Morbidity and Medication Checklists

CO-MORBIDITY AND MEDICATION CHECKLISTS

Purpose

The purpose of these checklists is to identify those co-morbidities (or other medical conditions that complicate obesity management) and those medications that are typically or most commonly seen amongst youth with severe complex obesity.

Instructions

To be completed by the endocrinologist or paediatrician for treatment and comparison group participants at intake, 6 months, 12 months, 18 months, and 24 months.

Please answer – yes, no, or don’t know – for each co-morbidity and medication listed.

At the time of intake, please answer ‘yes’ if the patient presents the co-morbidity (or uses the medication) at that time, or if the patient has a history of the co-morbidity (or medication use).

For subsequent reporting periods (i.e., 6 months, 12 months, 18 months, and 24 months), please answer ‘yes’ if the patient presents the co-morbidity (or uses the medication) at that time, or if the patient presented the co-morbidity (or used the medication) within the six month timeframe since the last time the checklist was completed.

Patient Name: __________________________ Date: __________________________

Completed by: __________________________
<table>
<thead>
<tr>
<th>Co-morbidity presented by patient</th>
<th>Please circle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 Diabetes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>Yes</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Yes</td>
</tr>
<tr>
<td>Gastroesophageal reflux</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-alcoholic fatty liver disease</td>
<td>Yes</td>
</tr>
<tr>
<td>Gall bladder disease/stones</td>
<td>Yes</td>
</tr>
<tr>
<td>Polycystic ovarian syndrome (PCOS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Musculoskeletal system (MSK) obesity complications</td>
<td>Yes</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
<td>Yes</td>
</tr>
<tr>
<td>Asthma</td>
<td>Yes</td>
</tr>
<tr>
<td>Depression</td>
<td>Yes</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Yes</td>
</tr>
<tr>
<td>Attention Deficit/Hyperactivity Disorder (ADHD)</td>
<td>Yes</td>
</tr>
<tr>
<td>Learning disability</td>
<td>Yes</td>
</tr>
<tr>
<td>Disordered eating</td>
<td>Yes</td>
</tr>
<tr>
<td>CNS tumour</td>
<td>Yes</td>
</tr>
<tr>
<td>Developmental delay</td>
<td>Yes</td>
</tr>
<tr>
<td>Difficulties with ambulation</td>
<td>Yes</td>
</tr>
<tr>
<td>Genetic syndrome</td>
<td>Yes</td>
</tr>
<tr>
<td>Other co-morbidity please specify:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Don’t know
<table>
<thead>
<tr>
<th>Medication used by patient</th>
<th>Please circle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin</td>
<td>Yes</td>
</tr>
<tr>
<td>Insulin</td>
<td>Yes</td>
</tr>
<tr>
<td>Lipid lowering medication (statin, fibrate)</td>
<td>Yes</td>
</tr>
<tr>
<td>Medication for GERD (prevacid, omeprazole, ranitidine)</td>
<td>Yes</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>Yes</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Yes</td>
</tr>
<tr>
<td>Anti-inflammatory / pain medication</td>
<td>Yes</td>
</tr>
<tr>
<td>Inhaled corticosteroids</td>
<td>Yes</td>
</tr>
<tr>
<td>Oral Corticosteroids</td>
<td>Yes</td>
</tr>
<tr>
<td>BiPAP / CPAP</td>
<td>Yes</td>
</tr>
<tr>
<td>Atypical antipsychotics</td>
<td>Yes</td>
</tr>
<tr>
<td>Valproic acid</td>
<td>Yes</td>
</tr>
<tr>
<td>Other please specify:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

9.6.3 Comparison Participants’ Data Collection Form
STOMP Control - CRF

Patient ID: ________

Date of Birth: mm/dd/yyyy

Gender: ________

Date of visit: ________________

Reason for not attending STOMP: ________________________________

Enrolled in other lifestyle clinic: ________________________________

A. PATIENT HEALTH

Body Composition and Anthropometric Measurements

<table>
<thead>
<tr>
<th>Date</th>
<th>Measurement</th>
<th>Baseline</th>
<th>+ 6 months</th>
<th>+12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Height (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Weight (kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BMI percentiles</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(WHO BMI curve)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>WHO BMI z-scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Waist circumference (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood pressure (mmHg)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Biochemical Assays

<table>
<thead>
<tr>
<th>Date</th>
<th>Test</th>
<th>Baseline</th>
<th>Test</th>
<th>+6 months</th>
<th>+12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Chol (mmol/L)</td>
<td></td>
<td>Total Chol</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HDL (mmol/L)</td>
<td></td>
<td>HDL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LDL (mmol/L)</td>
<td></td>
<td>LDL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TG (mmol/L)</td>
<td></td>
<td>TG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

STOMP CRF Updated September 21, 2011
<table>
<thead>
<tr>
<th>Non-HDL (mmol/L)</th>
<th>Non-HDL</th>
<th>Non-HDL</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOMA-IR</td>
<td>HOMA-IR</td>
<td>HOMA-IR</td>
</tr>
<tr>
<td>Fasting BG</td>
<td>Fasting BG</td>
<td>Fasting BG</td>
</tr>
<tr>
<td>(mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin (pmol/L)</td>
<td>Insulin</td>
<td>Insulin</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>HbA1c</td>
<td>HbA1c</td>
</tr>
<tr>
<td>Glucose homeostasis* (normal or abnormal)</td>
<td>Glucose homeostasis* (normal or abnormal)</td>
<td>Glucose homeostasis* (normal or abnormal)</td>
</tr>
<tr>
<td>T2DM or IFT or IGT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Glucose Homeostasis* (normal/abnormal based on fasting BG, insulin, HbA1c)

**B. PARENT HEALTH**

Parents’ height and weight (weigh if present, by recall if not present)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measuremnt</td>
<td>Baseline</td>
<td>+ 6 months</td>
</tr>
<tr>
<td>Height (cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>By scale or recall</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Father</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measuremnt</td>
<td>Baseline</td>
<td>+ 6 months</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>By scale or recall</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

STOMP CRF Updated September 21, 2011