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Weight Regain Following Sleeve Gastrectomy

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ABSTRACT

Aim

To decrease weight regain following sleeve gastrectomy.

Methods

A mixed methods approach was used to address the study aim. All study populations were taken from Counties Manukau Health patients who had undergone sleeve gastrectomy. The following studies were conducted:

1. Systematic review of weight regain specifically following sleeve gastrectomy in relation to its definition, rate and aetiology
2. Retrospective review of the cohort of first sleeve gastrectomy patients to investigate the significance of weight regain
3. Focus group discussions with patients who had experienced weight regain following sleeve gastrectomy to understand the patients' perspective
4. Randomised controlled clinical trial of an intervention to reduce weight regain following sleeve gastrectomy developed using the knowledge gained from the previous studies.

Results

Systematic review identified several definitions for weight regain employed in the literature. Rates of reported regain ranged from 6% at two years to 76% at six years and varied according to the definition used. Five causes for weight regain following sleeve gastrectomy were identified. These were technical factors contributing to sleeve size, sleeve dilatation, ghrelin levels, follow-up support and maladaptive lifestyle behaviours.

Applying the range of identified definitions to the cohort of first sleeve gastrectomy patients demonstrated the significant effect non-standardised definitions have on reporting clinical outcomes. The rates of regain ranged from 9% to 91% when these different definitions were applied to this same group of patients.

Focus group discussions with almost 40 weight regain patients who had undergone sleeve gastrectomy at least two years prior also identified a lack of follow-up support, maladaptive eating and exercise behaviours as important factors contributing to weight regain. In addition, patients described non-traditional methods of increased support, such as text messaging, as appropriate delivery methods for follow-up care.

Based on these findings, a text message intervention was designed to reduce weight regain and implemented at the time of discharge from the bariatric service. Following one year of receiving a daily text message, patients tended to have less weight regain, though this did not reach statistical significance, and a significantly better Bariatric Analysis and Reporting Outcome System score than those randomised to standard care.

Conclusion

Weight regain following sleeve gastrectomy is an important and common, but not well understood, phenomenon. The lack of standardised reporting has significant effects not only on understanding weight regain but also on reporting patient outcomes. Despite this, both patients and clinicians have identified maladaptive behaviours and a lack of follow-up support as important contributors to weight regain. Targeting interventions to these factors appears to be promising for reducing weight regain and improving patient well-being.

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ABBREVIATIONS

ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
ASMBS	American Society for Metabolic and Bariatric Surgery
BAROS	Bariatric Analysis and Reporting Outcome System
BMI	Body mass index
BNS	Bariatric nurse specialist
BOBS	Better Outcomes after Bariatric Surgery
CMDHB	Counties Manukau District Health Board
CMH	Counties Manukau Health
COREQ	Consolidated criteria for reporting qualitative
DM	Diabetes mellitus
EBMIL	Excess body mass index loss
EW	Excess weight
EWL	Excess weight loss
FSA	First specialist assessment
GLP-1	Glucagon-like peptide-1
GORD	Gastro-oesophageal reflux disease
GP	General practitioners
HDL	High density lipoproteins
HR	Hazard ratio
HRQL	Health-related quality of life
LABS-2	The Longitudinal Assessment of Bariatric Surgery-2
LAGB	Laparoscopic adjustable gastric band
LSG	Laparoscopic sleeve gastrectomy
NCD(s)	Non-communicable diseases(s)
NR	Not reported
OSA	Obstructive sleep apnoea
PROM(s)	Patient-reported outcome measure(s)
QOL	Quality of life
REWL	Rebound in excess weight loss
RYGB	Roux-en-Y gastric bypass
SF-36	36-Item Short Form Health Survey
SG	Sleeve gastrectomy

SMS	Short message service
SOS	Swedish Obese Subjects
T2DM	Type 2 diabetes mellitus
TWL	Total weight loss
VBG	Vertical banded gastroplasty
WR	Weight regain

Chapter 1
INTRODUCTION

Obesity

Obesity is a major global health problem.⁽¹⁾ Obese individuals are more likely to suffer and die prematurely from cardiovascular disease, diabetes, respiratory disease and malignant conditions.⁽²⁾ In fact, these non-communicable diseases (NCDs) have become the leading cause of deaths globally, inciting many world leaders in 2011 to declare the need for a coordinated response to NCD prevention.^(3, 4) Despite this, the prevalence of obesity has continued to climb, with children and developing nations increasingly affected.⁽¹⁾ Currently, more people are dying from being overweight than underweight.⁽⁵⁾ Never has it been more important to address issues that can ameliorate morbid obesity.

Definitions

Obesity is defined as abnormal or excessive fat accumulation that may impair health.⁽⁵⁾ Clinically, it is defined as a body mass index (BMI) greater than 30kg/m².⁽⁵⁾ Further classifications of obesity can be reviewed in Table 1-1.

Table 1-1. Definitions of body weight disorders in adults by BMI.⁽⁶⁾

BMI (kg/m ²)	Classification
< 18 (♀) or < 19 (♂)	Underweight
18 – 25 (♀) or 19 – 25 (♂)	Normal weight
25 – 30	Overweight
> 30	Obesity
30 – 35	Class I obesity
35 – 40	Class II obesity
> 40	Class III obesity
40 – 50	Class IIIr obesity
50 – 60	Class IV obesity (super obese)
> 60	Class V obesity (super-super obese)

Notes. BMI, body mass index; kg/m², kilograms per metre-squared; ♀, women; ♂, men.

Epidemiology

Over recent decades, the prevalence of overweight and obesity has increased globally such that over two billion individuals are affected.⁽¹⁾ The prevalence of obesity is influenced by

age, gender, ethnicity, geography and social factors.^(1, 3, 5, 7) In New Zealand, 31% of adults are classified as obese with Māori (47%), Pacific people (66%) and/or those living in the most deprived areas more likely to be affected.⁽⁸⁾

Aetiology

The aetiology of obesity in simplistic terms results from an excess of calorie consumption (eating too much) when compared with energy expended (too little physical activity).^(6, 9, 10) Regulation of energy balance has evolved to protect against starvation by storing energy;^(6, 9) thus, an imbalance in the simple energy equation is easily achieved within the current obesogenic environment. Furthermore, any imbalance need only be slight, yet when sustained will have significant results.⁽⁹⁾

Unsurprisingly, it is not that simple. *'Obesity is a complex heterogeneous disease with numerous subtypes.'*⁽¹¹⁾ The simple energy equation is in fact significantly influenced by a variety of factors including an individual's gut-brain axis, genome, gut microbiota, medications, medical history, behaviours, socio-economic status and environment.^(9, 11-13) Thus, with no single common aetiological pathway, obesity remains a complex enigma to understand and treat.

Complications

Obesity has an array of significant medical complications (co-morbidities) associated with it, as illustrated in Table 1-2.⁽⁶⁾ The morbidity and mortality of these co-morbidities may be linearly or exponentially associated with increasing BMI.⁽⁶⁾ Furthermore, these very consequences of obesity may also exacerbate obesity, precipitating a vicious cycle.⁽⁶⁾

Table 1-2. Medical complications of obesity.⁽¹⁴⁾

Medical complications of obesity
Metabolic complications
<ul style="list-style-type: none">• Type two diabetes mellitus• Hypertriglyceridemia• Hypercholesterolemia• Hypertension• Gallstones• Fatty liver disease• Pancreatitis• Central sleep apnoea (obesity hypoventilation syndrome)• Platelet dysfunction (hypercoagulability)
Anatomic/structural complications
<ul style="list-style-type: none">• Obstructive sleep apnoea (OSA)• Gastro-oesophageal reflux disease (GORD)• GORD-associated asthma• Stress incontinence• Pseudotumour cerebri• Venous stasis• Stasis-associated cellulitis• Deep venous thrombosis• Pulmonary embolus• Fungal skin infections• Decubitus ulcers• Accidental injuries
Degenerative complications (following obesity over an extended time)
<ul style="list-style-type: none">• Atherosclerotic cardiovascular disease• Neurologic, ophthalmologic and renal diabetic complications• Heart failure• Joint disease• Vertebral disc disease• Non-alcoholic steatohepatitis-related cirrhosis
Neoplastic complications
<ul style="list-style-type: none">• Breast carcinoma• Ovarian carcinoma• Endometrial carcinoma• Prostate carcinoma• Colorectal carcinoma• Gallbladder carcinoma• Pancreatic adenocarcinoma• Oesophageal adenocarcinoma• Renal cell carcinoma
Psychological complications
<ul style="list-style-type: none">• Anxiety disorders• Depression• Binge eating disorder• Reactive bulimia

Obesity is also associated with increased surgical complications. Although the extent of this association with morbidity and mortality is debated in the literature, obesity certainly and significantly increases rates of surgical site infections.^(15, 16)

The cost of obesity

Obesity is unsustainably expensive to already resource-constrained health systems. In the United States of America (USA), the aggregate national cost of overweight and obesity in 2008 dollars was estimated at US\$114 billion with the incremental per-person cost of obese individuals calculated as US\$1,723 more than normal weight individuals.⁽¹⁷⁾ The direct medical costs of overweight and obesity combined is approximately 5% to 10% of USA health care expenditure.⁽¹⁷⁾

Obesity-related health care costs in New Zealand are also substantial and rank amongst the highest in the world.^(18, 19) Conservative yet well-calculated estimations for 2006 suggest that health care costs related to overweight and obesity were at least NZ\$624m or 4.4% of New Zealand's total health care expenditure.⁽¹⁹⁾ Costs associated with loss of productivity were estimated as at least NZ\$98m.⁽¹⁹⁾ The cost of major colorectal surgery has also been shown to be significantly more expensive in obese patients compared with normal weight patients, further suggesting any overall calculations of obesity-related health care costs are just the tip of the iceberg.⁽¹⁵⁾

Treatment

Obesity is a chronic disease that, while it may be preventable,^(20, 21) is not currently curable. Yet, treating obesity is associated with amelioration or resolution of its significant co-morbidities. Treatments for obesity range from lifestyle modifications, pharmaco-therapies, endoscopic procedures to major abdominal surgery; with the best results achieved with the

most invasive interventions. Generally, patients undergo a step-up approach to treating their obesity, depending on their BMI, and frequently multi-modal treatment is employed.⁽²²⁾

Bariatric Surgery

Definition

Although weight-loss procedures have been performed since the early 1950s, bariatric surgery as a surgical subspecialty is relatively new, established by the founding of various national bariatric societies in the 1980s.^(23, 24) The term 'bariatric' derives from Greek origins where 'baros' means weight. Bariatric denotes a branch of medicine dealing with causes, prevention and treatment of obesity.⁽²³⁾ As the indications and benefits of bariatric surgery extend beyond merely weight loss, it is also referred to as 'metabolic' surgery, where metabolic, also derived from Greek, pertains to a changing of form or state. Metabolic surgery is defined as '*the operative manipulation of a normal organ or organ system to achieve a biological result for a potential health gain*'.⁽²⁵⁾

Indication

In New Zealand, weight management guidelines for adults recommend bariatric surgery when all other treatment modalities have failed and patients have a BMI of 40kg/m² or 35kg/m² with other significant disease.⁽²²⁾ Examples of significant disease include type two diabetes (T2DM), sleep apnoea, hypertension and arthritis requiring joint replacement. These criteria are consistent with those from the American National Institute of Consensus Statement.⁽²⁶⁾

More recent guidelines have highlighted the need for bariatric surgery to be offered at a lower threshold to Asian individuals due to adverse health outcomes at lower BMIs.⁽²⁷⁾ The Interdisciplinary European Guidelines suggest considering reducing the BMI thresholds

suggested above by $2.5\text{kg}/\text{m}^2$ for individuals of Asian genetic background.⁽²⁸⁾ The IFSO-APC* Consensus Statements go further by recommending bariatric surgery be considered in acceptable Asian candidates with $\text{BMI} \geq 35\text{kg}/\text{m}^2$ with or without co-morbidities.⁽²⁹⁾ This is further reduced to a lower limit BMI of $27.5\text{kg}/\text{m}^2$ in the setting of inadequately controlled T2DM or metabolic syndrome.

Most recently and significantly, the 2nd Diabetes Surgery Summit was held to decide how to include bariatric surgery in consensus guidelines for the management of T2DM.⁽³⁰⁾ A multidisciplinary group of 48 international clinicians and academics representing leading clinical organisations agreed that metabolic surgery achieves excellent glycaemic control and reduction in cardiovascular risk factors. In addition to the above, their recommendations include considering surgery for individuals with a BMI as low as 30 when hyperglycaemia is inadequately controlled despite optimal medical treatment.

Procedures

Bariatric and metabolic surgery encompass a range of laparoscopic procedures for achieving significant weight loss and co-morbidity resolution. Several bariatric operations have become or are becoming obsolete due to unacceptable complication profiles in the long term.^(31, 32) In addition, a variety of newer procedures are gaining traction.^(33, 34) The three most commonly performed procedures with proven efficacy and safety profiles to remain in the mainstream bariatric surgeon's toolkit are the laparoscopic adjustable gastric band (LAGB), the laparoscopic sleeve gastrectomy (SG) and the laparoscopic Roux-en-Y gastric bypass (RYGB).^(35, 36) Presently, the bariatric procedure performed on a patient is often selected based on surgeon and institute experience and/or preference. It is hoped that with

* IFSO-APC refers to the International Federation for the Surgery of Obesity and Metabolic Disorders – Asian Pacific Chapter

increased understanding of the underlying mechanisms of bariatric procedures, both patient and procedure selection will be optimised.

Effectiveness

Large longitudinal studies have reported good long-term outcomes following bariatric surgery. The first of these, the Swedish Obese Subjects (SOS) study, compared 2,010 obese subjects who underwent bariatric surgery to 2,037 non-surgically treated obese subjects.⁽³⁷⁾ Mean changes in body weight after 10, 15 and 20 years were -17%, -16% and -18% in subjects who underwent bariatric surgery compared to 1%, -1% and -1% in the non-surgically treated subjects respectively. Bariatric surgery was also significantly associated with reduced overall mortality (hazard ratio (HR) = 0.71), decreased incidence of diabetes (HR = 0.17), myocardial infarction (HR = 0.71), stroke (HR = 0.66) and cancer in women (HR = 0.58). When considering these results, it is important to acknowledge the different eligibility criteria employed and that 70% of the procedures included the now obsolete vertical banded gastroplasty (VBG).

In a more contemporary study, the Utah Obesity Study, 418 obese subjects who sought and received RYGB were compared with 417 obese subjects who sought but did not receive RYGB and 321 randomly selected obese controls who were not seeking bariatric surgery.⁽³⁸⁾ Six years following surgery, patients who received RYGB lost 27.7% of their initial body weight compared with 0.2% and 0.0% in the respective control groups. Significant rates of diabetes remission and reduced cardiovascular risk were also achieved in obese subjects who underwent surgery.

The superiority of bariatric surgery to non-surgical management for obesity has also been substantiated by randomised trials. An extensive Cochrane review compared bariatric surgery with non-surgical weight loss management as well as comparing different bariatric procedures.⁽³⁹⁾ Seven randomised trials comparing surgical and non-surgical management

reported that surgical treatments for obesity were consistently superior for both weight loss and diabetes remission outcomes. Although RYGB is commonly touted as the gold standard procedure in bariatric surgery, Cochrane review of seven relevant trials found no overall significant benefit from RYGB compared with SG up to three years following surgery for both weight loss and co-morbidity outcomes.

Assessing effectiveness following bariatric surgery is incomplete without an assessment of patient-reported outcome measures (PROMs).⁽⁴⁰⁾ PROMs are essential to assess effectiveness as patients and clinicians often differ in their opinions regarding the most important outcome(s).⁽⁴¹⁾ The aforementioned SOS study demonstrated net gains in health-related quality of life (HRQL) at 10 years compared with baseline, using a battery of generic and condition-specific measures.⁽⁴²⁾ Furthermore, improvements and deteriorations in HRQL were associated with the magnitude of weight loss and regain. Statistically significant improvements in quality of life measures have also been corroborated by the Utah Obesity Study.⁽³⁸⁾ They reported statistically significant quality of life (QOL) improvements, as measured by the Lite Impact of Weight Quality of Life and physical component score of the 36-Item Short Form Health Survey (SF-36) in patients six years after RYGB, when compared with controls. Most recently, the Longitudinal Assessment of Bariatric Surgery-2 (LABS-2) has reported improved pain, physical function and walk time over three years in an observation cohort of 2,221 bariatric patients.⁽⁴³⁾ Together, the results of these large observational studies confirm significant improvement in PROMs following bariatric surgery.

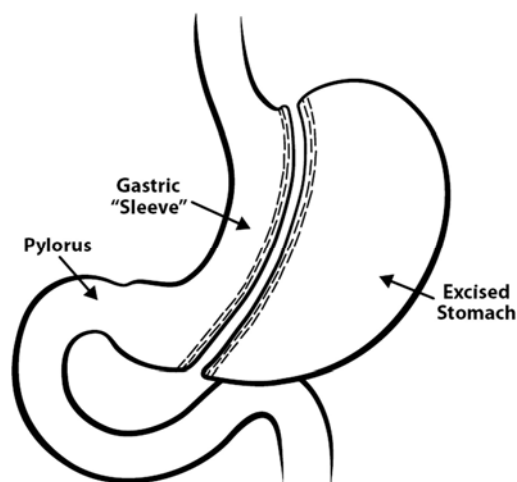
Sleeve Gastrectomy

Description

Sleeve gastrectomy is a vertical gastrectomy and involves removing most of the stomach to leave a tubular remnant, as illustrated in Figure 1-1. In the early 1990s, the technique was

referred to as a parietal gastrectomy, left a more capacious gastric remnant, was performed using an open approach and was developed as a modification to the biliopancreatic diversion with duodenal switch (BPD-DS).⁽⁴⁴⁾ From there, it became safe to perform laparoscopically, evolving into the first stage of a two-stage procedure for super obese patients and subsequently becoming recognised as an effective procedure in isolation.⁽⁴⁵⁻⁴⁷⁾ Since then, SG has become one of the most commonly performed bariatric procedures employed today.⁽³⁵⁾

Figure 1-1. Sleeve gastrectomy taken from Baker (2011).⁽⁴⁸⁾



Rationale for use

The rapid adoption of SG is attributable to its technical simplicity, lack of significant nutritional problems, absent risk of internal herniation and ongoing routine endoscopic access to the duodenum and biliary tree.^(35, 49) Furthermore, as no relatively inaccessible remnant stomach is left in-situ, it is a good choice for patients who would otherwise need ongoing gastric surveillance.⁽⁵⁰⁾ SG is also a strong choice for patients who live rurally, or who may be poorly compliant with follow-up, given the significantly reduced risks of internal herniation and significant nutritional deficiencies.

Technique

Sleeve gastrectomy is routinely performed using a laparoscopic approach with four to five incisions used to place instruments for liver retraction and working ports. The first step is to assess the oesophageal hiatus in the diaphragm to ensure the procedure can proceed. This involves excluding a large liver which obstructs the view of the potential surgical field and a hiatus hernia to ensure remnant fundus is not left behind. Once this is established, the greater omentum is resected from the greater curvature of the stomach using an energy device.⁽⁵¹⁾ A calibration bougie is passed trans-orally to lie against the lesser curve of the stomach. A stapling and cutting device is used to transect the stomach alongside the bougie to form the gastric sleeve.⁽⁵¹⁾ The omentum is variably reattached and the excised portion of stomach is removed from the intra-abdominal cavity.

The exact surgical technique varies depending on the surgeon, the institution and the patient. Common points of variation include size of the calibration bougie, where the antrum is divided in relation to the pylorus, management of the staple-line and how the omentum is reattached. These variations do not change the basic concept of creating a gastric tubular remnant but may influence the frequency of complications following SG.

Mechanism of action

The obvious mechanism for weight loss following SG is restriction. Normally, a human stomach can expand to encompass a capacity of between one to two litres.⁽⁵²⁾ Following SG, the gastric capacity is reduced to a volume no greater than 200ml, considerably restricting portion size and thus caloric intake.⁽⁵³⁾ This restrictive effect on caloric intake is further potentiated by a loss of hunger sensation as oxygenic ghrelin levels are markedly reduced given their primary source of production (gastric fundus) has been excised.⁽⁵⁴⁻⁵⁹⁾ Restriction

alone, however, does not account for all of the weight loss effects nor the more immediate metabolic effects.^(60, 61)

The ameliorating metabolic effects on glucose homeostasis following SG are similar to those occurring after RYGB, despite the markedly different anatomical aspects of the two procedures.⁽⁶²⁾ It is proposed that excising the majority of the stomach, together with changes in gastric emptying, may evoke changes in the neuro-hormonal axis of energy homeostasis.⁽⁶³⁾ Human studies following SG have demonstrated elevated levels of incretins[†] amongst other gut hormones which are thought to explain these metabolic effects.^(58, 62) Yet knock-out mice models of some of these same incretin receptors had similar weight loss and metabolic outcomes compared with wild-type controls.⁽⁶⁵⁾ This suggests a complicated and as yet incompletely understood mechanism for the improved glucose homeostasis following SG. Most recently, animal studies have suggested elevated serum bile acids and changes in the gut microbiome as mechanistic agents in the metabolic and weight loss outcomes of SG.⁽⁶⁶⁾ What is clear is that underlying signalling mechanisms for weight loss and energy homeostasis following bariatric surgery require further elucidation.

Efficacy

Sleeve gastrectomy is efficacious for weight loss and improving glycaemic control. The well-designed STAMPEDE randomised trial was powered to compare intensive medical therapy and SG with intensive medical therapy in 150 patients (mean BMI 36kg/m²) with poorly controlled T2DM, using a glycated haemoglobin level of 6.0% or less as the primary outcome at 12 months.⁽⁶⁷⁾ Glycated haemoglobin and weight loss were significantly ($p = 0.003$, $p < 0.001$) better in the SG group ($6.6 \pm 1.0\%$, $-25.1 \pm 8.5\text{kg}$) than the intensive medical

[†] Incretins are hormones that decrease blood glucose concentrations by increasing insulin production and release.⁽⁶⁴⁾

therapy group ($7.5 \pm 1.8\%$, $-5.5 \pm 8.0\text{kg}$). This study had a third arm for patients undergoing RYGB with intensive medical therapy. When these patients were compared to SG patients, there were no significant differences in changes from baseline for glycosylated haemoglobin, high-density lipoprotein cholesterol or triglycerides. A significant difference in degree of weight loss was reported however, with RYGB achieving a change in weight of $-29.4 \pm 8.9\text{kg}$ compared with $-25.1 \pm 8.5\text{kg}$ following SG ($p = 0.02$). Although not powered for three- and five-year outcomes, these have been reported.^(68, 69) At five years, weight loss and glycosylated haemoglobin levels were significantly better ($p = 0.003$, $p = 0.003$) in patients who had a SG ($-18.6 \pm 7.5\text{kg}$, $-2.1 \pm 2.3\%$) than intensive medical therapy alone ($-5.3 \pm 10.8\text{kg}$, $-0.3 \pm 2.0\%$). Although no significant difference between procedures for glycosylated haemoglobin at five years, patients who had a RYGB achieved better weight loss than those who had a SG ($-23.2 \pm 9.6\text{kg}$, $-18.6 \pm 7.5\text{kg}$, $p = 0.01$). Although this suggests durability for both weight loss and glycaemic control with SG, both parameters were slightly less improved than at the three-year time point ($-21.1 \pm 8.9\text{kg}$, $-2.5 \pm 2.1\%$).

Longer-term outcomes following SG are only just becoming available. A systematic review of weight loss results reported on 492 patients with at least five years of follow-up.⁽⁷⁰⁾ Seventy-one percent of patients were women, had a mean age of 45 years and a pre-operative BMI of $49\text{kg}/\text{m}^2$. The mean percent of excess weight loss (%EWL) was 62.3, 53.8, 43.0 and 54.8 at five, six, seven and eight or more years respectively. While these figures support SG as a durable procedure, they are limited by the poor quality of the included studies, high attrition (31.2%) and having data on only small numbers of patients available at seven (13 patients) and eight years (34 patients). Seven of 16 studies included in this review also provided data about obesity-related co-morbidities. Improvement and/or resolution was reported in 72.4% of hypertensives, 61.5% of patients with hyperlipidaemia,

87% of patients with OSA and 70.9% of diabetics. These figures must be interpreted cautiously as again numbers are small and it is not clear how these figures were obtained from the heterogenous studies they originated from.

Complications

Bariatric surgery is safe and SG is no exception.^(71, 72) The most serious complications following SG occur in the early post-operative period and are related to a problem occurring at the staple-line. If an early issue is avoided, the risk of significant morbidity or mortality from later complications is extremely low. This is in contrast to RYGB procedures where there remains ongoing risk beyond the peri-operative period due to the possibilities of stomal ulcers complicated by bleeding, intestinal obstruction and more severe nutritional deficits.⁽⁷³⁾

Leak

Staple-line leak is the most feared complication of SG because of the subsequent morbidity and mortality.⁽⁷⁴⁾ On average, 1.5% of SG procedures will be complicated by a leak.⁽⁷⁴⁻⁷⁶⁾ A variety of factors that may be associated with leak include: surgeon or centre experience, bougie size, staple-line management, revision surgery, operation time, intra-operative mishap and distal obstruction.^(74, 76, 77) The majority of leaks occur in close proximity to the gastro-oesophageal junction, which makes them difficult to manage.⁽⁷⁴⁾ Treatment varies depending on the time of presentation, the location of the leak and the patient's clinical condition.^(74, 76) General principles include resuscitation, drainage of sepsis and ensuring adequate nutrition.⁽⁷⁴⁻⁷⁶⁾ Therapeutic interventions range from intra-venous antibiotics, endoscopic therapies, percutaneous drainage to laparoscopic and/or open reoperations.⁽⁷⁴⁻⁷⁷⁾ They are rarely able to be repaired primarily and often result in prolonged and costly hospital admissions both economically and presumably also for the patient's QOL.⁽⁷⁷⁾

Haemorrhage

Clinically significant haemorrhage is thought to occur in less than 2% of SG cases.^(75, 76)

Classically, the bleeding originates from the staple-line or from the short gastric vessels which are at risk when the omentum is dissected from the greater curve. In the stable patient, blood transfusion may suffice but significant bleeding usually requires surgical exploration and management.

Stricture/stenosis

The terms 'stricture' and 'stenosis' appear to be employed interchangeably in the literature.

A survey of experienced SG surgeons suggests the stricture/stenosis rate is approximately 1% of cases, though may be as high as 8%.^(75, 78) Stricture/stenosis can be an early or late complication and ranges from being considered as a minor, successfully treated with endoscopic dilatation, to a major complication such that revision surgery may be required.^{(79,}

⁸⁰⁾ Almost 90% of strictures occur at the incisura angularis in the distal stomach.⁽⁸¹⁾ Small bougie size, staple-line angulation and dividing the stomach too close to the incisura are all thought to be contributory factors.^(78, 80)

Gastro-oesophageal reflux disease (GORD)

The effect of SG on GORD continues to be controversial.⁽⁸²⁾ Obesity is an independent risk factor for GORD which will often improve following weight loss induced by SG.^(83, 84) On the other hand, there are significant cases of de novo or exacerbated GORD following SG.^(63, 85, 86) Systematic reviews have repeatedly failed to draw a definite conclusion due to heterogeneity of studies with paradoxical outcomes.^(82, 86) The current standard of care is for patients with significant pre-operative GORD to undergo a RYGB procedure in preference to SG.⁽⁸⁷⁾ For those with intractable reflux post SG, RYGB is generally the revision procedure of choice.⁽⁸⁷⁾

Nutritional deficiencies

Sleeve gastrectomy is considered lower risk for developing significant nutritional deficiencies compared to several other bariatric procedures as there is no bypass component. Despite this, recommended nutrition supplementation and follow-up are similar to patients who have undergone RYGB.^(75, 88) Even though SG patients have no bypass component to their procedure, they are theoretically still at risk of nutritional deficiencies due to pre-operative malnutrition, post-operatively reduced nutrient intake, and reduced production of hydrochloric acid and intrinsic factor.⁽⁸⁹⁾ Furthermore, SG patients, like RYGB patients, are at risk of metabolic bone disease; a phenomenon increasingly recognised but uncommonly discussed.⁽⁹⁰⁾

While sub-clinical nutritional deficiencies are not uncommonly reported, clinically significant nutritional deficiencies following SG are rare.^(49, 91) The most serious of these relate to B group vitamin deficiencies with, usually reversible, neurological sequelae.⁽⁹²⁻⁹⁴⁾ Less clinically impressive deficiencies in iron and zinc have also been reported, but the literature concerning such deficiencies is conflicting and limited by its quality.⁽⁹⁵⁻⁹⁷⁾ Recent, larger and longer-term studies which include the nutritional status pre-operatively and following SG suggest that when micronutrient deficiencies do exist, these are generally not significantly worse than the pre-operative values.^(49, 98-100) Importantly, the vast majority of nutritional deficiencies are preventable provided dietary advice, nutrition supplementation and appropriate follow-up regimes are complied with.

Local Situation

Counties Manukau Health

Counties Manukau Health (CMH) is one of 20 publicly funded district health boards in New Zealand. Located in South Auckland, it serves a population of over half a million people.⁽¹⁰¹⁾

This population is unique in New Zealand for its ethnic diversity, youth and social deprivation.⁽¹⁰¹⁾ Despite this, CMH continues to perform well for caring for its population and meeting government health targets.⁽¹⁰¹⁾

Counties Manukau Health Bariatric Service

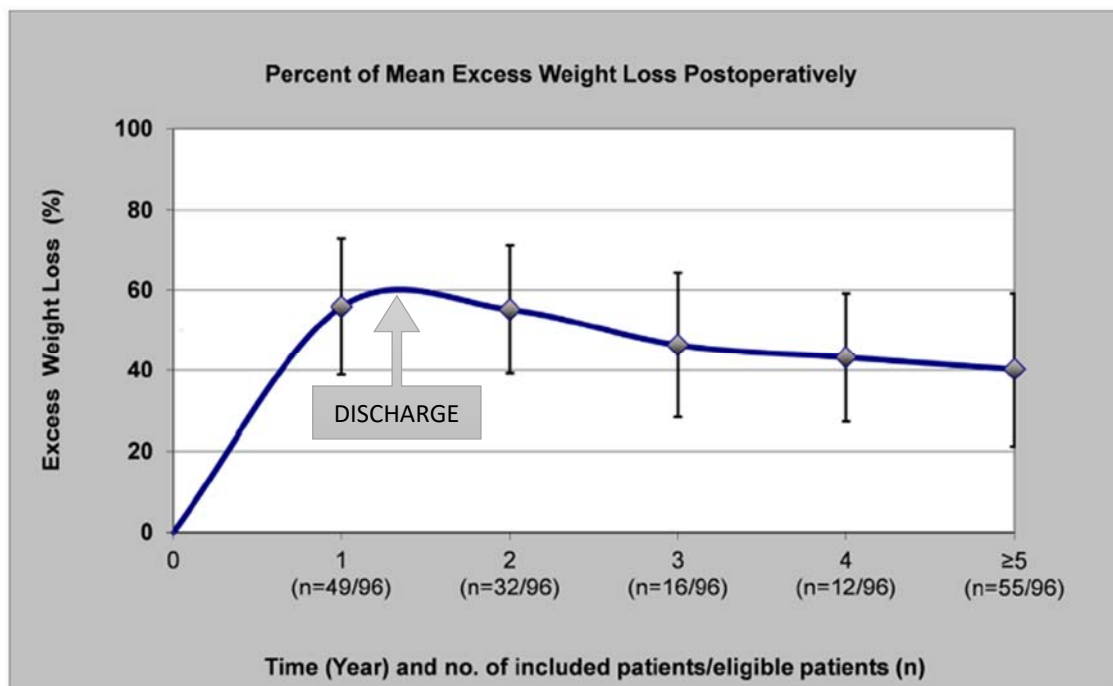
CMH bariatric service was established in 2007. The initial team consisted of a sole bariatric surgeon, part-time dietician and part-time bariatric nurse specialist (BNS). Today the team consists of five general surgeons specialising in bariatric surgery, several part-time dieticians and a part-time BNS. Each year, approximately 150 bariatric cases are undertaken, of which the vast majority are SGs.

The CMH bariatric pathway is similar to that of other centres nationally and abroad. Patients are referred to the service by general practitioners (GPs) or other hospital specialists. Referred patients must then attend a one-hour information session facilitated by a bariatric surgeon. This session educates patients about obesity together with the potential risks and benefits of bariatric surgery. Patients who would like to proceed with surgery are subsequently assessed by the bariatric team and a pre-operative weight loss goal is set. Patients are supported by the dieticians and BNS to achieve this goal. Once achieved, patients are booked for surgery following three to four weeks of a very low calorie diet. The surgery is undertaken in the context of enhanced recovery after surgery principles.⁽¹⁰²⁾ Patients are discharged after a median length of stay of one day.⁽¹⁰²⁾ The follow-up regime is with the BNS at 2 weeks, then at 3, 6, 9, 12 and 18 months; and with the dieticians at 3 weeks, then at 3, 6 and 12 months. Patients are generally discharged 18 months following SG.

Early long-term results from CMH bariatric service suggest SG outcomes are comparable with other centres.^(103, 104) Almost 60% of the first 96 patients were followed up at five years post-operatively.⁽¹⁰³⁾ Their pre-operative BMI was 51kg/m² with maximal weight loss of

approximately 60%EWL (Figure 1-2) at 18 months which decreased to 40%EWL at five years post-operatively, suggesting significant weight regain in the longer-term.⁽¹⁰³⁾ Interestingly, the onset of the weight regain appeared to coincide with the time patients were discharged from the bariatric service. Himpens et al (2010) have also noticed the onset of weight regain occurring at the time patients were discharged from follow-up care.⁽¹⁰⁵⁾ In their series of 53 patients who underwent SG, 76% of patients were reported as having regained weight at six years post-operatively. The definition used to calculate this regain rate, however, was not reported.

Figure 1-2. Mean percentage of excess weight loss modified from Lemanu et al (2015).⁽¹⁰³⁾



Weight Regain

Background

Weight regain following bariatric surgery is a well-recognised phenomenon from long-term outcome reporting. In the prospective SOS study, which included over 2,000 patients undergoing bariatric surgery, weight regain began in the second year then tended to level off after eight to 10 years through to 20 years.⁽³⁷⁾ The applicability of these results to

contemporary bariatric practice must be interpreted with the knowledge that the majority of the study population underwent the now obsolete VBG. Furthermore, the attrition after 10 years of follow-up was significant.

More relevant to current practice is the Utah-based prospective study that compared long-term weight loss in the severely obese undergoing RYGB with those who had no surgery.⁽³⁸⁾ In this study, an excellent follow-up rate of 93% of the original 418 surgical patients was obtained. Their results demonstrated a 7% (95% CI 5% – 10%) increase in mean unadjusted weight loss from year two to six following surgery. Thus, it appears that weight regain following bariatric surgery is a phenomenon common to all procedure types. Recent work, however, suggests that the proportion of patients who regain weight following SG may be higher than after RYGB.^(105, 106)

Weight regain and obesity-related co-morbidities

The significance of weight regain following bariatric surgery is unclear. Even in the presence of the weight regain outlined above, bariatric surgical recipients still overall reap the benefits of reduced incidence of diabetes, cardiovascular disease and overall mortality as well as significant rates of diabetes remission.^(37, 38) Yet when the relationship between weight regain and co-morbidities is further explored, important trends emerge. Brethauer et al (2013) reported on a Cleveland Clinic cohort of 162 diabetic patients who had undergone RYGB on average five years previously, with remission rates of 71% and 61% in the short and long term respectively.⁽¹⁰⁷⁾ They further demonstrated that diabetes recurrence following partial or complete remission was associated with an increase in BMI of 5kg/m² or more, following the weight loss nadir (OR 13, 95% CI 1 – 99).

Weight regain and quality of life

The SOS study employed a battery of generic and condition-specific QOL measures to assess HRQL at regular intervals over 10 years following bariatric surgery.⁽⁴²⁾ The pattern of change in HRQL largely followed that of weight change over the same period, particularly in mental well-being domains. That is, a gradual reduction in HRQL was associated with the slow weight regain occurring between one and six years post-operatively. Importantly, however, and similar to the metabolic effects, overall HRQL net gains were noted in all domains at 10 years, when compared to baseline.

The cost of weight regain

Bariatric surgery is a cost-effective approach to the treatment of obesity, particularly in diabetic patients.^(108, 109) How weight regain affects these estimated cost benefits is less clear and has previously not been incorporated into economic analyses. Sheppard et al (2013) attempted to elucidate the direct costs of weight regain by systematic review.⁽¹¹⁰⁾ Their efforts were hampered by a lack of adequate reporting with respect to regain rates, cost of revision procedures and relevant Canadian literature. They concluded that economic analyses to date have not incorporated the financial impact of assessing and managing weight regain, which is likely to have a significant effect on the cost-effectiveness of bariatric surgery as a treatment for obesity. Certainly, simulation modelling has confirmed that weight regain is likely to significantly affect cost-effectiveness.⁽¹¹¹⁾

Aetiology of weight regain

A systematic review of weight regain following bariatric surgery identified a multitude of factors contributing to weight regain.⁽¹¹²⁾ Patient-related factors identified included hormonal/ metabolic causes, dietary non-compliance, mental health issues and physical inactivity. Surgery-related factors were dependent on the procedure performed. For LAGB,

this included pouch distension and band removal. For RYGB, stoma dilatation, pouch dilation and gastro-gastric fistulae were identified. Only sleeve dilatation was highlighted for SG. A lack of follow-up support itself was not definitively identified as a causative mechanism. The review, however, was limited by the available evidence and its associated quality.

Summary

Weight regain following bariatric surgery is a well-recognised complication. It appears to have important consequences with respect to diabetes, HRQL and health economics. The aetiology of weight regain seems to be composed of many factors which are both patient- and procedure-dependent. SG has been identified as having high rates of weight regain but there is a limited literature base, given the relative newness of the procedure.

Aim of thesis

Obesity continues to be a significant burden on our population. The most effective treatment for obesity is bariatric surgery with SG being a safe and effective option. Yet SG is not a perfectly understood procedure and recent work suggests a significant proportion of patients experience weight regain.⁽¹⁰⁶⁾ Local data from CMH bariatric service and work from other centres suggest that the onset of weight regain may be associated with the time patients are discharged from the bariatric service.⁽¹⁰⁵⁾ This thesis focuses on:

1. Understanding how weight regain is described in the literature.
2. Understanding why patients regain weight following SG.
3. Exploring the relationship between weight regain and follow-up care.
4. Consolidating the above points to design then evaluate an intervention to reduce weight regain and improve outcomes following SG.

Chapter 2

**SYSTEMATIC REVIEW OF WEIGHT
REGAIN FOLLOWING SLEEVE
GASTRECTOMY**

Introduction

Weight regain, also referred to as secondary weight gain or recidivism, is a complication of bariatric surgery evidenced by a gradual decline in percentage of weight change observed in longitudinal studies.^(38, 113) It is associated with the recurrence of obesity-related co-morbidities including T2DM, deterioration in HRQL and is likely to have a significant economic burden.^(42, 107, 110, 114)

Sleeve gastrectomy has become one of the most commonly performed bariatric procedures and has become so without a large knowledge base of long-term outcomes. Recent systematic review of longer-term series suggest weight loss following SG is durable with sustained loss of over 50% of excess weight after five years.⁽⁷⁰⁾ Now that long-term data are being reported, it is evident that weight regain following SG is significant.^(49, 103, 105, 115, 116) Yet the defining, reporting and understanding of this phenomenon remains largely neglected.

With an increasing number of SGs performed, the significant issue of weight regain is becoming more prevalent. Consensus statements and reporting guidelines seldom mention this phenomenon and the true incidence of weight regain, and what constitutes significance, is not well defined.^(75, 79, 117) Accordingly, this chapter presents a systematic review to determine the current definitions of weight regain employed in the literature, as well as the rate and cause of weight regain specifically following SG.

Methods

This systematic review was performed according to the PRISMA statement where applicable.⁽¹¹⁸⁾

Search strategy

A series of electronic searches was conducted in MEDLINE, Embase, PubMed and the Cochrane Library in November 2015. The strategies combined search terms for SG and weight regain (Table 2-1). There were no limits for study design or language. Results were filtered for human-only studies and limited to 2007 onwards. Search results were downloaded and managed with Endnote X7.4 citation management software (Thomson Reuters, USA). The bibliographies of full-text papers were also reviewed to identify further references for possible inclusion.

Table 2-1. Search strategy used in Ovid MEDLINE®In-Process & Other Non-Indexed Citations. Strategy was modified as needed to use with other databases.

Sleeve gastrectomy	Weight regain
1. sleeve gastrectomy.mp	1. weight regain.mp
2. vertical gastrectomy.mp	2. exp Weight Gain
3. gastrectomy.mp	3. weight recidivism
4. exp Gastrectomy	
5. Bariatric surgery.mp	
6. exp Bariatric Surgery	

Notes. Terms for 'sleeve gastrectomy' and 'weight regain' combined.

Search limited to human studies published from 2007 onwards.

For MeSH terms, all subheadings were selected.

exp, exploded MeSH term; mp, key word.

Study selection

Abstracts were screened and full-text papers obtained to identify primary research studies reporting definitions, rates and causes of weight regain following SG. Papers were excluded if no definition, rate or proposed mechanism of weight regain was reported. Other exclusion criteria were papers reporting exclusively non-primary SG, follow-up of less than two years, and papers not reporting primary research (e.g., review papers).

Abstracts were initially screened for inclusion by two researchers independently. Screening of full text articles was also performed independently by two researchers. Any uncertainties about inclusion were discussed with the project supervisors.

Data extraction

Data extraction for weight regain definition, rate and cause was performed independently by two researchers using pre-designed electronic tables. Once all data were extracted, the researchers conferred to minimise errors.

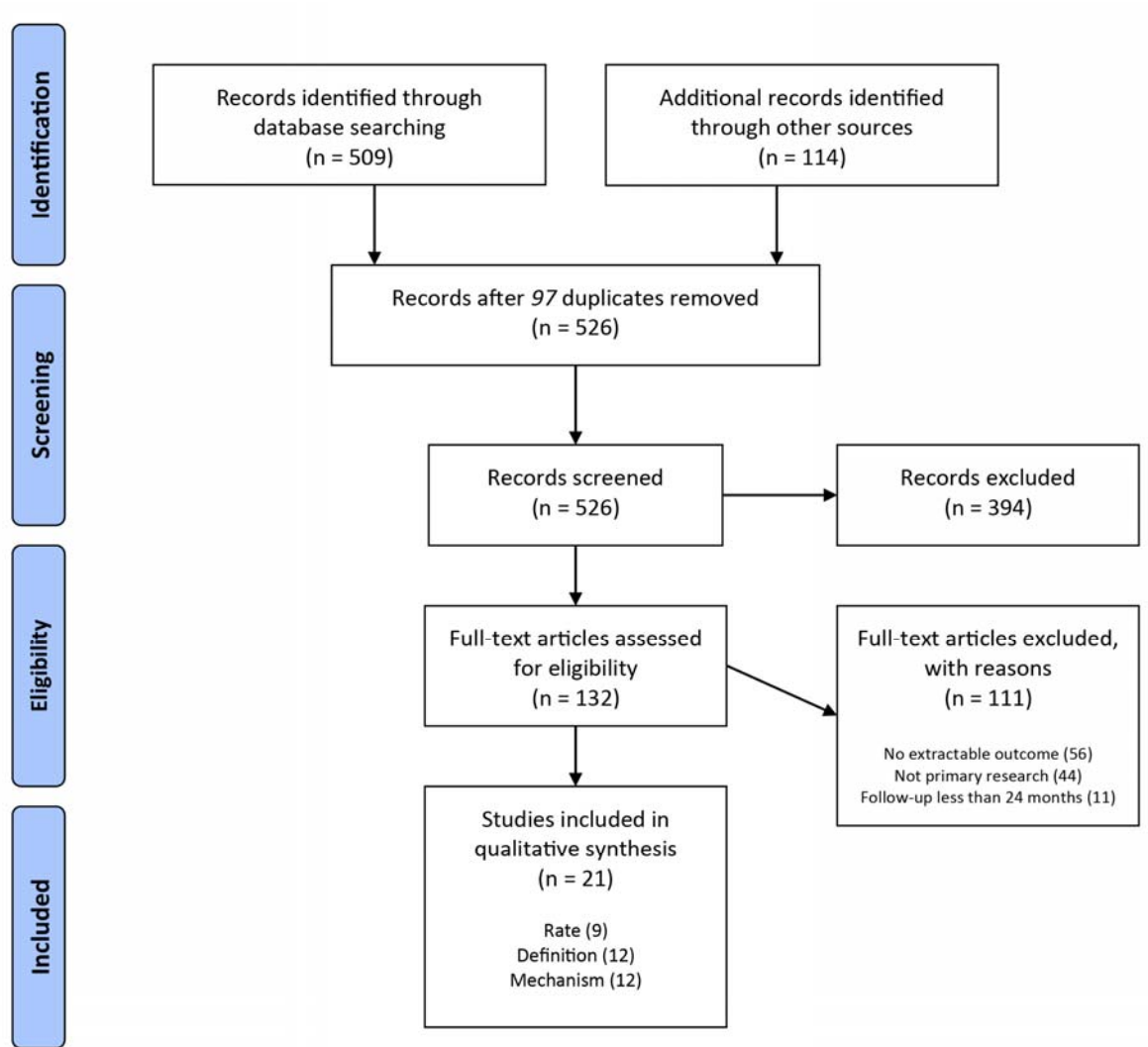
Data analysis

Due to both the nature of the data extracted and the heterogeneity of included studies, the results are presented as a narrative review. Significant variations in the study cohorts, operative details and definition of weight regain employed meant calculation of standardised mean differences would not be meaningful. As such, where data are quantitative, they are presented in a tabulated form.

Results

After abstract screening, the review yielded 132 full text papers, of which 21 met the inclusion criteria (Figure 2-1). Of these 21 papers, 12 reported a weight regain definition, nine reported the rate of weight regain in a clinical series and 12 proposed mechanisms that may be responsible for weight regain following SG.

Figure 2-1. PRISMA flow diagram demonstrating study selection.



Definition of weight regain

Twelve papers from 10 research groups were identified that specifically defined weight regain following SG. These are reported in Table 2-2.

Table 2-2. Reported definitions of weight regain employed in the literature for sleeve gastrectomy series with at least two years of follow-up.

Origin of definition (Author, year, country ^{ref})	Definition
Abdallah et al, 2014, Egypt ⁽¹¹⁹⁾	An increase of body weight of more than 10kg from the nadir
Bohdjalian et al, 2010, Austria ⁽¹²⁰⁾	An increase of body weight of more than 10kg from the nadir
Braghetto et al, 2012, Chile ⁽¹²¹⁾	Greater than 10kg
Brethauer et al, 2013, United States ⁽¹⁰⁷⁾	An increase in BMI of 5kg/m ² or more above the weight loss nadir
Carmeli et al, 2015, Israel ⁽¹²²⁾	Regaining weight after successful loss to achieve a BMI greater than 35kg/m ²
Casella et al, 2015, Italy ⁽¹²³⁾	Weight increase greater than 10kg from weight loss nadir
de Hollanda et al, 2015, Spain ⁽¹²⁴⁾	The difference between weight at last follow-up and nadir weight expressed in kilograms or as percent of maximum weight loss
Homan et al, 2015, Netherlands ⁽¹²⁵⁾	Greater than 25%EWL regain with respect to the minimal weight after LSG, or when a patient met the criteria for bariatric surgery again as established by the International Federation for the Surgery of Obesity
Jimenez et al, 2012, Spain ⁽¹¹⁴⁾	Any weight regain after T2DM remission to last follow-up
Langer et al, 2010, Austria ⁽¹²⁶⁾	An increase of body weight of more than 10kg from the nadir
Liu et al, 2015, Hong Kong ⁽¹²⁷⁾	When the percentage of rebound in excess weight loss (%REWL) is greater than 25% where %REWL is the difference between the best post-operative %EWL and the current measured %EWL
Obeidat et al, 2015, Jordan ⁽¹²⁸⁾	An increase in body weight of more than 10kg from the nadir

Rates of weight regain

Nine papers were identified that reported weight regain rates for SG series, of which six reported the definition used to calculate these rates. Table 2-3 presents the rates of weight regain and demonstrates that included studies were small, with significant heterogeneity and attrition rates. It can be seen that not all studies reported the definition used to calculate weight regain and that the majority of studies presented results from the short- to medium-term.

Table 2-3. Weight regain rates reported in the literature for sleeve gastrectomy series with at least two years of follow-up.

Author ^{ref} Country Year	Number of patients	Patient cohort	Mean pre- operative BMI kg/m ² (n)	Bougie size <i>French</i>	Antral division from pylorus <i>cm</i>	Follow-up period years	Follow-up schedule	Mean post- operative BMI kg/m ² (n)	Mean %EWL % (n)	Regain rate % (n)	Definition used
Abdallah et al ⁽¹¹⁹⁾ Egypt 2014	105	Morbidly obese patients aged between 18-60 years	51.7 (105)	38	2 or 6	2	2 weeks then 3, 6, 12 and 24 months	NR	66.5 (105)	5.7% (6)	More than 10kg from nadir
Nocca et al ⁽¹²⁹⁾ France 2008	163	BMI > 40 with high-volume eating disorder BMI > 35 high-volume eating disorder and severe co-morbidities BMI > 50 Sweet-eating disorders were a contra-indication	45.9 (163)	36	Where the calibration tube makes contact with the greater curve	2	1,6,12, 18 and 24 months	31.6 (98)	61.5 (98)	10.2% (10)	NR
Obeidat et al ⁽¹²⁸⁾ Jordan 2015	125	Patients selected according to the 1991 NIH guidelines with all patients having a BMI of > 40 or > 35 with a major co-morbidity	46.1 (110)	38	2 or 6	2	1 week then 1, 3, 6, 12 and 24 months	NR	73.2 (110)	12.7 (14)	An increase in body weight of more than 10kg from the nadir
Braghetto et al ⁽¹³⁰⁾ Chile 2009	15	NR	39.7 (15)	32	2-3	2-3	NR	NR	NR	20.0% (3)	NR
Bohdjalian et al ⁽¹²⁰⁾ Austria 2010	26	NR	48.2 (26)	48	Division described as starting opposite the nerve of Latarjet ⁽¹³¹⁾	5	3, 6, 9, 12, 18, 24 months then annually	NR	55.0 (22) ^a	19.2% (5)	More than 10kg from nadir

Author ^{ref} Country Year	Number of patients	Patient cohort	Mean pre- operative BMI kg/m ² (n)	Bougie size <i>French</i>	Antral division from pylorus cm	Follow-up period years	Follow-up schedule	Mean post- operative BMI kg/m ² (n)	Mean %EWL % (n)	Regain rate % (n)	Definition used
Liu et al ⁽¹²⁷⁾ Hong Kong 2015	140	Asia-Pacific Bariatric Surgery Group consensus guidelines 2005 initially then the International Federation for the Surgery of Obesity and Metabolic Disorders – Asia Pacific Chapter consensus statement. BMI > 35 or > 30 with inadequately controlled T2DM or metabolic syndrome	41.0 (140)	58.6% with a bougie less than 40 and 41.4% with a bougie above 40	6	5	1, 6, 12, 18, 24 months then annually	33.7 (52)	57.2 (52)	29.5% (NR)	Rebound in excess weight loss greater than 25%
Braghetto et al ⁽¹²¹⁾ Chile 2012	560	NR	38.4 (560)	32 or 40 ⁽⁵¹⁾	2-3 ⁽⁵¹⁾	5+	NR	29.9 (60)	57.3 (60)	39.5% (NR)	Greater than 10kg
Himpens et al ⁽¹⁰⁵⁾ Belgium 2010	53	Patients selected according to 1991 NIH guidelines and were volume eaters but not diabetics nor subject to significant reflux disease	39.5 (41)	34	6	6	On a regular basis until 3 years	31.1 (30) ^b 30.1 (41)	53.3 (30) ^b 57.3 (41)	75.6% (31)^c	NR
Casella et al ⁽¹²³⁾ Italy 2016	182 ^d	NR	45.9 (182)	48	4-6	6	3, 6, 9, 12, 18 and 24 months then annually	30.2 (148) ^e	67.3 (148)	26.3% (39)^f	Weight increase greater than 10kg from weight loss nadir

Notes. BMI, body mass index; %EWL, percent of excess weight loss; NR, not reported.

^a Excludes the four patients converted to RYGB – three for weight regain, one for reflux.

^b Excludes the 11 patients who had a duodenal switch between three and six years but includes two re-sleeve procedures.

^c Of the 53 consecutive patients, 12 patients were unable to be followed up.

^d In eight of these cases the sleeve was a revision procedure (six following gastric banding and two following VBG).

^e 32 patients excluded for not attending follow-up and a further four excluded as they underwent biliopancreatic diversion with duodenal switch for insufficient weight loss within 18 months.

^f Amount of weight regained was between 11-20kg for 27 patients, 21-30kg for nine patients and > 30kg for three patients.

Causes of weight regain following sleeve gastrectomy

Twelve papers proposed a cause for weight regain following SG based on their findings. They are summarised in Table 2-4.

Table 2-4. Proposed mechanisms for weight regain following sleeve gastrectomy.

Proposed mechanism for weight regain following SG
Technical factors contributing to initial sleeve size
Bougie size ^(132, 133)
Leaving fundal remnant ⁽¹⁰⁵⁾
Size of antral remnant ^(119, 128, 133)
Sleeve dilatation ^(121, 130)
Ghrelin levels ⁽¹²⁰⁾
Follow-up support ^(105, 115, 134)
Lifestyle behaviours ^(135, 136)

Initial sleeve size/technical factors

Weiner et al (2007) were among the first to perform the SG as a single stage procedure in super obese patients.⁽¹³²⁾ They initially formed gastric sleeves with no calibration, aiming to resect two-thirds of the stomach to leave a residual volume of 150 – 200ml. This was succeeded by sleeve calibration using a 44 French (Fr) and later a 32 Fr bougie. Both sleeve volume and the capacity of the excised stomach were measured. They reported that a removed gastric volume of less than 500cc appeared to be a predictor of treatment failure or early weight regain, though the latter was not defined. This was not a randomised trial, though the baseline demographics of each group were similar, and the weight regain rate was not clear.

Himpens et al (2010) introduced the concept of a ‘neofundus’ caused by leaving too much fundus at the time of operation to avoid fistulas. They gave examples of two cases of weight regain in a series of 53 who benefited from a re-sleeve to correct an oversized fundus demonstrated by a barium upper gastro-intestinal series.⁽¹⁰⁵⁾ In a subsequent publication,

Weiner et al (2011) reported on more than 900 SGs and had changed to 42 Fr bougie, as the 32 Fr was associated with an increase in staple-line leaks.⁽¹³³⁾ They described performing 88 secondary procedures for insufficient weight loss (< 50%EWL) and weight regain (not defined) in which more than 50% had anatomically incorrect sleeves. In their discussion, they further described that approximately 50% of primary treatment failure (poor weight loss from the beginning) is due to a technical issue such as an incompletely resected fundus. In cases with successful weight loss complicated by weight regain, they observed a dilated antrum acting as a new reservoir within two to four years when the stomach was divided 4-6cm from the pylorus.

Two recent papers have reported that creating a larger antral remnant at the time of SG is associated with higher rates of weight regain.^(119, 128) Abdallah et al (2014) performed a randomised trial comparing 52 patients with a remnant antrum of two centimetres and 53 patients with a remnant antrum of six centimetres. At 24 months following SG, only one patient (1.9%) with a two-centimetre remnant antrum had regained weight (defined as at least 10kg from nadir weight) compared with five patients (9.4%) with six-centimetre antral remnants. Although this difference did not reach statistical significance ($p = 0.09$), the findings have been corroborated. Obeidat et al (2015) performed a retrospective review of prospectively collected data of 125 consecutive patients who underwent SG.⁽¹²⁸⁾ Of the 110 patients with available data, 54 had the antrum divided six centimetres from the pylorus and 56 patients at two centimetres. At two years following surgery, 12 patients (22%) with a six-centimetre remnant antrum had regained weight (again defined as at least 10kg from nadir weight) compared with only two patients (4%) with a two-centimetre antral remnant ($p = 0.003$).

Sleeve dilatation

Braghetto et al (2009) demonstrated a doubling in gastric sleeve size two to three years post-operatively.⁽¹³⁰⁾ Their capacity calculations should be reliable given that two different techniques for measuring gastric capacity achieved similar results. While they postulate that this increase in sleeve size may be a cause of weight regain, this did not correlate with patient outcome in this small series with follow-up at two years. Similarly, when these same patients were followed up at five years, only 17/108 (15.7%) patients demonstrated weight regain which was associated with more than quadrupling of the sleeve capacity.⁽¹²¹⁾

Ghrelin levels

Bohdjalian et al (2010) demonstrated halving of pre-operative ghrelin levels that persisted up to five years post-operatively in a small series of 12 patients of whom three had regained at least 10kg from the nadir weight.⁽¹²⁰⁾ They observed slightly higher plasma ghrelin levels in patients with weight regain throughout the observation period but this was not statistically significant due to high variability and small patient numbers.

Follow-up support

Sarela et al (2012) proposed that the lifelong follow-up provided by the National Health Service in the United Kingdom is responsible for less weight regain in the long term.⁽¹¹⁵⁾ They reported on a series of 20 patients with a median pre-operative BMI of 45.8kg/m² who underwent SG with a 32 Fr bougie. There was a median EWL of 68% at eight or nine years in the 16 patients they were able to follow up, which included three patients who went on to have a duodenal switch or bypass. They attributed their excellent result for %EWL in the long term to the comprehensive support care pathway, which involved continuous dietary support, patient-support group meetings and standard follow-up visits to the outpatient

clinic every three months for the first year, every six months for the second year and annually thereafter.

In their series, Himpens et al (2010) noticed that weight regain coincided with discharge from follow-up at three years.⁽¹⁰⁵⁾ Exactly what their regular office visits entailed prior to discharge was not described. Their EWL results in a series of 53 patients, with an initial BMI of 39.5kg/m² who underwent SG with a 34 Fr bougie, were less impressive at 57.3% at six years, compared to Sarela et al (2012). These results included an attrition rate of 23% (similar to Sarela et al) and 11 cases that were converted to a duodenal switch and a further two re-sleeve procedures.

Lombardo et al (2015) performed the only study that specifically aimed to investigate whether or not more frequent follow-up visits prevent weight regain.⁽¹³⁴⁾ In their series of 71 patients, that included 43 patients who had undergone SG with a baseline BMI of 49.8kg/m², they compared a group of patients who had follow-up visits at 9, 12, 15, 18, 24, 30 and 36 months with a group that had follow-up at only 12, 18, 24 and 36 months. They concluded that more follow-up visits may help reduce weight regain based on significant differences between the groups for change in body weight, change in BMI and change in %EWL. However, no definition or rate of weight regain were reported in this retrospective, non-randomised study.

Lifestyle behaviours

In a retrospective analysis of prospectively collected data, Kehagias et al (2013) reported a series of 208 patients with an initial BMI of 34.3kg/m² who underwent SG as a sole procedure with a 32 Fr bougie to have a 78% EWL at two years but only 58% at five years.⁽¹³⁵⁾ Patients attended outpatient clinics at one, three, six and 12 months post-operatively then annually thereafter. There was an attrition rate of 22% in the 27 patients who were five years post-

procedure. Regardless, this gradual decline in %EWL was attributed to maladaptive eating and lack of exercise based on data obtained from annual dietary questionnaires.

Keren et al (2014) corroborated these findings when they reported a series of 115 patients with an initial BMI of 44.1kg/m² who underwent SG calibrated with a 39 Fr bougie.⁽¹³⁶⁾ The post-operative support provided to patients was described as '24/7' – in web forums, internet support groups, telephone and mail support and regular clinic visits. Five patients were excluded as they went on to biliopancreatic diversion, with the remainder showing a gradual decrease in EWL from 66.5% at two years to 45.3% at five years. They developed a lifestyle modification score based on two questions from the BAROS and found that it correlated well with sufficient weight loss (%EWL > 50) at five years.^(137, 138) Specifically, over 80% of patients with sufficient weight loss had a lifestyle modification score of ≥ 0.5 compared with none of the patients with insufficient weight loss.

Discussion

This systematic review brings together relevant literature pertaining to the increasingly recognised issue of weight regain following SG and highlights the lack of standardised clinical terms, understanding and reporting in this area. This review is an important first step in properly defining this issue.

Several different definitions have been employed in the literature to define weight regain following SG. The most common of these, an increase of at least 10kg from nadir weight, does little to define the significance of the amount of weight regained in the affected individual. For example, a 10kg weight gain is far more significant in a 60kg person than a 100kg person. Nor does it allow for comparability between individuals or research studies.

As such, a measure allowing more comparability, such as a BMI, percent of total weight loss (TWL) or percent of EWL, may be more clinically meaningful and useful.

While conducting this review, it became apparent that the phenomenon of weight regain, insufficient weight loss and SG failure are often confusingly combined as indications for revision procedures following SG.^(133, 139, 140) Weight regain is a medium- to late-term complication occurring after the weight loss nadir. Insufficient weight loss may be identified in the shorter-term and is often defined as never achieving more than 50%EWL.⁽¹⁴¹⁾ Finally, procedure failure is variably defined and interpreted.⁽¹⁴²⁾ Importantly, weight regain and insufficient weight loss are likely to have different causative mechanisms and thus management may differ.^(133, 143)

Weight regain following a variety of bariatric procedures is well recognised but poorly reported.^(112, 117) Rates of regain specifically following SG are reported in nine heterogeneous studies as 5.7% at two years to 75.6% at six years.^(105, 119-121, 123, 127-130) Nothing further can be extrapolated from these data as studies were small, consisted of different populations, had different (if any) definitions for weight regain, and reported rates in a variable manner. The number of studies that even attempted to report a regain rate is small compared to the number of published clinical series. This is unsurprising given the lack of prominence this subject has in the literature and expert statements.

Liu et al (2015) have been the only group to report weight regain rates yearly alongside other outcome data.⁽¹²⁷⁾ When they employed their definition of weight regain (an increase in %EWL of 25), they had regain rates of 0%, 1.0%, 11.6%, 19.2% and 29.5% at one, two, three, four and five years post-operatively respectively. This clearly demonstrates the increasing

susceptibility to weight regain experienced by patients as time from surgery increases, a trend also illustrated in Table 2-3.

A systematic review of weight regain following any bariatric surgery identified five principal aetiologies: nutritional non-compliance, hormonal/metabolic imbalance, mental health, physical inactivity and anatomical/surgical factors.⁽¹¹²⁾ The current review of weight regain, specifically following SG in patients at least two years post-surgery, similarly identified initial sleeve size, sleeve dilatation, increased ghrelin levels, inadequate follow-up support and maladaptive lifestyle behaviours as proposed mechanisms contributing to weight regain in the sleeve patient.

Sleeve anatomy is commonly proposed as a mechanism for weight regain following SG.^(121, 130, 140, 144) It is difficult to understand how an initially 'large' sleeve, or primary dilation,^(140, 145) is a cause of weight regain, rather than insufficient weight loss. The answer may lie in the fact that this often results from an incompletely excised fundus, the most distensible part of the stomach, which may then increasingly distend and release larger amounts of ghrelin.⁽¹⁴⁶⁾ It does seem logical, however, that progressive sleeve dilatation, or secondary dilatation,^(140, 145) would contribute to weight regain. Deguines et al (2013) have demonstrated a correlation between residual gastric volume and SG success as defined by %EWL > 50%, BAROS > 3, BMI < 35kg/m², and/or the Biron criteria.⁽¹⁴⁷⁾ Yet to date, the association between sleeve dilatation and weight regain has not been convincing.^(121, 123, 130, 131)

Reduced ghrelin levels following SG reduce appetite and contribute to the restrictive effect in promoting weight loss.⁽⁵⁸⁾ Most previous work in this area has been in the short term, but Bohdjalian et al (2010) demonstrated that ghrelin levels remained diminished up to five years post-operatively.^(55, 56, 120) Furthermore, they observed slightly higher ghrelin levels in

patients who regained weight, though this was not significant due to the small number of patients. This is an important finding that needs further investigation.

Five-year outcomes following SG at CMH were recently reported and demonstrated a trend towards weight regain commencing at 18 months, which coincided with discharge from the bariatric service.⁽¹⁰³⁾ Himpens et al (2010) noticed the same phenomenon at three years and Sarela et al (2012) attribute their superior %EWL results at eight years to lifelong support.^(105, 115) This is consistent with previous work that reported a significantly improved %EWL in patients who were 100% compliant with clinic follow-up, compared to those who were not, at 30 months.⁽¹⁴⁸⁾ However, when those same patients were followed up at five years, they found significant weight gain despite ongoing annual follow-up visits.⁽¹³⁶⁾ This suggests a more complex interaction between weight regain and follow-up requiring further investigation and highlights the need for clinical series to adequately report the follow-up provided to their patients.

Two papers were identified that specifically attributed weight regain to behaviours related to diet and/or exercise.^(135, 136) Work investigating weight regain following RYGB report similar associations.^(149, 150) Following SG, compliance to appropriate diet may be hindered by faster gastric emptying and the onset of an increased hunger sensation and craving for sweets at three years.^(57, 60) While there are no sleeve-specific factors affecting exercise adherence, the recognised barriers include motivation, health-related problems and time constraints.⁽¹⁵¹⁾ Screening tools to assess and manage behavioural risk in bariatric patients may prove beneficial in reducing weight regain rates if the tools themselves are shown to be effective.⁽¹⁵²⁾

Conclusion

Weight regain is a common phenomenon following SG. It is variably defined, described and reported in the literature. The bariatric literature would benefit from standardising the definitions used to report weight regain and its rate in clinical series. Authors should also be encouraged to refrain from grouping together patients with insufficient weight loss, procedure failure and weight regain. Larger prospective studies are required to further understand the underlying mechanisms of weight regain following SG. These studies will need to adequately report operative technique (bougie size and size of remnant antrum), residual sleeve size, ghrelin levels, post-operative follow-up care and assess patient behaviours in a longitudinal manner.

Chapter 3

**THE IMPACT OF NON-
STANDARDISED REPORTING FOR
UNDERSTANDING WEIGHT
REGAIN**

Introduction

The previous chapter demonstrated that a variety of definitions are employed in the literature to describe weight regain following SG. Comprehensive systematic review revealed only 12 papers from 10 research groups, amongst a plethora of SG series, reported the definition used to describe weight regain (Table 2-2, Chapter 2). In these 12 instances where a definition was described, there were six significantly different definitions in use.

The lack of – and need for – a uniform definition for weight regain has recently been highlighted in the literature.⁽¹⁵³⁾ The implications of non-standardised reporting are far-reaching. For example, if researchers published rates of diabetes based on their preferred glycated haemoglobin cut-off value, rather than the standardised value approved by expert consensus groups, studies in different populations or investigating different treatments would not be able to be compared. The same is true for weight regain, and perhaps more significantly so. Not only is the underlying aetiology of weight regain less well understood than that of diabetes, patients with weight regain are often grouped with those identified as having insufficient weight loss or procedure failure – further terms lacking standardised definitions and thus limiting the interpretation of published research to better understand weight regain following bariatric surgery.

The aims of the current chapter are to illustrate how the lack of a standard definition significantly alters reported SG outcomes and to contribute to the discussion of how weight regain should be defined.

Methods

Definitions for weight regain reported in the literature (Table 3-1) and identified in Chapter 2 were applied to a previously reported retrospective cohort of patients who had undergone

SG five years prior (2007 – 2013).⁽¹⁰³⁾ The extended use of this cohort was approved by The University of Auckland Human Participants Ethics Committee (reference number 9061) and by the CMH Research Office (registration number 1433).

Table 3-1. Definitions of weight regain following sleeve gastrectomy reported by systematic review (Chapter 2). Number in brackets refers to the number of times the definitions were employed in the literature when referring to sleeve gastrectomy outcomes.

Definition	
I.	An increase of more than 10kg from nadir (6)
II.	An increase of more than 25%EWL from nadir (2)
III.	An increase in BMI of 5kg/m ² from nadir (1)
IV.	Any weight regain after T2DM remission (1)
V.	Weight regain to a BMI > 35kg/m ² after successful loss (1)
VI.	Any weight regain (1)

Notes. kg, kilograms; %EWL, percent excess weight loss; BMI, body mass index; m, metres; T2DM, type two diabetes mellitus

The retrospective cohort was conducted at CMH between June and August 2013. All patients who had had a SG at least five years prior were eligible. Patients who were unable to be contacted by telephone, despite numerous attempts at contact, were excluded. For those who were contactable and agreeable, an appointment was made to collect follow-up data. Data were collected by postal questionnaire when patients were unable to travel. Baseline pre-operative characteristics were extracted from electronic patient records. Baseline weight was that taken on the day of surgery. Subsequent yearly weight data were also extracted from electronic records. A current weight was measured at the follow-up appointment using an electronic scale. Pre-operative co-morbidity data were similarly extracted from electronic records. At the follow-up appointment, patients were asked to classify their current treatment status for relevant co-morbidities as one of the four following categories: (1) no longer on treatment, (2) reduced treatment, (3) same treatment, or (4) increased treatment. This treatment status was then confirmed using electronic records and contacting the patient’s primary care physician. Finally, assessment of surgical outcome was

assessed by participants answering yes or no as to whether they considered their surgery successful, as well as being scored on the BAROS.^(137, 138) The BAROS score is a validated composite outcome measure compiled from a weight loss measure (%EWL or %EBMIL), assessment of obesity-related co-morbidity improvement, evaluation of QOL and complication assessment.

The data set was expanded to include variables relating specifically to weight regain as identified in Chapter 2. Newly extracted variables included: distance from the pylorus of antral division, number of follow-up appointments attended, lowest (nadir) post-operative weight and the date nadir weight was measured from the clinical records. Additional variables were calculated in accordance with recently published reporting guidelines.⁽⁷⁹⁾ These included percent of TWL and percent of excess body mass index loss (%EBMIL) for the nadir weight and five-year time points. Once the expansion of the database was complete, the various definitions of weight regain were applied to it. IBM SPSS Statistics for Macintosh (Version 23.0, Armonk, NY: IBM Corp) and SAS software for Windows Version 9.4 of the SAS System for Windows (Copyright © [2002 – 2012] SAS Institute Inc., Cary, NC, USA) were used to derive descriptive statistics. Multiple logistic regression was used to assess the effect of potential confounders (age, gender, ethnicity, pre-operative BMI, bougie size and number of follow-up appointments) on these definitions. The effect of remaining antrum size was not explored as all patients had the antrum divided between two and four centimetres proximal to the pylorus.

After assessing the distribution of continuous variables, analysis of covariance (ANCOVA) was used to explore the relationship between weight regain definitions and the continuous outcome of the BAROS score.⁽¹³⁷⁾ Logistic regression was used to explore the relationship

between the definitions and the dichotomous outcome of whether patients considered their surgery successful.

Finally, the relationships between weight change and surgical outcomes were explored separately from the definitions employed in the literature. This was performed by analysing the relationship between various measures of weight change and surgical outcomes using ANCOVA for continuous variables or logistic regression for binary variables. Weight change measures refer to the change in weight from the nadir to five-year time point expressed as change in BMI, change in %TWL, change in %EBMIL and change in %EWL. Surgical outcomes explored were the BAROS score and the dichotomous outcome of whether patients considered their surgery successful.

Covariates for all analyses included age, gender, ethnicity and pre-operative BMI. Residual plots and studentised residuals were used to diagnose ANCOVA and logistic regression respectively.

Results

Ninety-six patients underwent SG between March 2007 and July 2008. Of these, 55 patients had follow-up data and were included in the current study. Of those who were not included, 10 declined to participate, 28 were not contactable and three had died.⁽¹⁰³⁾ The demographic, peri-operative, pre-operative, lowest achieved (nadir) weight time point and five-year follow-up characteristics of the cohort are presented in Table 3-2. With the additional weight outcome data points, the timing of the nadir weight was found to be closer to 12 months than 18 months.

The proportion of patients with weight regain ranged from 9% to 91% depending on the definition used (Table 3-3). Definitions I to III appeared to be the most clinically meaningful and statistical investigation was limited to these three definitions to minimise the number of

statistical tests performed. When only these three definitions were considered, the range of the proportion of patients who had regained weight ranged from 40% to 64%. Potential confounders of age, gender, ethnicity, pre-operative BMI, bougie size and number of follow-up appointments had no significant effect on the classification of weight regain (Table 3-4).

Table 3-2. The demographic pre-operative, peri-operative, nadir weight and five-year follow-up characteristics of the cohort.

Characteristic (n = 55)	Mean (SD) unless otherwise stated		
Age, years	49.9 (9.0)		
Female gender, n (%)	45 (81.8)		
Ethnicity, n (%)			
European	37 (67.3)		
Māori	10 (18.2)		
Pacific	6 (10.9)		
Other	2 (3.6)		
Bougie size, n (%)			
34 Fr	20 (36)		
38 Fr	13 (24)		
39 Fr	22 (40)		
Antral division from pylorus, cm	2 – 4		
Number of follow-up appointments, median (IQR)			
Surgeon	2 (0,3)		
Nurse specialist	2 (1,4)		
Dietician	1 (1,2)		
Other	0 (0,1)		
<u>Outcome measure</u>	<u>Pre-operative value</u>	<u>Nadir weight value</u> <u>11.7 (6.2) months</u> <u>after surgery</u>	<u>Five-year value</u>
Weight, kg	141.3 (21.0)	96.0 (17.0)	110.5 (20.3)
BMI, kg/m ²	50.7 (6.3)	34.5 (6.1)	39.8 (7.2)
Excess weight, kg	77.2 (18.2)	32.0 (15.9)	46.5 (19.3)
%EBMIL, %	-	64.9 (17.5)	43.7 (21.3)
%EWL, %	-	59.7 (15.7)	40.2 (19.2)
%TWL, %	-	32.0 (7.8)	21.6 (10.1)
HbA _{1c} , mmol/mol ^a	46.5 (10.8)	-	39.8 (7.4)
Total cholesterol/HDL ratio ^b	3.9 (1.2)	-	3.5 (0.8)

Notes. n, number; SD, standard deviation; %, percent; Fr, French; IQR, interquartile range; kg, kilograms; BMI, body mass index; m, metres; %EBMIL, percent excess BMI loss; %EWL, percent excess weight loss; %TWL, percent total weight loss; HbA_{1c}, serum hemoglobin A_{1c}; mmol/mol, millimole per mole; HDL, high density lipoproteins.

^a Pre-operative and five-year HbA_{1c} data were available for 31 and 44 participants respectively.

^b Pre-operative and five-year total cholesterol/HDL ratio data were available for 51 and 41 participants respectively.

Table 3-3. Proportion of 55 patients with and without weight regain applied using the varying definitions of weight regain following sleeve gastrectomy in the literature.

Definition	Patients with weight regain, n (%)	Patients without weight regain, n (%)
I. An increase of more than 10kg from nadir	35 (64)	20 (36)
II. An increase of more than 25%EWL from nadir	22 (40)	33 (60)
III. An increase in BMI of 5kg/m ² from nadir	29 (53)	26 (47)
IV. Any weight regain after T2DM remission	5 (9)	50 (91)
V. Weight regain to a BMI > 35kg/m ² after successful loss	11 (20)	44 (80)
VI. Any weight regain	50 (91)	5 (9)

Notes. n, number of patients; %, percent; kg, kilograms; %EWL, percent excess weight loss; BMI, body mass index; m, metres; T2DM, type two diabetes mellitus.

Table 3-4. Multiple logistic regression exploring the effect of potential confounders (age, gender, ethnicity, pre-operative BMI, bougie size and number of follow-up appointments) for when patients are classified as having weight regain based on the definitions of weight regain following sleeve gastrectomy employed in the literature.

Confounders	Definition I (> 10kg)		Definition II (> 25%EWL)		Definition III (> 5kg/m ²)	
	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value
Age	1.04 (0.97-1.11)	0.33	1.02 (0.96-1.09)	0.50	1.03 (0.96-1.10)	0.45
Gender, female vs male	1.11 (0.20-6.24)	0.90	0.79 (0.16-4.01)	0.78	0.49 (0.09-2.56)	0.40
Ethnicity, European/Other vs Māori/PI ^a	0.74 (0.17-3.18)	0.69	0.66 (0.17-2.65)	0.56	0.44 (0.10-1.83)	0.26
Pre-operative BMI	1.00 (0.91-1.10)	0.99	1.03 (0.94-1.14)	0.51	0.99 (0.91-1.09)	0.89
Bougie size						
38 vs 34 Fr	1.56 (0.34-7.16)	0.67	0.63 (0.14-2.73)	0.71	1.12 (0.26-4.82)	0.91
39 vs 34 Fr	1.36 (0.35-5.29)	0.89	0.65 (0.17-2.42)	0.74	1.08 (0.30-3.90)	0.98
Number of follow-up appointments	1.12 (0.91-1.39)	0.28	0.91 (0.76-1.09)	0.28	1.11 (0.92-1.35)	0.26

Notes. BMI, body mass index; >, greater than; kg, kilograms; %EWL, percent excess weight loss; m, metres; CI, confidence interval; vs, versus; PI, Pacific Islander; Fr, French
^a Due to small numbers for certain ethnic groups, these were re-categorised by combining New Zealand European with Other and Māori with Pacific Islanders for the regression analysis.

The BAROS score was normally distributed. ANCOVA demonstrated that when patients had weight regain as defined by definition I (> 10kg), II (> 25%EWL) or III (> 5kg/m²), they had lower BAROS scores and were less likely to feel that their surgery was successful (Table 3-5). These reached statistical significance in all but one case (definition I and patient opinion of success). Where findings were significant, it should be noted that standard errors and confidence intervals were large.

All change in weight measures were significantly related to the BAROS score and patient opinion regarding success of surgery such that the larger the weight regain, the lower the BAROS score and likelihood that the patient felt their surgery was successful (Table 3-6). Again, standard errors and confidence intervals were relatively large.

Table 3-5. Results demonstrating weight regain definitions for the continuous outcome BAROS score using ANCOVA. Results are also demonstrated for weight regain definitions and whether or not patients deemed their surgery successful using multiple logistic regression. Covariates included age, gender, ethnicity and pre-operative BMI in all models.

	BAROS score			Patient opinion of success		
	Coefficient (SE)	p value	Adjusted R squared	Odds ratio (95% CI)	p value	Cox & Snell R squared
Definition I (> 10kg)	-2.68 (0.72)	0.001	0.26	0.31 (0.07–1.37)	0.12	0.09
Age	-0.03 (0.04)	0.48		1.01 (0.93–1.10)	0.77	
Gender, female vs male	-1.89 (0.92)	0.046		1.68 (0.26–10.89)	0.59	
Ethnicity, European/Other vs Māori/PI ^a	-0.88 (0.83)	0.30		0.32 (0.05–2.04)	0.23	
Pre-operative BMI	-0.07 (0.06)	0.26		1.00 (0.89–1.12)	0.98	
Definition II (> 25%EWL)	-2.73 (0.69)	< 0.001	0.28	0.16 (0.04–0.65)	0.01	0.17
Age	-0.02 (0.04)	0.68		1.01 (0.93–1.10)	0.74	
Gender, female vs male	-1.72 (0.90)	0.06		2.02 (0.29–14.27)	0.48	
Ethnicity, European/Other vs Māori/PI ^a	-0.93 (0.81)	0.26		0.23 (0.03–1.97)	0.18	
Pre-operative BMI	-0.09 (0.06)	0.14		0.98 (0.87–1.11)	0.75	
Definition III (> 5kg/m²)	-2.78 (0.67)	< 0.001	0.30	0.23 (0.06–0.98)	0.047	0.12
Age	-0.02 (0.04)	0.66		1.02 (0.94–1.11)	0.66	
Gender, female vs male	-1.4 (0.89)	0.13		2.37 (0.34–16.35)	0.38	
Ethnicity, European/Other vs Māori/PI ^a	-1.25 (0.81)	0.13		0.24 (0.03–1.70)	0.15	
Pre-operative BMI	-0.06 (0.06)	0.27		1.01 (0.90–1.13)	0.92	

Notes. ANCOVA, analysis of covariance; BAROS, Bariatric Analysis and Reporting Outcome System; SE, standard error; CI, confidence interval; >, greater than; kg, kilogram; vs, versus; PI, Pacific Islander; BMI, body mass index; %EWL, percent excess weight loss; m, metres.

^a Due to small numbers for certain ethnic groups, these were re-categorised by combining New Zealand European with Other and Māori with Pacific Islanders for the regression analysis.

Table 3-6. Results demonstrating change in weight measures for the continuous outcome BAROS score using ANCOVA. Results are also demonstrated for change in weight measures and whether or not patients deemed their surgery successful using multiple logistic regression. Covariates included age, gender, ethnicity and pre-operative BMI in all models.

	BAROS score			Patient opinion of success ^a		
	Coefficient (SE)	p value	Adjusted R squared	Odds ratio (95% CI)	p value	Cox & Snell R squared
ΔBMI	-0.37 (0.08)	< 0.001	0.37	0.79 (0.64–0.96)	0.02	0.18
Age	-0.04 (0.04)	0.32		1.03 (0.95–1.13)	0.48	
Gender, female vs male	-1.67 (0.85)	0.06		2.60 (0.35–19.3)	0.35	
Ethnicity, European/Other vs Māori/PI ^b	-0.94 (0.76)	0.23		0.27 (0.03–2.10)	0.21	
Pre-operative BMI	-0.04 (0.05)	0.48		1.03 (0.91–1.18)	0.61	
Δ%TWL	-0.19 (0.04)	< 0.001	0.38	0.89 (0.80–0.98)	0.02	0.18
Age	-0.03 (0.04)	0.38		1.04 (0.95–1.13)	0.45	
Gender, female vs male	-1.77 (0.84)	0.037		2.47 (0.34–18.2)	0.38	
Ethnicity, European/Other vs Māori/PI ^b	-0.84 (0.76)	0.27		0.28 (0.04–2.19)	0.23	
Pre-operative BMI	-0.08 (0.05)	0.14		1.00 (0.88–1.13)	0.99	
Δ%EBMIL	-0.09 (0.02)	< 0.001	0.38	0.94 (0.90–0.99)	0.02	0.18
Age	-0.03 (0.04)	0.48		1.04 (0.95–1.13)	0.41	
Gender, female vs male	-1.80 (0.84)	0.037		2.46 (0.33–18.1)	0.38	
Ethnicity, European/Other vs Māori/PI ^b	-0.78 (0.75)	0.31		0.28 (0.04–2.2)	0.23	
Pre-operative BMI	-0.12 (0.05)	0.03		0.97 (0.85–1.10)	0.60	
Δ%EWL	-0.10 (0.02)	< 0.001	0.38	0.94 (0.86–0.99)	0.02	0.18
Age	-0.03 (0.04)	0.48		1.04 (0.95–1.13)	0.41	
Gender, female vs male	-1.82 (0.84)	0.036		2.4 (0.33–17.7)	0.39	
Ethnicity, European/Other vs Māori/PI ^b	-0.80 (0.76)	0.30		0.28 (0.04–2.2)	0.23	
Pre-operative BMI	-0.11 (0.05)	0.04		0.97 (0.86–1.10)	0.66	

Notes. BAROS, Bariatric Analysis and Reporting Outcome System; ANCOVA, analysis of covariance; BMI, body mass index; SE, standard error; %, percent; CI, confidence interval; vs, versus; ΔBMI, change in body mass index; PI, Pacific Islander; BMI, body mass index; Δ%TWL, change in percent total weight loss; Δ%EBMIL, change in percent excess body mass index loss, Δ%EWL change in percent excess weight loss where change in weight refers to the difference between nadir value and five-year value.

^a For patient opinion of success, one outlying case was excluded from the analysis due to a high studentised residual.

^b Due to small numbers for certain ethnic groups, these were re-categorised by combining New Zealand European with Other and Māori with Pacific Islanders for the regression analysis.

Discussion

Applying the variety of weight regain definitions employed in the bariatric literature to the same cohort of patients' results demonstrated that a wide range of weight regain rates may be obtained. Exploration of the relationships between definitions and weight changes with clinical outcomes implied that weight regain is inversely associated with the BAROS score and patient opinion about success of surgery.

This study illustrates the importance of standardised reporting of weight regain in the bariatric literature. It clearly demonstrates how the use of different definitions applied to the same population significantly alters the proportion of patients categorised as regaining weight. This is a significant finding and highlights how imperative it is that standardised reporting of weight regain in bariatric series be addressed by expert groups.

Outcome reporting for weight loss has long been scrutinised and many of the arguments are applicable to the weight regain definition. Clinicians have tended to quantify outcomes for various procedures in terms of %EWL. Yet the various ways of calculating %EWL have demonstrated significant variability and even erroneous results.^(154, 155) Montero et al (2011) demonstrated the %EWL for the same cohort ranged from 65% to 82% depending on which calculation method was employed.⁽¹⁵⁵⁾ The recent publication of guidelines for standardised reporting should help to address this variability.⁽⁷⁹⁾ Even so, there is also an inherent lack of clinical meaningfulness in %EWL. For example, the absolute clinical benefits of the often-used cut-off point of 50%EWL is unknown as it depends on the absolute weights and weight change. In contrast, it is known that every kilogram of weight loss results in a 16% risk reduction in progression to diabetes, while a 3% to 5% reduction in weight improves triglycerides and confers significant benefits for blood pressure and cholesterol levels.^(156, 157) Thus, perhaps the use of %TWL is a more meaningful outcome measure for weight change

outcomes. This has previously been demonstrated and current standardised reporting guidelines support this.^(79, 141) A weight regain definition should be similarly meaningful rather than employing the arbitrary values of 10 kilograms or a change in EWL of 25%.

The BMI measure continues to be widely used despite awareness of its limitations. It is incorporated in many of the weight loss outcome measures recommended for reporting by the American Society for Metabolic and Bariatric Surgery (ASMBS) and the academic journal *Surgery for Obesity and Related Diseases*.⁽⁷⁹⁾ Its clear advantage is that by incorporating the height of an individual in its calculation, it allows for increased comparability. When %EBMIL is considered, the formula for its calculation provides less variability than that of the historical formula for %EWL (though the most recently recommended formula produces the same result as for %EBMIL).⁽⁷⁹⁾ Similar to %EWL however, the clinical meaningfulness of a change in %EBMIL is not clear. While there is evidence to support an increase in mortality of 30% with an increase in BMI of five, similar clinical statements cannot be made for changes in the relative measure.⁽²⁾ Again, this highlights the importance of including more robust measures for outcome reporting and suggests that, of all the weight regain definitions currently employed in the literature, an increase in BMI of five may be the most clinically meaningful and comparable.

The current study has also reiterated the importance of PROMs. Being categorised as having regained weight, by definition or by an increase in a variety of weight change outcome measures, was significantly associated with the BAROS score (which incorporates the Moorehead-Ardelt Quality of Life Questionnaire) and patient opinion regarding the success of surgery.⁽¹³⁷⁾ This is consistent with previous work that describes deterioration in QOL associated with weight regain.⁽⁴²⁾ Such PROMs are important to include in any outcome assessment as often outcomes important to patients are different from those important to

clinicians.⁽⁴¹⁾ It may be, then, that a comprehensive weight regain definition should include such a measure.

The decision to proceed with analyses of only three definitions deserves justification. As alluded to in the results section, the statistical reason was to minimise the number of statistical tests performed on a small data set to reduce the likelihood of finding a significant result due to chance. The explanation for classifying an increase in weight of more than 10kg, more than 25%EWL and more than 5kg/m² as the most clinically meaningful definitions was multifactorial. The excluded definition of weight regain relating to any weight regain after T2DM remission applies only to patients who had diabetes prior to SG which subsequently resolved, and thus excludes a significant proportion of not only this study's cohort but also those of most SG cohorts. The excluded definition relating to weight regain above a BMI of 35kg/m² after successful loss is a static measure and such measures have already been demonstrated to be flawed in bariatric outcome reporting.⁽¹⁴¹⁾ Furthermore, the current study's pre-operative and nadir BMI values were 51kg/m² and 35kg/m² respectively, suggesting that a BMI cut-off value of 35kg/m² for a weight regain definition cannot be a suitable criterion for all cohorts. Finally, the excluded definition of any weight regain implies that any increase, regardless of amount, of weight from the nadir value would result in a patient being classified as having weight regain. This would not be clinically meaningful when a small degree of weight regain is generally expected once the nadir weight has been achieved following any bariatric procedure.

This study is limited by its retrospective design, small numbers and significant attrition. Furthermore, the %EWL formula employed is the historically and not the currently recommended version, so as to remain consistent with the previously published related article for this cohort.^(79, 103, 158) The post hoc analyses were exploratory and should not be

considered definitive. These limitations should not, however, alter the impact of how drastically the rate of weight regain changes when different definitions are applied to the same cohort.

Conclusion

Weight regain following bariatric surgery is a significant clinical problem. It remains poorly reported in the literature largely due to a lack of standardised reporting. The development of consensus statements and guidelines would go some way to ameliorating this problem. Ideally, research groups with access to large robust databases would aid in the development of any proposed weight regain definitions. Furthermore, a comprehensive definition may well include a PROM. In the interim, the bariatric literature would benefit by all published series clearly reporting how weight regain is defined in the study population.

Chapter 4

**EXPLORING PATIENTS'
PERSPECTIVE ABOUT WEIGHT
REGAIN AND FOLLOW-UP CARE
FOLLOWING SLEEVE
GASTRECTOMY**

Introduction

Previous chapters have demonstrated that weight regain following SG is common, affects important clinical and PROMs and has a variety of potential causative mechanisms. The systematic review presented in Chapter 2 identified initial sleeve size, sleeve dilatation, ghrelin levels, lack of follow-up support and maladaptive lifestyle behaviours as contributing factors to weight regain. These factors were all derived from papers presenting information from the clinicians' or researchers' perspective. No studies were identified that specifically addressed weight regain from the patients' perspective.

The onset of weight regain following SG at CMH has already been noted to coincide with the time of discharge from the bariatric service at 18 months following surgery (Chapter 1). The follow-up care provided prior to that involves outpatient appointments with the BNS at 2 weeks, and at 3, 6, 12 and 18 months post-operatively. Patients also see a bariatric dietician at 1, 6 and 12 months post-operatively.

The aim of the study presented in this chapter was to understand the opinions and perceptions of follow-up care in patients who had experienced weight regain following SG.

Methods

This qualitative study used focus group discussions and is reported in compliance with the COREQ Checklist.⁽¹⁵⁹⁾

Research team and reflexivity

The thesis author (BSC, BMedSci(Hons), PGDipSurgAnat, MBChB), a senior general surgery trainee and research fellow in bariatric surgery with prior experience in conducting both focus group and semi-structured interviews, facilitated the focus group discussions. Participants were informed that the focus group facilitator was undertaking research in

bariatric surgery as part of her post-graduate studies and that she was intending to become a bariatric surgeon. No relationship was formally established with participants prior to the study. Participants were invited by letter which was accompanied by an information sheet (Appendix A), consent form (Appendix B) and postage-paid return envelope. Potential participants were informed that this was a study to understand their perceptions about the follow-up care and issues around weight regain and that results would be used to optimise care pathways.

Study design

Potential participants were purposefully selected from all CMH patients who had undergone a SG at least two years prior. All patients who had evidence of weight regain were sent an invitation. Evidence of weight regain was determined by searching electronic medical records and the bariatric service database and identifying patients who had a weight recorded of at least five kilograms heavier than their nadir weight. If no postal response was received, patients were approached by telephone.

Focus group discussions were conducted in a conference room at the elective hospital and appropriate refreshments were provided. Prior to each focus group, participants were asked to complete a short demographic questionnaire (Appendix C) which included questions about access to technology and satisfaction with surgery. Discussions were facilitated using an interview guide (Appendix D) that had not been pilot tested. Data were captured by multiple digital recorders and no field notes were made. Only the interviewer and participants were present during the discussions. No repeat interviews or focus groups were conducted. Transcripts were not returned to participants prior to analysis.

Data analysis

Content analysis was conducted independently by two researchers using NVivo 10 and an inductive approach with themes derived from the data.

Results

In September 2014, there were 164 potentially eligible participants who had experienced weight regain and were at least two-years post-operative from SG since March 2007. Of these, 38 participated in one of seven focus group discussions conducted in October 2014 (Figure 4-1). The coding tree derived from inductive content analysis is depicted in Table 4-1.

The demographic information of participants is presented in Table 4-2. The majority of participants were female and European. A minority of participants did not have a smart phone, access to the internet or use email.

Figure 4-1. Diagram of participant flow.

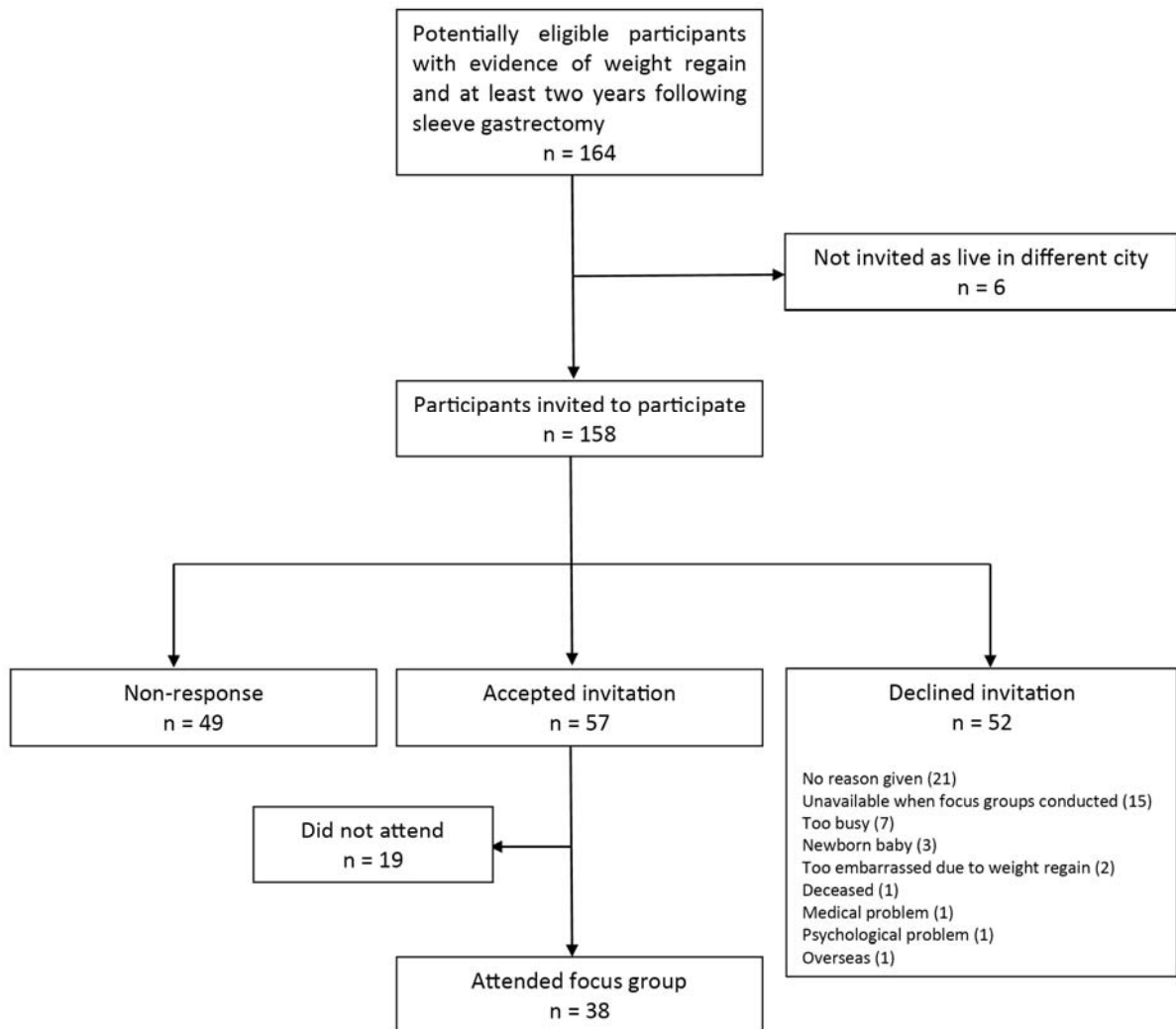


Table 4-1. Coding tree developed from inductive content analysis.

Attitudes about surgery
<ul style="list-style-type: none">● Honeymoon period● Operation is a gift● Opinion about surgery● Still feel fat
Attitudes about follow-up care
<ul style="list-style-type: none">● Negative aspects of follow-up care<ul style="list-style-type: none">– Not enough support– Poor rapport● Patient support group● Perceptions about follow-up care● Positive aspects of follow-up care
Contributors to weight regain
<ul style="list-style-type: none">● Behavioural<ul style="list-style-type: none">– Diet– Exercise– Taking responsibility● Cost● Health● Support● Psychological aspects
What participants want from follow-up
<ul style="list-style-type: none">● More support<ul style="list-style-type: none">– Individualised support– Information– Medical support– Motivation– Psychological support– Specialised support● Delivery of support<ul style="list-style-type: none">– Buddy system– Internet support– Face-to-face follow-up– Group sessions– Text message support– Patient-initiated follow-up

Table 4-2. Demographic information about participants.

Characteristic	Mean \pm SD or % (n)
Age (years)	51.4 \pm 6.7
Years since SG	3.9 \pm 1.6 (range 2 – 7)
Initial weight (kg)	137.2 \pm 29.4 (range 94 – 195)
Lowest post-operative weight (kg) [#]	88.6 \pm 19.2 (range 46 – 134)
Current weight (kg) [#]	103.17 \pm 21.1 (range 75 – 154)
Percent of excess weight loss [#]	52.2 \pm 16.9 (range 27.2 – 83.5)
Increase in BMI from nadir weight (kg/m ²) [*]	5.1 \pm 3.1
Gender	
Female	68.4 (26)
Male	31.6 (12)
Ethnicity	
European	65.8 (25)
Māori	23.7 (9)
Pacific	10.5 (4)
Access to the internet	
No	5.3 (2)
Yes	94.7 (36)
Own a smart phone	
No	23.7 (9)
Yes	76.3 (29)
Use email	
No	2.6 (1)
Yes	97.4 (37)
Complications	18.4 (7)
Leak	7.9 (3)
Haemorrhage	5.3 (2)
Leak and haemorrhage	2.6 (1)
Stricture	2.6 (1)

Notes. [#] Based on patient-reported current weight. Data available for only 35 participants.

^{*} Based on patient-reported nadir and current weight. Data available for only 34 participants.

Attitudes about surgery

The majority of participants were satisfied with the result from SG and would recommend the surgery to others (Figure 4-2). Having a SG was described as *'a gift'* or *'opportunity'*, with one participant feeling *'honoured to be able to have the operation for free'*. Consequently, participants described feeling *'accountable'* or *'obligated'* to do well and did not *'want to have wasted the taxpayers' money'*. Interestingly, most participants who had serious complications said they *'would do it again in a heartbeat'*, *'recommend it to anybody'* and described having a SG as *'the best thing I've done'*. While participants were satisfied with the result of their surgery, they still admitted to ongoing struggles post-operatively as they described that they *'still felt fat'*; *'even at my lightest, I still saw a fat person. So I never really enjoyed it'*. This highlights the ongoing struggle with the psychological side of obesity. Once the surgeons *'fix the physical side of it'*, the patient must then *'fix the inside'*.

Participants described the first 18 months following surgery as a *'honeymoon'*, *'with the weight just dropping off'* and *'feeling ten foot tall and bullet proof'*. This early stage was further described as *'exciting'* and feeling like you're *'on a bit of a high'* as *'no matter what you do, the weight keeps falling off'*. Once the *'honeymoon'* was over, however, participants described *'coming down to reality'* when the weight loss just stopped and *'everything went to custard'*, with some specifically stating that was when the support stopped: *'I just don't think there is enough support when you're coming out of that honeymoon stage, especially the psychological'*.

Over 80% of participants would recommend surgery to others (Figure 4-2) and would *'shout it from the rooftops for people to get surgery'*. Only one participant would not recommend surgery to others and regretted *'having it done because it didn't get rid of the diabetes...if it was purely for the weight loss that would have been my best option, but this wasn't about*

the weight loss for me... I'm now on more medication now than I was before I had the surgery, and that's what makes me angry'. Although this participant did not have an early surgical complication, the post-operative journey was difficult, 'after nearly three years I'd still be chronically fatigued, I'd still be losing my hair, I'd still be losing my eyebrows, be losing the hair on my body'.

Attitudes about follow-up

Almost 80% of participants were satisfied with the follow-up care they received (Figure 4-2). The most valuable part of follow-up was with the BNS: *'she knew exactly what she was talking about, she hasn't been through the surgery but she knows what we went through'.* Participants felt she was *'doing a superb job under really tight resources'* and further described her as *'very supportive and helpful', 'brilliant and they should clone her'.*

Another important aspect of follow-up care that emerged for some participants was the patient-initiated support group. It was *'a monthly group. We started off with those that had had surgery and then realised actually those that were building up to have surgery also needed support.'* It appeared to be most useful in the early post-operative period with it being described by one participant as *'very fundamental at the early stages'* and another felt that it *'got to a point where it was enough for me and I needed to do something else'.* Not all participants viewed it positively with one participant reporting *'the support group gave me no help at all'* and another stating *'I'm not coming here, this is not supporting me, it's not supporting anyone else'.*

Despite the majority being satisfied with follow-up care (Figure 4-2), not enough support was one of the most predominant themes from the focus group discussions (Table 4-1). In

general, participants felt that the follow-up period was too short and that there was an unmet psychological need.

'I think that emotional eating type psychological stuff was missing and I think that's what needs to kick in from twelve months onwards.'

'I felt that I was suddenly cut off and abandoned...I would like to have continued, where I left off...I actually still needed someone.'

A second important theme with regards to the negative aspects of follow-up care was poor rapport (Table 4-1). This often resulted from participants feeling like they were not being listened to, a lack of consistency in dietician staff and the need to repeat one's story again.

'They didn't look in to the real problem which I'm having right now, and I'm reluctant to come back to them because they'll probably do the same thing, they'll say, "it's no problem".'

'I anticipated that I would have the same dietician all the way through, and each visit I had a different dietician. So you were going through your history all over again. And I was like, "Can't you read the notes?" It just felt like you were repeating yourself, over and over.'

Causes of weight regain

Emergent themes for causes of weight regain can be seen in the coding tree (Table 4-1). Participants recognised the importance of good behavioural patterns with diet and exercise as the cornerstone to keeping their weight loss sustained: *'I've given up on doing exercise and stuff like that and I'm eating, and what goes in must come out. Well it's not going out, obviously'*. Only a small minority of participants reported not knowing why they were

regaining weight: *'I'm not eating enough to keep a four-year-old alive, so there's no reason why I'm having this weight gain'*. Four key themes emerged as factors which influenced behaviours of good eating and exercise patterns (Figure 4-3):

1. Psychological factors such as stress, eating disorders, emotional eating
2. Health factors such as pregnancy, injuries, dentition and joint problems
3. The financial burden of good food and to a lesser extent access to exercise facilities
4. The available support to assist with ongoing information and motivation.

Despite this, participants *'taking responsibility'* for their own behaviours was an important emergent theme.

'It sort of switched the light on for me. I thought hey there's more to this as in actually it is about doing it for yourself, but it's knowing when you fall over or things go wrong that you've got somewhere to go to ask questions.'

What participants want from follow-up

The most predominant emergent theme regarding follow-up was that participants wanted more of it. Seventy-four percent of participants described either that there was not enough support provided or that more support was needed. The provision of good information and psychological support were the most common forms of desired increased support. Participants also wanted better medical support for complications and co-morbidities, and more support for maintaining healthy lifestyle behaviours. Furthermore, this support should be delivered within the overarching principles of providing individualised, specialised care with providers that maintain good rapport and assist in maintaining motivation (Table 4-1). These themes and their interaction are presented visually in Figure 4-4.

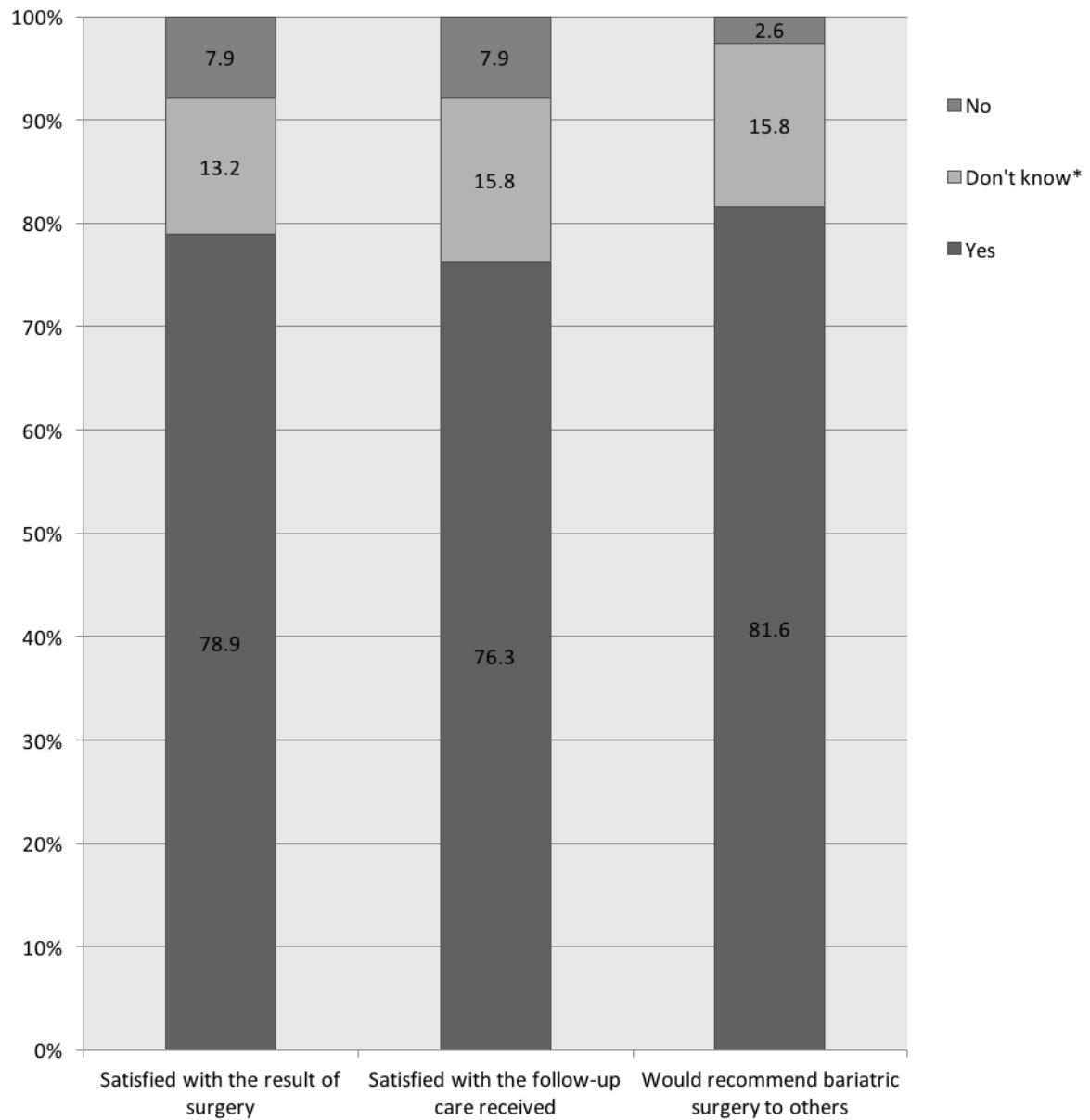
The method of delivery for the desired increased support did not necessarily need to be in the traditional sense: *'I think you need some other sort of support and I don't know whether it's group support or it might be motivational texts. "Are you eating too much?" "Are you still drinking your water?" I don't think coming here is the answer.'* Other types of follow-up that emerged included using a buddy system and the internet.

'It's also something that they could put on a website that you've got a buddy, here's your buddy list or these are the people that are willing to buddy. Pick your own.'

'Something internet-based that you could go on and they would also give you a list of bariatric nurses, or a list of dieticians, or a list of counsellors, or whoever, that if you need that extra specialised help, you can actually contact those people direct and set up an appointment.'

'Have a website that has forums on it as well, so that everybody can, at any stage, just go on and plonk their question in there. Someone with the knowledge, not necessarily the doctors, but someone else that's got access to it can give the advice. "You had this, I had that as well, I got over it doing this." Or, "If you can't eat meat, maybe try this." Just so that, not only have we got professionals looking at it, but we've got all the other people that have had the same experiences able to help out as well.'

Figure 4-2. Participant responses to questions about their satisfaction with sleeve gastrectomy, the follow-up care they received and whether or not they would recommend the surgery to others.



Note. *One participant did not respond to the question regarding their satisfaction with the result of surgery and this was included with the 'don't know' responses. Another participant did not respond to the question regarding their satisfaction with the follow-up care received and this was again coded with the 'don't know' responses.

Figure 4-3. Participant reported factors causing weight regain. Participants reported behaviours resulting in poor diet (poor food choices, portion size, snacking) and not enough exercise as the reasons for weight regain. These factors were themselves influenced by participant health, psychological problems, cost and lack of support.

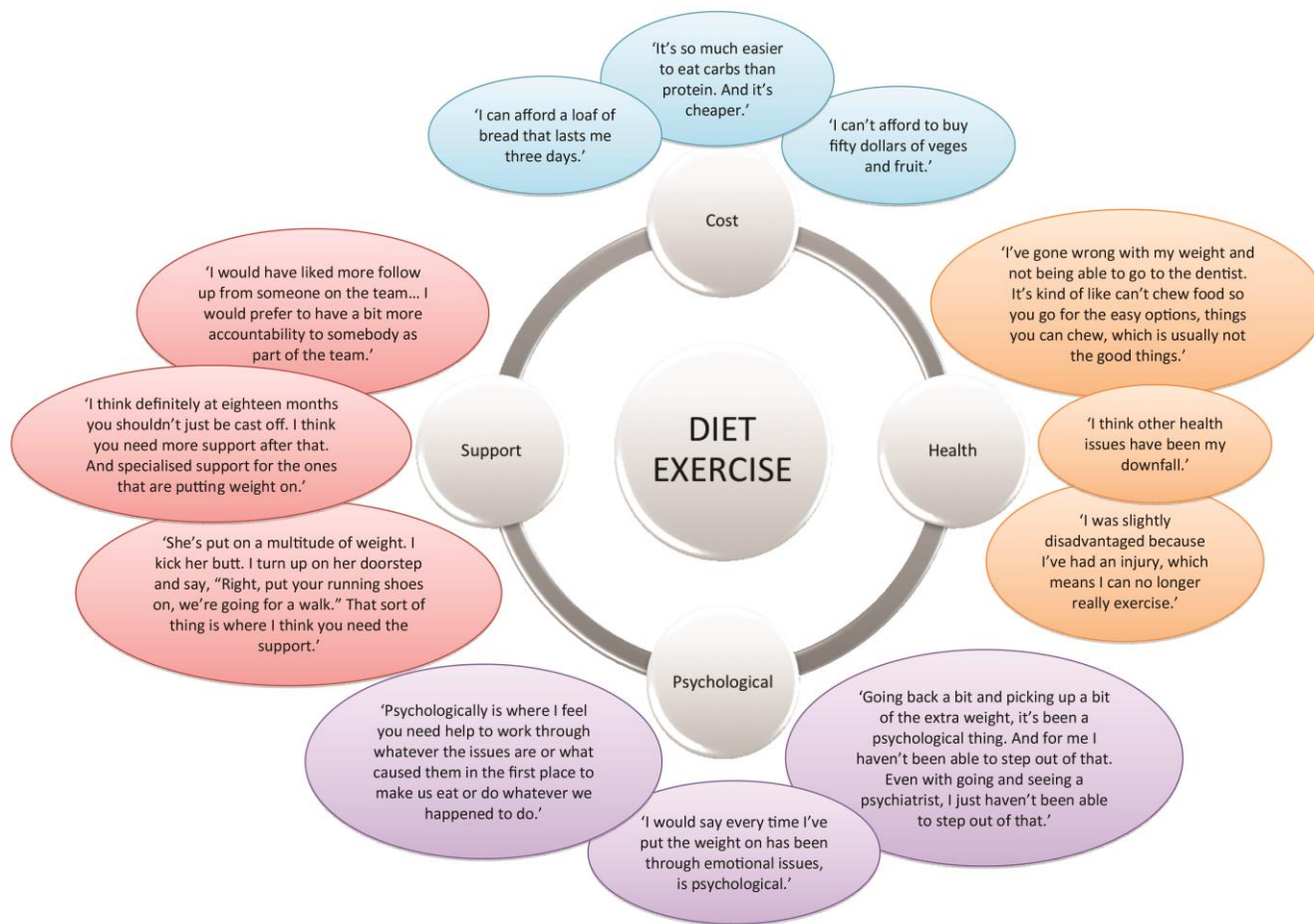
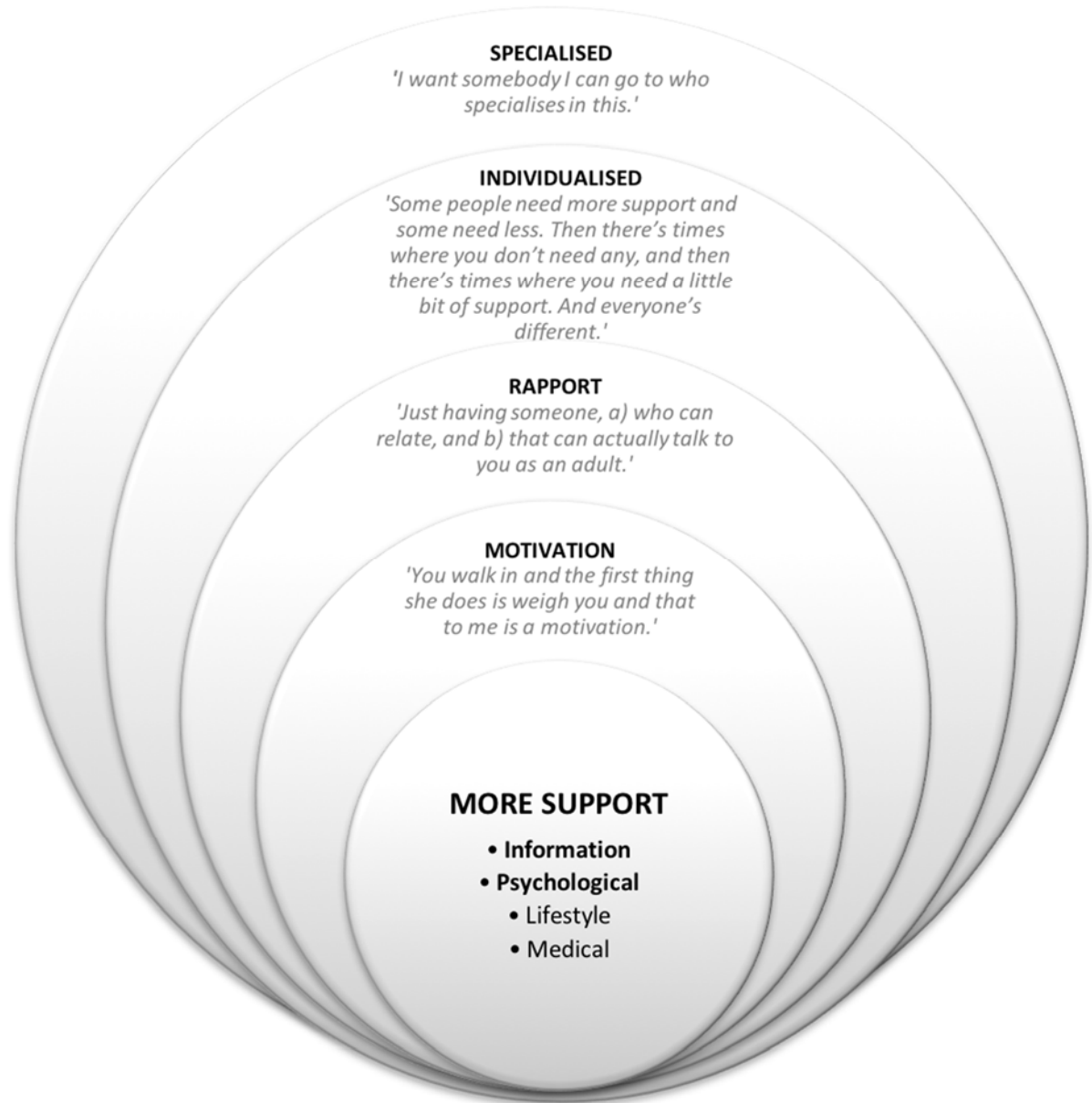


Figure 4-4. What participants want from follow-up. Participants described wanting more follow-up, particularly relating to meeting information and psychological needs. Furthermore, they described ideal support as being delivered within the overarching principles of providing individualised, specialised care with providers that maintain good rapport and assist in maintaining motivation.



Discussion

This study describes the experience, perceptions and opinions of almost 40 patients who experienced weight regain following SG. The majority of participants were satisfied with the results from their surgery and their follow-up care, and would recommend the surgery to others. Despite this, there was a strong desire for more support after discharge from the bariatric service.

Behavioural patient-reported predictors for weight regain following RYGB have been identified and include increased food urges, concerns regarding addictive behaviours, decreased well-being, fewer post-operative follow-up visits and lack of self-monitoring.⁽¹⁶⁰⁾

This certainly agrees with this study's model for patient-reported causes of weight regain following SG which is centred around the behaviours associated with diet and exercise but influenced by cost, health, psychology and support. Importantly, this new model is also similar to self-reported causes of weight gain in pre-bariatric surgery patients in whom stress, diet, medical condition, financial problems, injury affecting mobility and significant changes in life circumstances are important contributors.⁽¹⁶¹⁾ This suggests that bariatric patients need to be educated early in the pathway with ongoing reinforcement of good behaviours and encouragement to self-monitor throughout their follow-up care with the bariatric service.

The need for increased psychological support emerged as a predominant theme and is stated as a requirement in several guidelines.^(88, 162) A meta-analysis of post-bariatric surgery psychotherapeutic interventions and support groups reported significantly improved weight loss (not weight regain) with these interventions and that they had similar effect sizes.⁽¹⁶³⁾ In this review, support groups referred to meetings of 15 – 20 participants led by trained nurses or dieticians that lasted between one and two hours. While the authors caution that their

findings are preliminary due to a lack of methodological rigour in the studies assessed, it could still be that the psychological support desired from participants need not be from trained psychologists – making the provision of such a service achievable for resource-constrained centres. A recent randomised trial showed no difference in weight loss between patients who had psychological support compared with those who did not at one year after surgery.⁽¹⁶⁴⁾ This same group of patients were followed up at two years post-operatively to assess their experiences of the psychological support they received.⁽¹⁶⁵⁾ They had similar findings to the current study whereby the majority of patients would have liked more support over a longer period despite high levels of satisfaction. Furthermore, the need for individualised care was again highlighted as many patients wanted less support as time progressed or felt that psychological support was not required at all. The authors suggested that targeting psychological support at individuals who demonstrate weight regain may be a more appropriate recommendation.⁽¹⁶⁴⁾

A predominant theme from the focus group discussion was the need for more support – to increase satisfaction with follow-up care and possibly even reduce weight regain. This is consistent with previous work that demonstrated significantly improved weight loss, QOL and food tolerance scores in patients 100% compliant with follow-up compared with those who were not almost three years post-operatively.⁽¹⁴⁸⁾ Yet when these patients were followed up at five years, they had experienced significant weight gain and reduction in QOL despite ongoing annual follow-up visits.⁽¹³⁶⁾ They also demonstrated that sufficient weight loss at five years was associated with successful change in patients' lifestyle – namely healthy eating and physical activity behaviours.

Clinical support, psychological or otherwise, has traditionally been with face-to-face consultations which is prohibitively expensive for many public health services in the long

term. The current study suggests patients may be open to more innovative methods of follow-up such as a buddy system, group sessions, using the internet and text messaging. The latter is particularly financially sustainable to the public health sector, with text message support already known to increase exercise adherence before SG and sustain weight loss in non-surgical patients.^(166, 167)

This qualitative explorative study does have limitations. Study findings may have been enhanced by investigating a comparative group of patients who had not regained weight. Secondly, a significant proportion of patients were unable to be contacted to invite them to participate in the study, potentially limiting the representativeness of the focus group discussions. Finally, it is important to highlight that serious surgical complications were over-represented in this study's participants as almost 16% of participants had experienced a staple-line leak or haemorrhage, compared with only 3.5% in a previously published CMH clinical series.⁽¹⁰⁴⁾

Conclusion

The majority of participants who experienced weight regain were satisfied with their results and follow-up care following SG, and they would recommend the surgery to others. They identified poor eating and exercise behaviours as causes of weight regain; aspects which themselves were influenced by cost, follow-up support, psychological and health factors. Participants expressed a desire for more support following discharge from the bariatric service and were open to any increased support being delivered by non-traditional methods.

Chapter 5

**RANDOMISED TRIAL OF TEXT
MESSAGE SUPPORT FOR
REDUCING WEIGHT REGAIN
FOLLOWING SLEEVE
GASTRECTOMY**

Introduction

Chapters 2 and 4 demonstrated that a lack of follow-up support and maladaptive lifestyle behaviours have been identified by both clinicians and patients as important contributors to weight regain following SG. Furthermore, both factors seem amenable for targeting an intervention to reduce weight regain.

Text messaging is a recognised tool for behaviour change in disease management.⁽¹⁶⁸⁾ Advantages of text message support include the prevalence of text message-capable mobile phones, the relatively low cost of delivery and that patients can access the message(s) at their own convenience.⁽¹⁶⁸⁾ Furthermore, text message support has been shown to be effective for weight loss in non-surgical patients by randomised trial.⁽¹⁶⁹⁾ Its feasibility in an ethnically diverse New Zealand population has also been established.⁽¹⁷⁰⁾ The use of text message support in bariatric patients to reduce weight regain, however, has not been investigated.

The aim of the current study was to assess the effectiveness of a text message support intervention for reducing weight regain following SG.

Methods

This trial is reported in concordance with the CONSORT 2010 checklist,⁽¹⁷¹⁾ has a Universal Trial Number of U1111-1164-5085 and has been registered with clinicaltrials.gov with an identification reference of NCT02341001. It was approved by the Northern B Health and Disability Ethics Committee in December 2014 (reference 14/NTB/206). It was funded by a Health Research Council of New Zealand Clinical Research Training Fellowship (reference 15/008).

Trial design

The study was a randomised controlled trial employing a one-to-one allocation ratio.

One important change to methods after trial commencement was a broadening of the eligibility criteria to facilitate recruitment. Initially, patients were to be recruited at their post-operative 18-month discharge appointment. In reality, the 18-month post-operative follow-up appointment was not consistently the discharge appointment, nor was it always undertaken at 18 months post-operatively. Therefore, the eligibility criteria regarding time interval from surgery was broadened to 14 – 24 months.

Participants

All patients attending follow-up with the BNS 14 – 24 months after having a SG were eligible. Potentially eligible patients were excluded if they were psychologically or cognitively impaired, pregnant or at risk of being underweight. Other reasons for exclusion included not having a mobile phone or non-fluency in English.

Participants were recruited and followed up at a public, tertiary level, hospital outpatient clinic where all bariatric follow-up appointments occurred. All data were collected at the appointment where possible. In the instances where participants were unable to attend the clinic, data were collected over the phone or via an online survey.

Interventions

Participants were randomised to text message support or usual care. Text message support consisted of a daily text message delivered each morning for a period of one year (Appendix E), together with usual care. Usual care consisted of discharge from the bariatric service if appropriate, or else ongoing BNS and/or dietician follow-up as required. The timing of the intervention to commence at the 18-month or discharge appointment was to coincide with

the onset of weight regain identified in the institution's original cohort and to align with focus group discussion results which described a desire for ongoing longer-term support following discharge from the bariatric service (Chapter 4).⁽¹⁰³⁾

The content of the text message support intervention was designed based on the needs identified by patients who had experienced weight regain following SG by focus group discussions (Chapter 4).⁽¹⁷²⁾ Intervention design was guided by the Behaviour Change Wheel framework and each message was coded according to the Behaviour Change Technique Taxonomy version one (Appendix E).^(173, 174) The daily text messages were scheduled to be delivered to participants at 8am based on results from a previous feasibility study.⁽¹⁶⁷⁾ The one-year series of daily text messages of support were uploaded to and sent from a web-based New Zealand short message service (SMS) provider (One Way SMS, New Zealand). This was a one-way messaging system only and participants were made aware that there was no capacity to reply. Participants were given instructions on how to stop and start text messages as desired independently.

Outcomes

Demographic data, including age, gender and ethnicity, were collected. First specialist assessment (FSA) and peri-operative characteristics were obtained from electronic clinical records. These included FSA date, FSA height, FSA weight, date of operation and operative weight.

The primary outcome was change in %EWL calculated at recruitment, six and 12 months following recruitment.⁽⁷⁹⁾ Other weight parameters (initial mean BMI, change in BMI and percent of TWL) were also calculated at these time points in concordance with reporting guidelines.⁽⁷⁹⁾

The secondary outcome was the change in BAROS score also calculated at recruitment, six and 12 months following recruitment (Appendix H).^(137, 138) The BAROS score is a composite outcome measure that incorporates measures of weight change, obesity-related co-morbidity change, complications and QOL.

Variables previously identified as contributors to weight regain were also recorded for each participant.⁽¹⁷⁵⁾ These included size of the calibration bougie for fashioning the sleeve, where the antrum was divided at the time of surgery and whether or not the participant had been discharged from the bariatric service.

At the end of the trial, all participants were asked to complete an online satisfaction survey tailored according to participants' allocated group (Appendix I).

Sample size

There was no previous similar work on which to robustly perform a definitive power calculation. As such, the sample size was determined by performing an *a priori* power calculation using variance data (SD of 22.7 for %EWL at three years post-operatively) from a previous follow-up study of a SG patient cohort at the same institution.⁽¹⁰³⁾ A clinically important difference in weight regain between groups was defined as 15%EWL. Using these values, an 85% power analysis with a significance of 0.05 was performed and yielded a sample size of 84 (42 in each arm). As there are approximately 150 SG operations performed at CMH annually, and there was one year recruitment period, a recruitment target of 100 patients was made to allow for attrition.

Randomisation

Sequence generation

A third party online software application (sealedenvelope.com) randomised patients to either group A or group B. Randomisation was simple with no blocking or stratification employed.

Allocation concealment mechanism

Once randomisation was performed, the information was forwarded to a University of Auckland staff member not associated with the trial. This individual was responsible for designating which group (A or B) was to be the intervention or text message support group. This information was concealed from the researcher. This staff member was then responsible for entering participants and their allocated group into the web-based SMS provider.

Implementation

Once participants and their allocated group were entered into the web-based SMS provider, the system then automatically sent them either a one-off text message (*Welcome to the BOBS Study![‡] You are in the group who will not receive a daily text message. We will be in touch again in six months to see how you are getting on. Thank you for participating.*), or the first message of the one-year support series. The researchers did not know where the code break for group allocation was stored.

[‡] The BOBS Study is an abbreviation referring to the Better Outcomes after Bariatric Surgery Study which is an overarching term used to encompass the work presented in this thesis and is employed in patient information sheets (Appendices A-C, F).

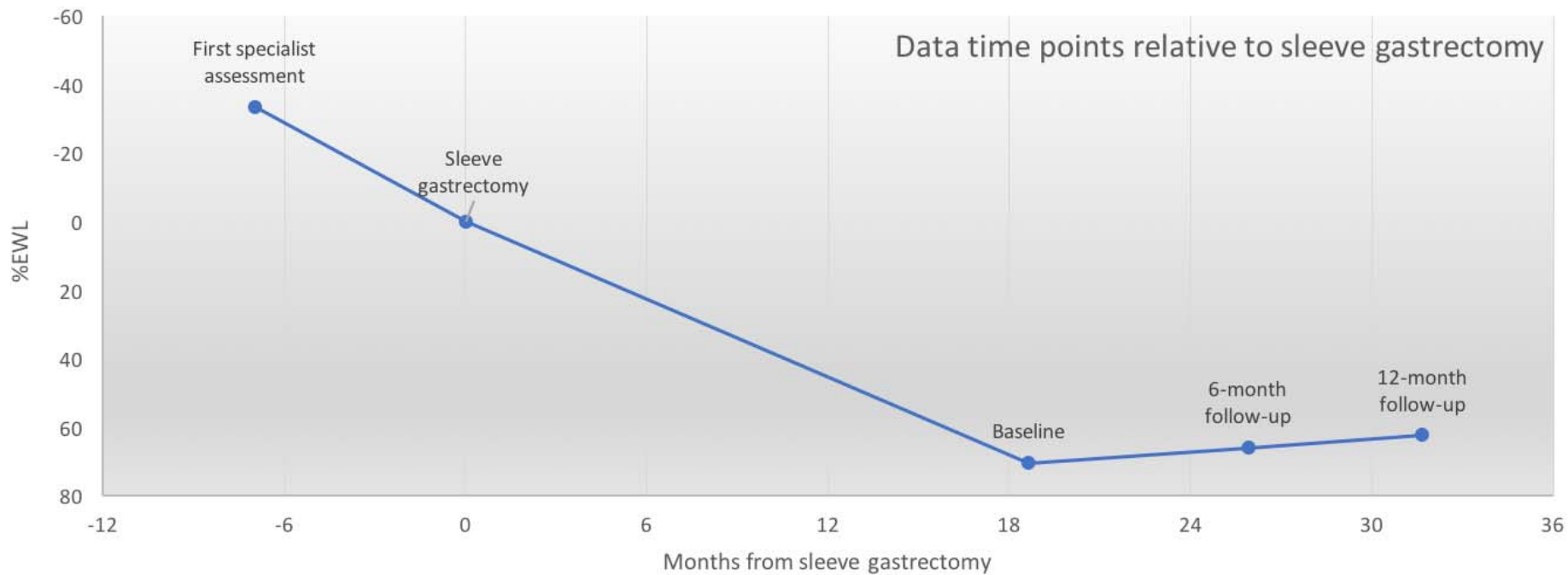
Blinding

Patients were unable to be blinded to the intervention of receiving a daily text message. Study investigators requested participants did not disclose their allocated group during six-month and 12-month assessments.

Statistical methods

For each participant, data were collected at recruitment (baseline), six months and 12 months after recruitment (Figure 5-1). These data were entered into a Microsoft Access database. Once all data were entered, these were transferred to the IBM SPSS Statistics for Macintosh, Version 23 and transformed as required in preparation for analysis.

Figure 5-1. Data time points related to timing of sleeve gastrectomy and expressed using the primary outcome measure of %EWL. Note that the study baseline occurs 18 months following sleeve gastrectomy, which is when the onset of weight regain is thought to occur in our cohort (Chapter 1).



Data were checked for logic and consistency errors. All variables were checked for normal distribution prior to undertaking an intention to treat analysis. Outcome measure data from participants who did not complete follow-up assessments were considered missing data. The effect of missing data was not investigated. Descriptive statistics for the satisfaction survey are presented. All data analysis was performed independently by two researchers.

Baseline comparison

Means with their standard deviations for continuous data or proportions for categorical data are presented for descriptive analysis.

Primary analysis

Outcome measure data from the two groups were compared using analysis of variance (ANOVA). Equal variances were assumed throughout the analysis since there was no reason to suspect that the intervention would alter the variability of outcome measures.

Secondary analysis

Analysis of co-variance (ANCOVA) was used to adjust outcome measures for potential confounders of age, gender, ethnicity, operative BMI, time from surgery, discharge status, bougie size and where the antrum was divided. The baseline value of the outcome measure was also adjusted for when the outcome was not a change measure or BMI which was already adjusted for the operative time point.

Results

Participant flow

Participant flow is presented in Figure 5-2 and reasons for potential participants being excluded from randomisation is presented in Table 5-1. Ninety-five participants were randomised, 48 to group A (standard care) and 47 to group B (text message support). Over

90% (43/47) of participants receiving text message support appeared to receive all messages. Four participants ceased their messages and received between one and 263 of the 364 message series. Additionally, several patients changed phone number during the study and may not have received the messages even though they were deemed as successfully sent from the SMS system.

Most six-month follow-up assessments were undertaken at the outpatient clinic (84% in group A and 91% in group B), with the remainder completed as either an online questionnaire (A – 14%, B – 9%) or over the telephone (A – 2%, B – 0%). Most 12-month follow-up assessments were undertaken at the outpatient clinic (A – 79%, B – 93%), with the remainder completed as either an online questionnaire (A – 16%, B – 5%) or over the telephone (A – 5%, B – 2%).

Recruitment

Patients were screened for recruitment at bariatric outpatient clinics between January and December 2015. Randomisation began in April 2015. Six-month follow-up assessments were undertaken from October 2015 until July 2016. The final 12-month assessments took place from April through to December 2016.

Figure 5-2. Participant flow.

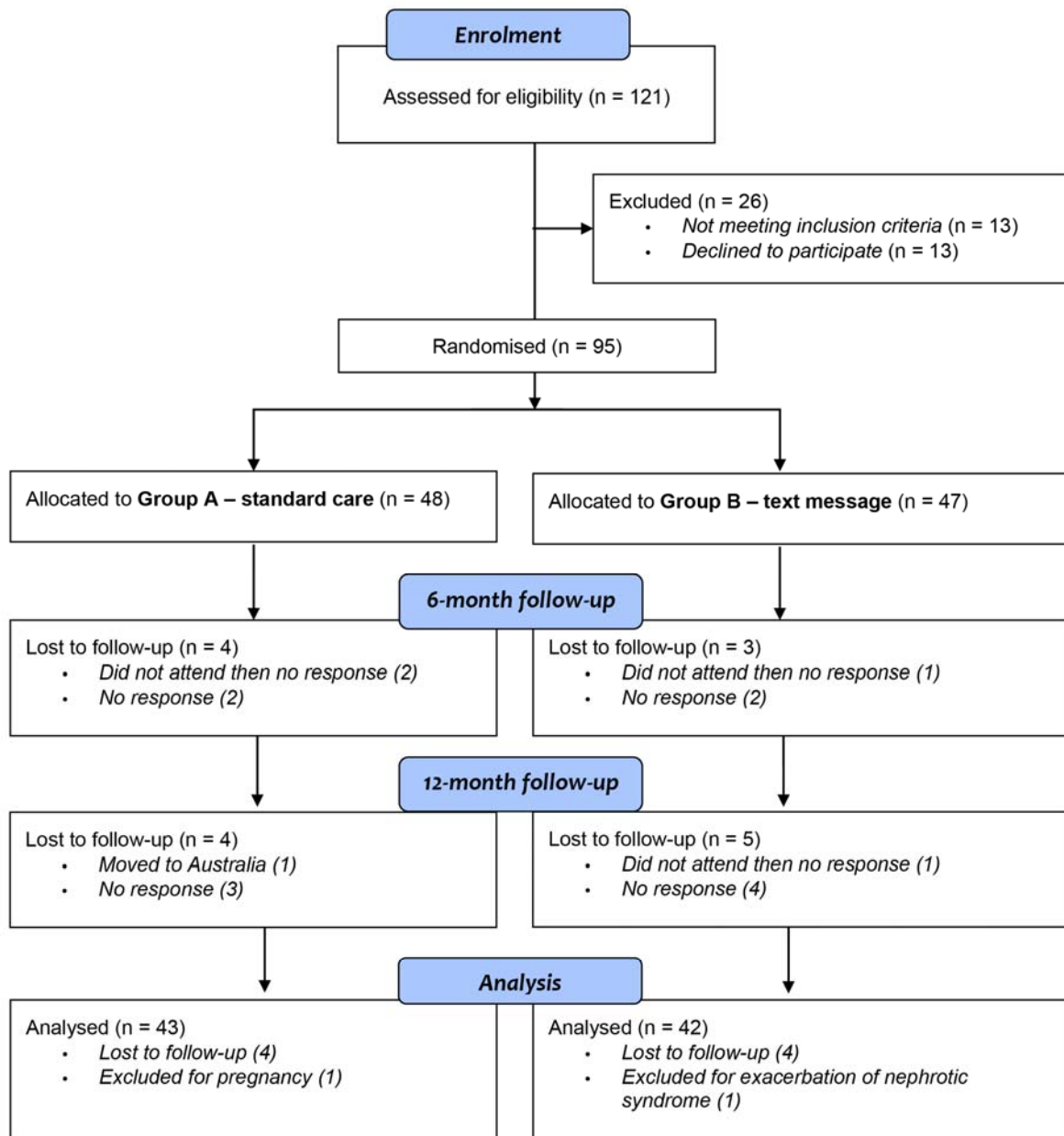


Table 5-1. Reasons potential participants were excluded from randomisation.

	Number of potential participants n (%)
Did not meet inclusion criteria	13 (50)
Pregnant	4 (15.4)
Proceeding to revision surgery	2 (7.7)
Moving away	2 (7.7)
Irregular mobile phone use	1 (3.8)
Domestic violence safety issues	1 (3.8)
Significant psychological diagnosis	1 (3.8)
Traumatic brain injury	1 (3.8)
Trouble maintaining adequate weight	1 (3.8)
Declined to participate	13 (50)
Too busy	4 (15.4)
No reason given	3 (11.5)
Already motivated enough	2 (7.7)
Did not think text message intervention would be helpful	2 (7.7)
Undergoing treatment for cancer	1 (3.8)
Private person	1 (3.8)

Baseline data

Baseline characteristics are presented in Table 5-2. Data were available for all participants for all measures, except for calibration bougie size and where the antrum was divided in relation to the pylorus when they were not reported in the operation notes.

Table 5-2. Baseline characteristics. This table presents demographic data, characteristics of patients at their FSA, the day of surgery and the day of recruitment (study baseline).

	Group A n = 48	Group B n = 47
Mean age \pm SD, years	47.0 \pm 8.8	45.6 \pm 7.2
Gender, n (%) females	38 (79.2)	32 (68.1)
Ethnicity, n (%)		
NZ European	17 (35.4)	19 (40.4)
Māori	13 (27.1)	16 (34.0)
Samoaan	4 (8.3)	3 (6.4)
CI Māori	1 (2.1)	2 (4.3)
Indian	4 (8.3)	1 (2.1)
Other	9 (18.8)	6 (12.8)
FSA characteristics		
Mean time prior to surgery \pm SD, months	6.5 \pm 3.7	7.5 \pm 8.1
Mean weight \pm SD, kg	132.7 \pm 26.7	136.7 \pm 26.2
Mean excess weight \pm SD, kg	61.4 \pm 21.0	64.6 \pm 23.4
Mean BMI \pm SD, kg/m ²	46.4 \pm 6.5	47.5 \pm 8.2
Mean excess BMI \pm SD, kg/m ²	21.4 \pm 6.5	22.5 \pm 8.2
Operative characteristics		
Mean weight \pm SD, kg	121.6 \pm 25.5	122.2 \pm 24.1
Mean excess weight \pm SD, kg	50.3 \pm 19.9	50.1 \pm 21.8
Mean BMI \pm SD, kg/m ²	42.4 \pm 6.0	42.5 \pm 7.9
Mean excess BMI \pm SD, kg/m ²	17.4 \pm 6.0	17.5 \pm 7.9
Bougie size, n (%)		
32F	7 (15)	3 (6)
34F	41 (85)	41 (87)
NR	0 (0)	3 (6)
Division of antrum, n (%)		
3.5cm	7 (15)	0 (0)
5cm	5 (10)	10 (21)
4 – 6cm	26(54)	30 (64)
NR	10 (21)	7 (15)
Baseline characteristics		
Mean time since to surgery \pm SD, months	18.6 \pm 3.2	18.7 \pm 3.7
Mean weight \pm SD, kg	89.1 \pm 18.3	87.5 \pm 16.4
Mean excess weight \pm SD, kg	17.8 \pm 15.4	15.5 \pm 14.4
Mean BMI \pm SD, kg/m ²	31.2 \pm 5.5	30.4 \pm 5.1
Mean excess BMI \pm SD, kg/m ²	6.2 \pm 5.5	5.4 \pm 5.1

	Group A <i>n</i> = 48	Group B <i>n</i> = 47
Mean change in BMI \pm SD, kg/m ²	11.2 \pm 4.8	12.1 \pm 6.0
Mean %TWL \pm SD, %	26.1 \pm 9.8	27.5 \pm 10.3
Mean %EBMIL \pm SD, %	66.9 \pm 25.7	74.1 \pm 30.2
Mean %EWL \pm SD, %	66.9 \pm 25.7	74.1 \pm 30.2
Mean BAROS score \pm SD*	4.6 \pm 2.0	5.1 \pm 1.7
Discharged at baseline, <i>n</i> (%)	31 (5)	36 (77)

Notes. * Eight participants (8.4%), four from each group, did not answer 'the pleasure I get out of sex is...' in the QOL component of the BAROS score.

n, number of participants; SD, standard deviation; %, percentage of participants; NZ, New Zealand; CI, Cook Island; FSA, first specialist assessment; kg, kilograms; BMI, body mass index; m, metres; F, French; NR, not reported; cm, centimetres; %TWL, percent of total weight loss; %EBMIL, percent excess BMI loss; %EWL, percent excess weight loss; BAROS, Bariatric Analysis and Reporting Outcome System.

Numbers analysed (summarised in Table 5-3)

All randomised participants were included in the baseline data descriptive statistics, 48 participants in group A and 47 participants in group B. Six-month assessment data were available for 44 participants in both groups, however one patient was excluded from analysis in group B due to an exacerbation of nephrotic syndrome. This participant subsequently moved away and did not complete the 12-month assessment. At 12 months, 44 patients in group A and 42 patients in group B completed the final assessment. One patient was excluded from analysis in group A at 12 months due to pregnancy thus reducing group A to 43 participants. Only 42 patients in group A and 41 patients in group B were analysed in the primary and secondary outcomes as one participant from each group was unable to provide their current weight.

All analyses were performed on an intention to treat basis, regardless of how many text messages were received.

Table 5-3. Summary of number of patients included in weight and BAROS score outcome analyses. Group A is standard care and group B received text message support.

Data time point	Group A	Group B
Baseline	48	47
6-month assessment	44	43
12-month assessment	42	41

Outcomes and estimation

Data time points related to the trial are presented in Figure 5-1. The outcome measures of %EWL, change in %EWL, BAROS score and change in BAROS score are presented in Table 5-4. Although patients allocated to group B (text message support) tended to have less weight regain, there were no significant differences between groups and the confidence intervals were large. At 12 months, group B had a significantly better BAROS score than group A (standard care).

Ancillary analyses

The outcome measures of %EWL, change in %EWL, BAROS score and change in BAROS score after adjustment for confounders and baseline values are also presented in Table 5-4. The adjustments did not significantly alter the results when compared with the primary analysis and the significant difference in the BAROS score between groups at 12 months was maintained. Further exploration of the individual components of the BAROS score are presented in Table 5-5.

Overall, participants randomised to group B found the text message support beneficial with the majority of group B participants feeling supported by the text messages and wishing them to continue (Table 5-6). Three patients in group A reported receiving the messages by another participant forwarding them on to them and also reported the text message support as beneficial. Over 80% of group B participants felt that the text message support helped

them to minimise weight gain. The timing and frequency of the messages seemed appropriate for participants.

Harms

There were no important harms or unintended effects detected in either group.

Table 5-4. Outcome measures presented as means with standard deviations and mean difference between groups with 95% confidence intervals before and after adjustment for confounders and baseline values as appropriate. To comply with recent standardised outcome reporting recommendations, outcome measures in addition (in italics) to those predetermined have been included. Where a measure is reported as a change, it refers to the six- or 12-month value with the baseline value (not the operative value) subtracted from it. Group A is standard care and group B received text message support.

	SIX MONTHS AFTER RANDOMISATION						TWELVE MONTHS AFTER RANDOMISATION					
	Group A n = 44	Group B n = 43	Mean difference (95% CI)	Sig	Adjusted mean difference (95% CI)	Sig	Group A n = 42	Group B n = 41	Mean difference (95% CI)	Sig	Adjusted mean difference (95% CI)	Sig
%EWL, %	61.4 ± 28.6	70.6 ± 33.0	-9.2 (-22.3 – 4.0)	0.170	-2.9 (-8.2 – 2.4)	0.273	57.1 ± 28.0	67.6 ± 30.5	-10.5 (-23.3 – 2.3)	0.106	-2.6 (-9.6 – 4.4)	0.456
Change in %EWL, %	-5.1 ± 9.4	-2.2 ± 10.0	-2.8 (-7.0 – 1.3)	0.178	-3.3 (-8.6 – 1.9)	0.204	-8.3 ± 10.7	-7.1 ± 13.7	-1.3 (-6.6 – 4.1)	0.637	-2.0 (-8.8 – 4.8)	0.550
BAROS score*	4.6 ± 2.3	5.0 ± 1.7	-0.4 (-1.3 – 0.5)	0.363	-0.2 (-0.7 – 0.2)	0.325	4.1 ± 2.2	5.3 ± 2.0	-1.2 (-2.1 – 0.3)	0.011	-0.7 (-1.4 – -0.1)	0.020
Change in BAROS score	0.1 ± 1.0	0.0 ± 1.0	0.1 (-0.4 – 0.5)	0.811	-0.1 (-0.6 – 0.4)	0.650	-0.5 ± 1.2	-0.1 ± 1.2	-0.4 (-1.0 – 0.1)	0.106	-0.5 (-1.1 – 0.1)	0.092
<i>BMI, kg/m²</i>	<i>32.2 ± 5.9</i>	<i>31.1 ± 5.6</i>	<i>1.0 (-1.4 – 3.5)</i>	<i>0.410</i>	<i>1.2 (-0.9 – 3.3)</i>	<i>0.251</i>	<i>32.7 ± 5.5</i>	<i>31.3 ± 5.0</i>	<i>1.4 (-0.9 – 3.7)</i>	<i>0.220</i>	<i>1.4 (-0.5 – 3.2)</i>	<i>0.151</i>
<i>Change in BMI</i>	<i>0.8 ± 1.4</i>	<i>0.4 ± 1.6</i>	<i>0.4 (-0.3 – 1.0)</i>	<i>0.259</i>	<i>0.6 (-0.1 – 1.4)</i>	<i>0.106</i>	<i>1.3 ± 1.7</i>	<i>1.0 ± 2.1</i>	<i>0.3 (-0.5 ± 1.1)</i>	<i>0.473</i>	<i>0.4 (-0.7 – 1.5)</i>	<i>0.452</i>
%TWL, %	24.2 ± 11.1	25.9 ± 11.1	-1.8 (-6.5 – 3.0)	0.463	-1.3 (-3.1 – 0.5)	0.148	22.8 ± 11.0	25.0 ± 11.1	-2.2 (-7.1 – 2.6)	0.360	-1.2 (-3.6 – 1.3)	0.339
<i>Change in %TWL</i>	<i>-1.9 ± 3.3</i>	<i>-1.0 ± 3.6</i>	<i>-0.9 (-2.4 – 0.6)</i>	<i>0.234</i>	<i>-1.4 (-3.2 – 0.4)</i>	<i>0.125</i>	<i>-3.1 ± 3.9</i>	<i>-2.4 ± 4.7</i>	<i>-0.6 (-2.5 ± 1.2)</i>	<i>0.498</i>	<i>-0.9 (-3.3 – 1.5)</i>	<i>0.447</i>

Note. * At six months, four participants (4.6%), three from group A and one from group B, did not answer 'the pleasure I get out of sex is...' in the QOL component of the BAROS score. At 12 months, seven participants (8.4%), five from group A and two from group B did not answer the same question. A further participant (1.2%) did not answer the question 'the way I approach food is...'.

Table 5-5. Exploratory analysis of the components of the BAROS score (Appendix H, Chapter 5) at 12 months presented as means with standard deviations and mean difference between groups with 95% confidence intervals. Group A is standard care and group B received text message support.

BAROS Component	Group A n = 43 Mean ± SD	Group B n = 42 Mean ± SD	Mean difference (95% CI)	Significance
Weight loss	1.7 ± 1.0	2.0 ± 0.9	-0.2 (-0.7 – 0.2)	0.258
Medical conditions	1.1 ± 1.0	1.6 ± 0.7	-0.6 (-0.9 – -0.2)	0.003
Quality of life	1.4 ± 1.1	1.9 ± 0.9	-0.5 (-1.0 – -0.1)	0.021
Complications and reoperation	-0.1 ± 0.3	-0.3 ± 0.4	0.1 (-0.0 – 0.3)	0.107

Table 5-6. Descriptive statistics of the 42 group B (text message support) participants' responses to the satisfaction survey questions undertaken at the 12-month assessment on completion of the intervention.

Satisfaction survey question	Scale, % (n)				
	<i>Strongly disagree</i>	<i>Somewhat disagree</i>	<i>Neither agree nor disagree</i>	<i>Somewhat agree</i>	<i>Strongly agree</i>
The daily messages made me feel supported	2.4 (1)	0 (0)	2.4 (1)	26.2 (11)	69.0 (29)
The daily text messages helped me with motivation	2.4 (1)	0 (0)	2.4 (1)	47.6 (20)	47.6 (20)
The daily text messages were developed by experts in the follow-up care of bariatric surgery	0 (0)	2.4 (1)	19.0 (8)	38.1 (16)	40.5 (17)
The daily text messages helped me to minimise weight regain	0 (0)	2.4 (1)	16.7 (7)	35.7 (15)	45.2 (19)
I would like to continue receiving these daily text messages	2.4 (1)	0 (0)	19.0 (8)	14.3 (6)	64.3 (27)
	<i>Far too little</i>	<i>Somewhat too little</i>	<i>Just right</i>	<i>Somewhat too much</i>	<i>Far too much</i>
How did you find the frequency of the text messages?	0 (0)	0 (0)	85.7 (36)	9.5 (4)	4.8 (2)
	<i>Far too early</i>	<i>Somewhat too early</i>	<i>Just right</i>	<i>Somewhat too late</i>	<i>Far too late</i>
How did you find the timing of the text messages?*	0 (0)	0 (0)	97.6 (41)	2.4 (1)	0 (0)

Note. * Even though text messages were initially programmed to be delivered at 8am, this became 9am early on in the trial as the messages were sent from offshore and the service provider did not incorporate the change when clocks were adjusted for daylight savings time.

Discussion

This study evaluated the effectiveness of a text message intervention designed to reduce weight regain following SG. When compared to standard care, participants who received the intervention tended to have less weight regain. The only significant difference was an improved BAROS score at 12 months from recruitment. Importantly, the majority of participants who received text messages were satisfied and felt that the intervention made them feel supported, motivated and assisted in reducing weight regain.

While participants who received text message support had better weight loss and less weight regain compared to standard care, none of these differences were significant and the variance measures remained large after adjustment for baseline differences and potential confounders. The *a priori* power calculation was based on data from a five-year follow-up study at the same institution.⁽¹⁰³⁾ It used the standard deviation for %EWL at three years following SG which was available for only a small number of patients. A further reason for the results seen may be because weight outcome measures were pragmatically assessed at certain time points, thus potentially missing the weight loss nadir of many patients. It follows then that weight regain has likely been underestimated. Arguably, the intervention could still be applied in clinical practice without further evaluation given the low risk of harm, the significantly improved BAROS score and participants' obvious satisfaction with it.

The BAROS score is a validated composite score composed of a weight loss measure (%EWL or %EBMIL), co-morbidity assessment, presence of surgical and medical complications and the Moorehead-Ardelt Quality of Life Questionnaire (Appendix H). Further exploration of this relationship by testing each of the BAROS components individually revealed that it was improvements in the components relating to co-morbidities and QOL that resulted in a better BAROS score in the patients who received text message support compared with those who

did not. While these findings are consistent with other work,^(42, 107, 114) it should be noted that this further exploratory analysis was not planned *a priori* and as such the results need to be interpreted cautiously.

Outcome measures continue to be an issue in the bariatric literature.^(154, 155) The predetermined outcome measures for this study were %EWL and the BAROS score. Since this trial was designed, however, standardised outcome reporting guidelines have been published and recommend complete reporting of weight change to include the initial BMI of the cohort, change in BMI, %TWL and %EWL or %EBMIL.⁽⁷⁹⁾ As such, and provided no consensus weight regain definition emerges in the interim, the authors suggest using %TWL and/or change in BMI as the primary outcome to avoid the increasingly recognised issues of reporting relative weight change measures.⁽¹⁴¹⁾

The text message support intervention was well liked by participants. Interestingly, three participants in the standard care group also received the messages by way of a group B participant forwarding them on to them; these participants were all satisfied with the intervention. This contamination will have also contributed to not finding a significant difference in most outcomes between groups. Furthermore, it could be that text message support is of more benefit to certain patients over others. Importantly, only one participant who received text message support would not have liked the messages to continue after one year and no participants disagreed with the timing (8am/9am) or frequency (daily) of the intervention. This supports previous work that suggested such an itinerary as optimal for sustaining weight loss.⁽¹⁶⁷⁾

This trial is the first to investigate a text message intervention for reducing weight regain in bariatric patients and adds to the growing body of literature which uses text message support

in weight management.⁽¹⁷⁶⁻¹⁷⁹⁾ The intervention designed and evaluated was the most basic of mHealth modalities. Employing more sophisticated mHealth modalities that allow patients to respond to messages, receive individualised messages and/or in combination with a self-monitoring application may produce more superior results.⁽¹⁸⁰⁾

Several practical issues arose during the conduct of the study. These included participants changing their mobile phone number and therefore not subsequently receiving the messages, ceasing their messages, and forwarding the messages to participants in the standard care group. Furthermore, although attrition was reasonable at 10.5%, this was only achieved by persistent follow-up by the study investigator in conjunction with providing alternate means of assessment by online and telephone modalities. These alternate methods relied on participants self-reporting their current weight and may also have influenced the effect of the intervention.⁽¹⁸¹⁾ Finally, as this intervention was specifically designed to reduce weight regain, only limited outcome assessment was undertaken. Future similar work, however, should comply with recently published reporting guidelines.⁽⁷⁹⁾ These recommend outcome measures for diabetes, hypertension, dyslipidaemia, OSA and GORD.

Conclusion

A year-long text message support programme consisting of a daily text message seemed to reduce weight regain and significantly improved the BAROS score when compared to standard care. The text message support was also valued by patients. Further investigation with a more sophisticated intervention in a larger study may demonstrate better effectiveness in reducing weight regain.

Chapter 6
DISCUSSION

Summary of Background

Chapter 1 outlined the global health problem of obesity, its significant sequelae to both individuals and society and that bariatric surgery is currently the most effective treatment available.

SG involves excising the majority of the stomach to leave a small tubular remnant and has rapidly become one of the most commonly performed bariatric procedures around the world. While its weight loss and metabolic effects are similar to that of RYGB, it appears to have higher rates of weight regain.

While it is known that weight regain is associated with recurrence of diabetes and a deterioration in QOL, the amount constituting or defining significant regain, its rates and underlying mechanisms are not. Thus the objective of this thesis was to generate a better understanding of weight regain following SG and attempt to reduce it.

Thesis Aims

This thesis had the following aims:

1. To understand how weight regain is described in the literature.
2. To understand why patients regain weight following SG.
3. To explore the relationship between weight regain and follow-up care.
4. To consolidate the above points to design then evaluate an intervention to reduce weight regain and improve outcomes following SG.

Understanding how weight regain is described in the literature

Chapter 2 assessed the literature base of weight regain following SG by specifically addressing the definition of weight regain, its rate beyond the second year from surgery and its aetiology. It became evident that a clear and consistent foundation for reporting and

understanding the phenomenon of weight regain was lacking. Despite a plethora of published SG series, only a minority reported rates of weight regain and an even smaller proportion stated the definition employed to do so.

At the time the review was conducted, a definition for weight regain following SG had been reported only 12 times, and in half of those, the definition used was an increase of 10kg from the weight loss nadir. Subsequently, a further two studies have been published on SG introducing yet another definition of weight regain – $\%EWL \leq 50\%$ after an initial successful weight loss defined as $\%EWL > 50\%$.^(145, 182) The impact of this ongoing non-standardised outcome reporting was emphasised in Chapter 3 that impressively demonstrated significantly different regain rates in the same patient cohort.

The weight regain rates following SG identified by the systematic review presented in Chapter 2 ranged from 6% at two years to 76% at six years. It is likely that the rate reported by Himpens et al (2010) of 76% at six years (with no accompanying definition) is an overestimation, given that other series reported rates, at a similar post-operative time point (together with a definition), of between 26% and 40%.^(105, 121, 123) Furthermore, Felsenreich et al (2016) have subsequently published their 10-year series using the definition of weight regain as an increase of at least 10kg and reported a regain rate of 59%.⁽¹⁸³⁾ Regardless of the imprecision, all of these figures confirm weight regain as a common phenomenon following SG.

The implications of non-standardised reporting reach farther than accurately assessing weight regain rates. The literature consistently groups patients together using not only the term 'regain' but also 'insufficient weight loss' and 'procedure failure'. Insufficient weight loss is not synonymous with progressive weight regain and failure encompasses any number

of scenarios, including, but not limited to, severe GORD. Thus, when patients are grouped together using these terms when describing indications for revision surgery or similar, there will be ongoing difficulties in interpreting the literature and further understanding the underlying causative mechanisms.

As the work conducted in this thesis was with a relatively small and unique cohort, it is an unsuitable data set from which to derive an appropriate definition for weight regain. It is possible, however, to propose a definition as an investigative starting point. Based on the work presented in this thesis, a potential definition could be an increase in the nadir BMI of five, or any BMI increase from nadir that is associated with a deterioration in obesity-related co-morbidities and/or HRQL. The reasons for proposing this definition include:

- That BMI is more meaningfully comparable than a relative measure
- Change in BMI is already an endorsed reporting outcome measure by ASMBS⁽⁷⁹⁾
- An increase in BMI of five is known to be associated with an increase in mortality of 30%⁽²⁾
- An increase in BMI of at least five has been demonstrated as being associated with recurrence of diabetes following RYGB⁽¹⁰⁷⁾
- Table 3-6 suggested that for each unit increase in BMI, the BAROS score is reduced by 0.4. It follows, then that a BMI change of five is associated with a two-point reduction in the BAROS score, a clinically significant difference.

Research groups with access to large robust databases need to evaluate whether the suggested cut off point of five for BMI is appropriate, or better still, explore and describe the relationship between weight regain and comorbidity status and HRQL. Furthermore, a series of systematic reviews would need to be undertaken to determine the best outcomes

measures for detecting change in comorbidities and HRQL. Any proposed definition(s) would then need to be endorsed by the relevant bariatric professional communities, such as the International Federation for the Surgery of Obesity and Metabolic Disorders and the ASMBS.⁽¹⁵³⁾ In the interim, the bariatric literature would benefit from all published series clearly reporting how weight regain is defined in the study population.

Understanding why patients regain weight following sleeve gastrectomy

The systematic review presented in Chapter 2 identified the following potential causes of weight regain specifically following SG: technical factors contributing to sleeve size, sleeve dilatation and ghrelin levels, plus issues with follow-up support and maladaptive lifestyle behaviours pertaining to eating and exercising. The extent to which each of these factors contribute to weight regain is unclear due to the quality of available studies and subsequent relevant publications have not changed these findings.^(182, 183)

While the findings of Chapter 2 summarised the potential causes of weight regain from a clinician's or researcher's perspective, the perspective of affected patients had not been investigated. Chapter 4 presented qualitative data from almost 40 CMH patients who had experienced weight regain following SG. The findings were strikingly congruent with those from the systematic review. Patients themselves identified behaviours relating to eating and exercise as the cornerstone of preventing weight regain. Additionally, however, they described four factors that influenced their ability to maintain appropriate behaviours relating to eating and physical activity. These were their health, potential psychological problems, financial cost and a lack of support.

These findings have important implications. The congruent findings from both clinicians and patients—that follow-up support and lifestyle behaviours are important influences for

weight regain—suggest these to be important areas to optimise for improving outcomes following bariatric surgery. Furthermore, the new findings of the patient-identified influencing factors on lifestyle behaviours will further aid in targeting such optimisation strategies.

Exploring the relationship between weight regain and follow-up care

Based on previous work investigating CMH's cohort of bariatric patients, it was noted that the onset of weight regain began at the time patients were discharged from bariatric follow-up around 18 months following surgery (Chapter 1).⁽¹⁰³⁾ This finding was corroborated by another centre, though they reported the onset occurring at 36 months, and was the starting point for the development of this thesis.⁽¹⁰⁵⁾

Chapters 2 and 4 confirmed the role of a lack of support or follow-up as a key contributor to weight regain from both the clinicians' and patients' perspective. Chapter 3, with its inclusion of additional weight outcome data points, however, demonstrated that the weight loss nadir in the CMH cohort may be closer to 12 months than 18 months (the time of discharge), differing to previous work using the CMH cohort but similar to that of Felsenreich et al (2016).⁽¹⁸³⁾ Certainly, this makes the relationship between weight regain and follow-up support less clear, yet does not completely disprove it. Work in this area, including aspects of this thesis, is limited by its largely retrospective nature and the fact that weight measurements are generally only recorded when patients attend outpatient clinics and/or research appointments. As such, the nadir weight for patients may be missed. A better understanding of the relationship between weight regain and follow-up support would be obtained if more regular weight measurements were able to be obtained, regardless of whether or not patients attended scheduled visits.

Designing and evaluating an intervention to reduce weight regain and improve outcomes following sleeve gastrectomy

Based on the findings of the systematic review and the thematic models developed from content analysis of focus group discussions, an intervention was designed to reduce weight regain that targeted behaviour change maintenance and increasing support for patients. A text message support intervention was chosen as this had previously had some success in the CMH cohort and other similar populations, is known to have improved sustained weight loss in non-surgical patients and was suggested and felt to be an appropriate method by patients in the focus group discussions (Chapter 4).

While it was clear from the results of the satisfaction survey that patients valued the text message support and patients who received the messages tended to have less weight regain, this did not reach statistical significance. Interestingly, however, there was a significant improvement in the BAROS score at 12 months in those who did receive the text message support. This echoes the findings in Chapter 3 that also consistently found a significant association between less weight regain and a better BAROS score (Tables 3-5 and 3-6). Further exploration of this relationship by testing each of the BAROS components individually in Chapter 5 revealed that it was improvements in the components relating to co-morbidities and QOL that resulted in a better BAROS score in the patients who received text message support compared with those who did not (Table 5-5).

Unfortunately, the large variance measures seen in the analyses from the trial suggest it was underpowered for the primary outcome of %EWL despite an *a priori* power calculation. When the power calculation is repeated using the variance data from the current study, it suggests 72 participants are needed in each arm to detect a difference in %EWL of 15 with a power of 0.85. With the new insights this thesis has provided, new recommendations for

weight outcome reporting and the trial's data set, a revised power calculation can be performed for future similar work. Ideally, this would be when a robust weight regain definition has been standardised.


Future Studies

This thesis has demonstrated the need for several future research studies to better understand the phenomenon of weight regain following bariatric surgery.

To adequately understand any clinical problem, both clinicians and researchers must use universally accepted and meaningful language to describe the entity. This thesis clearly demonstrated that the lack of standardised weight regain reporting affected both outcome reporting and the understanding of underlying causative mechanisms relating to weight regain. To rectify this issue, a robust definition for weight regain needs to be developed. Such a definition should be developed using a large data set to determine appropriate cut off values for weight, comorbidity and HRQL changes. A further recommendation from this thesis is that consideration should be given to including a PROM within the definition, given that weight regain is consistently associated with a reduction in QOL within this thesis and beyond.⁽⁴²⁾ Systematic reviews will be required prior to any work developing a definition to determine the best outcome measures for detecting changes in comorbidity and HRQL status. Any proposed definition must then be endorsed by relevant experts and specialist associations. Once such a definition is established, the true rates of significant regain will be able to be consistently reported, outcome reporting will be improved and the understanding of the underlying mechanisms will be able to be advanced.

This thesis has included the first randomised trial to evaluate a non-surgical intervention for weight regain following bariatric surgery.⁽¹¹⁷⁾ Although probably underpowered⁽¹¹⁷⁾ for the

primary outcome, it did demonstrate that a year-long text message support intervention statistically significantly improved the BAROS score. Similar studies are required to reproduce these findings and may produce more significant benefits if a more sophisticated mHealth technology, rather than simply one-way text messaging, is employed.



Chapter 7
CONCLUSION

From the body of work outlined in this thesis, the following conclusions can be made.

Weight regain following SG is an important and common problem. Its understanding is hampered by a literature base that lacks standardised reporting and robust prospective studies.

There needs to be a standardised definition of weight regain to improve both understanding and outcome reporting.

There are many proposed causes of weight regain following SG, yet how each possible mechanism contributes to the problem remains uncertain. Optimising follow-up support and behaviours relating to healthy eating and physical activity appear to be reasonable targets for minimising weight regain.

A text message intervention to reduce weight regain is feasible and acceptable to patients. It also appears to improve outcomes following bariatric surgery and may reduce weight regain.

APPENDICES

Appendix A Chapter 4 – Information Sheet



THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

Department of Surgery
South Auckland Clinical School
PO Box 93311, Otahuhu, Auckland, New Zealand

PARTICIPANT INFORMATION SHEET

Project title: Better Outcomes after Bariatric Surgery (BOBS) – Patient perspectives about follow-up and outcomes after bariatric surgery

Names of Researchers: Mr Andrew MacCormick

Dr Melanie Lauti

Researcher introduction

Mr Andrew MacCormick is a bariatric surgeon at Middlemore Hospital and Manukau Surgical Centre as an employee of Counties Manukau District Health Board (CMDHB). He is also a senior lecturer at the University of Auckland.

Dr Melanie Lauti is a senior surgical registrar currently undertaking a PhD in bariatric surgery under the supervision of Mr Andrew MacCormick.

Project description and invitation

Obesity is an important health issue and obesity surgery is one of the best ways to treat it together with lifestyle changes. After a laparoscopic sleeve gastrectomy, patients lose weight early on but may start to put weight back on in the following years. Some patients report that better follow-up after surgery may help them with lifestyle modifications and keeping the weight off.

Patients who may have experienced weight regain after laparoscopic sleeve gastrectomy at CMDHB are invited to participate in this study to improve follow-up after surgery. You have been selected to be invited to participate in a two-hour group discussion about follow-up after your surgery. These groups will be held at Manukau Surgical Centre.

Refreshments will be provided and transport costs will be reimbursed in the form of petrol vouchers.

Project procedures

If you choose to participate you will be asked to attend a two-hour group discussion with up to nine other individuals who have also had a laparoscopic sleeve gastrectomy. Refreshments will be provided and transport costs will be reimbursed in the form of petrol vouchers. Dr Melanie Lauti will guide and transcribe the discussion about follow-up after your surgery. You can participate as much or as little as you desire and may withdraw from the study at any time with no negative consequence. You will receive a summary of the findings on completion of the study.

Data storage/retention/destruction/future use

Dr Melanie Lauti will guide and transcribe discussions. Transcriptions will be in a de-identified form. Only Drs MacCormick and Lauti will have access to the information.

Audio data will be destroyed once transcription is complete. The transcribed documents will be stored anonymously on password protected computers. Consent forms will be stored separately in a locked cabinet. All data will be destroyed by six years from the date the study was commenced. A summary of the findings will be provided to you on completion of the study if you wish, and you can indicate on the Consent Form whether you want to receive this summary.

Right to withdraw from participation

You may withdraw from the study at any time without giving reasons. Withdrawal from the study will in no way affect any future treatment that may be provided by Counties Manukau District Health Board. Even after you withdraw from the study, your part of the discussion may be used in the final analysis due to the difficulty in extracting conversational data.

Anonymity and confidentiality

Anonymity and confidentiality will be maintained wherever possible. All recorded and transcribed data will be de-identified. Because up to nine other individuals will be in your discussion group, we ask that you maintain confidentiality after the discussion has been completed. When the work from this study is published or presented, it will be completely anonymous.

Contact details

All investigators belong to the Department of Surgery, University of Auckland.

Dr Melanie Lauti Co-investigator	+64 9 373 599 extn 2219	m.lauti@auckland.ac.nz
Mr Andrew MacCormick Lead investigator	+64 9 276 0044	andrew.maccormick@auckland.ac.nz
Associate Professor Ian Bisset Department Head	+64 9 373 7599 ext 89821	i.bissett@auckland.ac.nz

For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 extn. 87830/83761. Email: humanethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON THE 15th July 2014 for 3 years - Reference Number 012320



THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

Department of Surgery
South Auckland Clinical School
PO Box 93311, Otahuhu, Auckland, New Zealand

CONSENT FORM

**Project title: Better Outcomes after Bariatric Surgery (BOBS) – Patient perspectives
about follow-up and outcomes after bariatric surgery**

Names of Researchers: Mr Andrew MacCormick

Dr Melanie Lauti

I have read the Participant Information Sheet and have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions and have them answered to my satisfaction.

- I agree to take part in this research, understanding that the focus group will be audio-recorded and that de-identified transcriptions will be made.
- I understand that I am free to withdraw participation at any time.
- I agree to not disclose anything discussed in the focus group.
- I understand that Dr Melanie Lauti will moderate the discussion and transcribe the recording.
- I understand the results may be presented and/or published at relevant forums or in medical journals.
- I understand that data will be kept for six years, after which they will be destroyed.
- I would like a summary of the findings to be sent to me on completion
 - NO
 - YES - Address/email: _____

Name: _____

Signature: _____

Date: _____



THE UNIVERSITY OF AUCKLAND
NEW ZEALAND

Department of Surgery
South Auckland Clinical School
PO Box 93311, Otahuhu, Auckland, New Zealand

DEMOGRAPHICS

Project title: Better Outcomes after Bariatric Surgery (BOBS) – Patient perspectives

about follow-up and outcomes after bariatric surgery

Names of Researchers: Mr Andrew MacCormick

Dr Melanie Lauti

Name: _____

Ethnicity: _____

Lowest weight since surgery: _____

Current weight: _____

Height: _____

Do you have access to the internet? Yes No

Do you have a smartphone? Yes No

Do you use email? Yes No

Are you satisfied with the result of your surgery?

Yes No Don't know

Are you satisfied with the follow-up you received?

Yes No Don't know

Would you recommend bariatric surgery to others?

Yes No Don't know

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON THE 15th JULY 2014
FOR 3 YEARS - REFERENCE NUMBER 012320

Introduction

Welcome

Thanks for agreeing to be part of the focus group. We appreciate your willingness to participate.

Introduction

Purpose of focus groups

To understand your opinions regarding **follow-up** after bariatric surgery as well as issues contributing to **weight regain**.

Ground rules

1. We want you to do the talking

- We would like everyone to participate.
- I may call on you if I haven't heard from you in a while.

2. There are no right or wrong answers

- Every person's experiences and opinions are important.
- Speak up whether you agree or disagree.
- We want to hear a wide range of opinions.

3. What is said in this room stays here

- We want folks to feel comfortable sharing when sensitive issues come up.

4. We will be tape recording the group

- We want to capture everything you have to say.
- We don't identify anyone by name in our report so you will remain anonymous.
- The labels are to help me facilitate the discussion.

Interview guide

What follow-up did you receive after your surgery?

- Positive aspects
- Negative aspects

In what way could follow-up be better?

- Physical trainer
- Psychologist
- Dietician
 - Prefer to see dietician more prior to surgery?
 - Prefer to see dietician more one year after surgery?
- Surgeon
- Nurse specialist

How much of your time is acceptable for follow-up?

- Travel / traffic
- Time off work
- Waiting

Do you think follow-up affects how much weight loss you achieve after surgery?

- Reasons

What about follow-up and exercise?

- Reasons

What do you think about text messaging using the internet as part of follow-up?

- Regular tips
- Regular motivational reminders

What do you think about GP follow-up?

- Your own GP?
- GPwSIs

- Locality GP

What were the issues most concerning to you after surgery?

- Expected / unexpected
- How did you deal with them?

What about patient-initiated follow-up?

- With specific health or allied-health professionals?

How do you feel about group follow-up?

- Dietician facilitated
- BNS facilitated
- Patient facilitated

Did your family or support people have any concerns about your follow-up?

Appendix E Chapter 5 – Text Message Support Intervention

One-year daily text message intervention designed using the Behaviour Change Wheel and coded using the Behaviour Change Technique Taxonomy version 1 (BCTTv1).^(173, 174)

Week.Day	BCTTv1	Genre	Message
1.1	3.1	G1	Welcome to the BOBS study! We want to help you feel supported & motivated. From tomorrow you will receive a daily text. This is a one-way service only, so do not reply. Pause messages by texting STOPTXT to 2667 & restart them by texting START to 2667. Standard charges apply for sending texts.
1.2	3.1	G2	Not all messages will suit everyone but there should be something for everyone. Contact Mel on andrew.maccormick@auckland.ac.nz with ideas, concerns or queries.
1.3	15.3	M1	Think back to before your surgery and congratulate yourself for the things you have already achieved.
1.4	3.2	G3	If you are pregnant or trying to get pregnant you will need special nutritional advice. Get in touch with your GP. Obviously this message isn't for everyone!
1.5	3.1	D1	This week is protein week. How much is enough and why is it so important?
1.6	3.1	D2	You need at least 60 grams of protein every day and much more if you want to build muscle. Are you getting enough?
1.7	5.1	D3	Protein is the building block for muscle. If you aren't getting enough protein you will lose your muscle mass and strength.
2.1	5.1	D4	You need protein for good skin and hair. If your hair is thinning or falling out, it may be because you aren't getting enough protein.
2.2	3.1	D5	Good protein foods are meat, chicken, fish, eggs, baked beans, tofu, soy beans, lentils, chick-peas, and protein shakes.
2.3	4.1	D6	Half of each meal should be protein – and eat this portion first as it is the most important.
2.4	15.3	G4	That was the first week, onto the second... Remember to congratulate yourself for the things you have already achieved since you had your surgery. Well done!
2.5	8.2/8.4	D7	Try sucking on a sugar-free lolly, chewing sugar-free gum or brushing your teeth at times when you are in danger of snacking.
2.6	3.1	H1	Are you getting enough sleep? Aim for at least seven hours per night.
2.7	4.1	E1	Exercise means keeping active and does not just mean going to the gym. It includes walking, jogging, running, cycling, swimming and sports.
3.1	5.1	E2	Exercise helps to keep weight off and helps to prevent cancer.
3.2	1.2	E3	It's normal to not feel like exercising but bargain with yourself to do at least ten minutes and then see how you feel.
3.3	3.2	E4	Any exercise or physical activity is better than no movement. Be creative to find strategies to get more activity into your day.
3.4	3.1	M2	Remember you are not alone. More than 1000 people in South Auckland alone have had the same surgery as you since 2007.
3.5	2.4	H2	There is no point weighing yourself daily as it reflects fluid changes only. Weighing yourself once each week will reflect actual changes.
3.6	3.1	D8	Water has no calories and helps you to feel full between meals.
3.7	3.1	M3	A healthy outside starts from the inside.
4.1	4.1	E5	You need to be doing at least 150 minutes of exercise per week for weight maintenance.
4.2	4.1	E6	If your regular exercise becomes easy, you need to make it harder by going faster or going further. Walking the same distance in the same time is not enough.
4.3	3.1	M4	Small changes can lead to big results.
4.4	12.3	D9	Don't do the groceries when you are hungry! It's harder to make healthy choices.
4.5	5.1	H3	Don't drink and drive after any alcohol. Your body now processes alcohol differently and it will affect you more.
4.6	13.1	E7	When you exercise, you set a great example to family and friends. Encourage them to get involved!
4.7	12.3	D10	Avoid temptation! Only buy the items on your shopping list and avoid buying those foods that get you into trouble.

Week.Day	BCTTv1	Genre	Message
5.1	3.1	G5	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
5.2	3.1	M5	Don't let anyone tell you bariatric surgery is cheating. The surgery is just a tool to get you on track and only works if you work hard too.
5.3	3.2	D11	Looking for a low fat food when shopping? Choose items with less than 10 grams of fat per 100g.
5.4	5.6	E8	No-one wants to exercise when it's raining but you won't melt and you will feel great afterwards!
5.5	3.1	H4	Are you still taking your multivitamin every day?
5.6	2.3	D12	Keeping a food diary can help your weight stay on track. There are even some smart phone applications that can help you with this.
5.7	3.1	M6	Setting goals is important to keep your weight stable.
6.1	3.1	D13	Don't drink your calories!
6.2	5.6	E9	When you're feeling tired or stressed, going for a walk is good way of waking yourself up and melting away your tension.
6.3	8.2/8.4	D14	Try brushing your teeth after dinner to avoid the temptation to snack.
6.4	13.2	M7	If what you're doing isn't working, change what you are doing.
6.5	5.1	H5	Caffeine can make acid reflux worse.
6.6	13.2	M8	Eat to fuel your body and not to feed your emotions.
6.7	3.2	E10	Figure out if you are a morning or an evening exercise person then plan your exercise accordingly.
7.1	3.1	M9	People in support groups are better at keeping their weight stable.
7.2	3.2	H6	Are you losing your hair? If yes, you may be deficient in iron, zinc or protein. See your GP to check it out.
7.3	1.3	H7	Are you drinking enough water? Aim for one and a half litres every day.
7.4	4.1	H8	You shouldn't drink 30 minutes before a meal, during a meal or until 30 minutes after a meal. Do you know why?
7.5	3.1	H9	Not drinking around the time of a meal keeps your stomach fuller for longer and improves food tolerance.
7.6	13.2	M10	If you fall off the band wagon, pull yourself together, get back on track and focus on the future which you can change.
7.7	5.6	E11	Exercise has a positive effect on your mood and boosts your energy.
8.1	3.1	M11	Are you really hungry or are your emotions triggering you to eat?
8.2	13.2	M12	Each meal is a new opportunity to nourish your body and to achieve your goals.
8.3	5.1	D15	The less you eat sweets, the less you crave them because your taste buds adapt!
8.4	5.1	E12	Exercise helps to keep your weight stable and reduces heart disease.
8.5	12.1	D16	Don't keep tempting bad food in the house.
8.6	3.3	H10	You aren't alone. Most people have to deal with excess skin after surgery especially around the tummy, upper arms and inner thighs.
8.7	5.5	M13	30 minutes after a binge you will have forgotten how good it was but you will still be regretting it 3 hours later.
9.1	3.1	D17	If you feel full when eating...stop eating!
9.2	8.2/8.4	E13	Increase your daily activity by standing rather than sitting.
9.3	3.2	D18	Meal idea: blend high calcium milk, low fat yoghurt and fruit like banana or berries. Include a protein powder to increase your protein intake.
9.4	13.2	E14	If I don't exercise today, am I treating myself or mistreating myself?
9.5	3.2	M14	Make your goals SMART. S=Specific, M=Measureable, A=Achievable, R=Realistic, T=Time-based.
9.6	3.1	H11	Small changes in your weight are normal.
9.7	8.2/8.4	D19	Sometimes the sensation of hunger may actually be thirst. Try drinking water first.

Week.Day	BCTTv1	Genre	Message
10.1	8.2/8.4	E15	Take the stairs rather than the lift. Every little bit of increased activity helps to burn more calories.
10.2	12.4	M15	Write a list of things to do when you get stressed – go for a walk, cry, phone a friend, etc. Refer to this list rather than food next time you get stressed.
10.3	3.1	H12	Alcohol is full of calories and no goodness.
10.4	5.1	H13	Chocolate can make acid reflux worse.
10.5	3.2	E16	You don't have to join a gym to keep fit. Sit-ups, press-ups, triceps dips, step-ups, squats, lunges, walking and jogging are all free!
10.6	3.1	G6	Sometimes these text messages may prompt you to get more information. It may be from the internet or other people. That's exactly what you should do!
10.7	3.3	M16	Do you have a good support network?
11.1	3.1	M17	Be honest with yourself.
11.2	5.1	D20	Are your portion sizes creeping up? Increasing portion size is associated with weight regain.
11.3	1.4	E17	The best type of exercise is one you can enjoy and continue to do on a regular basis.
11.4	11.3	E18	Have you checked out any smart phone applications that help you stay on track with exercise?
11.5	3.2	H14	Some people require iron supplements as well as multivitamins after surgery. Check with your GP to see if that is you.
11.6	3.2	D21	Meal idea: tuna & cottage cheese on a cracker base.
11.7	13.2	M18	Junk food satisfies you for a minute, being healthy satisfies you for a lifetime.
12.1	3.1	G7	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
12.2	3.1	M19	Head hunger is when you think you are hungry for food but are actually hungry because you are bored, sad, lonely, scared, etc.
12.3	13.2	E19	Look at things differently - instead of fitting exercise into your day, try fitting your day around exercise!
12.4	12.1	H15	Carrying a bottle of water with you helps to drink enough throughout the day.
12.5	12.3	D22	Don't eat when in front of the TV or computer – you may not even be hungry!
12.6	3.1	M20	You must want to succeed to sustain your weight loss.
12.7	5.6	E20	Exercise decreases stress!
13.1	3.1	M21	Surgery is just a tool to boost weight loss. You still need to work hard to maintain it.
13.2	12.1	D23	Don't eat directly from the bag or packet. Measure out your serving and store the rest.
13.3	4.1	D24	Always choose the low fat option for dairy products.
13.4	2.4	H16	Weigh yourself once each week. If you regain weight, review your lifestyle.
13.5	5.1	E21	Exercise helps you live longer.
13.6	11.2	M22	Be careful how you talk to yourself because you are listening.
13.7	13.1	E22	When you exercise, you set a great example to family and friends. Encourage them to get involved!
14.1	3.2	H17	Calcium supplements should be taken 2 hours apart from iron or multivitamin supplements.
14.2	3.2	D25	Looking for a low fat food when shopping? Choose items with less than 10 grams of fat per 100g.
14.3	4.1	E23	You need to go harder or longer for exercise to continue to be effective. Walking the same distance in the same time is not enough.
14.4	3.1	M23	Remember why you had surgery in the first place?
14.5	7.1	M24	Write down your motivation for having surgery and keeping healthy. Stick it on the fridge as a reminder.
14.6	12.4	M25	Read the list of reasons why you had bariatric surgery at those difficult times to help get back on track.
14.7	5.1	H18	Alcohol may be responsible if you are having difficulty keeping your weight off. How much are you drinking?

Week.Day	BCTTv1	Genre	Message
15.1	4.1	D26	Practise mindful eating – sitting down, chewing thoroughly and not in front of the TV!
15.2	5.1	E24	Exercise reduces your cholesterol level.
15.3	1.4	D27	Going out for a meal? Plan ahead to avoid feelings of embarrassment. Are they happy you share a meal, have a child's meal or eat an entrée portion only.
15.4	12.4	M26	Make a distraction box for when you want to eat for emotional reasons. It may include your list of reasons for surgery, people to contact, websites & puzzles.
15.5	8.2	M27	Polishing your nails (if appropriate) is a great way to prevent snack hand!
15.6	8.6	E25	Instead of meeting a friend over lunch, meet at a park or beach and chat while you walk – better for your health and your wallet!
15.7	4.1	D28	Drink only sugar-free drinks to keep hydrated.
16.1	3.1	G8	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
16.2	3.1	H19	After surgery, some people replace food addiction with alcohol or drugs. If it is you, see your GP to get back on track.
16.3	3.1	M28	Celebrate the small wins.
16.4	1.4	E26	Stay motivated! Plan your exercise at the beginning of the week and make it a priority.
16.5	4.1	D29	Stick to three meals per day and avoid snacks.
16.6	3.2	H20	If your bowels are sluggish, increase your dietary fibre, fluid intake and exercise.
16.7	3.1	M29	Today is a brand new day, start fresh if you need to.
17.1	1.2	D30	Eating too quickly? Put your cutlery down between mouthfuls.
17.2	3.1	H21	Are you still taking your multivitamin every day?
17.3	3.1	D31	How's that protein intake going? Getting at least 60g in each day?
17.4	8.3	E27	Increase your daily activity by parking further away from where you need to go so you can walk more.
17.5	12.3	D32	Don't watch TV while eating because you won't be practising mindful eating.
17.6	3.1	M30	Success post-surgery depends on your commitment and lifelong efforts to change your lifestyle.
17.7	5.1	H22	Spicy food can make acid reflux worse.
18.1	13.2	M31	Whatever the problem, the answer is not in the fridge.
18.2	5.1	E28	Exercise reduces anxiety and depression.
18.3	3.1	D33	Avoid eating whilst preparing food.
18.4	5.1	H23	The safe drinking alcohol guidelines do not apply to you because your body processes alcohol differently after surgery.
18.5	13.2	M32	People make time for things that are really important to them. Keep that in mind when you think you are too busy to exercise.
18.6	3.1	D34	Avoid being tempted by foods and habits that lead to binges.
18.7	3.2	D35	Meal idea: scramble egg whites with spinach, ham and cheese.
19.1	1.2	E29	Prevent boredom and injury by cross-training with different activities – walk, jog, cycle, swim, aqua-aerobics, etc.
19.2	5.5	M33	If you eat when you are upset, you will have two problems – the one that made you upset and feeling bad for eating.
19.3	2.4	H24	Weigh yourself once each week. If you start regaining weight, review your lifestyle.
19.4	3.2	H25	Some people require additional calcium supplements as well as multivitamins after surgery. Check with your GP to see if that is you.
19.5	3.2	D36	If you are a vegetarian, make sure you include protein at each meal in the form of tofu, lentils, legumes, low fat dairy foods or meat replacements.
19.6	13.2	E30	When life gets busy, exercise is often the first thing to go. Make it a priority as it will help you feel better.
19.7	13.2	M34	Food is fuel not therapy.

Week.Day	BCTTv1	Genre	Message
20.1	3.2	E31	Exercise tip: use a low platform to step-up onto. Try doing ten on each side. Do more or add free weights as they get easier.
20.2	3.1	G9	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
20.3	13.1	M35	Be the role model for your whanau and yourself!
20.4	4.1	D37	Remember to eat slowly. You should aim to complete a meal within 10-30 minutes.
20.5	3.1	H26	Are you looking after yourself?
20.6	12.3	D38	Try cooking/baking batches of healthy food in the weekend and freezing it so you are never caught without healthy options during the week.
20.7	3.2	M36	Set small goals that are achievable to help keep you on track and motivated.
21.1	3.1	G10	You can pause these text messages by texting STOPTXT to 2667. Restart messages by texting START to 2667. Standard charges apply for sending texts.
21.2	5.1	E32	Exercise helps to prevent and improve diabetes.
21.3	13.2	M37	Bariatric surgery is not magic. You still have a lifetime of healthy living to work on.
21.4	3.2	D39	If a product says 'no added sugar' that does not mean it is sugar-free. It just means no extra sugar has been added.
21.5	5.1	H27	Drinks with caffeine in them can dehydrate you.
21.6	8.2/8.4	E33	Choose to walk rather than take the car for those short distances. Save on petrol and good for you.
21.7	3.3	M38	Wake up and be awesome today.
22.1	3.2	D40	Looking for a low sugar food? Choose items with less than 10 grams of sugar per 100 grams.
22.2	5.1	H28	Avoid tea and coffee when you take your supplements as they reduce the amount of nutrients absorbed.
22.3	10.7	M39	Use non-food rewards to celebrate achieving your goals.
22.4	5.1	E34	Exercise reduces high blood pressure.
22.5	1.1	E35	To maintain your weight loss, you need to do at least 150 minutes of exercise each week.
22.6	1.1	E36	If you need to lose weight, you need to do more than 150 minutes of exercise per week.
22.7	4.1	E37	If you can sing a song while exercising, you need to increase the intensity so that you are no longer able to sing a song and exercise at the same time.
23.1	3.1	D41	Watch out for sneaky eating habits.
23.2	3.1	D42	Are you including protein at each meal?
23.3	11.2	M40	If you trip up, don't be too hard on yourself. Focus on what you can control and get back on track at your next meal or snack time.
23.4	12.1	D43	Using a side plate or small bowl to serve your meal helps to keep your portion size small.
23.5	3.2	E38	Exercise tip: push-ups can be done from your knees. Do as many as you can, rest and do the same number again. Repeat once more.
23.6	13.2	M41	We are all given 24 hours/day, 7 days/week – the trick is how we choose to use and prioritise this time.
23.7	3.3	M42	Be kind to yourself.
24.1	4.1	D44	Practise mindful eating by taking your time with each mouthful and savouring it.
24.2	3.1	G11	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
24.3	8.6	E39	Incorporate physical activity when you spend time with your children or grandchildren. Walk to the park, play outside, kick a ball around...
24.4	13.2	M43	People make time for things that are really important to them. Keep that in mind when you think you are too busy to make a healthy meal.
24.5	3.1	M44	Are you truly hungry or head hungry?
24.6	3.1	H29	You need good sleep to be healthy.
24.7	3.2	E40	Squats are a great free work out for the whole body! Make sure you find out how to do them properly by asking at a gym, your GP or even looking it up yourself.

Week.Day	BCTTv1	Genre	Message
25.1	4.1	D45	Include at least two serves of low fat dairy products per day for calcium and protein.
25.2	3.1	M45	Guilt is not positive or productive and will not serve you well.
25.3	4.2	D46	Don't leave all your eating until the evening. Being ravenous at the end of the day is a trigger for overeating late at night.
25.4	3.1	M46	YOU are important so prioritise time for yourself.
25.5	3.1	H30	Being overweight is like a chronic medical condition and needs special attention and management -> this means healthy eating and an active lifestyle.
25.6	1.2	D47	Eating too quickly? Wait until you have swallowed before cutting the next piece.
25.7	3.2	E41	Setting goals is important to keep active. Have you thought about doing a 5-kilometre fun run or walk?
26.1	13.2	D48	Instead of "I can't have this" think "I don't want to put this rubbish into my body".
26.2	5.1	D49	Avoid snacking to avoid weight gain. If you are truly hungry, make sure your snack will provide you with goodness.
26.3	3.2	D50	Snack idea: crunch on a carrot. Add hummus or cottage cheese for extra protein.
26.4	8.2/8.4	D51	Sometimes just sipping on water will remove the need for a snack.
26.5	5.1	E42	Keeping active burns energy and helps keep your weight stable.
26.6	12.6	H31	Excess skin can cause troublesome chafing when exercising. Try applying a gel to sensitive areas or skin folds to reduce friction.
26.7	13.2	M47	Eating healthily and exercising is not easy but it is possible.
27.1	3.2	M48	Have you checked out any of the online support sites for people after bariatric surgery?
27.2	3.1	G12	If you haven't heard from us already, we will contact you in the near future to see how you are getting on.
27.3	1.2	D52	Finding it difficult to eat slowly? Use your cutlery in the opposite hand to slow you down.
27.4	3.2	E43	Tricep dips are another great exercise you can do at home. Make sure you learn how to do them correctly by asking at a gym, your GP or looking it up yourself.
27.5	3.1	M49	You have come this far. Keep up the good work!
27.6	3.3	M50	Always treat yourself with kindness and compassion.
27.7	11.3	D53	Have you checked out any smart phone applications that help you monitor your calories?
28.1	3.2	H32	Have you weighed yourself recently? Keeping a track of your weight helps to maintain your weight. If you are putting on weight, what can you change?
28.2	12.1	D54	If you keep only good food in your kitchen then you will only eat good food.
28.3	3.1	D55	You can't exercise out a bad diet!
28.4	3.2	H33	Have you ever tried a green prescription from your GP?
28.5	3.1	M51	You are more likely to achieve your goals if you write them down or tell them to other people.
28.6	1.3	H34	Are drinking enough water? Remember to aim for 1.5 litres every day.
28.7	1.1	E44	Aim to do 30 minutes of exercise each day.
29.1	3.1	D56	How are your portion sizes?
29.2	4.1	D57	Do not eat and drink at the same time. Leave 30 minutes before and after meals with no fluids.
29.3	3.1	M52	You are worth it! Your body is entitled to a fit and healthy lifestyle.
29.4	3.2	D58	Snack idea: crunch on slices of apple dipped in low fat yoghurt for extra calcium and protein.
29.5	13.2	M53	Surgery is not a quick fix or a magic wand. It's a kick-start.
29.6	13.2	M54	Keeping weight off is not just about exercise and healthy eating – it's also about reducing stress, getting enough sleep and being emotionally healthy.
29.7	3.3	E45	Having an exercise buddy can help you stay motivated especially during those tricky winter months.

Week.Day	BCTTv1	Genre	Message
30.1	5.3	E46	Have you considered gardening? Keeps you active and you can grow vegetables. You might even save some money!
30.2	3.1	H35	Still taking your multivitamin every day?
30.3	4.1	D59	Mindful eating is planning what you'll eat before you eat it to avoid "that-looks-good syndrome".
30.4	3.1	M55	Surgery is only step one in the weight loss marathon. Keep going!
30.5	3.1	M56	Every day is a choice.
30.6	12.1	D60	Don't store food in sneaky places. If it isn't there, you can't eat it!
30.7	3.1	D61	Before you go to eat something... are you actually hungry?
31.1	3.1	E47	Are you keeping active?
31.2	12.1	D62	Leave quick and easy lunch options at work so you don't have to buy unhealthy food. A tin of tuna and crackers are a good option.
31.3	3.1	H36	Relationship changes are common after surgery as loved ones get used to the new you.
31.4	4.1	H37	30 is the magic number! 30 times to chew each mouthful. 30 minutes of exercise per day. 30 minutes to avoid drinking before and after meals.
31.5	3.2	D63	Mindful eating means not eating directly from the bag or packet.
31.6	1.4	D64	When eating out, try to choose a high protein option such as a protein filled wrap, omelette or protein based soup.
31.7	3.1	H38	Have you got bad reflux or heart burn? Avoid alcohol, spicy foods, chocolate and caffeine. If it's still bad then see your GP.
32.1	3.2	E48	Ever tried yoga? It's great for strength and relaxation so good for your body and your soul. Go to a community class or on a DVD in your own home.
32.2	3.1	D65	Are you on track with protein? If not you should be taking a protein supplement.
32.3	3.1	G13	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
32.4	1.2	D66	Eating too quickly? Try replacing your cutlery with chopsticks.
32.5	13.2	M57	Change the way you think. Instead of thinking I can't have those chocolates, think I choose not to have those chocolates.
32.6	3.2	E49	Lunges are a great free work out for the whole body! Make sure you find out how to do them properly by asking at a gym, your GP or even looking it up yourself.
32.7	3.2	H39	When you are buying medications at the chemist, make sure you tell your pharmacist that you have had weight loss surgery so they can advise properly.
33.1	1.4	D67	If you are physically hungry and need to snack, make a healthy choice like fruit, vegetables, nuts or yoghurt.
33.2	11.2	M58	When you start doubting yourself, remember how far you have come.
33.3	3.2	E50	If you can sing and maintain your level of effort during exercise, you're probably not working hard enough.
33.4	4.1	D68	Mindful eating is chewing slowly and tasting what you eat.
33.5	13.2	H40	Excess skin is troublesome but look at how much more you can achieve now compared to before your surgery (when you didn't have excess skin).
33.6	3.1	M59	Old ways won't open new doors.
33.7	3.2	E51	Exercise balls are like giant balloons. They aren't too expensive. Just sitting on them while you sit at a desk will work your abs, sides and lower back.
34.1	3.2	D69	Limit carbohydrates – these will reduce the room for the all-important protein and don't keep you feeling as full.
34.2	3.2	H41	Make a real effort to drink water during and after exercise as your smaller stomach can make it tough for your body to absorb the water it needs.
34.3	10.7	M60	Set a goal and then set out to achieve it. Remember to reward yourself when you do with a non-food reward!
34.4	3.1	D70	Remember to ask yourself; am I physically hungry or emotionally hungry?
34.5	4.1	E52	Did you know hoola hoop strengthens your core, arms and legs. Use it to exercise by swinging it around your waist, arms and legs.
34.6	3.2	D71	Are you keeping a food diary? If not, might be time to start one. You might be surprised by what you find.
34.7	5.1	D72	People who keep a food diary are less likely to regain weight.

Week.Day	BCTTv1	Genre	Message
35.1	3.2	H42	If you are feeling very tired or fatigued it may be a good idea to get your bloods checked and make sure your nutrition is on track.
35.2	13.2	M61	Food can be an addiction. Surgery does not fix the addiction, it just helps you to start fixing it.
35.3	12.1	D73	Use a teaspoon when eating to help keep your mouthfuls small.
35.4	3.2	E53	Feeling sore from exercise is normal and is often worse two days after exercising! Your muscles recover faster by keeping them moving.
35.5	3.2	H43	Try to avoid non-steroidal anti-inflammatories such as ibuprofen (Nurofen). If you must take them it is even more important that you drink plenty of water.
35.6	3.3	M62	Most people need help on their journey. It may be your whanau, your GP, a dietician, a psychologist or all of these people. Make sure you get the help you need.
35.7	4.1	D74	Mindful eating is sitting down when you eat.
36.1	3.1	E54	Everyone feels the urge to let their exercise routine slip from time to time. The trick is to get back on track.
36.2	3.2	D75	Snack attack? If you really are hungry try edamame or soy beans. They are a good source of protein.
36.3	3.1	G14	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
36.4	3.2	H44	If you are pregnant or trying to get pregnant you will need special nutritional advice. Get in touch with your GP. Obviously this message isn't for everyone!
36.5	3.2	D76	If you are choosing a protein shake, look for one with more than 15g protein per serve.
36.6	3.2	D77	Remember you need 60g of protein per day at the very least.
36.7	3.2	E55	Try carrying light weights when walking to increase your exercise.
37.1	3.2	H45	Wanting to build muscle at the gym? You are going to really need to increase your protein intake to allow those muscles to grow.
37.2	3.1	M63	What goals are you aiming for at the moment?
37.3	3.1	M64	People who set goals are more likely to keep their weight off.
37.4	3.2	E56	Many of us have knee problems limiting the exercise we can do. If this is you, try cycling, swimming or an elliptical machine (if you belong to a gym).
37.5	12.4	D78	If you are craving unhealthy food, distract yourself by doing something you enjoy and the craving is likely to pass.
37.6	5.1	H46	Avoid tea and coffee around meal times; they reduce your iron absorption.
37.7	4.1	D79	Portion your food in the kitchen and then take your serving to the table to help control your portion size.
38.1	3.1	M65	How is your support network?
38.2	3.1	M66	People with a good support network are more likely to keep their weight off.
38.3	3.1	G15	You can pause these text messages by texting STOPTXT to 2667. Restart messages by texting START to 2667.
38.4	5.1	H47	Alcohol can make acid reflux worse.
38.5	12.6	E57	Supportive clothing to keep excess skin tight can help with chafing when exercising.
38.6	13.2	M67	At any given moment, you have the power to say: This is not how the story is going to end.
38.7	3.2	D80	Meal idea: hummus, cucumber and turkey, fish or shaved ham on low fat crackers.
39.1	5.1	H48	Wholegrain cereals, fruit, vegetables, drinking plenty of water and regular exercise will help to keep your bowels regular.
39.2	3.3	M68	It's common to feel like you need some help to deal with the issues behind your head hunger. Your GP can refer to a counsellor.
39.3	3.3	M69	Counselling can be expensive. There are some great resources on the internet though. Have a look for them if you need help with your head hunger.
39.4	3.2	D81	Sometimes we feel hungry when we are actually thirsty.
39.5	3.2	E58	If you have an exercise ball, look up all the neat exercises you can do with it at home. You can get ideas from magazines, the internet, your GP or a DVD.
39.6	3.2	H49	Infusing water with fruit, vegetables or herbs can make it more drinkable. Try berries, citrus, lavender, mint or cucumber.
39.7	1.2	D82	Trouble tolerating meat? Try softer options like stews or casseroles.

Week.Day	BCTTv1	Genre	Message
40.1	3.1	M70	It's a slow process. Don't make it slower by quitting.
40.2	3.1	E59	What is your fitness goal at the moment?
40.3	3.2	H50	Do not weigh yourself daily as this just reflects body fluid changes.
40.4	3.1	G16	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
40.5	1.2	D83	Eating healthily when you are on shift work is extra tricky. The best strategy is to plan carefully and prepare meals to take with you.
40.6	3.2	D84	Snack idea: low fat cottage cheese, thin apple slices and a dash of cinnamon on a low fat cracker.
40.7	3.2	H51	Did you know there are applications for your smartphone that help you track how much water you are drinking?
41.1	13.2	M71	The more you love your decisions, the less you need others to love them.
41.2	1.2	E60	Find exercise boring? Listen to an audio book while you exercise and only let yourself listen to the book when you exercise.
41.3	12.3	D85	Avoid getting really hungry as you will be more likely to eat quickly, take big bites and not chew properly.
41.4	5.1	H52	Eating too much can make reflux worse. Try smaller meals to see if your reflux improves.
41.5	3.3	M72	Don't be afraid to fail. Be afraid not to try.
41.6	3.2	D86	Did you know there is even a smart phone application to help you eat slowly?
41.7	3.2	D87	Meal idea: create a wrap using ham or turkey slices as the actual wrap to maximise protein and minimise carbohydrates.
42.1	2.4	H53	Customise your water bottle by marking times on it so you keep on track with your water intake.
42.2	3.1	M73	Are your goals on the fridge?
42.3	12.1	E61	Have you got an office job? Sit on an exercise ball instead of a chair. You will be working your muscles without even knowing it.
42.4	1.2	D88	Eating too quickly? Chew each mouthful 30 times.
42.5	3.2	H54	Bad reflux? Elevating the head of the bed can help.
42.6	12.1	D89	Some people find that they are less likely to binge eat when they wear less comfortable clothing around the house. Try it!
42.7	3.2	E62	Make an appointment with yourself to exercise. Keep the appointment like you would a doctor's appointment.
43.1	3.2	D90	Meal idea: avocado, hardboiled egg and salsa on low fat crackers.
43.2	3.1	M74	Take care of your body. It's the only place you have to live.
43.3	3.1	H55	Do you understand why it is so important to continue to have your multivitamin every day?
43.4	5.1	H56	Without a daily multivitamin, you are at risk of developing complications from not having enough minerals and vitamins.
43.5	3.1	D91	Set aside time for meals and avoid doing other things whilst you are eating.
43.6	8.6	E63	Be creative to increase your activity levels. For example, do heel raises when you are brushing your teeth.
43.7	3.1	M75	Little by little becomes a lot.
44.1	3.1	H57	Being healthy includes getting good quality sleep regularly.
44.2	3.3	M76	The next time you want to give up, remember why you started.
44.3	3.1	G17	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
44.4	3.2	E64	You can use canned foods as free weights to work your arm muscles.
44.5	3.2	D92	Meal idea: make a low carbohydrate lasagne by using sliced courgettes instead of pasta.
44.6	5.1	H58	Don't drink and drive after any alcohol. Your body now processes alcohol differently and it will affect you more.
44.7	3.1	M77	Be the best version of you.

Week.Day	BCTTv1	Genre	Message
45.1	3.2	D93	Overcoming binge eating rule: Never ever skip meals!
45.2	3.1	E65	Have you got an exercise buddy? If not try and find one so you can motivate each other.
45.3	3.1	H59	Are you keeping track of your weight?
45.4	2.4	H60	Reporting your weight to someone else can help to keep you motivated. This could be a family member, surgery buddy, GP or other health professional.
45.5	3.2	D94	Try freezing low fat yoghurt mixed with protein powder as an ice cream replacement.
45.6	3.1	M78	Don't be ashamed of trying, every journey has to start somewhere.
45.7	8.2/8.4	E66	Are you choosing the stairs instead of the elevator?
46.1	1.4	D95	Plan your meals ahead of time to avoid temptation and ensure a regular eating pattern.
46.2	5.1	H61	Don't drink and drive after any alcohol. Your body now processes alcohol differently and it will affect you more.
46.3	3.2	E67	You can use an old telephone book as a platform for step-ups.
46.4	3.1	D96	Is half of each meal protein?
46.5	11.2	M79	To stay motivated you need to surround yourself with positivity. Remove the toxic influences from your life.
46.6	3.1	D97	Is the head hunger under control?
46.7	5.1	H62	Large portion size is a common reason for weight regain.
47.1	4.1	E68	How much exercise are you doing? 150 minutes per week is required to keep your weight stable.
47.2	4.1	E69	You need to be doing more than 150 minutes of exercise each week if you are regaining weight.
47.3	3.1	M80	Weight loss is like driving – if you get lost, make a U-turn to head back in the right direction.
47.4	3.2	D98	Meal ideal: wrap chicken around asparagus for a low carb variation of asparagus rolls.
47.5	3.1	H63	Are you remembering to avoid drinking at meal times?
47.6	4.1	H64	Remember avoid drinking for 30 minutes before and after eating to stay fuller for longer.
47.7	3.3	M81	Today is another chance to make yourself proud.
48.1	8.6	E70	Spend time with whanau doing something active rather than sitting.
48.2	2.3	H65	Keeping a food and exercise journal is a great way to see what is causing you to regain weight.
48.3	3.1	G18	Remember you can contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns.
48.4	3.1	M82	It's my time to take care of myself... to make changes in my life for me.
48.5	3.1	D99	If you must snack, make sure there is protein in it.
48.6	5.1	H66	Drinking alcohol is a cause of weight regain.
48.7	3.2	E71	Doing the same exercise every day is boring. Keep motivated by trying lots of different things.
49.1	3.1	M83	Your attitude determines your direction.
49.2	3.2	H67	Have you had your bloods checked within the last year? If you are not sure, check with your GP and make sure you have.
49.3	5.1	D100	Being sad does not mean you are entitled to eat. The body still processes calories the same way. If you eat when sad you will regain weight.
49.4	3.3	M84	Nothing tastes as good as being fit feels.
49.5	11.3	E72	There are smart phone applications that count the number of steps you do every day. How many steps are you doing?
49.6	5.1	H68	Caffeine is dehydrating, makes reflux worse and interferes with absorbing important nutrients.
49.7	5.1	H69	Poor sleep contributes to weight regain.

Week.Day	BCTTv1	Genre	Message
50.1	8.3	E73	Don't forget to park further away from your destination so you can walk further.
50.2	1.4	D101	Going out for dinner? Choose items that are grilled, boiled, poached, steamed or chargrilled.
50.3	1.4	D102	Going out for dinner? Avoid items that are battered, fried, sautéed, or served with a cheese, butter or hollandaise sauce.
50.4	3.1	M85	Never forget why you had the surgery in the first place.
50.5	5.1	H70	If your nails and hair are unhealthy, you are missing some important nutrients.
50.6	5.1	D103	Too many carbohydrates and fat cause weight regain.
50.7	3.1	M86	There is no elevator to success. You have to take the stairs.
51.1	3.1	H71	Not being happy contributes to weight regain.
51.2	3.3	M87	You need to have good support to succeed.
51.3	1.4	D104	Going out to dinner can be tricky. Order an entrée or share a main.
51.4	4.1	E74	Can you sing while exercising? If yes, try pushing yourself a little harder.
51.5	3.1	D105	Are you eating mindfully?
51.6	3.3	M88	Never give up. Great things take time.
51.7	3.1	D106	Never forget the importance of protein.
52.1	13.2	M89	If it is important you will find a way. If not, you'll find an excuse.
52.2	12.4	M90	Don't forget to use the list of reasons you had surgery or your distraction box at those difficult times.
52.3	3.3	M91	Be honest with yourself, and kind.
52.4	13.2	M92	It's not just the weight you lose: but the life you gain.
52.5	15.3	M93	Think back to before your surgery and congratulate yourself for the things you have already achieved.
52.6	3.1	G19	Yesterday was your last text message from the BOBS Study. We will be in touch shortly to see how you are going. Thank you for participating.
52.7	3.1	G20	Contact Mel on andrew.maccormick@auckland.ac.nz if you have any feedback, questions or concerns. Thank you for participating!

Participant Information Sheet

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New Zealand

Study title:	<i>Better Outcomes following Bariatric Surgery</i>		
Locality:	Manukau Super Clinic	Ethics committee ref.:	14/NTB/206
Lead investigator:	Mr Andrew MacCormick	Contact phone number:	(09) 276-0000

You are invited to take part in a study about care provided after obesity surgery. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the study is to improve the support for patients after obesity surgery. Before we decide what extra support to provide, we need to test it first to make sure it is actually better than what we provide already. To do this we will randomly assign patients on the day of discharge from the bariatric service to one of:

- Standard care
- Standard care with text messaging support

Unfortunately, you can't choose what group to be assigned as that would make the results of the study unreliable.

The study is part of Dr Mel Lauti's doctorate with the University of Auckland. She has also received funding from the Health Research Council of New Zealand. Her contact details are on page 4 and you should feel free to contact her with any concerns or queries.

This study has been approved by the Northern B Health and Disability Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate in the study as you had bariatric surgery at least 14 months ago. If you choose to participate you may have the same care as if you did not participate or you may have more support in the form of text messages depending on which group you are randomly assigned to.

All participants will be required to attend a follow-up appointment at six months and at twelve months after randomization. These appointments will be for approximately 15 minutes. During each appointment you will be weighed, asked about your health and given a brief questionnaire to assess your quality of life. The quality of life questionnaire will ask you to rate different aspects of your life such as self-esteem, physical activity, interest in sex, work and social life. We may need to access your medical records to assess your general health.

All appointments will be at the Manukau Super Clinic where you had your appointments with the Bariatric Team. Your participation will be for approximately one year and the study will end by December 2016.

If you are assigned to the **standard care group**, you will be asked to attend a follow-up appointment six and twelve months later as described above.

If you are assigned to the **standard care with text messaging support group**, you will receive a text message of support at 8am each day for one year. You will be asked to attend a follow-up appointment six and twelve months later as described above.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We think that the patients assigned to the text messaging support groups may have better weight loss and quality of life than those assigned to standard care alone. The risks of the study are very small.

WHO PAYS FOR THE STUDY?

You will not have to pay for the text messages you receive as part of the study. Unfortunately, we are unable to reimburse you for your time and travel costs.

If you go overseas, just let us know. You can have the text messages stopped or we can reimburse the costs of the study's daily text messages you receive whilst overseas. You will need to provide us with an itemised account from your mobile phone service provider so we can reimburse your costs.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you may be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Taking part in this study is your choice and you are free to decline. If you choose to take part and later wish to withdraw that is also your choice. You will not experience any disadvantage from declining or withdrawing from the study.

If you do take part, you have the right to access the information we collect about you. We will tell you of any new adverse or beneficial effects to your health related to the study that become available.

We will keep your information private and confidential. All researchers are health care professionals or academics who have signed a confidentiality agreement.

WHAT HAPPENS AFTER THE STUDY?

Daily text messages of support will end with the study.

All data collected will be kept in a restricted access research office and on password-protected computers at the South Auckland Clinical Campus, University of Auckland. Your health information collected for this study will be linked to you using a special code accessible to the researchers only. Your name or other personally identifying information will not be used in reports or publications resulting from this study. All study data will be destroyed and/or deleted by ten years from the beginning of the study.

We will send you a copy of the results to the address or email address you indicate on the consent form. The results will be available in 2017.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Mel Lauti, Research Fellow
(09) 276-0044 extn 2219
m.lauti@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Māori health support please contact :

Ian Kaihe-Wetting,
Service Manager – Te Kaahui Ora Māori Health Counties Manukau Health
(09) 276 0138

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

Department of Surgery
South Auckland Clinical School
Private Bag 93311
Otahuhu
Auckland 1640

The University of Auckland
Private Bag 92019
Auckland 1142
New Zealand

If you need an INTERPRETER, please tell us.

By signing this consent form, you agree with the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I consent to the research staff collecting and processing my information, including information about my health.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study.

Yes No

If yes, I would like the results sent to:

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature:

Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.













Researcher's name:

Signature:

Date:

Appendix H Chapter 5 – Bariatric Analysis and Reporting Outcome System

**Bariatric Analysis and Reporting Outcome System
BAROS**

Weight Loss % of Excess Wt. or % of Excess BMI (POINTS)	Medical Conditions (POINTS)	Moorehead-Ardelt QUALITY OF LIFE QUESTIONNAIRE II
Weight Gain (-1)	Aggravated (-1)	<p>MOOREHEAD - ARDELTA QUALITY OF LIFE QUESTIONNAIRE SELF ESTEEM, AND ACTIVITY LEVELS</p> <p><i>Please make a check in the box provided to show your answer.</i></p> <p>1. Usually I Feel...</p> <p> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/></p> <p>Very Badly About Myself Very Good About Myself</p> <p>2. I Enjoy Physical Activities...</p> <p> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/></p> <p>Not At All Very Much</p> <p>3. I Have Satisfactory Social Contacts...</p> <p> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/></p> <p>None Very Many</p> <p>4. I Am Able To Work...</p> <p> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/></p> <p>Not At All Very Much</p> <p>5. The Pleasure I get Out Of Sex Is...</p> <p> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/></p> <p>Not At All Very Much</p> <p>6. The Way I Approach Food Is...</p> <p> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/></p> <p>I Live to Eat I Eat to Live</p>
0 – 24 (0)	Unchanged (0)	
25 – 49 (1)	Improved (1)	
50 – 74 (2)	One major resolved Others improved (2)	
75 – 100 (3)	All major resolved Others improved (3)	
SUB TOTAL	SUB TOTAL	SUB TOTAL

COMPLICATIONS:
Minor: Deduct 0.2 point
Major: Deduct 1 point

REOPERATION:
Deduct 1 point

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**TOTAL
SCORE**

OUTCOMES GROUP SCORING

- Failure ≤ 1
- Fair ☒ 1 to 3 points
- Good ☒ 3 to 5 points
- Very Good ☒ 5 to 7 points
- Excellent ☒ 7 to 9 points

MOOREHEAD - ARDELT QUALITY OF LIFE QUESTIONNAIRE

SELF ESTEEM, AND ACTIVITY LEVELS

Please make a check in the box provided to show your answer.

1. Usually I Feel...



Very Badly About
Myself



Very Good About
Myself

2. I Enjoy Physical Activities...



Not At All



Very Much

3. I Have Satisfactory Social Contacts...



None



Very Many

4. I Am Able to Work...



Not At All



Very Much

5. The Pleasure I get Out Of Sex Is...



Not At All



Very Much

6. The Way I Approach Food Is...



I Live to Eat



I Eat to Live

Melodie K. Moorehead, Ph. D., Bariatric Surgery Clinical Psychologist, 1201 E. Broward Blvd., Ft. Lauderdale, FL 33301.
 Elizabeth Ardel, Ph. D., Institute für Psychologie, Universität Salzburg.
 MOOREHEAD - ARDELT QUALITY OF LIFE QUESTIONNAIRE
 SELF ESTEEM, AND ACTIVITY LEVELS
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MA II
Self Esteem and Activity Levels
SCORING KEY

1. Usually I feel . . .



-50 -40 -30 -20 -10 +10 +20 +30 +40 +50

2. I Enjoy Physical Activities . . .



-50 -40 -30 -20 -10 +10 +20 +30 +40 +50

3. I Have Satisfactory Social Contacts . . .



-50 -40 -30 -20 -10 +10 +20 +30 +40 +50

4. I Am Able to Work . . .



-50 -40 -30 -20 -10 +10 +20 +30 +40 +50

5. The Pleasure I get Out of Sex Is . . .



-50 -40 -30 -20 -10 +10 +20 +30 +40 +50

6. The Way I Approach Food Is . . .



-50 -40 -30 -20 -10 +10 +20 +30 +40 +50

-3 to -2.1	-2 to -1.1	-1	0	1	1.1 to 2	2.1 to 3
Very Poor	Poor	Fair		Good		Very Good

Quality of Life

Appendix I Chapter 5 – Online Satisfaction Survey

Please enter the number given to you by the researcher to complete this survey.

Please enter today's date (dd/mm/yyyy).

Have you been receiving daily text messages as part of this study?

- Yes (1)
- No (2)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Did you forward the text messages on to other bariatric patients?

- Yes (1)
- No (2)

Display This Question:

If Have you been receiving daily text messages as part of this study? No Is Selected

Have you been receiving daily text messages by another bariatric patient forwarding them to you?

- Yes (1)
- No (2)

If Yes Is Selected, Then Skip To Did receiving the daily text messages...

Display This Question:

If Have you been receiving daily text messages as part of this study? No Is Selected

Would you like to have received a daily text message of support? Examples of text messages other participants received:

- You need at least 60 grams of protein every day and much more if you want to build muscle.*
- You need to be doing at least 150 minutes of exercise per week for weight maintenance.*
- Eat to fuel your body and not to feed your emotions.*
- Try brushing your teeth after dinner to avoid the temptation to snack.*
- Water has no calories and helps you to feel full between meals.*
- Are you still taking your multivitamin every day?*

- Yes (1)
- No (2)
- Don't know (3)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

The daily text messages made me feel supported.

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

The daily text messages helped me with motivation.

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

The daily text messages were developed by experts in the follow-up care of bariatric surgery.

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

The daily text messages helped me to minimise weight gain.

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

How did you find the frequency of the text messages? In other words, how did you find receiving a text message every day?

- Far too little (1)
- Somewhat too little (2)
- Just right (3)
- Somewhat too much (4)
- Far too much (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

How did you find the timing of the text messages? In other words, how did you find receiving a text message at 9am?

- Too early (1)
- Somewhat too early (2)
- Just right (3)
- Somewhat too late (4)
- Definitely too late (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

I would like to continue receiving these daily text messages.

- Strongly disagree (1)
- Somewhat disagree (2)
- Neither agree nor disagree (3)
- Somewhat agree (4)
- Strongly agree (5)

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

Which text messages did you find most useful?

Display This Question:

If Have you been receiving daily text messages as part of this study? Yes Is Selected

Or Have you been receiving daily text messages by another bariatric patient forwarding them to you? Yes Is Selected

Please describe below any ideas you have for supportive text messages for bariatric patients.

Please use this section to make any other comments, suggestions or give us additional feedback.

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